NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH

PERSONAL PROTECTIVE TECHNOLOGY PROGRAM

STAKEHOLDER MEETING

Thursday, September 17, 2009

Commencing at 9:00 a.m. at the Hyatt Regency, Pittsburgh International Airport.

MR. SZALAJDA: Good morning. Can everyone take your seats, please, and we will go ahead and get started.

Anyway, good morning. My name is Jon Szalajda, and I'm the Branch Chief for Policy and Standards Development at NPPTL. I would like to welcome you to the public meeting we are having today to discuss our respirator standards efforts.

What I would like to do initially is at least provide a couple of safety types of announcements. One is if you do hear the fire alarm go off, please exit on the right and go to the parking lot outside the doors on the right-hand side. Also, if you haven't found them already, the restrooms are located around the corner of the building here.

You know, from a logistics standpoint, during the course of the day, we will take a break, a couple of different breaks and also break for lunch. The hotel is providing a lunch service for us, which is $12.

I think if you preregistered for the

meeting, you had gotten an email talking about what the hotel is providing. If you would like some other options, there is the hotel restaurant which, if you continue following around the corners, moving out towards the terminal, there is a restaurant with the hotel as well as if you go into the terminal itself, there are a couple of options before you have to go through security.

With that, what I would like to do is introduce Les Boord, the Director of NPPTL, for a couple of opening remarks.

MR. BOORD: Good morning, and welcome to Pittsburgh and to this important stakeholder meeting.

A little earlier this morning, I was quizzing Jon a little bit about the last time that we had an opportunity or that we had a stakeholder meeting like this to discuss our concept, respirator standard concept development activities. And Jon tells me that was in December of last year, so December 2008.

So kind of to put it in perspective, there has been a lot of things that have happened since then. As I'm sure all of you aware, we have a new President, President Obama. We have a new Secretary of Health and Human Services, Secretary Sebelius. We have a new Director of CDC, Dr. Tom Frieden, and we have a new, again, Director for NIOSH, who is Dr. Howard. So there's been a lot of change.

And I think one thing that you can certainly see in that charge for those of us who are involved on a day-to-day basis, that there is what I would kind of refer to and classify as a renewed sense of energy and enthusiasm relative to the issues of occupational safety and health. And I think that speaks very well, obviously, for NPPTL and for our respirator standards development activities.

A little bit about the new, again, Director of NIOSH, Dr. Howard.

I think as most of you are aware, Dr. Howard was the previous Director for the Institute until I believe July of 2007, and then just recently reappointed again as the new Director for the Institute.

During the interim 14 months, Dr. Christine Branche served as the Acting Director. And I think during Dr. Howard's first tenure as Director and during Dr. Branche's bridging term as Acting Director, I think the programs and the initiatives of the Institute have remained constant.

So while there has been a lot of change from the President down, I think the programs of the Institute remain constant and on track, and I think that's good.

I think in the coming months that we will see -- and it's taking place, actually, as we speak -- reorganization, realignment within CDC, renewed energies for occupational safety and health and recognitions of the Institute. So I think that again speaks really well for the things that we do in the laboratory.

Upon announcement of Dr. Howard as the Director for the Institute, he paid a visit two days later to the laboratory in Pittsburgh. So he visited NPPTL and the Pittsburgh Research Laboratory last week.

And part of his mission in doing that was to again reassure everybody that the train is on the track and we are moving on course. And a large part of the discussions that we had with Dr. Howard last week centered on the H1N1, and I'm sure all of you are also keenly aware of the facts and the information surrounding the pandemic because it is unfolding in front of us.

I think every day we hear new stories of increased people with H1N1 and the consequences of that, the increased number of deaths and fatalities. And I think it continues to strike closer and closer to home probably for all us, no matter where we live in the United States.

So H1N1, needless to say, is a topic that consumes a lot of the time and a lot of the resources in the laboratory, in the Institute, in the agency, and in the department. And so much so that I think the H1N1 status and activities and government preparedness is part of the daily briefings to President Obama. So it is a high visibility and priority area.

But today, we are meeting here for this stakeholder meeting, and I couldn't help but think and try to draw some analogies to the town hall meetings that we have all seen on the news relative to health care reform.

I hope that our meeting today is lively. I hope that it is fruitful. I hope it provides good information and new insights into the requirements that we are developing in our concepts for respirator standards. But I hope it stops a little bit short of what we have seen on the news for the town hall meetings.

The agenda that Jon and his staff have put together I think is what I would say is a little bit creative and innovative for these types of meetings, and I give credit to the staff for doing that, for venturing in a new direction.

The topics, the types of things that we talk about may be the same, but it's a little different approach for how we conduct those conversations and try to facilitate good exchange with you, our stakeholders.

And as we said in the past at these meetings, the information in the exchanges are really important.

We are in what we refer to as a concept development stage where we talk about requirements. We do our laboratory evaluations and analyses. We come back and talk again about those. And we keep going through this process back and forth to really try to provide clarity to the issues and the requirements that we want to introduce into the standards.

So, again, I welcome you to Pittsburgh and welcome you to this meeting. And I hope that the course of the day will be meaningful to you, and I know it will be meaningful to us as we strive and use this meeting in order to live up to the vision and mission that we have established for the Personal Protective Technology Program in the Institute and for the National Personal Protective Technology Laboratory.

Thank you.

MR. SZALAJDA: Thank you, Les.

And I guess, as Les said -- I just wanted to follow up on something that Les had mentioned about change in looking at the format of these types of meetings.

We have tried several different things in the past, but really the focuses that we need to hear from our stakeholders with regard to what the performance requirements should be for these types of systems. And that's the really the focus behind, you know, having these types of sessions, to be able to solicit that feedback. And also in the past, we have gotten -- had a lot of frank discussions in these types of forums, and I hope that continues with what we are doing today.

In terms of the meeting itself, I think what you are going to see is a little bit different if you have been coming to these things in the past is the format.

You know, we have tried -- we have had lot of PowerPoint types of discussions and then comments immediately following the PowerPoints, which is just fine for a couple of hours, but then you kind of fall into a coma after seeing PowerPoint after PowerPoint.

So the last couple of meetings, we have tried to break that up with having poster sessions, which the project officers had the opportunity to meet and talk in either small groups or one on one with people regarding a specific aspect of the performance requirements that we are looking at.

And I think those work well, but the unfortunate thing was trying to be able to capture that information and make it available for all the participants in the meeting to take advantage of.

So what we are going to try today is a little bit different with regard to trying to facilitate the discussions through having a panel session.

And the way that we are going to approach the meeting today is for each specific topic, there is three presentations with different aspects of each particular performance criteria that we are looking at.

What we are going to do is we will have the presentations. We are not going to take questions at that time. We will take a break, and then we are going to have the panel discussion.

I think if you were able to take advantage of having the slides on the internet ahead of the meeting, you will be able -- you would see that the topics that we wanted to try to facilitate discussion on were listed in the panel discussion.

So what we would like to do at that point, if you have specific questions regarding the presentations, ask them. And then also we will use the panel discussion to have additional dialogue on other topics pertaining to supplied-air respirators to air-fed ensembles or to Total Inward Leakage.

We also are connected with LiveMeeting where people are connected remotely and being able to participate in the discussions with the review of the presentations as well as the opportunity to ask questions. So I think with the format, what we will do is when we begin the panel sessions, we will defer to the LiveMeeting first and see if there are any questions on the LiveMeeting, take those. And then we will have the dialogue with those that are involved -- are physically located here in the auditorium.

I think we have covered a couple of logistics as least as far as safety and food availability and that type of thing.

This is being recorded. The meeting is recorded verbatim. There will be a transcript that will be available in the NIOSH docket later on in the next month. The presentation is going to go in accordance with the established agenda.

What I would like to do is try to stick within the time frames that were identified in the agenda, at least from the standpoint of, you know, if people are particularly interested in one topic or another, I don't want to get too far off of schedule to disrupt starting the SAR at 9, the air-fed ensembles at 11, and then TIL at 2 this afternoon.

I would also ask that when you -- during the open comment period, when you come, there's microphones in the aisleway, just to state your name, your affiliation, and state your questions so at least that way we have it captured for the record and also if we do have need to have subsequent dialogue on a particular topic or another.

One other option that's available for you today, no one had expressed an interest prior to the meeting, but as part of the agenda, we do have the opportunity for people to give a presentation relative to the topics that are being discussed.

If you have a presentation that you would like to provide, please see me at some point during either a break or at lunch that we can get it integrated into the program.

And, again, I mentioned the agenda.

And what I'm going to do as we go through the discussions today, each topic will have a specific agenda onto itself, and I'll introduce that prior to the initiation of that part of the meeting.

