NIOSH/NPPTL TOTAL INWARD LEAKAGE

PUBLIC MEETING

ORIGINAL

Tuesday, June 26, 2007

Commencing at 9:00 a.m. at the Embassy Suites Pittsburgh International Airport Hotel, Coraopolis, Pennsylvania.

CONTENTS

WELCOME/OPENING REMARKS

MR. SZALAJDA: All right, good morning.

This is, I think, the first public meeting we have ever had that we have not been begging people to sit down, so it must be a very important topic.

My name is Jon Szalajda. I'm the chief of the policy and standards development branch at NPPTL. I would like to welcome you to today's public meeting.

As far as the discussions today, we're considering this as part of an open dialogue regarding the development of the performance requirements for Total Inward Leakage for half-mask and filtering facepiece respirators.

At this point, we have not begun the formal rulemaking type process to update 42 CFR Part 84 to include these requirements. At some point in the future, that process will begin, and the amount of dialogue that we have between the government, NPPTL, and stakeholders will be a little bit more controlled.

But at least at this point, this is an informal type dialogue to let you know what we're thinking of with regard to the requirements for inward leakage and to get your feedback.

Today we're planning on having a relatively short meeting, but a lot of information is going to be presented. We're going to discuss the development of an anthropometric respirator fit test panel, which will be led by Dr. Ziqing Zhuang. And Bill Newcomb will review for you the half-mask testing and analysis of work that has been done at NPPTL to evaluate and benchmark existing technologies and use that information to help us define what performance requirements should be for half-mask and filtering facepiece respirators.

As far as our agenda goes, we're going to be a little loose, I guess, based on the length of the discussion.

I think probably after we review the Institute of Medicine's report and analysis of the fit test panel, we'll take a break at that time. But depending on how quickly or slowly the dialogue

goes, we may adjust that as appropriate.

Regarding the presentations and information provided today, a docket has been opened relative to soliciting and accepting comments from the stakeholders. There's a variety of contact methods to formally submit your input to the docket.

At least as far as today's meeting, it is going to be transcribed.

After each presentation, there will be an opportunity for questions and answers. At that time, if you have a question, we would like you to come up to the microphone in the middle of the seating, state your name, who you're with, and then ask a question, and we'll do our best to address it at that time.

Administratively, at least as far as the operations for today, there is a survey in your packet of information. We would like you to fill that out and drop it off at the box in the back of the room upon the completion of the meeting today.

The restrooms are right outside the door at the rear of this room.

At least as far as making the presentations available, what we're planning on doing is having them on the website in the near future.

What we're planning on doing is sending an email to the attendees as well as to our list serve general mailbox to let you know that the presentations are available on the website, and we expect that to be done within the next few days.

And with that, I would like to introduce Mr. Les Boord, the director of NPPTL.

MR. BOORD: Thank you, Jon.

Good morning, and welcome to everybody participating in the meeting today.

I thought before we get into any of the technical discussions and issues, it would be good to kind of look at an overall perspective of what we're doing today and how it fits in -- how our activities today fit into the overall scheme of the NIOSH research program portfolio.

And many of you have probably seen this illustration before, but about two years ago, two

and a half years ago, NIOSH embarked on a program to organize its research activities into an industry sector-based and sector-based program portfolio.

And to do that, the Institute identified eight primary industry sectors that are indicated in the left-hand column of this illustration.

So the industry sectors that guide the research activities for the Institute are the Agriculture, forestry, and fishing sector; Construction; Healthcare and social assistance; Mining; Manufacturing; Services; Transportation, warehousing, and utilities; Wholesale and retail trade.

So those are the primary industry sectors served by the research activities of the Institute.

Now, in addition to that, we have identified 15 different cross-sector programs. Those are illustrated in the second column of the illustration.

And as you scan down the list of cross-sector programs for the Institute, you can see about two-thirds of the way down, we have the

Personal Protective Technology cross-sector. That's the home of the program that we're talking about today.

So our Total Inward Leakage for half-mask and filtering facepiece type respirators is part of the PPT, personal protective technology, cross-sector for the Institute.

Continuing on, in the right-hand column of the illustration, you have the other emphasis areas that have been identified for the Institute to govern and direct the programs, the overall programs for NIOSH.

Now, speaking a little bit about the Personal Protective Technology cross-sector. The laboratory, the National Personal Protective Technology Laboratory, within the Institute is the responsible area for managing and organizing and strategically directing the PPT cross-sector.

In that regard, the vision and the mission statements for the PPT cross-sector are as stated here. The vision is to be the leading provider of quality, relevant, and timely PPT research,

training, and evaluation.

And the mission of the PPT cross-sector program is to prevent work-related injury and illness by advancing the state of knowledge and application of personal protective technologies.

So those are the visions and missions that have been identified for PPT cross-sector within the Institute.

Now, I think it's important and interesting to actually look at the strategic goals that have been identified for the PPT cross-sector.

And you can see that there are three primary strategic goals followed by a set of intermediate goals that apply to each of the strategic goals.

So No. 1, Reduction of inhalation hazards; 2, Reduction of dermal hazards; and, 3, Reduction of injury hazards.

And I think it's pretty obvious that the program we're talking about today, the Total Inward Leakage for half-mask and filtering facepiece respirators, fits nicely into reduction of

inhalation hazards.

But I think if you drill down a little bit further and look at the intermediate goals associated with that strategic goal, to develop comprehensive research programs, to work for the development of harmonized PPT standards, to perform evaluation activities, and then the research to practice through communications and outreach and transfer activities, I think you'll see, as the day unfolds, that the Total Inward Leakage Program that we're talking about really hits on each of those areas.

So we're going to talk a little bit about the research that's leading the development of the Total Inward Leakage proposed requirement. We're going to talk about the development of that requirement and how we went about establishing the proposed performance levels.

The evaluation activities, we're going to spend a good deal of time talking about evaluation in terms of evaluation of programs and projects.

Evaluation is a key for the Institute to

improve and to instill the quality of the research in other programs that the Institute performs.

And then finally, our r2p, our research to practice. The impact and relevance of the research that's undertaken is important.

And I think that as the day unfolds, you'll see that the TIL program really hits in each of those four areas.

So with that, that will conclude my brief introductory comments. And I think we will turn it over to Mr. Newcomb, who will talk about the program concept for TIL.

PROGRAM CONCEPT

MR. NEWCOMB: Good morning.

Thank you, Les.

Most of you have probably seen a lot of this before. This is a review of the total program and the project within that program to look at Total Inward Leakage of half-mask filtering respirators.

Back in 1972, when 30 CFR 11 became the law -- or the regulation by which respirators were tested and certified, there was a schedule for

particular respirators called Schedule 21C.

And prior to this, there was a coal dust test for fitting of filtering respirators. And that was abolished when 30 CFR 11 came along because it was felt that spraying coal dust into people's faces wasn't exactly the best thing to do.

But there was an isoamyl acetate test that was instituted. But in order to test filtering facepieces or filtering half-mask or any type of particular filters, you needed to modify the respirator and put an organic vapor removing cartridge on it. So, therefore, the respirators weren't the same mass, weren't the same weight, and didn't fit the same way as they normally would.

When 42 CFR Part 84 was instituted in 1995, the isoamyl acetate test was eliminated because of the problems in the configuration. Also, the effectiveness of the isoamyl acetate and, at that time, the ANSI and OSHA fit testing methods were contentious.

But at that time, OSHA required individual fit testing. So the thought was that the best

practices used in qualifying respirators would remove any respirators from the market that did not fit properly.

In 2002, there was a study published that was contracted by NIOSH to look at respirator usage in the private sector. And in that study, 53 percent of the respondents said they conducted fit tests. And there's a question as to whether that was actually the right figure or whether it should be higher.

At the same time or very close after, OSHA published the proposed assigned protection factors. And during the hearings, NIOSH committed to add quantifying fit test methods to respirator certification requirements.

So as a continuation of NIOSH's unique approach to modular rulemaking, a program was established to add Total Inward Leakage requirements for half-mask particulate respirators, followed by PAPR and supplied-air respirators -- those are the ones that OSHA gives a 25 or 1,000 to, depending on how they're tested, followed by all other

respirators and other PPE -- such as encapsulating suits.

In the program for particulate respirators, there were three phases that were established.

Phase 1 was the investigative and concept draft stage where the TIL, existing TIL information was gathered.

There was a review of the test equipment and the capabilities and the technical specifications of that equipment.

We identified a peer review team composed of manufacturers, users, academia, and government; developed an initial TIL concept addressing performance requirements and test protocols; conducted a peer review and a public meeting; and established technical specifications for the test facility.

Phase 2 was actual benchmark testing and the establishments of the test facility to do that.

We performed benchmark testing to establish state-of-the-art respirator performance,

continued development of the concepts, and identified draft implementation plans.

Phase 3 would be consistency testing and implementation plan: Conduct a validation testing for the facility, finalize implementation plan, and finalize a concept requirements and protocol.

One thing that we set out as a criteria at the beginning of the program was that what we set for a TIL would not be a replacement for OSHA-mandated fit testing because the only way of accessing individual fit is a fit test. You cannot certify a respirator to fit people.

To establish the performance criteria, we said that it would be based on actual fit test results and not assigned protection factors.

We also felt it was inappropriate to use previously obtained fit test data because of the variety of methods used and the fact that a lot of the data was done on older Part 11 respirators.

We would conduct benchmark testing on state-of-the-art respirators within the class, rely on the manufacturer's user instructions. And

because there is no criteria established for what size respirators are, we decided to use the entire panel for the evaluation.

So for the half-mask project, when we looked at test methods, we looked at the ability to use the TIL in all styles of half-mask, quarter-mask, and filtering facepiece.

It should have the required sensitivity for the desired results, the ability to give accurate repeatable results, the ability to do the required test exercises without disturbing the fit due to the test equipment, ease of duplication, cost of equipment, need for a test chamber, and ease of preparation, use, and cleanup.

We felt that the best choice of measuring half-mask TIL is the PortaCount Plus with a Companion using a direct reading mode.

The most reproducible exercise methods were thought to be those used in the OSHA fit test protocol. One of the reasons for that is that a standardized workplace with standardized movements does not exist.

OSHA is wrestling with this at the present time when they're trying to establish what type of tests should be done for different PAPRs and SARs.

We decided to use a new test panel called a NIOSH Bivariate test panel that most of you have seen before, and we'll have a lot more elaboration on this in a few minutes. But it's a new panel that replaced the Los Alamos panel, which has more up-to-date sizes.

To summarize, the Phase 2 is complete, and we're now in Phase 3.

The study was designed to assess the overall capabilities of individual respirators. The benchmark data was derived by testing across a complete panel regardless of the respirator designated size, and, therefore, does not represent actual field use.

The data was analyzed in several ways, and conclusions have been reached concerning the proposed requirements for certification. Again, just proposed requirements at this point.

Thank you.

Are there any questions?

We will now hear from Dr. Ziqing Zhuang, who will go over the anthropometrics that we used to create the panel.

ANTHROPOMETRICS RESEARCH TO DEVELOP FIT TEST PANELS

MR. ZHUANG: Thank you, Bill.

Yeah, the title of my presentation is Anthropometrics Research to Develop Respirator Fit Test Panel.

And first of all, I would like to acknowledge my, yeah, co-authors on the paper and also the people work on the program.

Dr. Ron Shaffer, branch chief. And then Dr. Bruce Bradtmiller of Anthrotech. He is our contractor. And also Dennis Viscusi been working with me on this project for the last few hours.

And then lately, we have Dr. Ray Roberge, helping we with the BMI, body mass index paper. And then also Dr. Doug Landsittel also help with the statistical issue lately.

And I have a few summer student and a Ph.D. student working on the project as well.

So the test panel has been used quite a bit in the past, and then they have been relied upon to provide sizing reference for respirators in many application, and to select representative subject for bivariate testing.

As soon as the Los Alamos fit test panel was developed, it was used to collect a lot of fit test data. And then this data was used to establish a APF, assigned protection factor. And also the panel can be used for respirator design and development, and then also Total Inward Leakage testing. And then also they had been used for research purpose.

We can use them to recruit subjects.

And -- yes. So when the LANL panel was developed back in the earlier '70s, there was no survey of facial dimension of the U.S. civilian workers at that time.

So the only data set available was the '67 and '68 U.S. Air Force anthropometric survey of the pilot or Air Force personnel. And so the facial anthropometry was assumed to be representative of

U.S. adult at that time. They did a pilot study, and they also found some consistency there.

And they selected face length, face width, and lip length to develop a panel.

And this is the panel for testing full-facepiece respirator. And it is based on face width and face length and the dimension range from 93 and a half to 133 and a half millimeter for face length, and 117 and a half to 153 and a half for face width.

And based on the percentage of the population of the subject in the Air Force survey data, they divide the population into, yeah, 16 cells.

But some of the cells here, they have very few people or subject there, so they would delete it and leaving a ten-cells panel. And these are the subjects that they recommend to be sampled from each cell.

And for the half-mask panel, they used lip length and face length. And also, yeah, it's a ten-cells panel and 25 subjects.

And so lately, when we look at the panel, we thought the demographics of the U.S. population has changed over the last 30 years. And then military data may not fairly represent the diversity of the face size that we see in the civilian workers.

So we -- yeah. So we looked at -- closer looked at the data.

And if you can see from this figure, that yeah, U.S. Air Force male at that time, most of them are 90, yeah, 7 percent of them were white. And then for female, we have some African-American female in the Air Force at that time.

And but if you look at the census data, which is back in 2000, and you have quite diverse population here, about 70 percent of Caucasian. And then African-American or Hispanic, yeah, accounted for about 12 percent each. And then we have about a 6 percent others group, like Asian, Pacific Islander, or Native American, or -- yeah.

And if you look at the age distribution, we also think that there could be a problem there.

As you can see, age 18 and 29 or 30 to 44, and these are the two categories that the pilots, yeah, the Air Force subject were mainly less than 45.

And if you look it our 2000 census data, it's quite uniformly distributed among the three age groups as, yeah. Like from 45 to 66, we have a good portion of it.

And then after the LANL panel was developed, like, yeah, there are a couple of other studies to look at it earlier, yeah, in the 1970s.

The first study was conducted by, yes, by Leigh. And, yeah, he measure 1,467 of employees of a big corporation. I think it's called Dow Chemical USA, and it is a division in Colorado.

And they also have annual fit test program. They have fit test programs.

So they fit test employee and also measure their face length, face width, and lip length. And so what they found was, yeah, more than 12.6 percent of their employee were outside the LANL panel. And so they concluded that adjustment of the LANL panel

is needed.