I have to laugh just as part of a personal aside. You know, someone had mentioned to me the other day, they said, Boy, it must be a great time to be a federal employee. And I said, Why? And they said, Well, with the changes in the administration, they said, You guys can probably get a lot of stuff down now.

I didn't quite know how to take that. I don't know if he was implying that we hadn't been working on anything prior to the change in the administration or that we were going to be able to do more. And I would like to think from the standpoint that there's a lot going on, and over the next several years there is going to be a lot more being accomplished.

One of the things that NIOSH decided when the Code of Federal Regulations Part 84 was established in 1995 was to facilitate the evolution of the regulations for respirators, that we would take a modular approach to working on the performance requirements associated with identifying protections for respiratory users.

And here we are, you know, 14 years later, and the modular approach I think is finally starting to take hold. And there's a variety of reasons for that, you know, that the laboratory, NPPTL, was established in 2001. There were inherent issues associated with, you know, the development of the infrastructure to go along with the laboratory, and there was also the terrorist attacks, which took a lot of our time and effort looking at the development of the CBRN standards.

But I think, you know, over the past ten years or so, that the infrastructure has grown to the point where there's a lot of activity now with regard to looking at the different protections that can be afforded by different types of respirators and updating the Code of Federal Regulations to make it more amenable to looking at new technologies and encouraging manufacturers to invest the time and effort into evolving respiratory protection and having a standard that is supportive of that, a standard that focuses on the development of performance-based requirements and not necessarily design restrictive types of requirements that limit innovation.

To that extent, we have got a lot of

things going on. The first three modules are items which are in the formal regulatory process where, you know, we have had -- we have had public meetings or will have public meetings to discuss the proposed rules that we have gotten formal feedback from stakeholders regarding the content of the rules, and we are moving them towards finalization and implementation as part of the actual regulation.

We are completing requirements for Closed-Circuit SCBAs and powered-air purifying respirators. These are things I think that you are going to see in 2010. They will come out in the Federal Register for you to have the opportunity to comment on with regard to the proposed rules.

And then you have the items that we are going to discuss, the supplied-air respirators, the concept of air-fed ensembles, where the suit is the respirator, which is new for us with regard to developing performance requirements in the federal regulation.

And there's a lot -- there's a lot on the plate, you know. And I think from the opportunities that still exist are to learn from, you know, our experiences in rulemaking with the things that we have learned in the first three and take those lessons and apply them to how we go forward.

I think as stakeholders, one of things that you should aware of in looking forward is that next year, when we have our first public meeting, one of the things that we are going to be looking for feedback on is the approach for where do we go from here, you know, that we have -- you know, for a variety of reasons, we have taken an approach to look at these items first with regard to our rules.

But what may be appropriate for us to work on next? Is it an open-circuit SCBAs? Is it chemical cartridge respirators?

You know, that's where we are going to be looking -- we are going to propose a list of standards that we are going to approach in development in the future, but we would like to get your feedback on if that's the right list or if that's the right sequence of events. And that's something I think you will be able to look forward to commenting on early on in 2010.

For today, there's a variety of opportunities for you to submit comments to us. You know, one is the dialogue that we will have here in the meeting today that will be captured in the transcript. Another is for you to be able to formally submit items to the docket, which is NIOSH's historical repository for information.

And this will provide -- when you go to the docket, the docket site, the website, you will be able to -- what we are doing in terms of our development is trying to truly use it as a repository so that when you go to supplied-air respirators, for example, you will be able to see the evolution of the concept, the -- from the initial concept to the point of where the rule is actually developed, that everything will be packaged and available in that one location.

And we are making progress to that extent to be able to capture that.

Also, you will be able to submit air-fed ensemble comments to Docket 148-A.

And I think just the one thing for you to notice as you look at the significance of the docket number is that the docket number itself captures the topic. 148 is associated with air-fed ensembles.

The "A" signifies that we are specifically talking about the concept paper that was identified for this meeting that was on the web for your review. And any comments that we receive on that paper, that's all captured under Topic 148-A.

The next iteration will be 148-B, up to point of where we develop and propose a final rule.

And not to confuse the Total Inward Leakage for the half-mask and the filtering facepiece respirator that is currently going through the formal rulemaking processes right now, the other part of the program or project that we are going to talk about is TIL for everything that's not a filtering facepiece respirator or a half-mask.

And that will be the focus of our discussion for this afternoon.

And with that, does anyone have any general questions with regard to the content of the meeting?

I would be happy to take those right now. And then, if not, we will move into the supplied-air respirator discussions.

Okay. And at least topically, the way that the -- as I had mentioned, we will have three programs for each -- three presentations for each part of the program. The project officers for each of the respective areas will give an overview of what was in the concept paper with regard to what the performance requirements are, and also identification of the issues that we would like to discuss during the panel session.

And then we have also selectively picked other presentations to supplement the information, knowledge regarding the concept or regarding the research that goes into the support of the development of the concept.

Jeff Palcic is our project officer for the supplied-air respirators. And in terms of our dialogue, he will be your point man going forward if you have specific questions regarding the content of the concept paper as well as any discussions that you may like to schedule with him with regard to the performance requirements.

Many of you are familiar with Bill Hoffman, who was my predecessor as the Policy and Standards Development Branch Chief.

And we have been fortunate enough to -- I like to say we have Bill on retainer, but he is consulting with us with regard to the standards development efforts, and he is going to give a presentation on the concept of air source supplied-air respirators.

And the final presentation is part of the SAR discussion, which also feeds and supports the work that we are doing in the air-fed ensembles, is the development of a new system at NPPTL for testing carbon dioxide dead space.

And Gary Walbert has been our project officer on that for the last couple of years, and he is going to give you an overview of our research and developing that system and how it's being used, both with the supplied-air respirator and also the air-fed ensemble.

At that point, after Gary finishes, we will take a 10- or 15-minute break, let everyone get their thoughts together and their questions together, and then we will go into the panel discussion.

MR. PERROTTE: Jon, one thing I was ask you to do. If you guys could pull the mic closer to you. They are having a little bit of difficulty hearing over the LiveMeeting.

MR. SZALAJDA: Okay. That's all right.

And so with that, what I would like to do is let Jeff Palcic come up and go over the overview of the supplied-air respirator, and we will proceed with the rest of our program.

MR. PALCIC: All right. If anyone has a problem hearing me, please speak up.

UNIDENTIFIED PERSON: Speak up.

The volume in the back is very weak.

MR. PALCIC: The volume in the back is very weak. Why don't we try a new mic? Is that any better? Can you hear me? I see shaking heads, hands, no, yes.

UNIDENTIFIED PERSON: Speak up.

MR. PALCIC: Speak up. Okay.

NIOSH has initiated a program to update 42 CFR Part 84, Subpart J, for the improvement and reliability of supplied-air respirators. The purpose of this presentation is to review the supplied-air respirator proposed standard.

I'll be focusing primarily on the proposed changes and the requirements that we are adding to the standard.

Okay. The 083A docket comments. As a result of the July '08 supplied-air respirator draft concept paper and the August '08 public meeting, we received comments to the 083A docket. All of the comments received were reviewed and considered for inclusion into the revised draft.

A lot of the comments that were received were incorporated into the draft, but the comments related to issues such as airsource systems, pneumatic tool takeoff, to mention a couple, were not adjusted with the hope of soliciting additional stakeholder input.

Okay. This is a slide showing you the organization of the proposed standard. Starting with the base requirements, including respiratory, non-respiratory, and air source or air compressor requirements and air supply hose requirements. On top of that, we have the enhanced combination SAR/SCBA requirements and the CBRN requirements.

The technical actions required to complete the SAR draft standard will be to continue to revise the draft standard, and this will include continuing internal technical reviews, posting the revised draft standard on the NIOSH web for public comment, and reviewing additional docket comments and revising the draft as required.

We will also be updating the standard test procedures. This will include eliminating obsolete procedures, modifying existing procedures, and developing new procedures to test to the new performance requirements.

And finally, we will be evaluating, acquiring, and securing test capabilities, which will include the evaluation of current test capabilities with regard to the new standard, purchasing and installing new test equipment, and conducting validation tests to the new performance requirements.

Once again, a supplied-air standard will remain Subpart J of 42 CFR. And the subpart will contain optional requirements for both IDLH and CBRN applications. And SAR will continue to meet the requirements of Subparts A through G of 42 CFR Part 84.

We have established two types of supplied-air respirators, airline and airsource. An airline-type respirator consists of an air supply line, respiratory inlet covering, and a coupling for connection to Grade D or better breathing gas. An optional airsource-type respirator consists of a portable blower or air compressor, air supply line, respiratory inlet covering certified as a complete system.