And then 1978, Bureau of Mines also did a survey. They only had 48 male mine rescue workers. It's a small survey, but they also found significant differences from their workers than the LANL panel.

And so they concluded that a last survey of industrial users are needed.

And so lately, back in 2002, there was a project called CAESAR, which is Civilian American and European Surface Anthropometry Resources.

So it was a project to measure about -- they target 4,000 American and then 4,000 Italian and 4,000 in Netherland.

And but the sample sizes are a little bit smaller. They end up getting about 2,500 subjects in the U.S. because the, yeah, the different states, from all the way to over here to like Detroit and Washington DC, so across the country.

And so they -- this is a 3D, three-dimensional anthropometry approach. They use a whole body scanner to scan the subject. They also measure 40 traditional measurements. And so we can

use face length and face width to look at whether the LANL panel is okay or not.

So we find that 16 percent of their subjects were outside the limits.

And if we look at the literature, some other, yeah, study, they also said that lip length is one of the dimensions used to define the LANL panel, but did not have good correlation with respirator fit. And they concluded that like, yeah, for this case, it is Dr. Oestenstad in Alabama University.

And so since then, we, yeah, initiated a project, yeah, to develop a database detailing the face size of the distribution of respirator user. And we also evaluated the applicability of the LANL panels. And then also, we also had some data, so we look at the correlation between facial dimensions and fit.

And then the last step is to develop the new panel.

So this is the time line of the whole effort. And so back in 2002, we developed a

protocol. We have a panel of five reviewers to review the protocol. We went through NIOSH human subject review board review. They also asked a lot of question, and we need to address their question.

And then we also went through OMB review. Since it's a new study and so many subjects involved, the design was to measure over 4,000 workers, so we required to go through OMB review.

And they also review our statistical design, and we have a few discussion. And so we end up coming -- yeah, getting the way we wanted -- or the way it is right now for the design of the study.

And then the data collection was completed, yeah. We started the data collection earlier 2003, but finished by the, yeah, by September.

And so we went ahead and did the data analysis like, yeah, some quick summary report. And then also Anthrotech wrote a quick report also. And I just used that report to do a lot of further analysis.

So the first proposed NIOSH panel was made

back in August of 2004, when we had our first public meeting in Washington DC.

And then since then, I presented the new panel, the bivariate panel, and PCA panel at the ISRB meeting in Oklahoma.

And then in early 2005, we also went to meet with like 3M representatives and MSA, and then showed them the new panel.

And then later in 2005, we initiated the National Academy of Science review. And then they stopped for another effort, and then resumed back in July of 2006. And they finished their review by January of this year.

And then meanwhile, we prepared a manuscript and submitted that manuscript to the Journal of Occupational and Environmental Hygiene. And it is also finished by January of this year also.

So now it is in press, and, in fact, they have a PDF out. It may be posted soon. I will show you later on.

And so, anyway, so the design of the

survey was a stratified sampling approach.

We look at male, female, and also four race groups, White, African-American, Hispanic, and others. And we also divide the population into three age groups. Just this is arbitrary. And so just to ensure that we have subjects from various groups. And so the final sample was 3,997.

A couple of them we did not have complete measurement, and so we end up having about a good data for 3,994.

So these are the type of tools we use, a sliding caliper, spreading caliper. And this is the final tally of the database.

So we have 2,543 male and 1,454 female.

So as soon as we finished the data collection, we tabulate our data into the LANL panel, and quickly we found out that, yeah, only 84.7 percent of our subjects are included in the panel.

And you can see very few people in cells one and two. They are all less than 1 percent. And you can also they also scatter, like above, below,

and to the right of the panel, the subject.

And so we used two approach to develop the new test panels. And the first one, we follow the LANL approach, which is bivariate, using two facial dimension. And the other one we came up with is a principal component analysis approach.

And for the principal component analysis approach, it is yeah, like PCA defines a new coordinate system using linear combinations of the original variables to describe trends in the data.

So we have many dimensions here. So we try to reduce to like key principal components so we can look at the trend.

So for our case, it will be like from small to large, short and wide, or long and narrow. So based on this analysis, it will classify the subjects in such a way.

And the criteria we used to select the dimension were based on literature review and then also expert opinion.

So there are eight studies in the literature that look at respirator fit and facial

dimension. And they are all using half-mask. So far, no one has ever look at that using full-facepiece respirator.

And so the expert opinion, I talked to Alan Hack, who developed the LANL panel, and then also the ISO committee. So and then also various manufacturers.

That's what, yeah, what I call expert opinion, to gather their input and then come up with, yeah, this panel.

And then the other criteria we used is the dimension, like excluded, like can be predict by the dimension, including the PCA.

Like for this case, it is the PCA panel in the dimension. It can be like, by the other. We think it can be excluded.

And then also, we don't want to have too many dimensions, make it manageable. And then some dimensions are very difficult to measure, like with the hair. And if you press a little bit more, you can get a different number or less, yeah, you get a different number. And then those were the variable

we try to avoid.

So this is the, yeah, NIOSH bivariate panel.

So we continued to use ten cell, and then also 25 subjects is what Los Alamos used. So we just copied over here, but number of subjects can be adjusted as needed.

And then later on, Dr. Landsittel will explain how you adjust the number of subjects for the panel.

And then at least two subjects for each cell will be sampled, and we'll try to match the population, the distribution of the population also.

And face length and face width was selected to define the bivariate panel, which can be used for both half-mask and full-facepiece respirator.

So this is the new bivariate panel, and the new -- this show the panel. So it a -- we labeled them from one, two, three, four, five, six, seven, eight, nine, ten, and you can see the dimension different from the LANL panel.

So it range from 98 and a half to 138 and a half. And then also, yeah, from 120.5 to 158.5 millimeter of face width.

And so, as you can see, this is the figure to show. LANL panel is the red color, and then our panel right, yeah, pretty much surround the LANL panel and cover like, yeah, in all directions.

So if you want to consider like at one size here or there or there, it's not enough. So if you look at the whole panel and use the panel to adjust, then that may be appropriate.

And this is the percentage that we estimate of the workers in each of the cells. And we use the 2000 census data to weight our subject, to, yeah, determine -- to estimate these percentages. And they can be used to adjust the panel size if we need to.

And so for 25 members -- this is just an example -- basically we sample two persons from each cell. And these are the two cells have more workers in those two cells, so four and five subjects will be sampled.

And for the PCA approach, we end up selecting these ten dimension, and this is the loading factors, like item factors for the PCA analysis or panel.

And you can see like the first principal component, they are all positive. And these are the coefficient. That can be modified by the original measurement of each of the dimension here, and sum them up to get the first component score.

And so if any of the dimension is bigger, the overall score is bigger.

But for PCA2, it's different. We have like face length, nose protrusion, and nose length here. They are positive. So the longer these dimension, the larger the component score.

And then the other -- for the other dimension, they are negative. So the wider, the smaller the component score. So this is the PCA panel.

So we use the ellipse to include more than 95 percent of the subjects. And then we also use an inner ellipse to cover about 50 percent of the

subjects. And then dividing the subject into -- using these two lines, we divide them into eight cells.

So it's one, two, three, four, five, six, seven, and eight. And each cell represent about 10, 11, or 12 percent of the population, very uniform.

And so you can see the scatter -- this is the scatter chart of the NIOSH subject against the new panel. And so the people, yeah, on the left tend to be smaller. Everything is small. And then you go to the medium, and then large. So everything is large.

But for the people at the bottom, they are -- have a short face and then wider nose. And then the people up here, they tend to be longer faced and narrow and a high nose protrusion.

And these are the percentage that we estimate for each of the cell for male and female. And you can see 95.2 of the male are included in the panel. And then for female, we include more. And then the overall, I told you, is about 96.4 percent of the workers.

And then so if -- again, for example, you have a 25-person panel, member, we will recommend, yeah, like four from each of the cells because it's very uniform.

And then since like Cell No. 2 has a little bit more people, so you can sample like four people there. But, you know, in our paper, we just say like you can -- as soon as you can find someone from any other cell, it's easier. You can use that subject as well.

So two panels, yeah, were developed. And then respirator designed to fit these panels are expected to accommodate more than 95 percent of the current U.S. civilian workforce.

And both panels represent an improvement over the LANL panels used today.

And then we also prepare a training videotape video. It's a Media -- Windows Media Player file. So you can play on the computer to show how to do the landmarking and measurement.

And then we also have a computer program that you can enter the measurement while you are

doing the measurement to help you, yeah, correct problem or error. And then it also place the subject into various cells for the PCA or the bivariate panel for you as well.

And so these are the references that we have published over the years, and so this is the one that I mentioned earlier.

It's just -- the peer review was just completed earlier, January of this year. And now, they gave me this file last week, and they said it will be posted on the internet by the 28th of June, or by the end of this week.

So for you, for those of you AIHA member, you can go there and download the file. And you can also contact me for a copy of the paper. We describe how we, yeah, developed the panel, and then also provided some example there.

And then, again, this is a list of the presentations that I have made throughout the years to show what we have done in this area and, yeah, while getting input from the area stakeholders.

Okay. Thank you very much.

Yeah, any questions?

Okay.

MR. BURKNER: Jeff Burkner with Moldex.

Just to understand, your PCA panel, was that included -- is that incorporated in the NIOSH panel, in the other panel, in the bivariate panel?

MR. ZHUANG: They are two panels. So one used two dimensions. The other one used ten dimensions.

So let's say like for the bivariate panel, you just go out and measure face length and face width, and you look at the grid and see which one they are in.

For the PCA panel, you will go out and measure those ten dimensions. If you measure these ten dimensions here, and then you will use -- it's in the table. We also have an algorithm that you can follow to do the calculation.

You calculate PCA1, PCA2. It will give you two numbers. And based on that number, you go through that algorithm, and it will tell you which cell you are in. Or you may be outside the limit,

depending on the value.

Let's say if you have someone, like the value is 260, and then like ten something, it's outside here.

But if you have a PCA1 of 280, and you have someone like 25, then it will be in this cell. It will be similar.

MR. BURKNER: So in other words, you have an algorithm which will take the ten measurements and then put you in the bivariate grid?

MR. ZHUANG: We look at that and see how they relate, like how the two panels relate. Like someone -- let's say like someone here, like any subject here, it could go to some like cell or the bivariate panel. It doesn't correlate one to one.

Like if someone is one here, it can go there. It could go to one, two, or three of the other panel.

So but, yeah, that will also explain like how we're going to use these two panels for this particular application.

But if you just want to use this one for

your own development purpose, you just have the two set of number, like one is bivariate and one is PCA.

But the one, the Cell 1 for PCA may not be Cell 1 for the other one. It could be Cell 2 there. Or Cell 1 there could be Cell 1 or 2 or 3 here, as well.

So it could be the other way around.

MR. BURKNER: So I guess my question, I guess, Bill will answer it, is how -- can a manufacturer use either cell, either panel?

MR. NEWCOMB: We'll get into that a little later in the technical presentation.

MR. ZHUANG: Right.

Okay, any other question?

If not, I'll -- yeah.

MR. SZALAJDA: We, at least as far as with the presentations today, what we're trying to do is to go over the requirements for how we identified the new respirator fit test panel.

And part of that discussion is, you know, you have heard Dr. Zhuang's work, and he also alluded to the work that the Institute of Medicine

did in their review.

And what the next three presentations are going to address are our overview of the IOM report.

Dr. Pope from -- representing the IOM, at least as far as discussing their work. And then Dr. Shaffer is going to talk about our action plan to work on the plan forward for refining the fit test panel going forward into the future.

So with that, Dr. D'Alessandro had originally planned on giving this presentation, but in her absence today, Les is going to give the discussion.

IOM REPORT

MR. BOORD: Thanks, Jon.

Yeah, and to start off, I do want to extend the apologies to everyone for Dr. D'Alessandro, the associate director of science, who was unable to attend the meeting today, as well as for Roland Berry Ann, the deputy director for the laboratory. Both of them are heavily engaged in one of the acronyms that's on the screen here now, the PPT.

They're heavily engaged in developing an evidence package to be submitted to the National Academies for review of the personal protective technology program. So I extend to you their apologies for not being here.

And, you know, as we go through the discussions today, acronyms are everywhere.

A little bit earlier, we explained PPT. It's the personal protective technology. You know that.

We talk about NA, National Academy. The IOM, the Institute of Medicine. So by the time we get through with the next several presenters, I think the acronyms will even become more focused.

And what we would like to do is to talk to you a little bit about the National Academy's involvement in the Personal Protective Technology activities for the Institute. And specifically, we want to focus on the assessment of the NIOSH head-and-face anthropometric survey of U.S. respirator users.

And a little bit earlier, I had mentioned

that the intermediate goals for the PPT cross-sector program actually addressed four different topics, comprehensive research -- which I think you have just heard a presentation discussing the comprehensive anthropometric respirator research that the laboratory is performing.

The intermediate goals mention the development of PPT standards, which we're going to talk about after the break, the specifics of the proposed standards. The intermediate goals talk about evaluation activities and research to practice.

In this discussion, we want to talk a little bit about the evaluation activities for the laboratory and the r2p.

And basically, the Total Inward Leakage project for half-masks and filtering facepiece respirators, I equate it to an r2p in action. It really is the taking the research and putting it into practice. And it's unfolding right as we're speaking.

The Total Inward Leakage program combines

the very extensive respirator anthropometric research with the respirator benchmark testing to develop a proposed performance requirement which will eventually be implemented through rulemaking into a respirator certification requirement.

One of the key aspects in this evolution of research into practice is the quality of research that is established. And the way that we go about achieving that quality is through scientific review and evaluation.

What we have done at the laboratory is identify a key tactical priority, one of eight different priorities, that is focused on the Science Center of Excellence. And with that priority, we aim to improve the quality, consistency, and dependability of the science delivered to our customers and stakeholders through a program of rigorous evaluation.

And again, evaluation is the evaluation of the programs, the projects, and the research activities that are being performed.

Along with that, it's nice to have that as

a tactical priority. But if you don't put any substance behind it, nothing will really happen.

So attendant to that, we strategically plan for evaluation activities. And we very purposefully allocate between 3 and 8 percent of the standing base budget for the laboratory and dedicate it to evaluation activities.

So, again, 3 to 8 percent specifically aimed at these evaluation type activities.

We draw a similar comparison to other organizations and the cost of quality.

So what do we mean? And what is the laboratory doing in the world of evaluation activities, and specifically, with the National Academies?

And there are four primary efforts that are -- have been initiated several years ago and are in several different phases of continuation.