Bill Hoffman will be presenting the details specific to the airsource systems in an upcoming presentation.

Proposed technical updates for Subpart J Base respiratory requirements.

Airline type changes. We have eliminated Type A and AE, which is a hose mask respirator with a hand or motor-driven blower with and without abrasive blasting protection. We have also eliminated Type B and BE, which is also a hose mask respirator where the user's lung draws inspired air through a large diameter hose with and without abrasive blasting protection.

And we have redesignated Type C and CE as airline type, and we have also eliminated the demand-type apparatus.

Airline breathing air has remained unchanged, but we have updated the CGA G-7.1 reference.

Continuing with base respiratory requirements, exhalation valve leakage. A dry exhalation valve or valve seats will still be subject to a suction of 25 millimeters, but leakage between the valve and valve seat cannot exceed 15 milliliters per minute. The old limit was 15 (sic) milliliters per minute.

Carbon dioxide limit. This requirement has been added to include -- or this requirement has been included to ensure that the CO2 level in the breathing zone is acceptable to prior to human subject testing.

The human subject testing was included to determine the carbon dioxide and oxygen levels in a breathing zone prior to -- or during performance tests with subjects standing and walking at 3.5 miles per hour.

And, finally, the fit test will be accomplished through the Total Inward Leakage test, and that will finalized through benchmark testing.

Continuing with the base respiratory requirements, air flow rates, manufacturers will specify the air flow rate for which their system is to be approved. The system must maintain positive pressure in the breathing zone on both inhalation and exhalation at the specified flow rate.

These flow rates will be based on a

sinusoidal breathing profile.

This will replace the current flow rates of the 115 and 170 liters per minute for tight and loose-fitting respiratory inlet coverings. We have added a very high flow rate based on stakeholder comments from the previous draft.

As they stand today, the NIOSH proposed air flow rates are a low rate with a 25 liter minute volume, 1.3 liter tidal volume at 19.2 respirations per minute, a moderate rate with a 40 liter a minute volume, 1.67 liter tidal volume at 24 respirations a minute, a high rate with a 57 liter minute volume, 1.95 liter tidal volume at 29.1 respirations per minute.

And the new very high rate, which is 78 liter minute volume, two liter tidal volume and 39 respirations per minute. And that will be one of the discussion slides.

Proposed technical upgrades for Subpart J base nonrespiratory requirements.

Required components, airline systems consist of a respiratory inlet covering, air supply valve or orifice, air supply hose, detachable couplings, flexible breathing tube and harness.

General construction shall meet the requirements of Subpart G. General construction performance requirements of 42 CFR Part 84, and hose connections and couplings are required to prevent unintentional disconnection.

Continuing with base nonrespiratory requirements, shoulder strap test was increased from 250 pounds to 300 pounds for 30 minutes. The belt and rings were increased from 300 pounds to 500 pounds for 30 minutes, and the hose attachment to harness remained at 250 pounds.

If the harness is designed to act as a safety or rescue harness, it should meet ANSI Z359.1, fall/arrest standard. In addition to the ANSI standards, stakeholder feedback suggested NFPA 1983 standard on life safety rope for escape and emergency service as an alternative.

And finally, the total length of hose for approval in its heaviest configuration shall permit dragging over the concrete floor without compromising the harness or exerting force on the respiratory inlet covering.

Once again, continuing with base nonrespiratory requirements.

Visors and lenses. All lenses or respiratory inlet coverings shall be designed and constructed to be impact and penetration resistant in accordance with ANSI Z87.1. This is also a discussion slide.

Respiratory inlet coverings with visors shall obtain an average field score of 90 or greater.

Noise level. Noise levels generated by the respirator during normal operation shall be measured at the maximum airflow obtainable within the pressure and hose length requirements, and must be less than 80 decibels at both ear canals.

Finally, the failure mode effects analysis. Manufacturers shall demonstrate that reliability is assessed and controlled within their quality assurance plan by conducting a system FMEA on their device or component.

Proposed technical updates for subpart J base requirements for air supply hose.

The hose length requirement of 300 feet has been eliminated. Hose length will now be set by the manufacturers. Hose labeling. All breathing air hoses must be labeled "breathing air only."This is not the current draft, but it will be in the next draft.

Hose permeation. In addition to the gasoline permeation test, we are proposing the addition of permeation tests for kerosene and MEK/toluene. This will be finalized through benchmark testing, and that is also a discussion slide.

Proposed technical updates for subpart J enhanced combination SAR/SCBA requirements.

Airline combination SAR/SCBA will incorporate a five or 10-minute duration escape air cylinder. A 15-minute or longer duration SCBA air cylinder will allow for 20 percent of its capacity to be used for entry.

The system must automatically switch from the supplied air to the air cylinder if the air supply can no longer -- or if the air supply can no longer supply breathing air. An alarm will notify the user when the system is on cylinder air, and these systems require a tight-fitting full facepiece.

Continuing with the enhanced combination SAR/SCBA requirements, visors and lenses require haze luminous transmittance and abrasion test, impact and penetration resistance, low temperature and fogging. Communication will be achieved through the Modified Rhyme Test.

Proposed technical updates for Subpart J enhanced requirements for optional CBRN protection. They must the base and combination SAR requirements, SAR/SCBA requirements, a 15-minute or longer duration escape air cylinder is required. A system must automatically switch from the supplied air to the air cylinder if the supply line can no longer supply breathing air.

An alarm will notify the user when the system is on cylinder air.

Criteria which have been established for CBRN SCBA respirators will be applied to combination SAR/SCBAs, and they will also require a tight-fitting full facepiece, durability conditioning and agent testing.

Requirements for optional -- or additional options. Hydration, drink tube valve and valve seats shall not exceed 30 milliliters per minute of leakage at a 75 millimeter vacuum. And the pneumatic tool takeoff, which is being proposed, is an optional requirement.

Airline respirators equipped with a pneumatic tool takeoff manifold must have a check valve and filter at the takeoff point to prevent any backflow or contamination to the respirator.

Also, respirators must maintain positive pressure in the breathing zone at the manufacturer's highest specified flow rate regardless of occurrences in the pneumatic tool line, such as blockage or free flow.

Our plans for benchmark testing include live agent testing. The test setup will be similar to that of the open-circuit Self-Contained Breathing Apparatus.

We have developed a draft STP, and the test will be conducted at the current open-circuit SCBA challenge concentrations. That is also a discussion slide.

Continuing with the benchmark plans, CO2 machine tests or dead space tests will be conducted on the new CO2 dead space system, and Gary will be talking to you about that in an upcoming presentation.

Breathing gas concentration, human subject test, the equipment required to conduct this test has been purchased and installation is underway.

Total Inward Leakage benchmark testing, a cross-section of sample respirators has been purchased and is also pending equipment installation.

Continuing with the benchmark test plans, hose permeation testing. We will be developing a new test apparatus that will allow for a more controlled test and will depend on the finalization of the challenge agents.

Positive pressure determination. We will be benchmarking existing breathing systems at all four proposed flow rates to develop procedures and evaluate current equipment capabilities. That test will be conducted on a Ward breathing machine that will allow all four flow rates to be evaluated on a single breathing machine.

Standard test procedures. We will continue to develop new standard test procedures and derive them from existing procedures for other respiratory protective devices. We will also be updating existing -- the existing SAR test procedures to the new -- to test to the new performance requirements. And finally, we will eliminate the obsolete procedures due to changes in performance requirements and evaluation methods.

Projected timeline. We posted the supplied-air respirator concept standard on the NIOSH web in August. We will be using the comments from this public meeting in the 083B docket to revise the SAR concept standard in November. We will also be using the comments we received to the 083A docket and the original 083 docket.

This is the supplied-air respirator NIOSH docket 083B information. All written comments will be accepted through October 19 to the 083B docket.

Once again, I appreciate everyone that commented on the previous docket. And those comments -- the comments that did not make it into the draft have not been lost. We are just continuing to accumulate more data before we make any wholesale changes to the draft.

So I talked to a few of you guys. Don't get frustrated because the comments still exist. And once we get another round in, we should have a good base.

So I appreciate it.

Jon, did you want to go through the discussion slides and all now?

MR. SZALAJDA: Yeah, go ahead.

MR. PALCIC: Well, I'm just going to flip through the discussion slides so you have an idea where we are going to start.

We have a discussion slide on the airsource systems, optional approval, presently neither NIOSH nor OSHA evaluate portable airsource systems, inclusion of the cylinder carts in airsource systems, and NIOSH approves systems, when an SAR is offered as an airsource system, they should be tested in that configuration. That's one discussion slide.

This is the TIL discussion slide, which I kind of regret putting in, but we will talk about the numbers there.

A discussion slide for the helmet requirement, should NIOSH require making helmets that do not meet mechanical compliance tests and mark them as not impact and penetration resistant? The current SAR draft standard only requires ANSI Z89.1 2003 Type I or Type II protective cap standards.

This discussion slide for the lens requirements. Should NIOSH require marking lenses that do not meet mechanical compliance tests as not impact resistant.

The current SAR draft standard only requires ANSI Z87.1-2003 impact and penetration tests, not the entire standard.

To be marked as ANSI Z87.1-2003, the lens would need to pass all of the ANSI tests.

And a discussion slide on the flow rates. I put this up simply because we have added the high flow rate. Get some input on that. And also to determine if we should only be focusing on the high and very high rates for the IDLH and CBRN applications.

Discussion slide or hose permeation tests.

We are developing a new sealed test apparatus and a test procedure that can be conducted in a laboratory environment under controlled conditions. The proposed permeation tests include gasoline, kerosene, and MEK/toluene. We have also talked about possibly replacing all three of them with a custom blend.

We will talk about that.

And a discussion slide for the live agent testing. Should we have two available levels of protection is being considered for the PAPR standard. Right now, we are doing our benchmark testing to the open-circuit SCBA challenge concentrations, but is there a need to have a lower challenge concentration for support activities. You know, warm zone, cold zone. We will also talk about that.

That's it.

MR. HOFFMAN: Good morning, everybody. I'm going to talk some about the supplied-air respirator airsource systems. And that tends to be -- it tends to be a controversial subject up to this point, some people saying stay away from it, and other people saying it's about time NIOSH did something with these.

The first thing I want to mention is to give an overview for the airsource system. And all of the requirements, airsource and otherwise, are going to remain in Subpart J. And as many of you know, the present Subpart J regulations have been in place for literally decades. And a lot of things have changed over the years.

With the proposed changes, many of the airline SARs should be able to meet the change requirements without anything, without them doing anything at all.

We envision other SAR airline to require very little change. But I want to point out in the new Subpart J, the optional requirements are for IDLH, CBRN, and airsource. You don't have to get an airsource approval. You don't have to get CBRN. You don't have to get IDLH. These are different options.

We are kind of looking like it as an a la carte sort of approach to things where you can decide what works best for the product that you are offering.

The typical airline respirator -- and I'm sure you have seen this slide before. The respirator supplied with a Grade D air, typically from a stationary compressor generally at a plant or something like that.

When we are looking at the airsource requirements, we are looking at a portable source of air. Usually it's a turbine blower or some type of a small air compressor.

And in this type of system, the complete system would be looked at and approved. And it gives a lot of options, assuming that it's portable. It works very well for one of the places where we saw it, it was in firefighting search and rescue, where they need to move to a site and set up for something. An SCBA doesn't give them a long enough time to do what they need to do.

You can go in on an airline, and with the provisions we are looking for for IDLH, there's even an escape bottle provided. So people could go in, actually use a tool, actually do what they need to do, stay in there for a good period of time, come out, and have an escape mechanism.

Some background information. Under 42 CFR, as everybody knows, NIOSH sets the requirements from the stationary point of connection of the Grade D air up to and including the respiratory inlet covering.

OSHA, on the other hand, sets the

requirements for the stationary compressor up to the point of connection.

So when you are using the stationary compressor system, every part of the system has been evaluated to ensure a safe and adequate air supply on the part of the user. So there everything is covered. Everything has been looked at, and the user can be pretty assured that everything is good.

Presently, though, there are no standards to evaluate the airsource systems. And there is nothing to assure that they get a safe and adequate supply of air for the user.

Oftentimes the respirator manufacturers will take zero length respirator approvals, which were originally intended for the stationary work sites. Somebody saying they need a respirator to use, they are sitting at the bench. They don't want all of that hose curled up on the floor. It works very well for that application.

Others will take these respirators and combine them with the portable compressors or blowers and sell them as complete respirator systems.

Under this situation, users and others are selling the products, and oftentimes we believe they don't realize that only part of the system has been evaluated by NIOSH. And, as such, the user can't really be assured of a safe and reliable air supply.

Sales and other publicity that we have seen are often misleading and tend to reinforce that. Misinformed representatives that different ones of us have talked to have even been insistent that their portable systems are in fact NIOSH approved.

And NIOSH's position is it believes that the users of portable systems should be afforded the same assurance and the same level of adequate air supply, whether they are using a portable system or a stationary system. No matter what respirator system you use, we want to make sure that the users can be assured that the system is good and safe and it has been evaluated and everything works like it should.

Here's some examples of publicity

pertaining to airsource systems, and I will take a minute to read these.

These simple yet effective NIOSH approved fresh air breathing systems take the fear out of working with dangerous isocyanates, dusts, mists, and harmful vapors. Well, in fact, the systems aren't NIOSH approved.

Our -- excuse me. All of our products exceed NIOSH airflow requirements. Well, that may or may not be true, but it does tend to imply that NIOSH has looked at or approved the system.

One, and I don't want to mention the name, but a company that says modified to be NIOSH, OSHA, and MSHA approved. And we got some examples of this that I would encourage you to look on the internet and look under some of the headings such as fresh air respirator, and you'll find a lot of advertisements for that. Supplied-air respirator turbine respirator. If you do an internet search, you will find a lot of companies and a lot of distributors that are listing their systems as NIOSH approved.

With the airsource respirator outcome, manufacturers will be still able to obtain the typical SAR airline approval, but they will have expanded flexibility, as Jeff had mentioned. You will be able to get CBRN approval optional. IDLH is optional. And no airline length restrictions. That has been taken away.

And, in fact, if you read the abbreviated preamble, it goes into a little bit more depth than was posted on the web of some of the other changes.

Manufacturers will also be able to obtain new airsource approvals, which will also include CBRN, IDLH, and no airline length restrictions. And, again, this has been asked for by fire departments and others where they can take a system to the site, work where they have to go into a dangerous situation for a long period of time which far outlasts what an SCBA can supply, still have an escape mechanism, and do what they need to do.

The way we are proposing this, manufacturers can have respirators approved both ways. They can have it as an airline or as an airsource, and each of those has an option of CBRN or IDLH or neither if that's the choosing.

From the NIOSH perspective, users will be assured that the entire system is approved, whether it be an airline system or a portable airsource system.

Now, one of the highlights of the airsource requirement is we struggled with defining "portable." And the industry standard seemed to lend itself -- or seemed to lead us towards the definition of a system that's readily moved or carried, and we are looking at a hundred pounds maximum, or it can mounted on a manually propelled cart and be up to about 300 pounds, not including the respiratory inlet covering or hoses. But it does have to include the cords or batteries or transformers or whatever is needed to power the system.

It may not be attached or mounted in any way to a structure or self-propelled vehicle. Like it's mounted in the back of a pickup truck permanently or mounted on an ATV. We are trying to stick with what we consider to be a truly portable system.

The performance evaluation, we do want to check durability. One of the tests we are proposing is eight hours a day for 15 days in the most demanding configuration to make sure that the system will continue to work. And if somebody goes in there, you want the system to last.

Noise levels, we are looking at 85 decibels in a three-foot diameter around the unit itself so that it's not exceedingly noisy. We don't want the unit to get exceedingly hot either, so we are looking at it not exceeding 60 degrees C, or it could be protected with a shield or something from incidental contact.

We are looking at allowing multiple users. And, again, if you do an internet search for fresh air respirators, you will find several multiple-user systems out there now that are being offered. And they are also stating that they are NIOSH approved.

We are looking at multiple users, but with some stipulations, some criteria there, that it has to permit each hose or each user to be able to use the system regardless of what happens in an adjacent hose. So if an adjacent hose becomes blocked or is cut open, the person that's still wearing the first system still gets the airflow as they need to.

We are looking at a pneumatic takeoff, and one of the other ones I found online was you can buy a complete portable respirator system that includes an HVLP paint spray gun, all NIOSH approved, which is not correct either.

But it's some very creative, I guess, advertisers. And in some cases, I don't think it's done deliberately. Because, like I said, when I talk to the people, the sales representatives, they truly believe the products are approved. So it's just some misinformation, some misunderstanding, excuse me, misunderstanding.

But we do want to allow a pneumatic takeoff, and we don't see any reason to limit that technology if the technology is there to do it.

Some of the combination SAR/SCBA requirements, we are looking at the airsource to be very much similar to the airline respirators. For example, we are still looking at the five- to ten-minute duration escape bottle, cylinder, so you could be using a portable system, and you still carry the bottle.

We are also looking at if it's a 15-minute or longer duration air cylinder, you can use 20 percent of the capacity for entry, although on a portable, system that may not be necessary, but there's no reason to prohibit that. We are also looking at automatic switching from supplied air to the air cylinder with an alarm.