The first of those activities is a Committee on Personal Protective Equipment for the Workforce. The acronym is COPPE.

And this is a committee that has been

established within the Institute of Medicine in the National Academies to look at the evolving and emerging issues relative to personal protective equipment. That committee is an active committee. It has already met at three open meetings. The dates are illustrated.

And more recently, it conducted a workshop in February looking at PPE during an influenza pandemic, research, standards, certification, and testing directions. So it was an information gathering type workshop.

So the COPPE is one of those evaluation activities that provides input to the laboratory on the quality of our programs and the direction and emerging issues that are important to PPE.

The second program is the one that Ziqing just talked about, and that's the review of the anthropometrics survey and respirator panel modifications.

As Ziqing mentioned in his presentation, this evaluation activity with the National Academy was actually started -- it was actually started in

the fall of '05 or Fiscal Year '06.

And over the year-and-a-half period, there have been several meetings conducted to explain and look at and question and review the research. And that culminated with the National Academies' report on their findings and conclusions relative to that anthropometric survey.

The third area was a similar type review that was performed on the BLS survey of respirator use.

And similar to the anthropometrics review, that review activity had several open meetings to present and discuss the work and the research that had been done. And the final report for that activity was actually prepared in December, briefed to us in February, and is currently available.

And a fourth activity that really extends beyond the boundaries of the laboratory and into the Institute total, and that's the National Academies' review of the various programs, program sectors that I had illustrated a little bit earlier, as well as the cross-sector programs for the Institute.

So it's the National Academies' evaluation of the PPT cross-sector. That's the activity that Dr. D'Alessandro and Roland Berry Ann are heavily engaged in today and could not attend the meeting.

So we have a number of evaluation activities directly linked to the National Academy of Sciences that are looking at our programs and projects and research activities.

There are other evaluation activities occurring within the laboratory in the form of other peer reviews and project review programs, but those are the ones that are associated with our collaborations with the National Academy.

As I had mentioned, the National Academy Institute of Medicine completed that survey for the anthropometrics, published the report. I believe some of these reports will be available to you at the meeting today.

Is that correct, Jon?

So I think Jon may have a little bit of information on how to get that a little bit later, but this is the report.

The report has -- comes up with 15 conclusions and recommendations relative to the anthropometrics research.

So what I would like to do now is I would like to turn the discussions over to two other individuals, Dr. Andy Pope, who is representing the National Academies. And Dr. Pope will explain what the Academy did, and summarize for you some of the major findings.

Then following Dr. Pope's presentation, Dr. Ron Shaffer, who is the branch chief for our research branch at the laboratory, will give you a brief overview of the action plan that we are working on coming out of and developing from the National Academy review of the anthropometrics work.

So with that, I would like to turn it over to Dr. Pope.

MR. SZALAJDA: Yeah. Just as far as the availability of the report is concerned, if you see Betty or Tess back in the lobby, they have copies of the report available, and you can pick a version up from them.

So with that, I will introduce Dr. Pope.

MR. POPE: Thank you very much. It's a pleasure to be here. Thanks, Les.

I will -- I plan to be brief, no matter how long it takes, as the saying goes.

But I have been asked to talk a little bit about the IOM acronym, who we are, what do we do, what are our processes, and how did we come up with the report that has been mentioned, this report that we issued in January of this year that talks to a little bit of the background to today's meeting.

So I am going to -- let's see here -- talk about what the IOM is and then briefly some of the major findings and recommendations that came out of the report.

So who are we?

Basically the IOM is part of the larger collective organization called the National Academies. It's comprised of three membership organizations, the National Academy of Sciences, which is the initial organization and sort of the mother organization.

The National Academy of Engineering, Institute of Medicine, and the National Research Council, which is the operating arm through which we all operate. They give us our procedures, et cetera, and I'll talk a little more about that.

But basically, each of the circles, IOM, NAE, and NAS, are initially and perhaps, depending on your point of view, most importantly honorific membership organizations.

The National Academy of Sciences, the NAS, was created by a Congressional charter in 1863 in the middle of the Civil War, to provide scientific and technical advice to the government in the middle of the Civil War.

One of the first studies that was done, apparently -- or as I have been told. I wasn't here then -- was some advice on how to get compasses to work on metal ships, or ironclad ships. I don't know what the answer is, but somehow they figured that out.

Then in 1916, actually during World War I, the National Research Council was established to

help expand the pool of experts that the Academy could draw from.

Initially, in the NAS charter, there was just a membership organization of 50 scientists, and they were the ones who did all of the studies, however many there were.

Then in World War I, they got to the point where there was so much work to be done, they couldn't rely on those 50 people, so they expanded -- created this research council, which allowed them to bring in other experts, non-member experts to sit on committees.

And then the NAE was created in '64, and the IOM in 1970.

But we all operate under this original charter of the NAS, Congressional charter, which says "... the Academy shall, whenever called upon by any department of the Government, investigate, examine, experiment, and report upon any subject of science or art..."

And by art, we're told now they meant technology, what we refer to now as technology.

And I won't go into detail on this, but this is the organization of the IOM. I'm the little box on the top left, there, the Board on Health Sciences Policy, which is one of nine boards within the IOM program.

So where does our work come from?

About 10 percent of our work -- it varies tremendously -- comes directly from Congress through legislation that says the National Academy of Sciences or the IOM or the, you know, the National Academies will do X, Y, and Z.

It varies quite a bit, but somewhere around 10 percent of our work annually comes from that.

But the vast majority of our work comes directly from agencies, like NIOSH, who recognize the value of independent expert external advice and come to us for that type of assistance.

We are not part of the government. We're all soft money. We work only on contracts to the government.

So there's no annual budget. We're not

part of the government. And I think that's an important distinction that people often are unaware of.

There are a few self-initiated studies that we do. There's not much of that that happens, and frankly, we're not very good at it, I think, when we come up with our own ideas for things.

There have been ideas, but you need to have an audience in order to be effective. And the most effective work I think we do is the work that's asked for because then there's an avid receptor on the outside that's going to take our work and do something with it, as NIOSH has.

Our unique strengths, the Academies, the IOM, National Academy of Sciences, have a reputation for independence and objectivity. That is born out of -- from the original charter.

I guess, primarily, we're sometimes referred to by -- and I'm trying to be humble here -- the Supreme Court of Science. Some people refer to us as sort of the final arbiter.

We often get in the middle of

discrepancies between a regulator and a regulated industry and try to solve difficult issues. All of our work is evidence based. We don't get any easy questions.

We have the stature of the Academies' membership that I mentioned. We have the ability quite often to get people to serve on our committees who won't serve elsewhere, even if they get paid.

And people like to serve on our committees because of the stature of having served on an Academy committee or an IOM committee. And also because quite often, although not always, our reports have impact, and they have real effect. They can be effective out there. People will take them and actually do something in response to them.

It's not always the case. We only give advice and guidance, make recommendations. We don't make people do things. So we are often able to get people to serve on our committees that others don't have access to.

It's important, again, to mention that committee members serve pro bono. There's no --

they're all volunteers. There is a special relationship that we have to the government, that I mentioned. And then there's a great deal of attention that's given to quality assurance and control procedures that help protect the independence of the committees.

We do a lot -- we're very good at taking agency money and then telling them to go away and let us do our work.

We're very good at keeping arm's length and isolating or insulating, I guess, committees so that they can work independently.

We have exemptions to FACA, which you may know, another acronym, Federal Advisory Committee Act. So these committees can meet in closed session without having to be in public eye all the time.

And there's also the very rigorous review process that we go through, which is an independent anonymous review that's basically another committee that's set up that sort of mirrors the expertise of the initial committee. They review the report, and it's a very rigorous peer review process.

This is a sort of a sketch, very much of a sketch of the committee process. This is sort of a traditional study which shows committee assembly, and then the actual meat of the work and the report review, and publication. This is sort of a little more detail, but it's very nice and neat and linear.

And you can see, we hire staff at the beginning of each project. It's all soft money now. We like to continue people on staff if it's possible, but it's often difficult to make that bridge.

It's not really as neat as that, and many of you will probably recognize this kind of process, which is more realistic, where Congress asks us to do something, up in the left-hand corner, and we go through all of this hoo-ha. Somewhere in the middle there is public meetings, and then at the bottom there's a report that ultimately gets issued.

I think we can all relate to that kind of a process.

So the reason -- Les has already mentioned the recent work that we have been doing for NIOSH.

The currently ongoing study on protecting healthcare workforce and for a flu pandemic. The review of the anthropometric report that Dr. Zhuang had also mentioned. The BLS survey respirator use, and this ongoing -- actually, it's a review, I think, of 15 committees that we're going to do for NIOSH over a period of five or six years, reviewing each of whatever the 15 are that we are ultimately given to do review for.

I think we have done two at this point, mining and hearing loss. And we're about to produce one on respiratory. And I forget what the others are, but we're well into that.

And I want to say that, you know, I think it's -- I want to commend NIOSH for having the foresight and the willingness and the fortitude, whatever, to ask for this kind of independent external review because you don't know what you're going to get, quite frankly.

We do protect our process very carefully. We take their money and then tell them to go away, basically, and we do our review.

I mean, we do stay in touch, of course. There's a lot of information we need from the sponsors about what we're going to review. But you don't know what you're going to get out, and so quite often our reports are very critical.

And we have been -- and we were critical in this report of -- the anthropometric report, not terribly critical, I don't think, but we were asked in the review to examine the content and the form of the anthropometric study to determine if the revised panel was representative of the U.S. workforce, to identify some additional analysis or analyses that NIOSH might undertake following that.

And then to make a series of recommendations including additional information that NIOSH might derive from current and possible future efforts of this sort.

This was the committee, it was chaired by Jon Bailar. You probably recognize some of these folks, at least, like Alan Hack and Howard Cohen.

It was a wonderful committee. I think they did a tremendous job.

This was the project timeline. It was mentioned they were interrupted in the middle by a special request from the HHS secretary, who was freaking out at the time about the possibility of possible reuse of N95 respirators if the pandemic came, what we were going to do. There weren't enough N95s out there. Is there any way that they could be reused.

And so we actually hijacked the committee that was already underway because much of the expertise was there, interrupted their process, got them to do this other report, and then came back to this one.

The major findings of our report that has been -- this report which was released in January, is in sort of overview, was that this new panel was a clear improvement over the LANL panel, fit test panels that have been used since the 1970s.

This new panel is a clear improvement, but like anything else, there are weaknesses and things that could be improved.

And we made some recommendations, excuse

me, in our report for things that could be done in the future as NIOSH moves forward and other surveys of this sort are done. And I think that's what Ron is going to talk about next, primarily.

So thank you very much.

The report -- there are going to be copies here today. If not, I'm happy to send additional copies out here. But it's also available at the NAP website. If you go to nap.edu, you can download it for free, or order additional copies if you like.

It's also a tremendous website for just research if you -- on any topic.

All of our reports are up on this NAP, National Academies press website. It has a tremendous search engine. You can put in whatever you want, and it comes up with all the information from our reports.

So thank you very much. I'm happy to answer any questions if there are any at this point.

Thank you.

MR. SHAFFER: Thanks, Jon.

Today I'm going to talk a little bit

about, basically, a continuation or a follow-on to what Ziqing, Les, and Andy just mentioned in terms of what's next in our research in anthropometrics.

This is an ongoing effort, and our objective is really to develop a long-term strategy, what we'll call our action plan for facial anthropometrics and respirator fit research at NPPTL, with the goal to address the recommendations, of the 15 recommendations in the IOM report.

The approach that we have taken so far is listed on the slide.

Basically, we have analyzed the recommendations that are in the IOM report basically to determine what research needs to be done, what new data needs to be collected to address or to answer the questions that they have posed.

And we have done some additional analysis as part of that. We have reviewed what our ongoing research was as well as thought of what research projects need to be done in the future to address those gaps.

And we're also currently in the process of

reviewing what research is being done at NIOSH and the other divisions, academia, as well as other government and industry organizations, specifically related to anthropometrics and respirator fit research.

So basically, pulling that analysis together is basically culminating in an action plan.

There are two parts to the action plan that we have put together so far, and I want to emphasize that this is really an internal sort of working copy, and I'll be presenting some examples today.

We have a process that we will be putting this out for public comment, and I'll show that in a couple of slides. But this is basically kind of a snapshot of where we are today in developing this action plan.

And the action plan will consist really of two parts. One is a point-by-point response to each one of those 15 IOM recommendations. And then secondly, it's a research road map or a vision into the future of what projects need to be done over the

next ten years. So that's basically the 2008 to 2018 time frame. How do we sequence out those research projects so that we can address the gaps that were identified.

And so the next slide I'll show you a sort of a pictorial view of what research road map might look like, and this is our current draft version shown here.

So basically, let me explain this to you.

Across the top, these are -- this is by Calendar Year, here, so then in each column these are different projects. So, for example, each block is a project or a milestone occurring at a certain time frame over the next ten years.

So you will recognize some of the milestones on here. The NAS or the IOM report that Andy talked about came out in 2007. The current subject of this meeting, the half-mask TIL program, and basically the blocks, you know, represent approximate time frames for when those will happen.

Those are just, you know, some estimates on my part at this point. And we are continuing to,

you know, update this plan and continue to refine it.

So basically, if you look at the 2007, 2008 time frame -- so basically this time point here -- these are projects or efforts that are currently ongoing, or in the case of some that start in 2008, are certainly in the pipeline. They're -- and in the case of that project, is in the peer review process right now.

And so what you see from 2009 on would be proposed efforts going forward.

And so where this all culminates, essentially, is addressing one of the key recommendations in the IOM report, which is 5-1, specifically, if you go ahead and get a copy of that report.

But it basically says -- and I'll paraphrase it here, that you know, NIOSH needs to update the panel, the respirator fit test panel, more frequently than, you know, say the last time the LANL panel to the current panel, which is about a 20-, 30-year time frame.

NIOSH needs to update that panel more frequently, and also to consider the use of 3D head scan data in that -- in future panels.

And so basically, the research projects that we have proposed to going forward are really designed to get us toward that objective.

And I'll just mention two time points in the middle. I'm not going to go through all the research projects listed there. But certainly, you're more than welcome to talk to me afterwards if you have any questions or comments about any one of them in particular.

But basically, looking at one time point in the future that we could update or look at the panel again, is really around the, you know, about five years from now or so when the 2010 census data comes out. That would give us an opportunity to perhaps re-weight some of the cells a little bit to reflect the demographics that come out of the 2010 survey.

We would expect that to be a very small change, but something we would nonetheless want to

take a look at.