Again, we are requiring the same thing as with the airline respirator, where it would be a tight-fitting full facepiece.

As far as the CBRN component, it's also going to be the same as the airline. Fifteen minute or longer duration escape air cylinder. You can't use any of that air on entry because the CBRN environment is considered to be actually more dangerous than the IDLH.

Automatic switching, again, from supplied air to the air cylinder with the alarm. And the criteria that have been established mirror the airline and the airsource respirators, tight-fitting full facepiece, durability conditioning, and agent testing, which Jeff has already mentioned.

What we want to do, though, is encourage input on these things, all of the comments, questions, and discussions. It is encouraged here, but we also would like people to submit that to the docket.

I assure you that we do look at all the comments closely. We take those all into consideration. We try to incorporate what we can, and we look at the contradictory ones. Because where somebody is very in favor of one requirement, somebody else is very much against it.

So that's a summary. Again, I would encourage everybody to also read the standard and read the abbreviated preamble that we put in there that highlights a lot of the changes.

Thank you.

MR. WALBERT: Hi. I'm going to discuss

the final correlation test results for implementation of the new CO_2 dead space test system at NPPTL.

I gave previous updates on this project at the December 2005 and October 2006 manufacturer's meetings. At that time, I asked the question, Why upgrade the carbon dioxide dead space test system? And the reasons I gave were to, one, to improve the accuracy in setting test conditions and performing data analysis.

Also to reduce variability from test to test. And finally to allow manufacturers to duplicate the test system using commercially available components for direct correlation at their labs.

Okay. So what have we been doing for the last three years?

The project timeline shows that the new test system was completed in June of 2006, and shakedown testing was completed in December 2006. Efforts to equate the new test system with existing tests results were completed in December 2007.

Correlation testing between the existing and new test systems was completed in July of 2008, and statistical modeling of the test results was completed in May of 2009.

Okay. This slide shows a photograph of the existing carbon dioxide dead space test systems that is in the foreground, and the new carbon dioxide dead space test system, which is in the background.

Okay. The prominent features of the new carbon dioxide dead space system include a Sheffield headform and half-torso with a face width of 146 millimeters and a face length of 122 millimeters. And this places the Sheffield head in Cell No. 7 of the new NIOSH Bivariate Fit Test Panel representing a medium size face.

In addition to that, we also have a data monitoring/recording system powered by our custom LabVIEW software application, a data recording interval which is 25 milliseconds, which is about 40 times per minute -- or excuse me, 40 times per second. And this is four times more frequent than the existing system was using a strip tread recorder (phonetic).

We also employ mass flow controllers for controlling the flow rates of carbon dioxide and air to provide breathing gas with a 5 percent carbon dioxide level.

Okay, in addition, we have a revised sedentary cam design that provides breathing cycle component durations consistent with Leslie Silverman's human subject sedentary breathing research conducted back in the 1940s and the 1950s.

We have a solenoid valve state change data file stamping in order to determine when the breathing machine piston begins to retract and then stop to signify the beginning and then the end of inhalation phase of the breathing cycle. And we are also using an Excel spreadsheet-based data analysis routine.

Okay. These features have provided for enhanced performance capabilities of the new carbon dioxide dead space test system, and this includes the ability to control the peak carbon dioxide concentration at 5 percent plus or minus .02 percent.

Also control the sample gas extracted from the breathing zone for analysis, at 450 plus or minus .7 sccm.

We are able to obtain consistent blank carbon dioxide levels generally ranging from .39 percent to .44 percent, and it also allows us to precisely determine the start and end of the inhalation phase from the solenoid valve actuation times, and this is corroborated with facepiece resistance data.

Okay, during the correlation testing, 20 respirators were tested, both the existing and the new test systems. And a simple linear regression was subsequently fit to this data to predict carbon dioxide dead space levels for the existing test system as a function of the carbon dioxide dead space levels measured at the new system.

This provided a linear regression that took the form that you see here at the bottom of the slide. The carbon dioxide at the existing system is equal to minus 1.097 plus 1.209 times the carbon dioxide measured at the new system.

Okay. This plot shows -- each of the points in this plot represents a respirator that was tested at both the existing and new test system.

The straight line is the best fit linear regression fit for this -- for the model. In addition, I just want to mention that the offset between the existing and new CO2 dead space systems is about .7 percent, so the CO2 dead space level measured at the new system was about .7 percent higher than what we were measuring at the existing system.

Okay. In terms of the significance of the statistical analysis, both the intercept and slope of the model were highly statistically significant, with "p" being less than .001 for each coefficient. And also using this equation to predict the carbon dioxide level of the existing system as a function of the new system gives an R squared value of .909, and this means that approximately 91 percent of the variability in the new system's measurements can be explained by the variability in the measurements of the existing system.

Okay. This table shows data obtained during the correlation testing. The first column under "Existing" is the carbon dioxide dead space level data obtained at the existing system, and this is an average of three donnings of the respirator.

And then the corresponding CO2 dead space level for that same respirator at the new system, and, again, this is an average of three donnings of the respirator on the headform.

The third column shows the existing predicted carbon dioxide level based on what was measured at the new system and also using the correlation model that was established through the statistical analyses.

The fourth and fifth columns show whether or not that respirator passed. The fourth column is whether it passed at the existing system with 1 percent or less being the -- or less than 1 percent being the limit for passing the carbon dioxide dead space test.

And the last column shows the existing predicted pass or fail based on what was measured at the new system in the determination of the existing system carbon dioxide level based on a model that we used to determine that.

Okay. This table and results show that 19 of 20 respirators that passed or failed at the existing system were correctly predicted to pass or fail respectively at the new system using this model.

Okay. Going forward, our plans are for respirators that have been previously approved, our procedure is going to be to measure the carbon dioxide dead space level with the new system using the linear regression model, determine the existing test system equivalent carbon dioxide dead space level. And if the existing test system equivalent CO_2 dead space level is less than 1 percent, a passing grade will be assigned to the respirator tested.

And for all new respirators that are submitted for certification using the new test system, we will use it as it is with some consideration being given to taking a look at, instead of determining the carbon dioxide dead space level based on an arithmetic average of the CO2 measured during the inhalation phase, we are going to take a look at using a dead -- a volume weighted average for the future testing.

I will take any questions during the panel discussions after the break.

Thank you.

MR. SZALAJDA: All right. I think right now, Verizon says it's 9:38. So let's take 15 minutes for everyone to collect their thoughts, put their questions together. And then we will resume about five of 10. All right? Thank you.

(A recess is taken.)

MR. SZALAJDA: All right. Thank you.

We are going to go ahead and have the panel discussion. I just have a couple of remarks I found that -- hopefully the sound might be a little better now. We reoriented the one speaker, so hopefully the sound will carry to the back of the room a little better.

One thing, it was brought to my attention, at least on any slide earlier regarding the docket, the comments that you should submit should reference 83B. I think one of my earlier slides said 83A, but if you submit comments to the docket office, you should use 83B.

What I would like to do at least initially is introduce the members of the panel for the discussion. In addition to the speakers, Rich Palcic, Bill Hoffman, and Gary Walbert, they are also joined by Jay Parker from the Technology Evaluation Branch.

Jay has several years -- I won't say how many -- but he has several years of experience with respirator and product development and as a member of our evaluation branch. And also Rich Vojtko, who is the project officer from NPPTL for the powered air purifying respirator standard and has been actively involved with the development for the air flow requirements for system.

What I would like to do initially, if we are ready with the online part of the meeting, is if there are any questions from the online participants, if they could indicate to John Perrotte that they have questions, and we will go ahead and take them initially.

The way the set up is accomplished today is that for the online -- for this session, you will be able to hear the online participants' questions directly. John hopefully won't have to repeat them.

John, do we have anyone from LiveMeeting with a question?

MR. PERROTTE: Actually, I told them we were going to wait until we have the panel discussion -- Draeger did have a question.

MR. SZALAJDA: I think we are ready now.

MR. PERROTTE: Okay. Let me see if we have got questions.

I might have to read it off to you, Jon.

MR. SZALAJDA: One thing I did want to mention -- and I was hopeful to have more information available for today's discussion.

But relative to the questions and the

development related to the use of these -- of not only the SAR, but also the air-fed ensemble with the -- in IDLH types of environments, that we have initiated some conversations with OSHA to talk about this, at least with regard to the impact, not only on the 42 CFR Part 84 regulations, but also on how OSHA has prescribed things with their requirements.

And I did want to let you know that those discussions are ongoing. And when we meet again to continue discussing the conceptual development, we will probably have some good feedback from them at that time.

MR. PERROTTE: The one question is from Draeger, Michael Klaus, and it is regarding Jeff's slides.

On page 25, where the total value is 0.01 percent for the different versions, the concept updates show 0.001 percent. Which value is your correct ones?

For positive pressure devices, the values shown today seem to be fine. We still are missing the recommendation of the TIL method.

The second question is from that from our slide on that topic, what's the reason for the proposal here that one of the three samples is allowed to exceed the CO2 limit? Do you think that it would be better to propose that one of the three -- of the three units tested shall exceed the 1 percent level?

MR. SZALAJDA: Okay. We will take the first one.

And we may end up bouncing -- since this is the first time we have done this, we may end up bouncing around a little bit between the topics.

But for the TIL slides, if you were prompt and online early, there were some arithmetic errors with the TIL slides. The versions that were presented today are what we are currently conceptualizing for the requirement.

And the second question, John, can you repeat it on the CO2 dead space testing? Hold on a second so everyone can have the benefit of hearing it.

MR. PERROTTE: Let's see here.

The second question here, I'll get it here in a second.

It's from our slide on that topic, what's the reason for the proposal that one of the three samples is allowed to exceed the CO2 limit? Don't you think it would be better to propose that one of the three units tested should exceed the 1 percent level?

MR. PARKER: We are discussing the carbon dioxide?

MR. SZALAJDA: Yes.

MR. PARKER: I just had a discussion with Bill Hoffman. I guess Bill indicated that I guess previously there was some difficulty with getting the respirator on the headform and -- you want to do it?

MR. HOFFMAN: Yeah. One of the reasons it was proposed to be one out of three passes rather than three out of three is it's not really the -- what you are trying to see is if the respirator is capable of holding that level, not that it will do it every time. Because every time you put it on a headform, since it's a nonhuman headform, obviously, it's difficult to get it on the same way every time and to get a repeatable result. So if you do it a couple of times, you are really seeing is the respirator capable of achieving that, not that it will achieve that on a person every time.

So one out of three passing rather than two out of three or three out of three.

And how do we know if we answer their question?

MR. PERROTTE: There are a couple more.

MR. SZALAJDA: Okay. And I think the last part of Klaus' question related to the actual establishment or the benchmarking with TIL, and I think what I would like to do is defer that to this afternoon's discussion when we talk about our approach for determining inward leakage for the other parts of other types of respirators.

MR. PERROTTE: Okay. The second question is from Structural Composite Industries, Will. And the question is regarding bullet number five of Jeff Palcic's on Slide 16, is NIOSH approval for the system intended to include the cylinder? If so, why?

MR. SZALAJDA: Is the question the cylinder -- the cylinder associated -- is that with the -- Jeff, help me out here. Is that with the combination --

MR. PALCIC: Yeah, it's the combination --

MR. SZALAJDA: SAR --

MR. PALCIC: Combination SAR/SCBA.

What was the question again?

MR. PERROTTE: It says for Jeff Palcic regarding bullet point five on Slide 16, is the NIOSH approval for the system intended to include the cylinder? If so, why?

MR. PALCIC: This is for the IDLH environments. So in order to be approved in IDLH, we have to have the escape air cylinder.

MR. PARKER: What I think he means is like a supplied-air cylinder, you know, breathing air cylinder I think is what that gentleman is referring to. Because there are companies involved in using that type of system for supplied-air respirators, so

I think the question is, are we going to also approve cases where a cylinder of air is being used as the air supply, like for a pressure demand type SAR.

MR. PALCIC: You meaned as an airsource?

MR. PARKER: Yes.

MR. PERROTTE: Let me try to unmute them here, and we can...

Hello, Will, if you can ask your question.

MR. ANTUNIS: That's exactly what I'm asking. Is the cylinder part of the approval of the ensemble SCBA, or is it the entire system that gets the approval?

MR. SZALAJDA: Well, I think the short answer is NIOSH is still approving the respirator as a system. So if the cylinder is part of the system, it would be incorporated in the approval.

MR. ANTUNIS: For this kind of system, though, it's currently not. Why would it now be incorporated?

MR. SZALAJDA: Well, I think with -- the concept that's being discussed is that the cylinder would be providing an escape capability.

If the airline were to be compromised or the air flow were to be compromised in the SAR, that the cylinder of air that was included with the system would provide the user the opportunity to escape from that environment.

MR. ANTUNIS: The question is not whether a cylinder should be provided. I agree it should be provided. The question is, is the cylinder itself going to -- will the cylinder have its own approval?

In other words, can the end users purchase cylinders separately --

MR. SZALAJDA: No.

MR. ANTUNIS: Like from a different manufacturer?

MR. SZALAJDA: Yeah. I understand the question. The short answer is no. It still would be part of a system's approval.

MR. ANTUNIS: Thank you.

MR. SZALAJDA: You're welcome.

MR. PERROTTE: The last question is, Does the autoswitch feature in combination SAR/SCBA units have to remain latched?

MR. HOFFMAN: I think once it switches over, does it stay switched over? And we haven't stipulated that one way or the other. I don't know there would be an intermittent interruption to the air supply, could it switch back or not? I don't think we have really investigated that at this point.

MR. PERROTTE: Yeah, that question was from Avon International Safety Instruments from Danielle.

MR. PALCIC: With the CBRN application, once you switch over, you can't switch back. But we haven't said specifically that the system would be unable to switch back.

MR. PERROTTE: That's all of the questions from the LiveMeeting participants.

MR. SZALAJDA: Okay. Great. Thank you.

All right. Well, what we will do at this point is we will go through the discussion slides. And hopefully if you have questions that were -- that you identified as part of your review of the material as well as what you heard this morning, if you can integrate those questions into these slides.

And if we don't cover those questions as part of these topics, then, you know, after we have gone through the slides, please go ahead and state your questions, and we will address them at that time.

And then following the end of the questions, if there's any desire to state publicly for the record a position on something that you feel we should consider, there will be an opportunity for that as well.

Okay. Well, the first appears to be -- the first slide is on this noncontroversial airsource discussion.

And I think at least with regard to the feedback that we are looking for is to try to truly evaluate if there is a need for this type of capability in the workplace.

And we have received comments both pro and con regarding this type of system, and we would like to solicit your opinions now on the airsource topic.

Bob Sell from Draeger. Thank you for breaking the ice.

MR. SELL: Is this on? Yes. Bob Sell of Draeger Safety.

I guess the only thing I have no initial problem with including airsource systems. But mine is going to the third bullet point here, which I think maybe the gentleman from SEI may have also been referring to, about the inclusion of a cylinder cart as part of an airsource system.

Now right now, the NFPA Technical Committee for SCBAs is looking at things like RIC-packs, where a firefighter will have a self-contained breathing apparatus with a supplied-air capability who becomes trapped. Then you have your writ (ck team that runs in with a SCBA in a bag with a pressure reducer on it, airline attachments, whatever they think they need, and they plug in.

So when you take it in that scenario, would that system -- would that have to be approved as a system under your airsource requirements, or does it go back to a fixed-point attachment, like a supplied-air respirator.

And another scenario is some of the military. The CST teams and other agencies are now implementing larger cylinders, K size bottles, onto dune buggies and carts. And they are hauling them around for when they do their surveys. And they are also wearing a self-contained breathing apparatus with supplied-air capability.

So does that fall into an airsource or a fixed-point system?

Now, these cylinders are all supplying Grade D air, supposedly.

So, I mean, where does this fall?

MR. SZALAJDA: That's a good comment, Bob.

MR. HOFFMAN: I think if I understand you right, we look at -- that is -- that's still a cylinder, so it's still a closed system; correct?

MR. SELL: Correct.

MR. HOFFMAN: Okay. I would look more -- my initial thought on that is that is more falling on the line of the SCBA. I think we are looking at the airsource as being able to continuously supply ambient air from a remote source.

MR. SELL: Okay. Then why ask this third bullet point question about cylinder carts as airsource systems, unless I misunderstand the --

MR. PALCIC: No. What we are getting at is -- with an airsource that's sold as a system, if you have a cart with say two cylinders on it, and it was sold as a system with the respirators, there's no -- there's nothing to say that that's supplying the right amount of air from the cylinder.

It's Grade D air, but the regulator system and the delivery system is not looked at right now by anyone.

MR. SELL: Correct, right.

MR. PALCIC: So if it's sold as a package with the respirators -- and I will say I haven't seen that yet -- but just as an option, you buy the cart, you buy the respirator system, it would be tested as a complete system --

MR. SELL: Okay.

MR. PALCIC: -- under the airsource idea.

MR. SELL: Then going back to the writ pack (ck concept, then under this same scenario, it sounds like you would look at it as a system.