And then really culminating in about the 2014 time frame, sort of after a number of projects have finished, to really take a look it this whole issue again and basically answer these three questions: Do we need to go out and do another large scale survey? If so, do we do 3D data or traditional anthropometric measurements? And then what are the key facial parameters that one should be using in a respirator fit test panel?

And so if there was a new data collection, it would probably occur about this time frame. So that would be about 12 -- ten, 12 years after the last data collection had occurred, resulting in a possible new panel around the 2018 time frame.

So where do we go from here?

This is sort of the plan going forward, with the action plan at least.

We plan to host a detailed action plan, draft action plan to the NPPTL website sometime in the July/August time frame, open up a docket -- so this will be a separate docket in the TIL docket

that Jon talked about earlier, and it will also be mentioned by Bill later in the day.

So it will be a separate docket. It will be opened specific for this long-term research strategy.

That docket will be open for approximately 90 days. We're figuring the September to November time frame. There's a number of key meetings that are occurring at that time frame, and this will be an opportunity where some of this information will be presented at that -- during those meetings.

And so this will be an opportunity to get some additional feedback with the goal of revising the plan, 2008, and then that would be a ten-year plan going forward from there.

And we would use the plan, essentially, to prioritize what research projects we do, how we allocate funding internally, what staffing and equipment needs we would need to do to make that action plan happen.

And if there are any questions, I'll be happy to answer them.

MR. BURKNER: Hi, Jeff Burkner with Moldex.

Actually, it's not a -- it's not a question. It's more of a comment. I wasn't sure exactly what point I wanted to make my comment, but I think now is appropriate.

I think the work that Dr. Z has done is fantastic. I mean, I think it's extremely important that we be able to characterize the population and then, thereafter, for manufacturers to use that information in developing, you know, our respirators.

To be perfectly honest -- and this is not information or not comments that you haven't heard in the past -- but I do have a concern on the disconnect between NIOSH actually requiring fit testing as part of the certification, and the usefulness that it actually serves to the public in terms of we know -- we know that users have to be fit tested. Unfortunately, we also know that 53 percent, only 53 percent are doing fit testing.

And I'm just wondering if the money would

be better spent in terms of educational programs, that kind of thing, more on the OSHA side rather than actually requiring a manufacturer to actually go through fit testing, which -- I mean, the manufacturers believe that it's probably market driven. And the bottom line is if the end users aren't doing fit testing, that's really the crux of the problem. It's not that the masks aren't going to fit, that kind of thing.

So just my comments.

MR. SHAFFER: Thank you.

MR. PITTS: Sam Pitts. At the risk of exposing my Cro-Magnon genetic material one more time.

I understand -- I understand the need to do maintenance vacuum inspections on masks, and I understand the need to do fit testing of the mask then on an individual's face.

And I see the wisdom in getting all of this anthropology data on the dimensions of the face and the -- that mask has got to fit on.

The last gentleman that spoke, and I think

a lot of this is probably a training problem with the individuals who are at the pointy end of the spear, not doing their fit testing or maintenance, vacuum testing of the masks before they use them.

I guess what I'm failing to grasp is, in my mind, with SF6, Total Inward Leakage of like suits, which I'm very familiar with, are you going to have a chamber somewhere where these masks are tested in sulfur hexachloride?

And what -- I guess I'm grasping -- I'm not grasping what you intend to get from that, when you combine the three aspects of this, measurements, the vacuum testing, and the anthropological data, how that's actually going to affect us as operators down in the trenches.

MR. SHAFFER: I think, maybe Bill or Jon or Les.

That's a very good question, Sam. I'll have to defer to my colleagues.

MR. PITTS: I'm not grasping how -- is this going to be on an individual? We're going to fill a chamber with SF6 and then measure Total

Inward Leakage on the interior of the mask after we have utilized all this data that you have collected to manufacture masks to a certain more current standard?

MR. BOORD: Perhaps I can take a crack at it.

I think as we go through the continuing discussions this morning, you will see what the plan is for actually implementing a program to do this type of testing, okay.

And the activities that we have in the laboratory to build a fit test laboratory and to implement it on a Total Inward Leakage program for all classes of respirators.

MR. PITTS: Les, will this be something that's done on a -- as the masks are manufactured by the manufacturers?

MR. BOORD: It would be done for certification testing, just as we do other tests for certification testing.

So the objective is to define a performance requirement for Total Inward Leakage and

then test the respirator against an anthropometrically representative panel of human subjects to demonstrate compliance to the defined requirement.

So that is kind of the testing regime that will then be part of the performance requirements used to establish the approval or compliance with the NIOSH requirements for the respirator.

MR. PITTS: The leakage testing, would that test the integrity of the crimped seals on the masks as well as the fit around the individual's face?

MR. BOORD: Yes.

MR. PITTS: How would you be able to discern which was leaking in any particular case?

MR. BOORD: Well, in terms of the Total Inward Leakage, our objective would not be to isolate them where the leakage occurred. Okay? That would be for others perhaps to do.

But from a laboratory evaluation for compliance against the requirement, it's the total.

We're not focusing on where it might be

coming from. It's the total protective quality of the respirator.

MR. PITTS: Okay. Thank you.

MR. BOORD: All right, Sam.

Yeah, just to conclude the data -- any other questions, first?

MR. WATKINS: Jim Watkins with ArcOne.

My question is, just how does this test interrelate with all of the other testing that we're doing?

Are we just adding on something else? Or, you know, is there cross -- cross-information between these tests?

And how do we, as the manufacturers, determine, you know, from a cost perspective what's the best one to start testing first that we know is going to give us the most feedback to us, to tell us where we need to change our product?

MR. BOORD: Yeah. I think, too, that that answer may become a little more clear after the next several presentations.

But our plan and what the laboratory is

doing is establishing a Total Inward Leakage performance requirement for each class of respirator.

Now, we're not doing that today. Today we're only looking at the filtering facepiece and half-mask respirators. So that's the first step.

After we address those respirators, other classes of respirators will also be addressed for their Total Inward Leakage performance requirements.

Some of this work has been done and is in practice today on some of the CBRN respirator requirements that the laboratory has identified.

And in those, you will find that there is a fit test, a laboratory respirator protection level test that is identified and performed today. But that doesn't extend through all classes of respirators.

MR. WATKINS: Well, right. I understand that.

My question the more to, okay, well, how does this relate to silica dust? How does it relate to IAA? You know, which one is best to do first,

second, third?

Which one is going to tell us, you know, where we can cut costs, you know, because these take a lot of -- all these tests take a lot of money.

MR. BOORD: Yeah. The Total Inward Leakage performance requirement would actually be a replacement for the isoamyl acetate requirement and testing that is currently performed.

MR. WATKINS: Okay. That's what I was unclear on. Thank you.

MR. BOORD: Okay. So any other questions?

Just two summary comments. First of all, I would like to thank both of the presenters.

And Andy, Dr. Pope, I was really glad to see the illustration that you had for the work flow of the committee work. I thought our programs were the only ones that had a flow like that, so I was really glad to see that.

And the second thing I wanted to just note, that if you go back to pick up a copy of the report, you may find that we're being particularly nitpicky in determining how many we hand out.

That's not because we're cheap, okay. The reason is, see everything -- we tie a ribbon around everything. But the reason is because it really relates back to our personal protective technology evaluation activities that are going to be reviewed by the National Academy.

As it turns out, this is an output for one of the research programs and evaluation activities for the laboratory. So it becomes incumbent on us to know what we do with those outputs and who and how many go into circulation.

So when you go back and ask for it, and they say, Well, wait a minute, I have got to write it down and make a note of it, it's not because we are cheap. It's because we're trying to improve our recordkeeping for the outputs for the laboratory.

Okay. So with that, we're going to take a break for, how long?

MR. SZALAJDA: Ten minutes.

MR. BOORD: Ten minutes, so 20 until 11.

(A recess was taken.)

MR. SZALAJDA: What we're planning on

covering now for the balance of the meeting is to discuss the testing results from the benchmark testing program that Bill Newcomb led, as well as the proposed requirements for inward leakage, and then also a statistical explanation of the evaluation of our data.

So with that, the next couple of presentations are going to be led by Bill Newcomb, who is going to discuss the testing results and then the proposed performance criteria.

HALF-MASK TESTING RESULTS

MR. NEWCOMB: Thank you, Jon.

Enough talking about the measurements of people. Time to get talking about respirators, which I'm sure you all came to hear.

Benchmark testing. We tested 57 filtering facepiece respirators, 43 elastomerics, one quarter-mask.

As I said before, there were -- the entire panel of 25 subjects per model, three donnings per respirator, per subject, and 8,250 fit factor data points.

And while I dwell on that bottom line, I would like to extend my thanks to Courtney Neiderhiser, who is in the back here, who conducted over half of those herself. And also to Don Campbell, who helped me with some of the work in doing this testing.

Total Inward Leakage is 100 over a fit factor, the measured fit factor. And it is assumed that the measured fit factor is approximately equal to a protection factor because it is a Total Inward Leakage.

But that is not the assigned protection factor. That is a completely different subject that's assigned to a class of respirators.

So just to give you a little information concerning the next few graphs that you're going to see, the Total Inward Leakage of 1 percent is approximately a protection factor of 100. A Total Inward Leakage of 5 percent, a protection factor of 20, 10 percent, protection factor of 10, and a 20 percent, protection factor of 5.

Now, we get into the complicated data.

This graph is for 19 of the 25 subjects, attaining a certain fit or a certain Total Inward Leakage, okay.

This is the average results for 101 respirators. And it can be seen that a performance, a fit factor or a Total Inward Leakage of 10 percent, approximately 60 percent of the 101 respirators were able to attain that fit factor or that Total Inward Leakage for 19 out of the 25 subjects.

If we look at 5 percent, approximately 48 percent of the 110 respirators, again, tested across the board on 25 subjects, were able to attain that fit factor or that Total Inward Leakage only 48 percent of the time.

We looked at the elastomeric results, and there's three graphs, three plots on this graph, 15 out of 25, 19 out of 25, or 24 out of 25, showing the spread.

So for a TIL of 10 percent, you see approximately 50 percent were able to achieve a 24 out of 25, approximately 67 percent were able to

reach 19 out of 25, and about 92 percent, 15 out of 25.

For -- I'm sorry, that was for the -- I mixed up here. That's for a TIL of 5 percent here.

TIL of 10 percent, we were up to 98 percent or so were able to attain that fit factor.

Filtering facepiece models were slightly different in the fact that, given a TIL of 10 percent, only about less than 10 percent of the total filtering facepieces were able to reach that, achieve that with 24 out of 25 test subjects.

Approximately 42 percent, 19 out of 25 test subjects, and about 78 percent, 75 percent, 15 out of 25 test subjects.

If you look at what we'll get to later, a proposed criteria of TIL of 5 percent, you will see that virtually none of the filtering facepieces were able to reach -- achieve that, out of 24 -- out of 25 test subjects, approximately, a little -- about 20 percent on 19 of 25 test subjects and around 45 percent, 15 out of 25 test subjects.

What we did see is that there was a

statistical difference between the filtering facepieces and the elastomeric facepieces over the total.

Now, one of the reasons that you might ask why we took so long doing this is we had some anomalies in the data. And these anomalies were caused by the software that we were using to take the measurements.

It was not the software that came with the equipment. It was software that was used because it was easier to manipulate the data and look for things happening.

One of the data anomalies that we saw was there was no primary ambient sample. Another one was the missing last in that sample. Some other switching errors, and low ambient concentrations.

This is a typical data plot of the -- of a test where an initial ambient reading is taken, a normal breathing ambient, deep breathing, turning head from side to side, up and down, bending up and down, and this one, a normal breathing at the end.

Between each one, an ambient reading is

taken. The way that the Total Inward Leakage is calculated, the average of the before and after, the sample in-mask is divided by the average of the sample in -- before and after in each one of the cases.

In this data plot -- and these are actual data plots, by the way -- it failed to take an initial first reading. So if you were to average the before-the-test reading and the after-test reading, you're going to find a problem because this is obviously an in-mask sample and not an ambient sample.

So to correct this, what we did is took a look at the data and we said, We're going to disregard this, and we're going to calculate the Total Inward Leakage based on only the ambient sample after the exercise and disregard the ambient sample before the exercise.

In this instance, there was a failure to take the last normal breathing exercise, in-mask sample. So what we have done in this case is just ignore all this and said, We're going to base the

Total Inward Leakage on the six exercises and not the missing seventh exercise of normal breathing.

In this case, there was an ambient sample that was missing in the middle of the test.

What we did here was to look at the Total Inward Leakage or the penetration at this point. Instead of averaging this, in the sample that's missing, we just took this and used that as the -- instead of the average of two. And for this one, used the average of this rather than the average of two.

Comparison of the results that were corrected and uncorrected, you can see at the extremes, there's very little difference. In the middle, there's extremely a little difference.

So once we corrected the data, there was not that much difference shown in the data before correction and after correction.

But we wanted to make sure of that, so we went through all 8,000 data points and looked at graphs similar to the graphs that I showed you for all the data to make sure that we didn't have

anomalies in the data.

Now, we did have one test, which I didn't show, where the ambient aerosol, instead of being up in the four to 600 or above particles per cc, it showed 20.

We said that's not -- doesn't meet the criteria that we set, so we threw out that test completely.

To summarize the data review, the data was corrected where applicable, uncorrectable data was not used, and corrections did not significantly change the results.

Data availability, data will be made available to those manufacturers who wish to review the data. Not every manufacturer's product was tested, but everything that we could buy locally was evaluated.

In summary, we found a wide variety exists between the overall fitting characteristics of half-mask respirators.

There was a statistical difference between elastomeric half-masks and filtering facepieces, but

there was an overlap.

The conclusions from the summary, a TIL performance requirement as part of a respirator certification is necessary. There are products that do not perform that well.

Conclusion two, with the tested respirators, it should be easier for potential wearer to obtain the OSHA required fit factor during a fit test with a elastomeric half-mask than with a filtering facepiece.

In all cases, you should be able to do it with either, but because there is a difference in the fitting characteristics, it should be easier to do it with a elastomeric than with a filtering facepiece.

Thank you.

Any questions?

MR. METZLER: Rich Metzler, SEA.

Did you do anything in your protocol in collecting the data to make judgments about the fit checking nature of filtering facepieces versus elastomeric half-masks?

MR. NEWCOMB: No. There was no evaluation of user seal checks done during this process.

MS. FEINER: Lynn Feiner, North Safety Products.

What percentage of the test data were in the error group?

MR. NEWCOMB: I believe there were approximately 10 percent when we were all said and done.

MS. FEINER: Okay. Thank you.

MR. MICHAEL RUECK: Klaus-Michael Rueck from Draeger Safety, Germany.

We saw in your presentation values from 400 up to 800 parts per cubic centimeter. How did you ensure that the concentration of the particle amount is constant or stable?

Did you use any testing chamber, and will you describe in the procedure that you need to check after every step of the testing, that last 500 seconds, or each 600 seconds that you have to check the concentration, yeah, after every step.

MR. NEWCOMB: Yes. To answer the first

part of your question, we did this in a large room because we had four subjects going at once.

But we also had four sodium chloride generators generating background that we tried to keep as constant as possible.

Obviously, it's not -- it's not going to be entirely constant all the time.

In the actual future tests, we are now in the process of building a facility for Total Inward Leakage testing that should be more stable than what we did the benchmark testing in.

Was there another part?

Oh, the protocol calls for measuring ambient between each exercise. And the technician was instructed not to conduct a test if there wasn't a certain background in the room to begin with before the test.

Yes, Sam.

MR. PITTS: Sam Pitts, U.S. Marine Corps.

With our testing of garments in SF6, we have become concerned a little bit -- at least in some more cerebral circles than in the Marine

Corps -- the IAB, OSHA, NIOSH, NFPA, about the correlation between SF6, which is great for finding minute holes in garments, the actual correlation of that to some of the threat, the threat agents and how that very tiny molecule would correlate to actual agents of threat that we're concerned with.

We don't think we have got a real good handle on that correlation. And I would -- perhaps -- is there a possibility -- does the possibility exist where testing to a standard that's in reality higher magnitudes of order higher than what the actual threats are?

That's just a comment and a question.

MR. NEWCOMB: Okay. Actually, we're talking about two different concepts, really.

In the filtering facepiece or the half-mask respirators that we're testing are assigned protection factor of 10. And that means that they can go into ten times the TLV. That's for products that do have a TLV.

In the suits that you're testing with SF6, you're not sure what the threat is going to be, the

concentration of the threat, and so forth, and you're testing for a gas rather than a particulate.

So the testing that you're doing of suits is based on unknowns. Whereas the use of this type of respirator is based on knowns or should be based on knowns.

So what we're trying to do is set a minimum performance or minimum capability for the respirator, and we did that by testing them.

The use of the respirator is controlled by OSHA, and OSHA says that you can only use these respirators where the threat is known and where you're less than ten times the protection limit.

So it's really two different things.

We are not looking at quantifying the use of these products in the field to certain threats.

That's not the object here.

MR. PITTS: Thank you.

MR. SZALAJDA: Yeah, thanks, Sam.

Just kind of as a follow-up to Bill's comment, you know, when you talk about other categories of respirators, we're going to be

addressing those over the next several years, at least as far as moving and looking at powered air purifying respirators, SARs, and all the rest of the classes.

So, you know, we appreciate the comments and the issues that you bring up, and look forward to getting more of that information as we go along.

MR. PITTS: Thank you.

MR. SHAW: Dean Shaw with Mine Safety Appliances Company.

Bill, in your study, what testing protocol was used to train the users in donning and properly using the respirators?

MR. NEWCOMB: What we did is try to replicate what should be done in a respirator program where we took the instructions for the respirators and instructed the users on how to don and doff them.

This was not a donning and doffing exercise, so if someone were to put a filtering facepiece on upside down, we would not run the test. And if someone would put both headbands around their

neck rather than around the head as the respirator manufacturer would suggest, then we didn't run the test.

What we're trying to do is assess the capabilities of the respirator. Not at this point were we looking at the efficacy of the user instructions or the ability of the wearer to put it on without reading the instructions or so forth.

So it was really a more or less trained wearer.

PROPOSED CRITERIA AND IMPLEMENTATION PLAN

MR. NEWCOMB: Moving right along, our next speaker is Bill Newcomb. Bill.

Thank you.

What we're going to talk about is the technical concept and what we would like to do with all this data that we have gathered.

The technical concept has proposed requirements. We're going to talk about the test subjects, the test protocol, and the applicability and schedule.

Proposed requirements, as you might have

read on our website, is to use the NIOSH respirator fit test panel.

We would base the testing on the users instructions for sizing. We would have a maximum Total Inward Leakage of 5 percent on 26 out of 35 test subjects, and the applicability would be to all Subpart K half-mask respirators.

Process for test subjects.

What we will do is measure the ten facial dimensions that are used to establish a PCA panel. We would classify subjects as to whether they fit the PCA panel or whether they're outliers. If they're outliers, we're not going to use them.

Then we will classify the subjects by the ten-cell panel.

Why are we doing this?

Well, the panel as it is, is designed to cover 97.7 percent of the respirator wearers in the United States. And you can see the percentages of those wearers that are in each cell.

And don't try to add them up because they might not add to 97.7 if I typed it wrong.

What we have is a PCA panel that shows some of the types of subjects that you might have. And you notice there are a lot of outliers. These outliers, most of them are within that 97.7 percent.

There are outliers in this PCA panel because they have some feature on their face that is unlike other people of the same size. They might have a nose that's too large for the rest of their face, a jaw that's too pronounced, or something.

So what we don't want to do is have people in our fit test panel that are outside what we would consider the norm, suggesting that this is the norm for facial features.

If you remember the chart that Dr. Zhuang put up, when he took the ten facial measurements, there were weighting factors.

And two of the larger weighting factors were factors around the nose, the protrusion and the length. And those weighting factors may make a subject fall outside the PCA panel.

Because we have never used the PCA panel to -- we think it's much too complicated at this

point to use -- to tell people this is what they have to design to and this is what we're going to use.

We would still like to keep the bivariate panel. So the subjects, even though we will put them into a panel which is based on two dimensions, we want to screen them using the PCA panel so that they won't be people that have -- that are extremely hard to fit.

Again, the test subject selection will be based on the NIOSH panel. We'll screen out the subjects not fitting the PCA panel. We will test 35 subjects for each facepiece, unlike what we do today.

If you have three facepieces that cover the entire panel, each facepiece will be tested with 35 subjects. And those are the 35 subjects within that panel, which the respirator is designed to fit. And we'll go over that again in a second.

The user instructions must dictate which subject corresponds to a given facepiece, not necessarily in facial sizes, but some way of

determining that. Correlation of respirator size to facial dimensions is not required to follow the panel.

If we have a facepiece that's designed to fit everybody, a one-size facepiece, then these numbers are the numbers of test subjects in the panel in those boxes that will be used to test that facepiece. And they're based on the percentages of the 97.7 percent of the population of wearers.

If you have a small size that fits, for instance, one, two, three, four, and six, which are these boxes, then again, the facepiece will be tested with 35 subjects.

The numbers of subjects in the panel -- in the cells are based, again, on the total population in the original panel that covers 97.7 percent of the population.

You have a large facepiece that is designed to fit those characteristics that are found in seven, eight, nine, and ten, again, 35 subjects, the number in each cell based on the original percentages out of the entire panel.

The test protocol.

The instrumentation, we'll use a TSI PortaCount and Companion in a direct reading mode, or equivalent, if there is one.

The challenge agent would be sodium chloride, in this case, at least 500 particles per CC.

Sample penetration, flush probe located as close as possible between the subject's nose and mouth.

The donning will use training the user in the manufacturers -- by the users manufacturer's instruction -- by the manufacturer's user instructions.

There will be a pretest acclimation, similar to the OSHA protocol, where we wait at least five minutes before starting the test.

The exercises will be the OSHA exercises, but for 30 seconds apiece.

And those exercises, again, are normal breathing, deep breathing, turning your head from side to side, moving the head up and down, reciting

the Rainbow Passage out loud -- that's the one I missed before -- reaching for the floor and ceiling. Also grimacing, but grimacing is not used to calculation the Total Inward Leakage.

And again, normal breathing.

Individual TIL calculations will be the average for the seven exercises.

Duplication, each test will be repeated three times for each test subject respirator combination, and the TIL calculation will be the average for the three tests.

So to recap, each test subject will don the respirator three times and complete a range of exercises.

The calculation will be -- excuse me.

The average penetration for all the exercises will be calculated. The average for the three donnings, if the penetration is less -- greater than 5 percent, the fit would be considered. If it's less than 5 percent, the fit would be considered acceptable.

For each model, count the number of

subjects with acceptable fit out of 35. There must be 26 out of 35 that have achieved the acceptable fit. And just, again, to re-emphasize, Total Inward Leakage is not the same as Assigned Protection Factor.

I'm sure you all wanted to see this.

The estimated cost per testing of each facepiece based on what we have to pay test subjects, and technician time, is about 85,000 (sic) to $12,000 per test, estimated.

Proposed implementation concept.

What is in the proposal today says it's effective 30 days after codification, applicable to all new approvals, with a three-year grandfathering of all approvals.

One of the concerns that NIOSH and others have, obviously, is the availability of product. And there has been a great deal said about the availability of filtering facepieces, especially in a time of possible pandemic crisis. In fact, it was thought enough about to disturb our anthropometric data review, as was mentioned earlier.

So we're very cognizant of the fact that this is a timely process, and we're open to suggestions.

One of the things we did when we implemented Part 84 was to have a moratorium on extension of approvals for product that was approved under the old scenario.

We have suggested possible -- possibly two years. But this is an area where we would really like some input from all of the stakeholders, not only manufacturers, but also the users, those that, you know, have to supply people with filtering facepieces or elastomeric facepieces in the future, as well as now.

We need all your input on what you think is reasonable expectations for implementation of this plan.

Thank you.

I hope I have answered some of the questions that were brought up earlier.

If not, you're free to ask more at this point.

MR. METZLER: Rich Metzler, SEA.

Your slide indicated a time frame after codification.

Is that to say that this test is going to go through formal rulemaking?

MR. NEWCOMB: Yes. One of the things that I neglected to mention is the fact that it does go through formal rulemaking.

What we're expecting is that we will have comments from this public meeting that, towards the end of the year, hopefully, we will have some sort of a notice of -- at least a draft notice of proposed rulemaking, and go through the informal rulemaking process, which requires, you know, the proposed rule and the final rule, and all of the comment period and answering all the comments, and so forth.

It was also mentioned that we're not in the rulemaking process now. When we do get into the rulemaking process, it will be much more difficult to go over some of these things.

So any comments that you have now, please

put them into the docket so that we can look at them and deal with them before formal rulemaking starts.

MR. METZLER: I'm also representing Sundstrom, and they produce a small/medium and a medium/large mask, and you didn't give examples for the panel that would be covered under those two broad sizes at this point.

MR. NEWCOMB: Again, it would depend on what the manufacturer says these are to cover.

I gave you examples of extremes, and the one in the middle. You know, you could have one that's designed -- if you look at the PCA panel, you will notice that the oriental features are mostly in the wide short face category.

You might decide that you want a facepiece that's designed specifically for a certain ethnic population. We will test that for 35 test subjects based on the panel cells that represent that population.

But you, as the manufacturer, have to tell us, somehow, what that's designed to fit.

MS. TREMBLAY: Julie Tremblay, Aearo

Technologies.

Bill, on the fee for fit testing, is that for a particular size?

Just the example you just gave, if -- I think I'm interpreting your comments previously that if a manufacturer, say, designed a large respirator only -- there was no small or medium -- conceivably we could go to NIOSH and say, This is how you select large size faces, and we could get, I guess, a pass, if you will, if we only sold the large respirator; correct?

MR. NEWCOMB: Yes.

MS. TREMBLAY: Now, if we just said, okay, we want to fit everybody in that panel in the small, medium, and large, would the fit testing fee be for each size?

MR. NEWCOMB: The fit testing fee is per facepiece.

MS. TREMBLAY: Okay.

MR. NEWCOMB: So if you had three facepieces, then it would be $30,000 roughly, using an average.

MS. TREMBLAY: Okay, thanks.

MR. PFRIEM: Dale Pfriem, ICS Labs.

Bill, I missed it. You said you gave the small, large, and medium, I have the small, large, and one size fits all.

MR. NEWCOMB: I didn't give a medium.

MR. PFRIEM: Could you give a medium?

MR. NEWCOMB: A medium, if -- let me just go back for a second here.

I don't have a medium.

However, if a respirator were designed to fit, let's say, these blocks, then the number of subjects -- my battery just died -- in that would be based on the percentages that you see in the small letters there.

So you would take the blocks that is designed to -- the cells that it's designed to fit, and normalize those percentages to 100 percent of 35, and come up with a number of subjects based on that the same way that I did here. Okay?

It's still the 25 percent in this box and 10 in that box, just like it is here.

MR. PFRIEM: Okay. And will that kind of, you know, even though it's not really vague, but guidance be provided in the STP?

MR. NEWCOMB: Yes. Some of that guidance will be provided in the STP. Some of that guidance has to come from the manufacturer.

You know, we're not going to guess at --

MR. PFRIEM: Will there be language in the STP that the laboratory has to take the information from the manufacturer and use its best judgment, even if it's language like that, to fulfill the -- fulfill the test panel, because whatever you have in there, it has to be in writing?

MR. NEWCOMB: Yes, uh-huh.

MR. PFRIEM: That's it. Thanks.

MR. SHAW: Dean Shaw with MSA.

Bill, can you tell us why there seems to be a switch from identifying a respirator and its level of protection to the user -- you know, I know we're moving into this Total Inward Leakage situation here, but I'm confused as far as the terminology, why -- what's the analogy for shifting

from something that is very easy to understand when somebody mentions protection factor to something like Total Inward Leakage?

Because I, very quickly, Bill, I found myself calculating back what the protection factors were from the TIL number.

MR. NEWCOMB: You can do that.

One of the reasons is that there is so many different types of protection factors.

There's assigned protection factors. There's workplace protection factors. There's simulated workplace protection factors, and so forth.

What we're really looking at here is a minimum Total Inward Leakage for the respirator as a base performance level, not having to do with the usage.

That's why the Total Inward Leakage does not equate to an assigned protection factor. It doesn't equate really to a protection factor in use.

The only reason that I use the protection factor terminology was to give, as you say, what you

did, in trying to relate the percentage of inward leakage to the current protection factor levels, but we're not trying to establish protection factors nor assign protection factors.

What we want to do is have a base level of performance that all respirators are capable of doing, of meeting.

MR. WATKINS: Jim Watkins, ArcOne.

You had said, I believe, about the people -- the cost of this is in large part due to the test subjects.

MR. NEWCOMB: No. I said obviously we have to pay the test subjects.

MR. WATKINS: Correct.