MR. PALCIC: That's a new one.

I will have to think about that.

Les?

MR. SELL: Technical Committee Chairman.

(Laughter)

MR. BOORD: Bob, I think those are good comments. And I think that in the concept of the airsource cart, I think the examples you mentioned are really good examples that need to be factored into the analysis to determine, you know, whether they would be included as part of that.

But traditionally, that third bullet is thinking of the air cart, the traditional industrial air cart that you would move into the workplace setting. I think the examples you made, particularly the RIC-pack, and then maybe some of those military applications would be need to be factored into this consideration.

MR. SAVARIN: Mike Savarin, Sperian

Respiratory Protection. What a nightmare.

Mike Savarin, Sperian Respiratory Protection. I have very a brief question today.

In these systems that are deemed portable, there's a limit of 300 pounds maximum for the transportable systems.

The way the thing is currently written, they may not be attached or mounted in any way to a structure or vehicle.

How are you then going to treat those systems? Are they going to be viewed as fixed, the ones that are mounted to vehicles, or are they just not going to be covered by the new standard?

MR. HOFFMAN: At the present, we -- I also had a comment on that during the discussion. They said there are ATV-mounted systems that are presently being used as supplied-air systems.

And at this point, we haven't ventured there. We have tried to limit what portable is. Now, whether we would expand that included ones that are cart mounted or pickup truck mounted, we haven't at this point. But a couple of people pointed out that those are commonly used systems, and nobody is looking at that.

So I think that's one to submit to the docket that we need to consider where do we draw the line on what we consider to be portable and what does it include? Because the information keeps surfacing on that that's -- a lot of it is new to us, that we weren't familiar with that use before.

MR. SAVARIN: It may also be worth considering whether you just automatically assign the others as fixed because of excessive weight, they are just like smaller massive compressors, I guess, if you see what I mean.

So it just depends on how you want to classify them or categorize them.

MR. HOFFMAN: We have been told there's huge systems mounted literally on railroad cars that people the use, and when do you consider it not portable anymore?

You know, it's something that we have debated for quite a while.

SPEAKER: Thank you.

MR. SZALAJDA: Do we have any other airsource comments?

MR. COLTON: Craig Colton, 3M.

I maybe have a bit of confusion from reading the concept the first time and now.

Is what I'm hearing you say that the airsource systems are only for those systems that are sold that way, or does this include -- you know, there's ambient air pumps, or what I call ambient air pumps that might not be, quote, you know, true -- or a compressor. I mean, they both compress air. But for argument's sake, I'll say an ambient air pump that's sold separately from, you know, not by a manufacturer and a manufacturer that sells respirators, and then those get paired up as what I thought was meeting the airsource, but they are not sold that way. You know, they are not packaged as a product with respirators and the pump all together.

So my question is, Is it only those that are sold that way, packaged and sold that way, or does it include all ambient air pumps?

MR. PALCIC: It only includes the ones

that are packaged that way, Craig.

MR. COLTON: Okay. Thank you.

MR. HOFFMAN: I do want to point out, I mean, I think as far as distributors go, they will probably continue to sell systems where they buy a pump and put a zero hose length respirator and sell them as systems. But we do want to have the option again of having those systems approved so that users know that the whole system has been looked at and evaluated.

And, go ahead.

MR. PERROTTE: Will would like to ask another question from Structural Composite Industries.

MR. SZALAJDA: Okay.

MR. ANTUNIS: Point to inclusion of the air cart. I'm not sure that we have -- I have got an answer necessarily.

I understand that currently you want to change the approval process to include these carts whereby they are included at the present time.

Cylinders, as you know, are manufactured by one of two or three companies here in North America. It adds a significant amount of time to the end user's system when they need to buy cylinders from the respirator manufacturer -- supplied-air respirator manufacturer's system.

Since those folks do not do anything to the cylinder, it would be a tremendous opportunity for the end users to save money and purchase improvements, technical improvements in the area of cylinder development if they could purchase approved cylinders separate from the SAR.

With that, why not approve the cylinders separately or the cart separately?

MR. SZALAJDA: I think, Will, that probably the best thing to do is to submit that type of comment to the docket. Because I think conceptually when we are looking at a systems approval, you know, it all gets into the package that's been developed and offered for sale.

The -- you know, the component, at least in terms of the way the CFR is currently structured, is that, you know, the systems are approved -- or respirators are approved as systems, that we don't do the component types of approvals.

And understanding your comments about, you know, ultimately, ending up, you know, potentially saving money and giving the users options, you know, with that aside, I think one of the things that you look at when you are developing things on a component basis is now that you are -- you are looking at things more from a -- prescribing things in a configuration management type of system where we would be defining specific design parameters associated with the respirator, which traditionally NIOSH has tried not to do.

And from that standpoint, I think what you are suggesting would cause a paradigm change at least in how NIOSH does business.

So I think while you have I think a good point from the standpoint from looking at it from the user perspective and allowing options, there's other trade-offs that need to be considered, so I think that type of thing, a submittal to the docket at least in terms of what you are conceptualizing I think would be very worthwhile.

MR. ANTUNIS: I agree. Thank you.

To make sure I understand it, currently, the goal is to incorporate the airsource system now or moving forward.

But currently the airsource system is not part of the rule. Is that correct?

MR. HOFFMAN: Yes, that's correct.

MR. ANTUNIS: So with that being said, why not change and include the airsource system?

MR. HOFFMAN: Are you saying why not include the cylinder as a separate approval, or am I misunderstanding the question?

MR. ANTUNIS: No. I'm asking if I understand what the proposal is. The proposal is that currently the airsource system is not part of the approval, and you are proposing that it become part of the approval.

The question is why include the airsource system as part of the overall approval?

MR. HOFFMAN: Okay. If you look at it this way, if you have a stationary air compressor, everybody is assured -- or the user is assured that he is receiving adequate air because the compressor system is supplying Grade D air, and from the connection point on to the respiratory inlet covering has been approved. So the whole system is supplying -- or should be supplying an adequate air supply that has been evaluated.

If you go to the other end of what I will call a -- sort of a forced air system, if you look at a PAPR, every part of that system has been looked at and approved, and it is supplying a forced flow of breathing air.

But if you look in between those two and you look at these portable systems that are out there, only the breathing hose and the mask or the respiratory inlet covering has been approved in many cases, and the rest of the system has not been looked at.

So you don't know, one, if they are supplying a good quality of air. There could be particle flegging (phonetic) and things like that that occur within the compressor or the turbine fan.

And you also don't know if they are supplying inadequate air flow. And we have had people say that when you have the ones that in addition have a pneumatic tool takeoff, when you use the tool, you don't have any breathing air to the mask, which is something else that could be a problem.

So we have tried to address all of those issues and cover from stationary to airsource to PAPR and look at all of those forms of what I'm calling forced air for lack of a better term.

Does that answer your question?

MR. ANTUNIS: It goes to my question.

I think it goes to if you are not approving a stationary compressor with a supplied-air respirator, why then would you include a portable air supply?

MR. HOFFMAN: Because OSHA is looking at the stationary ones. They are -- when they do their inspections, they are to assure that it's Grade D air source. So in a sense, they are being looked at.

And the other -- and the SCBAs are being looked at by NIOSH. But it's the portable ones that have that portion of it that nobody is looking at it, and that's where the concern is.

And especially when some of the advertisement implies that it is approved, and some people indicate that some of the systems don't supply an adequate amount of air. There's a need there.

I guess in our way of looking at it, nobody is looking at that section, and that's where there has been indicated that there is a need for it.

MR. ANTUNIS: I wouldn't disagree that there is a need to look at it. I'm simply saying that I don't think a need is there to include the air cart airsource system as part of the respirator itself.

I think you should sever those two and give separate approvals there.

MR. HOFFMAN: Now, again, the trouble with the separate approval is now it moves into the realm of component approval. And the difficulty with that is knowing how different components with interact with each other.

For example, if we allowed the use of approving hoses, and since air hoses and the connection points can have different orifices and different inside diameters, you don't know how one will work the other necessarily until you have actually evaluated it.

So in concept I think it's a good idea, but it presents a lot of difficulties and a lot of hurdles that would have to be overcome.

I mean, I guess in an ideal world, it could all be based on a component approval, and if it fits and it works, it is approved that way. But that's quite a ways off from the way it has been done over the years.

MR. SZALAJDA: I think I would like to take one more comment within the meeting on this subject, and then we will move on to the next topic.

MR. BERRYANN: This is Roland BerryAnn from NPPTL.

I just -- listening to this, Will, I want to try and summarize in my words what I think addresses your concern. I think it has been said by the panel, but, again, let me try and summarize it.