MR. NEWCOMB: That's one of the things that goes into that calculation.

But also we have technician time and so forth. And there are -- you know, it takes a lot of time to run these tests.

MR. WATKINS: Correct.

MR. NEWCOMB: Most of that is labor.

MR. WATKINS: Are you looking into ways to

reduce that cost?

Thank you.

MR. NEWCOMB: Right now, that's an estimated cost.

And until we get up and running -- and hopefully we'll be doing some validation testing in the near future. And we're going to be taking some of the products again and trying to rerun the tests using 35 test subjects and see what we do, what we can come out with as far as tests.

At that time, we can do some more estimating as to the time that it takes to run the tests and so forth.

But it is all based on labor costs. That does not have any equipment costs or anything else in it.

MR. VINCENT: John Vincent with North Safety.

Bill, when a manufacturer submits a new respirator, typically, we provide fit test data with that submittal.

Would this same fit test data be required

for this? And if the costs are the same for small, medium, and large, it's going to cost us $30,000 to do the test and you, 30,000, for NIOSH -- additional $30,000 to do the test on a three-size respirator?

MR. NEWCOMB: Right now, pre-submittal test data is required for almost all of the NIOSH tests.

I don't believe this will be any different, but there are companies that have their own panels that conduct this type of test all the time. So I wouldn't see that the tests to a manufacturer, to do his own development tests, would be much different than what is done today.

He has to do that.

The difference is going to be the cost of having NIOSH do it as well.

MR. VINCENT: And how does this compare to the panel size for the current isoamyl acetate testing with a panel of 15 or 12 subjects?

MR. NEWCOMB: The panel is more test subjects, and the number of test subjects is the major subject of the next presentation on the

statistical analysis.

But one of the things that is concerned here is the ability of a manufacturer to have some assurance that his tests and NIOSH tests will result in the same -- the same outcome.

And the statistics play a big part in that, but I will defer that to the next presentation.

MR. METZLER: Rich Metzler, SEA.

My comment was on the same lines that John just brought up.

We recently have a respirator at RDECOM being laboratory protection fact tested as part of that approval process.

We paid them for our pretest data, and then they're retesting under the NIOSH certification. So we're paying twice for the data from RDECOM, which is very expensive.

So my comment would be for NIOSH to consider having other laboratories able to run this test. And if, while we are producing products, to use one of these laboratories, that the data that

they generate can be applied rather than having the test redone after the application is submitted.

MR. NEWCOMB: I suggest you put that comment in writing into the docket.

MR. COLTON: Craig Colton, 3M.

Bill, a couple of questions. Easy one, you mentioned that the probe was going to be flush mounted in your protocol, and the printed one says a quarter-inch off.

Which is it?

MR. NEWCOMB: It's -- we have used a flush probe, and we intend to use a flush probe.

If it says a quarter-inch off in the protocol, it is an error that I didn't get.

MR. COLTON: Oh, okay. So does that mean then elastomerics would be flush probed also, or can the, like the adaptors be used for -- that we make for people that are using TSI's PortaCount to be acceptable, too?

MR. NEWCOMB: The masks that we tested were all flush probed, no matter whether they were elastomeric or not because we were trying to

standardize on the least obtrusive.

As you know, some of the facepieces have exhalation valves right in front of the place where we normally put the probe, and there are other things that make it difficult to put probes in, especially if you use probes that are used in commercial fit testing like the -- and especially the European probes like the disk or the ball or something, they're good if you have got nothing obstructing your face.

But here, because we're trying to get a base level, we're not trying to quantify an individual's fit or measure an individual's fit, and so forth. We felt that using a standard probe for all the tests would be the most beneficial.

MR. COLTON: Okay. I just wanted to clear it up which way it was.

MR. NEWCOMB: Yeah. I'm glad you brought that up. I'll make sure that the protocol is changed.

MR. COLTON: The quarter-inch comes from the OSHA protocols.

MR. NEWCOMB: Yeah.

MR. COLTON: Another question. When submitting the elastomeric half-facepiece, which filters is it going to be tested with for the TIL, or is it going to be tested with all of the filters you have?

MR. NEWCOMB: That's a subject for the implementation that we have been a little concerned with.

Obviously, if you have got an elastomeric facepiece that has the ability to put a single pad N95 filter on it, and it also has the ability to put a multifunctional cartridge on it that weighs eight or nine times, ten times the amount that the filter does, which has a different mass, and so forth, that the fit of that respirator will be different.

And there have been suggestions that say that, Well, maybe you should just test it with the heaviest respirator cartridge filter combination.

The problem is what the heaviest one is today and what it is tomorrow might not be the same thing.

So theoretically, you would have to test it with every filter combination if you sell one that takes many filters.

Now, again, that's something that I would love to get comments on and ways to work around that because I know it becomes very cumbersome.

MR. COLTON: Jon, you may want to reconsider those figures or not offer so many.

Another question.

You mentioned that the results that you had for the three replicants was an average. What kind of average is NIOSH -- or are you planning on using?

MR. NEWCOMB: I think that was an arithmetic average.

MR. COLTON: Okay. We tried looking under data and really couldn't tell which -- I mean, the one data was arithmetic, but then when you looked on the benchmark that I think that you shared for our products, but it didn't -- it wasn't clear which one you're looking at.

MR. NEWCOMB: It might not have been an

arithmetic.

MR. COLTON: I have heard discussions talking about the harmonic means, and that's why I raised the question.

MR. NEWCOMB: Uh-huh, yeah. I think it was a harmonic mean on the seven exercises, but the average on the three donnings.

MR. COLTON: Donnings was arithmetic?

MR. NEWCOMB: Yeah.

MR. COLTON: Okay. And then last question is regarding the sizing.

Has NIOSH considered or thought about like what type of wording that they want the manufacturers to use since they review the packaging and user instructions, as to how we tell them who it fits?

I mean, is it small, medium, and large?

I mean, small faces, medium faces, and large faces, or if it fits Grid 5, or it fits Grid 6, or fits Grids 1, 2, 3, 4?

MR. NEWCOMB: What we're looking for is for the manufacturers to give us the same

information that they give the user on how to make the first selection as to what product they would buy, that they would normally get a fit with.

Not to say that -- that they will or this is an equivalent of fit, but the manufacturer should give guidance to the user as to how to make a judgment as to whether this is a small, medium, or large.

And we're looking for that type of information that we can take right off the instructions and interpret into this grid.

So I think it will take little more than saying this is a small, medium, or large.

MR. COLTON: Right. In fact, I don't think when it comes to users that either that or the grids would make much sense for them.

That's why I think a lot of people have used like the way you find which size it is, you hold it up to your face first and adjust it, and then do a fit test, and that's how you tell if you have got the right size.

So if that's the case, would NIOSH then

perform a qualitative fit test on that respirator if that's what the instructions say before they do this?

MR. NEWCOMB: I can't answer that right now, but it's -- obviously, it's a way, if that's what you're telling the user how to make the judgment, then possibly it's the same thing that would be done with NIOSH.

I won't commit one way or the other, but you know, there are innovative ways of doing this, and we welcome comment on it.

MR. COLTON: Okay. And then finally, regarding the user seal checks, you mentioned that these users were sort of -- it was to be sort of more or less of how they would be trained in the respirator program.

But if they performed the user seal check and didn't pass, you still allowed them to do the fit test, as I recall, or the TIL test.

Is that correct?

MR. NEWCOMB: We did in the benchmark testing. Okay.

If the manufacturer's user's instructions say you do a seal check and if you don't pass it, you don't do a fit test, that's the instructions that we're given as NIOSH.

My first inclination right now would be to say, that's the instructions we use in the testing. But you know, again, a good comment and please put it in writing.

MR. COLTON: Thank you, Bill.

MS. FEINER: Lynn Feiner, North Safety Products.

I have actually got more of a comment than a question, just to follow Craig's comment.

MR. NEWCOMB: Thank you.

MS. FEINER: The extreme panels for 5 and 6, which would be the bottom right, the top left panels are quite large.

MR. NEWCOMB: Yes.

MS. FEINER: And if we were to manufacture a respirator that is a medium, that would fit mainly 4 and 7, but it could get some of the outlying 6 and 5.

I don't know if you want to go back to one that shows the panel numbers for the --

MR. NEWCOMB: Okay. Well, one of the things that you'll see if you look into the data from Dr. Zhuang's presentation and so forth, is that if you look at the distribution of people in this panel, it is almost an ellipse.

MS. FEINER: Uh-huh.

MR. NEWCOMB: Okay. This 5 percent of the people is all in this area, very, very few people out there.

And the same here.

And I dare say that if you had someone that was out here, he probably wouldn't fit in the PCA panel either, so he would be an outlier and wouldn't be used.

Almost all of the population is an ellipse that fits in here. The only reason that these panels go out as large as they are, we could even cut them off diagonal, which we looked at doing in the first place, and you still get the same percentage because there aren't any people out

there. It just makes it very -- more difficult to calculation the number of people.

MS. FEINER: Okay.

MR. NEWCOMB: So as far as the panel is concerned, the people that we will be testing on are more or less in here and not out in that area.

MS. FEINER: And knowing the difficulty we have had in the past in getting enough subjects to be in panels, when you get outside the bulk of the population, just want to make sure that when we send respirators down that we can be assured that you get people that fit in the ellipse and not into the extreme outlying, which --

MR. NEWCOMB: Yes. And you notice, this panel no longer goes out -- what was it 93, or so forth?

MS. FEINER: Uh-huh.

MR. NEWCOMB: Where there virtually are no people.

That in today's population, they happen to exist in a population that the government looked at back in the '70s, or the late '60s, whenever those

measurements were taken, but they don't seem to exist today in the workforce.

MS. FEINER: And then final comment is the difficulty, if we do design a respirator that is for say an extreme size facepiece that is way outside the norm, but does fit into one of the panels, the difficulty of getting 35 people that fit into that panel in a timely manner so we can get the fit testing done in a timely manner.

MR. NEWCOMB: Needless to say, NIOSH is going to have to expand its fit test panel because we don't have that many test subjects in some of the outliers right at the moment.

And, you know, as a manufacturer, you might have problems if you wanted to use the same number in your pretest data.

It's difficult to find, if you -- if there are only three and a half percent of the total population in that panel, coming up with 35 that were just in that box, might be difficult.

However, I don't think anybody would design a respirator that only fits that box, so

hopefully you won't run into that difficulty.

MS. FEINER: Hopefully not.

Thank you.

MR. SZALAJDA: Okay. Let's maybe have one or two more, and then we need to move on with the presentation.

MR. VINCENT: John Vincent with North.

Bill, has NIOSH looked at using for the elastomeric facepiece or filtering facepiece as three sizes, using the total panel of 35 for all three sizes similar to IAA, or maybe some -- maybe a slight overlap rather than using 35 for each size just as a time saving, cost savings?

MR. NEWCOMB: Yes, we have, and that will be reviewed in a -- those numbers.

MR. VINCENT: Where the statistics and usableness merge here, and because eventually, I think, you know, if it becomes too costly to test things and to -- at the end of the day, the worker loses out because manufacturers aren't going to come out, and it's going to be prohibitive to develop new products.

MR. NEWCOMB: Yeah, I understand your concerns.

MR. METZLER: Rich Metzler, SEA.

This is a tough comment to make, and I want to follow up on what Lynn was saying. NIOSH needs to really specify the facial lengths and widths that you're really going to use in the test so that manufacturers know which facial sizes to use when they're preparing the equipment.

So part of the answer that you gave to Lynn was that subjects really don't fall up in those extremes, and that the edges could have been cut off.

You know, that is really ambiguous information to be giving manufacturers if you're expecting us to produce respirators that fit proper sizes of people.

So I think NIOSH needs to specify what facial sizes you're actually going to use in the test, so it's not a Russian roulette when we get to the testing.

MR. NEWCOMB: I understand your concerns,

Rich, but I also think that the manufacturer has to decide what market he wants to be in and what sizes he wants to fit, and then tell the user somehow which product is designed to fit.

And if you have a market where you have decided to only hit certain aspects, then you design the product to do that, and somehow in the user's instructions say this is who it's designed to fit and that's who we'll test.

MR. SZALAJDA: Okay. Let's -- and I guess let's --

MR. METZLER: Just one last one.

I would say that's not a problem for manufacturers. It is a problem if you say that there will be outliers within these larger cells, and you're not actually going to have those test subjects.

But if you want to be able to get a product that's going to meet a larger size and that has a very large box, you're not going to be using subjects of those facial sizes, it really presents a lot of problems being able to produce a respirator

that will pass your test because we don't know what sizes you're going to use.

MR. SZALAJDA: Okay. We'll take your comment under advisement.

We need to move on here.

MR. NEWCOMB: Let me just address that again. There might be some confusion.

We are going to use this panel for testing purposes, but we are going to screen people using the PCA panel. You will not have or should not have any outliers in our test panel.

So if there are -- first of all, you won't find anybody out here, so we won't have anybody and neither will the manufacturers.

But using the PCA panel, we're also going to screen out people that have facial anomalies. So it should be easier than it is today to fit subjects within this panel.

Thank you.

MR. SZALAJDA: This 35 subjects is of great interest.

Doug Landsittel, our NIOSH fellow, who has

been working statistical issues associated with the TIL will discuss his work in looking at the setting up the population for the criteria.

STATISTICAL EXPLANATIONS

MR. LANDSITTEL: The speakers, they're not between here and the screen because the last time -- the last public meeting, I wasn't coordinated enough to get past people's heads. So at least this will work better.

So firstly, just an outline of what I'll be going over.

I'll first start with, it just might help to point it the right way, too.

First, I'll talk about the overall statistical objectives and kind of set the stage, and make a brief note about the NIOSH test panel in terms of representativeness.

Then what I'll spend the bulk of time talking about is what is our statistical justification for an optimal criteria. And then I'll give some example calculations leading to the proposed criteria, which has already been defined

for you here. And I'll make a brief mention of interpretation of results, and then summarize and conclude from there.

So in terms of the overall statistical objectives, let me first say there are a couple of initial considerations that we're starting with.

There has been a lot of discussion to having a representative test panel, which as we said, the NIOSH test panels are best guess at this point.

Then also, we need to specify what an acceptable Total Inward Leakage is, which has been specified at 5 percent or less.

And, again, as mentioned, that's not the same thing as the Assigned Protection Factor.

Then, where I'm going to spend the bulk of my time is, like I say, kind of discussing here today, is to view the total -- the TIL criteria, which is going to be in the form of a fraction of subjects meeting a certain acceptable TIL level and look at that as a statistical test and say why we have chosen that as optimal.

So I need to spend a little time, as unpleasant as it may be, defining the concept behind what makes or what justifies an optimal statistical test. And that will lead us into two things that we need to specify.

One, what's an adequate number of subjects. That, we have already said, is 35.

And two, what is the minimum number of subjects that we should specify to have to have an acceptable TIL level, which, as mentioned in one of the previous ones, is going to be 26 out of 35.

Okay. So before I get into the main part of this discussion, I want to just remind you it's a NIOSH test panel that we're using to get a sample that is our best guess at representative.

So first, though, however, since there are other facial dimensions that may be significant in terms of fit, we would screen a subject's based on the PCA panel.

So if John Smith comes to you, and you have all those ten measurements that Dr. Zhuang mentioned earlier, you could calculate, just as an

easy way of combination, using those numbers he showed, you could calculate what the two principal components are, or two numbers are for the X and Y axis, and we could determine if that person is outside the bulk of the population or over 95 percent.

If the person is outside that range, then they're booted out, and they're not an eligible subject to be used in the test panel.

If they are within that range, then we put them in one of ten different cells based on their face width and face length. And so from all eligible subjects within a given cell, then we randomly select a given number where the cell frequencies are representative of the U.S. workforce.

And one of the previous talks just gave some examples of what those frequencies would be to add up to 35 total subjects for a given respirator model.

And so another point I want to briefly make here is then we have the random selection of

then available subjects from within the cell, a given cell of the panel. And the issue here is that we're not saying that there aren't other facial dimensions that might be significant, but just that we're randomly selecting from the eligible ones to avoid any systematic error in subject selection.

Okay. So now we get into sort of the main part of what I wanted to discuss here, which is the statistical justification for saying we want 26, or require 26 out of 35 subjects to meet an acceptable fit.

So let me start with just saying what we have to work on is that we have some assumption, is that a given model achieves acceptable fit on some percentage of the subjects across -- if we knew what percent across the entire population of U.S. workers the model actually achieved acceptable fit. I'm going to call that, just to be more concise, the effectiveness of that model.

So what we want to do is we want to formulate a criteria, which we have already defined, with the following characteristics.

First of all, if the model is highly effective, that is achieves an acceptable fit on a high percentage of the population, if that in fact is true, which we won't know going in, we would want that model to almost always pass the criteria, ideally always pass.

If it's an ineffective model, so it achieves an acceptable fit on a low percentage of subjects across the entire workforce, we would want that model to fail the test.

So hopefully, those are kind of intuitive concepts here, but that's sort of our starting point for saying what criteria should we have.

Now, that leads to a couple of questions.

One is, Well, what's effective and what's ineffective? What do you mean by that?

Well, I already said we're going to judge that by the percentage of subjects that achieve an acceptable fit, but where do we put the effective range and the ineffective range?

How many subjects do we actually test since we can't go out and test it on everyone across

the entire workforce?

And when I have said it should almost always fail or almost always pass, what do I mean by almost always?

Now, the answer to these three questions I have to address jointly because they're all interrelated. And what we're going to do is just use standard statistical calculations to come up with some results here to lead us what criteria we should get.

And I won't torture everyone with the details, the statistical calculations, but those are defined a lot more in the appendix, and it's a pretty standard calculations, relatively speaking, using something called the binomial distribution.

All right? So we need some initial assumptions, and these are not -- these numbers I'm picking out are not statistically calculated. They're numbers that, through discussion, were determined to be reasonable starting points for formulating the criteria.

So we're going to consider a model, if we

knew what percentage of the population that it was designed for, if we knew that it achieved an acceptable fit over 80 percent of the subjects, we're going to consider that effective. And we would like to have a criteria that should almost always pass a model that is in that effective range.

If a model is in the range where it's -- achieves an acceptable fit on less than 60 percent of the subjects, we're going to deem that to be ineffective, and we would like a criteria that should -- where as a model in this range should almost always fail the test.

Now, there's always going to be some kind of gray area here, and it's between the 60 and 80 percent where we're saying it's not a high enough result that we need to insist on it always passing or almost always passing a test, but it's not low enough that we need to insist on it almost always failing the test.

So in this range, we can expect some variability in results.

And so in order to come up with this

criteria, we need to look at the sample size, how many subjects we tested, which we have already said in previous presentations can be 35, and how should we define almost always.

And as you might guess, the larger the sample or the larger panel we test, the more certainty there's going to be in results.

Okay. So what I'm going to do over the next three slides and actually a fourth one which will summarize those three, is just give some example calculations I did to look at some different criteria in terms of number of subjects and what's the minimum percent that we deem to be passing the test, and show you what results we get with those different scenarios, and then use that to culminate in some criteria.

So it turns out that if you specify 25 subjects -- and let's just say -- so I started with a fairly low cutoff here and said, We require 15 out of 25, which would only be 60 percent, to achieve acceptable fit. Okay, if that's our criteria that we end up picking, which it's not.

It turns out -- and, again, this falls into that standard probability calculation I won't go into the details of. But it turns out that if we knew the model was 85 percent effective, there's a very small chance that it would fail to meet this cutoff, less than a 10th of a percent chance. Okay?

So that's good because we want -- I picked 85 percent, by the way, because it's just into that above-80 range. I needed to pick one number. It's into that above-80 range that we deem to be effective, but not too far into the range.

As I go further into the range, as I'll show in a minute, you get even more certainty.

Now, let's pick a model that's just into that ineffective range, let's say -- let's say we said below 60 percent. We'll take 55 percent. It turns out you can calculate that there's a 62 percent chance that this model would fail to reach that criteria.

And that's not an optimal result because we deem this area below 60 percent effective to be what we're calling ineffective, and we want it to

fail the test almost all the time.

So this cutoff, then, is not stringent enough is the conclusion we come up with. So we're going to raise this to 19 out of 25.

Now, we actually did this for a much bigger range of numbers. I'm just showing a few of them here to give examples.

So let's raise this up to 19 out of 25, which happens to the 76 percent, and say we want to require 19 out of 25 to achieve acceptable fit or a TIL of 5 percent or less.

It turns out we could calculate the model that's 85 percent effective is still going to fail that a relatively small percent of the time, but more often, obviously, about 7 percent of the time.

A model which is just into that ineffective range is still going to -- is now going to fail to reach this kind of tougher criteria here, a very high percentage of the time, 97 percent.

So depending on your perspective, it seems that 19 out of 25, then, provides a better criteria because we have -- it's really the second bullet

here. It should fall first, with far more certainty in rejecting these ineffective models.

Now, we do obviously have the down side that a model that's in the effective range is going to fail a higher percentage of the time, but it's actually still not a real high percent as you go further into that effective range.

So, for instance, just another example calculation, a model that's 90 percent effective is going to fail to meet that criteria 19 out of 25, less than one percent of the time. Okay.

Well, what happens if we raise the number of subjects we're going to test to 35?

I already said if we're going to raise the sample size or our number of subjects, that's going to give us more certainty, which is what you'll see on this next slide.

So I kept that 60 percent and then about three-quarters, around 75 percent constant here for comparison sake.

So let's go with a cutoff here that's not real high, 21 out of 35, which is that 60 percent,

and we can do these calculations.

It turns out that if you have a model that you know to be 85 percent effective, we don't want that model to fail the test very often. And it turns out it will fail to meet this criteria very few -- very small chance, well, under a .1 percent of the time.

However, a model that's just into our ineffective range is it's going to fail the test most of the time, about two-thirds, but it's still a fairly appreciable chance that a model in this ineffective range, there is about a one-third chance that it's going to meet that criteria or exceed it. okay.

And just a random sample, 35, a representative sample 35.

So that leaves us to then raise the bar to let's say 26 out of 35, which is again around three-quarters of the subjects, and say we want 26 out of 35 to exceed, to achieve acceptable fit, TIL of 5 percent of less.

So now, we can repeat these calculations,

and it turns out a model just into the effective range will fail the test some percentage of the time. But, now, after we have raised the sample size, you'll recall this was 7 percent with 25 subjects, before.

It's a smaller percent because we have a higher sample size so we get a little more certainty. So it will only fail the criteria 3 percent of the time.

Now, a model which is just into the ineffective range or below 60 percent is going to achieve what we want, which is that it fails the test or to meet this criteria a high percentage of the time, about 98 percent of the time, okay.

So that leaves us to the conclusion of 26 out of 35 provides a better criteria. Again, we have more certainty than the previous slide and also this criteria versus 21 out of 35, in rejecting the models in the ineffective range.

And if we raise the expectation here or raise the assumption, the assumed value or the assumed effectiveness of the motel, say we take a

model that truly works 90 percent of the time, achieves acceptable fit on 90 percent of subjects, there's a very small chance that -- that we would just have sample variable, which would lead to a failure to meet that criteria.

It would only fail to meet that cutoff under .2 percent of the time.

So I think you get the idea here, but just to show one other result.

If we raised the sample or test panel to 50 subjects, just as a for-instance, let's again go with these percentages. Say we require 30 out of 50 to achieve acceptable fit. We would see the same terms we saw in the last two slides, which is the model in the effective range is going to very seldom fail to meet that, which is good.

The model that's just into the ineffective range will fail the test a appreciable percentage of the time, if this went up from two-thirds in the last slide, but still there's a pretty good chance -- here it's just under 30 percent -- that a model with this effectiveness is still going to pass

this criteria. So that was a -- that's not a good thing from our perspective.

So let's, again, raise the criteria, say 37 out of 50, and it turns out the model just in the effective range will fail the test a small percentage of the time, it goes down from 3 percent in the last slide, with about three-quarters of 35 subjects.

A model just into the ineffective range, now, will fail the test almost every time or over a 99 percent chance. So it seems that this 37 out of 50 provides a better criteria.

And, again, it's the same trends, more certainty in rejecting ineffective models, models in that effective range, which we deem to be over 80 percent fail rarely, rarely are going to fail just by chance.

And just, as another example calculation, a model that, in fact, works on 90 or achieves acceptable fit on 90 percent of all subjects, there's less than a .1 percent chance they would fail to meet this 37 out of 50.

So that was a lot of stuff, so let me just summarize one more time here.

Requiring around -- and again, we looked at other examples, other than just 60 percent of subjects and three-quarters, but there's just some selected results to give you the idea.

Requiring about three-quarters of the subjects to achieve acceptable fit seems to give optimal results. If we lower that to below three-quarters, what happens is more often we pass ineffective models or models that are in that range of achieving acceptable fit on 60 percent or less of the population.

If we raise that criteria, then we have the negative consequence that we would more often fail effective models. So we're trying to achieve both of those at the same time and figure out the number of subjects and the percentage of subjects that achieves each of these.

Larger sample size, as is the case with almost any type of statistical issue, gives more optimal results.

Increasing from 25 to 35 gave a larger improvement than subsequent increases, as you could see with this -- just examples. But obviously as we have talked about a lot today, there's a definite need to balance practical and statistical issues here.

So that's were we get this proposed criteria of 26 out of 35, with the TIL of 5 percent or less being our initial assumption on what's an acceptable fit.

Now, let me just say a word about reproducibility.

26 out of 35, again, is the criteria we're proposing for a minimally passing result. And again, to summarize what we have discussed up to this point, the reason -- the logic behind that is we want to achieve optimal results from a statistical perspective.

So the idea, a little more intuitively, is to say that if you have a model -- and you're not going to know that in practice. But if we had a model that we knew across the whole population was

effective, we would want it to pass.

If we had a model that we knew to be ineffective, we would want it to fail whatever criteria we proposed.

The important thing that I want to point out in this slide is the converse is not necessarily true.

That is, if you achieve 26 out of 35, that doesn't -- so that's passing, that the arrow doesn't go the other way here all the time or the same percentage of the time. The arrow in this direction is what we're trying to optimize with this criteria.

And just intuitively, you can guess that if you achieve 26 out of 35, with a TIL of 5 percent or less, that doesn't mean that the next time that you won't get 25 out of 35.

It could be that you, in fact, have a respirator model that's in that grey area of, let's say, truly achieves an acceptable fit on 70 percent of the population.

And so obviously it goes beyond the scope of this presentation to give all the details, but

reproducibility requires a higher standard than, say, well, we get on a sample to work on 76 percent.

So let me summarize and draw some conclusions.

So we're looking at selecting 35 subjects based on the NIOSH panels, specifying 5 percent TIL as an acceptable fit, which is the TIL, again, as we have said here, is not the same as the assigned protection factor.

Specifying 26 out of 35 is the minimum fraction of subjects required to achieve that acceptable fit. And the logic behind this is that this achieves optimal statistical properties, or the models that -- which is an unknown, but models that, in fact, achieve acceptable fit on a high percentage of the population across all workers, say 80, 85 percent or higher, are going to pass that criteria high percentage of the time.

Obviously, the further you get, if you a have model -- and we did have in the benchmark analysis, as Bill Newcomb showed before. We have models that, in fact, achieved a TIL of 5 percent or

less on all the subjects or 24 out of 25.

Then that -- it's going to -- even more optimistic results as far as achieving this 26 out of 35 on a subsequent test.

Models which achieve acceptable fit for no more than 60 percent of the subjects will fail a high percentage of the tests.

And, again, just in terms of that last slide I had shown on reproducibility, you have to have some caution in just interpreting results of one test.

And so at this point, I want to open it up for questions.

MR. VINCENT: John Vincent, North Safety.

The testing that you came up with statistical analysis saying 19 out of -- or was it 26 out of 35 need to pass, 35, I'm still having a hard time getting use to that big of a sampling size.

Can you, instead of giving 19 out of -- I'm mean, 26 out of 35, could it be on a smaller number, ten out of 12, which we current -- we have

to currently work with 12 out of 12, a smaller number, so less test subjects, less cost, less time?

MR. LANDSITTEL: So basically, yeah. Let me answer that by saying I don't have the specific calculation or specific answer to that specific number off the top of my head.

But certainly at some point, if you have 100 percentage of the subjects -- so let's say you had 15 out of 15 make it, you could then do a calculation -- I would have to look into that in more detail -- but you could certainly then do a calculation if it was, let's say, 15 out of 15 just for example.

So we're requiring 26 out of 35, and saying, Well, what's, you know, what's the probability that you would get 12 out of 12 on the first 12 subjects, all 12 of them would meet that, but then only meet it on what would be 14 out of 22.

Right. On the 14 out of the next 22. And that would be -- I can say with some certainty, that would be a small chance. I don't know what it is exactly, but certainly -- and again, we had some

discussion on this ahead of time, but it's hard to give specifics without going off on so many tangents and giving so many details.

But certainly you could do that type of thing where you would say, Well, we want to have 100 percent of a smaller number, and that would assure us that if they did it on a larger number, they would at least get three-quarters.

Exactly what those numbers would be, we would have to follow up. And I think my email is in there. We would have to follow up on that, or -- and also I think that probably would be a good thing to put in as a written comment, just maybe more specific things, or just what you have said, put that as a written comment too.

So basically, yes, although, specifically it's hard to answer without S plus and a statistical package in front of me.

Other questions?

Okay. Les, I would like some type of an award for a presentation that solicited the least number of questions. Maybe there's a punishment

that goes with that.

NPPTL TIL TESTING CAPABILITIES

MR. SZALAJDA: It's that math stuff that always does everybody in.

At least as far as one thing we wanted to share with you today, and it's something new that we're trying for the meeting, so I hope that it works.

But we mentioned a couple of times during the discussion that we are establishing inward leakage testing capability at our facility here in Pittsburgh.

And we thought it might be neat since we know we all physically can't go there, taking off the home shows that you may see on TV, or if you cruise the internet looking for a house, often you can go on a virtual tour.

And so what we wanted to do is spend at least a couple of minutes to go through what we're currently doing in Building 40 on our site to establish inward leakage testing capability.

This is a very exciting picture of our

carpet coming into the facility, but if you came in the main door, the locker rooms for the test subjects are down here at the end of the hall.

The first door on the left, when you come in, is going to be our staging area for the testing. It also can be set up, in this configuration, to do the communications test that we currently require for the CBRN respirators. And right now, it's set up in that configuration.

This setting, when you come in, would be the training classroom type setting for the individuals that would be involved with the respirator fit testing.

This room is where we're going to install the PortaCounts, as well as the isoamyl acetate chamber for doing those types of testing. It's a decent size, at least as of a couple of weeks ago when we made the video. We didn't have the PortaCounts installed in this room yet.

This is a control room for our larger test chamber, which right now is based on using the corn oil technology for those of you involved with the --

been involved with the program over the years, this is Terry Thornton, at least as far as trying to set up the monitoring parameters associated with the test subjects that are going into the chamber.

We're going to have the capability to do four tests at a time. In the design of the chamber, there's a plenum system here where the corn oil is generated in the back of the system and comes into the facility.

These are the corn oil generators here in the back. And the instrumentation requirements, if you're familiar with the CBRN STPs, it's that type of equipment that's currently specified, and the STPs are available on the website.

Here's another view of the aerosol generators.

It's an interesting design, at least as far as when aerosol is generated, it comes up the piping that you saw in the outside. In the plenum type system, it comes out through these vents in the adjacent room.

And the aerosol comes down, and there are

these panels that you're able to see through the control room where the aerosol then seeps into the testing chamber.

Now, this view is from inside the chamber, and you're looking at the plenum system.

And I have to give some kudos to Mike Monahan from our laboratory. He has been very instrumental in the setup of this capability and definitely has gone through some innovative approaches in establishing the capability.

And then the aerosol here, and then it exhausts through that port, eventually.

This is the back of the chamber.

The facility is climatically controlled both for temperature and for humidity.

And here's Mike, just not that we're actually doing a test, but we wanted to kind of give you an indication of what it looks like when you come into the chamber under the small staging area.

You come in, now we're currently generating aerosol in the facility. The test subject, as Mike is doing right now, plugs into the

port. And then we go through the series of exercises that are identified in the STP.

Now, again, this is just not that he's actually doing the exercises, but just to kind of give you an indication of how the testing will be done.

Actually, this is a lot better when you run it in fast forward mode, but torture. We'll torture Mike in running it in a standard mode.

But again, you know, we do have the capability to do four. And we're optimistic with filling out our panel, we'll be able to run four at any given test.

And then there's another room for a laboratory manager, at least as far as office space for data collection.

We also have, and I believe this is the secured storage room when you come in, to submit items for certification that we secure the items in this room for safe keeping until testing.

Then here's a back view of the hallway down from the control room for the chamber, and then

an exit door for the chamber.

And then this is just a bench area where we'll do our probing of the respirators.

Any questions?

And I'm glad Mike is here because he will be able to fill in the technical details that I don't know.

MR. PFRIEM: Mike?

MR. MONAHAN: Yeah.

MR. PFRIEM: We just saw a lot of video about LRPL testing, but the subject matter here is PortaCount testing.

So at the very beginning, we saw a very quick clip of where you intend to do the PortaCount tests.

And, Jon, you had mentioned that you're going to move your IAA booth into that same room, and so you're going to be doing IAA testing in the same environment where you're going to be doing PortaCount testing.

MR. MONAHAN: Right.

MR. PFRIEM: Okay.

MR. SZALAJDA: Not necessarily at the same time.

But at least the thought was, with the capabilities that we currently have in Building 37, the room is large enough that we can accommodate and move the testers from 37 and put them in 40, plus the four PortaCounts that have been identified for doing the TIL.

MR. PFRIEM: You're going to do four TILs also at the same time?

MR. SZALAJDA: That was the original concept parallel to what was done with the benchmark testing.

MR. PFRIEM: Okay, I -- oh, okay.

I have to think more, but I would say, you guys have got a poop load more room than I have, and I would think you could, with all that room, you could have a room just for TIL testing where, you know, it could remain secure and conditioned and stable all the time for, in that type of environment, and you know, do something else with your IAA chamber, but...

MR. SZALAJDA: Yeah, that's a good idea.

And I think -- well, at least let us -- as where we are right now, we're still going through the process of getting the facility established.

The room that was empty is still empty at this point, but I think what we need to do is strategically look at the placement of the equipment as far as how we make everything work.

I think when, you can kind of get the appreciation for what we're doing is not -- yeah, is looking at the facility right now in terms of being able to support the half-mask filtering facepiece type testing and using the PortaCount, and also establishing the corn oil capability to do the LRPL for the CBRN type respirators.

MR. BOORD: Dale, could you identify yourself for the court reporter?

MR. PFRIEM: I'm sorry, Dale Pfriem, ICS Labs.

When you guys get a bottleneck.

MR. NEWCOMB: Thank you.

QUESTIONS AND COMMENTS/CLOSING

MR. SZALAJDA: Okay. At least as far as wrapping up our discussions for today, just to reiterate a little bit what we covered, or I covered this morning, the presentations will be available on the website, and we will notify the attendees via email and also send out a letter to our list serve to all the stakeholders that we maintain correspondence with that this information is there.

At the time of the posting, we will advise you that we're going to have the docket open for 30 days to solicit your technical administrative comments related to the requirements for the program.

Now, I think we put the comments that we have heard so far today, I think there's a lot of opportunity for stakeholders to be able to contribute to the process.

Bill had mentioned earlier that, you know, we have accumulated thousands of data points relative to inward leakage. And you know, we would like to open up that opportunity for manufacturers to come and review that data with us.

I think at least -- at least as far as administratively how to do that, there's a couple of different ways. One, you can contact me. You can contact Bill. There's also a phone number for the branch, which is (412) 386-5200, which you can contact to set up an appointment to come in and discuss the information.

I would also suggest that if you had additional questions regarding the statistics in the analysis, you could process those through myself or Bill, or through the branch as well, and we can make the appropriate arrangements for you to work out details with Doug Landsittel.

And at least at this point, you know, as we had mentioned earlier, Bill had mentioned earlier that at the incorporation of the requirements will be done through a formal change to Part 84, and that we anticipate that by the end of the year we will begin the rulemaking process.

And, again, the criteria -- and I think you get an appreciation of what we discussed today, that there's two aspects to what we're doing.

One, is the introduction of the NIOSH -- oh, I'm sorry. Here I'm showing slides, and I'm looking at them on the thing, and unfortunately, you're not seeing them. Okay.

But anyway, as far as the performance, I'm not going to go back because I know it's lunch time and people want to do their thing. And if you have any comments, to make them, but at least as far as you get an appreciation for the criteria that there's two aspects.

One, is the introduction of the NIOSH respirator fit test panel, which will be used initially for the half-mask program, but then also evolving into the other categories of respirators.

The action for -- as part of the proposed rule will be to introduce that panel into part 84 for use as a certification program.

And then the other aspect relates to the actual criteria for inward leakage for the half-mask, which covers, you know, the test subjects and how we're going to actually do the test.

And as Bill had mentioned in his

presentation, any insight that you may have or comments you may have relative to how best to implement that, we would appreciate at this point.

Again, the docket information, comments, we will accept comments for 30 days after we send out notification the information is on the website.

On the back of your agenda is all this information relative to how to get in contact with the docket office. And I encourage you to think about what we have discussed here today and submit your recommendations or comments to us.

And also, at some point in closing with the surveys, if you could fill out the surveys before you depart and put them in the box at the back of the room, I would appreciate it.

We would like your input to help, you know, continue and make these types of discussions advantageous for you as well as for ourselves.

So with that, that concludes our presentations. We do have an open comment period where you can come up -- if you have any comments you would like to make prior to the close of the

meeting, you can come up, follow the same rules as far as identify yourself and your organization, and you can state your comment.

Thank you.

MR. NEWCOMB: I have one comment.

The 35 test subjects, obviously, was based on statistics.

And if you have comments on the number of test subjects, I would hope that you will base your comments also on the statistics of the tests of passing, the passing criteria, failing criteria, and so forth, and not on the cost of the tests, although the cost is obviously something that has to be considered.

The criteria basis was not cost. It was on doing statistically valid tests and having product pass or fail if they deserved to pass or fail.

So please keep that in mind in your comments.

Thank you.

MR. SZALAJDA: Any comments?

MR. GREEN: Yeah. Larry Green, Syntec International, PABBAN Development.

We don't make facepieces, but we are interested in going forward with our loose-fitting products and things like that.

And in the past, all of the face sizes are very -- they really don't mean much for a loose-fitting product, and they are all measuring the eyes and the nose and stuff like that.

And as you get into, I think, what looked to be on the two-measurement panel, where you have length and width, those are much more significant in terms of the fits of the loose-fitting products versus nose. Nose doesn't matter at all because there's no fit near it.

And you get into well, some of these ethnic populations and things like that, the loose-fitting is -- address it a little bit better, we think, if you can look at different sizes and actually get a better feel for what you're doing, and if there's a -- any studies that you're proposing to see how the panels are or if that panel

was appropriate for loose fitting products as opposed to the facepieces.

Thank you.

MR. SZALAJDA: Thank you.

MR. NEWCOMB: One comment on that.

Obviously, we're not looking at the loose-fitting at the moment, but we do know that there are other criteria. For instance, we have a neck sizing that we're using for hoods that seal around the neck.

But the fact still remains that the panel, as we know it, covers the 97.7 percent of the population.

So, therefore, even though you might not categorize a hood by those dimensions, we know the people in that panel should fit any product you make. So the panel is not -- the panel itself still should be applicable.

How we use that panel, when we get to doing loose-fitting product, is still up for discussion when we get to looking at the TIL for those type of products.

MS. FEINER: Lynn Feiner, North Safety Products.

As long as loose-fitting has been brought up, OSHA has created more questions than answers with their 25 versus 1,000 assigned protection factor.

And I understand that OSHA is working with NIOSH on helping us manufacturers come up with criteria that we can use in a standardized testing.

Is that going to be involved -- is the TIL project involved in that, or is that being fast tracked with a different project, or how is that being addressed?

Can you help me out there in understanding what's happening?

MR. SZALAJDA: Yeah, I think I can help on this one a little bit.

OSHA is in the process of developing guidance, which I believe is currently with their legal solicitors to -- for review at this point in time.

But at least as far as trying to provide

some clarity to the protocols that could be used to show acceptable performance to get the assigned protection factor for PAPRs.

And at least the last time we were in touch with OSHA, it's still in that legal review, but probably will be issued at some point in the summer.

And I think that will provide, at least provide some clarity to the types of methods that OSHA is going to deem as acceptable for doing testing, whether it's done by a manufacturer or by a third-party, at least in terms of developing the data, the support, assigning a protection factor.

So that's in process.

We have been in discussions with them. You know, again, it gets back to what we have been saying, the TIL doesn't equal APF, at least as far as our performance requirements, but, yeah, we do want to work with OSHA, you know, at least as far as potentially being able to do tests to support manufacturers and other stakeholders, and to help make some of these deliberations.

MR. VINCENT: John Vincent, North Safety.

Getting back to this TIL, in a three-year grandfather clause for existing approved products, what kind of leeway is being proposed if it was two years and six months go by before somebody brings their respirator back in and then there's quite a bit of a backlog?

Is there going to be -- is that going to be considered, or is three years a cutoff date?

MR. NEWCOMB: Right now it's open for suggestions.

The problem is, once it gets codified, it's kind of hard to change it. So it would be better to get all of the cards on the table before this goes into a final rulemaking.

And if two years is not practical or three years is not practical, then it would be better to do it before it comes in the Federal Register and then you have to go back to change it.

MR. VINCENT: Has there been any analysis by the lab that does the testing to see if they could meet the demands of this proposal?

MR. NEWCOMB: We really don't know what the demands will be.

We know there are over 4,000 products that are certified to Part 84, and we know that -- having tried to purchase a lot of them, that there are a lot of them that aren't manufactured anymore.

So I don't know what the scope is of the products that are active out there right now.

You know, if someone could give us that information, if the ISCA could give us some idea through CLEMS data, it would be great, but we don't know how many products, right now, are actively sold that would be applicable to this regulation.

MR. VINCENT: Somewhere between 100 and 4,000?

MR. NEWCOMB: Yeah.

MR. SZALAJDA: But, John, actually, you did bring up a good point that we are aware of and have been looking at, yeah, with regard to what our testing capabilities are, you know, and trying to determine how many tests we can do, comfortably do, you know, within the laboratory at this time.

And then we can make some determinations whether we need to do additional things, infrastructuralize to help support the testing, or you know, go back and look at other options for getting the testing done.

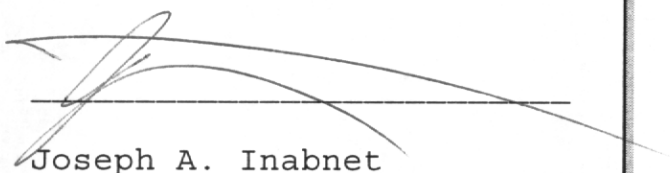
Okay. Well, if there's nothing else at this point, thank you for your attendance, and look forward to hearing from us in the near term about the presentation availability.

Thank you.

(Whereupon, the proceedings in the above-captioned matter were concluded at 12:39 p.m.)

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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