I think the concern has been raised that when you have an air supply system supplying to a respirator, that we should be -- have a mechanism whereby we can assure that the quantity and quality of the air being supplied to the respirator is adequate both in quantity and quality.

So this is an option that's being presented, not a requirement on the respirator.

So if you're looking at the quality and quantity is sufficient, you have to include the airsource.

And as Bill said, these stationary systems are included because they are already being taken care of, and they are site specific. They are not generally supplied.

Thank you.

MR. SZALAJDA: I would like to move -- since we have about 30 minutes left to cover SAR, I would like to move into the other slides at this point.

And, again, on the airsource, I recognize that it's something that we are not going to resolve today. I would encourage your continued dialogue and submittal of positions to the docket regarding the concept as well as any time we have remainder at the end of the meeting for public comment.

The next discussion slide is regarding Total Inward Leakage, and without trying to steal too much of Gary's presentation this afternoon, the approach that we are taking with regard to inward leakage is to integrate inward leakage requirements into our respirator standards as they are developed.

So I think going forward with the closed-circuit SCBA, with the PAPR, with the supplied-air respirator, with the air-fed suits, air-fed ensembles, you are going to see Total Inward Leakage requirements indicated in those standards.

Initially, we are going to accomplish that through the use of the LRPL testing capabilities that we have at NPPTL.

With this slide, there was a math error

which somehow slipped through everyone for the things that were initially posted. The values that are indicated on the discussion slide are what's currently in the concept.

You know, at this point I would like to take any comments and dialogue with the panel on inward leakage.

MR. COLTON: Craig Colton, 3M.

This gets to be one of my dear topics.

And, yeah, the correction makes a lot of difference, so my first question isn't maybe why, but, Jeff, we talked earlier, and I'll maybe ask you a question so you can repeat that for the audience, how you got to the numbers that you did for the TIL. What was the reasoning behind that or the thought process?

MR. PALCIC: What we did is we took the highest APFs times ten to get the fit factor. And then it was 100 over the fit factor is how we came to the maximum TIL values.

The error was in the fact that I used the fit factor instead of the APF when I did the calculation.

MR. COLTON: Right. So it was ten times you say the highest APF?

MR. PALCIC: The highest APF.

MR. COLTON: And then whose APFs I guess is my next question.

MR. PALCIC: It was OSHA, NIOSH.

MR. COLTON: Well, then the question I have, and maybe you can either expound on it or even consider it, is that in that group where you have the hood helmet and loose-fitting facepiece, those don't all have the same protection factor for -- according to OSHA, the loose-fitting facepiece, the highest one it has is 25 regardless of what the situation is.

MR. PALCIC: If we are doing the TIL testing, then there will be data to back it up. If it's going to be a higher value, then we will have the benchmarking to prove it.

MR. HOFFMAN: I think maybe what is being misunderstood is these aren't the final values. These are sort of the starting values. And the data will dictate what it should be rather than the APF that's currently established dictating it.

We might find that the APF nowhere close on one type of system, and then we will need to change that. But at this point, that's sort of the starting parameters we are using.

MR. COLTON: Well, that's fine. As I understand it, though, your starting parameter to get something to talk about was going to be ten times the protection factor to get your TIL value that you were ending up with.

MR. HOFFMAN: Right.

MR. COLTON: And for loose-fitting facepieces, that highest APF number under OSHA is 25. So ten times 25 is 250, which is a lot different than 10,000.

So I was just calling it to your attention, that that doesn't seem to be consistent.

MR. SZALAJDA: I appreciate that, Craig because I think with the approach that we have taken is we just wanted to set a target value initially. And, you know, we have made an investment at least in terms of identifying and getting existing technology that we are planning on benchmarking, and then I think between now and the next time that we get together, you know, we will be in a position to present the data that we have accumulated on the laboratory basis and then make adjustments as appropriate to the values.

MR. PARKER: John, I just wanted to say one thing to Craig's comment, and that is that NIOSH does not separate out the loose-fitting type facepiece like OSHA does.

Maybe we should, but the fact remains that we kind of treat loose-fitting facepieces like other hoods and helmets at this point, so maybe that's part of the reason why it seems to be a little different here.

MR. PERROTTE: There is one other question from Danielle (sic) Ford from Avon-International Safety Instruments.

I'm going to allow her to speak in a moment here.

MR. FORD: (Garbled question).

MR. SZALAJDA: Could you repeat the question? We didn't get it on this end.

MR. FORD: Yes. We want to know if the TIL is going to replace the IAA testing.

MR. HOFFMAN: The intention is it will replace the LRPL testing and the IAA testing once all of the laboratory work is done.

It's looked as better. It is quantitative rather that qualitative. So in a short answer, yes.

MR. FORD: Thank you.

MR. SZALAJDA: Do we have any other questions regarding questions -- comments regarding Total Inward Leakage?

The next couple of slides are somewhat related when you get into marking requirements for not only helmets, for but also for lenses. And there has been some discussion back and forth about what is appropriate to mark on lenses and helmets, whether it is only appropriate to mark that the fact that they do meet a requirement, such as ANSI Z88 -- Z89.1, or whether there's any merit to not marking the helmet and leaving it open, or saying it doesn't need a requirement.

I think kind of at this point, we are looking for feedback on how the stakeholders feel, whether it is appropriate to mark or not mark these types of components.

MR. SELL: Bob Sell, Draeger Safety.

Most definitely yes, these should be marked. I mean, you are The National Personal Protection Testing Laboratory.

You may not test the equipment. You can go to third-party agencies or other places to do that. But for worker health and safety, I think that's all part and parcel.

MR. SZALAJDA: Okay. So your comment is that if it does meet the standard, it should be marked?

MR. SELL: It should be marked or be required to be marked and meet the standard.

If you are going to use it for an industrial setting, then any sort of personal protection equipment should meet some sort of requirement, whether it's ANSI, ASTM, whatever, even

NFPA.

MR. SZALAJDA: Thank you, Bob.

MR. HOFFMAN: Bob, there's a little bit of confusion. Are you saying if it's not impact resistant, that should be marked as well, or just if it is?

MR. SELL: I'm saying that you should make it mandatory that all of these, the lenses, the helmets, have to meet some start of protection requirement, some sort of protection standard.

MR. HOFFMAN: So there's no option not to. You have to meet it.

MR. SELL: You have to mark it saying this is not approved.

MR. HOFFMAN: Okay.

MR. PARKER: I think one issue there might be that when it comes to these national consensus standards, the ANSI standards, you have to meet the entire standard. You can't call out that you meet part of a standard. So we have to be careful I think how we do that.

The eye and face standard actually has a respirator section now, so the -- you know, Z87 does cover respirators. The helmet standard does not.

So in other words, what I'm saying is I'm not sure you could say that you meet the impact and penetration requirements of the helmet standard without meeting the whole standard. But then again, NIOSH could pull requirements out of ANSI and then just require that part of it.

MS. FEINER: Lynn Feiner, Honeywell Safety.

I disagree that it needs to meet a standard. I think the market should demand what standards the manufacturer wants a respirator and its components to meet and then market if it meets those standards.

And this is again for discussion, the problem I see with putting in what it does not meet is where do you stop? If it doesn't meet an impact, someone else says, yeah, but it doesn't meet this or doesn't meet that. So I think these need to be addressed in the user instructions, not on the markings.

MR. SZALAJDA: Thank you, Lynn.

Do we have any other comments regarding helmet or lens markings?

Well, I'm going to -- since these two topics were interrelated and I'm the moderator, I'm going to take the liberty of moving on to the next topic, which is specified air flow rates.

And the one point I did want to make with regard to this slide -- actually, two points.

One is the addition of this very high -- the very high air flow rate and its applicability in certain environments, in particular when we are looking at it from the standpoint of IDLH or CBRN types of applications.

The other thing that I wanted to bring to your attention is the fact that these air flow rates are going to be consistent with all the -- I hate to use the term "powered air," but when you look at how we do our testing and evaluation processes, that we want to maintain consistency between the different standards.

So if you look at these air flow rates,

they are consistent with what we are anticipating implementing in the PAPR standard as well.

So I would like to take any comments regarding the air flow rates at this time.

MR. PALCIC: Some of the comments we got from the last draft, people didn't think we needed the low flow rate, which is -- you can offer a low flow rate, or you can't offer a low flow rate.

But also, one of our questions is with the IDLH and CBRN situations, should we only offer it in high and very high and eliminate the moderate and low for the IDLH environments?

If anyone has any comments.

MR. SZALAJDA: John, do we have anything from LiveMeeting on this subject?

MR. PERROTTE: No.

MR. GREEN: Yeah. Larry Green with Syntech International.

In doing some testing things, say for like the CBRN and things like that, one of the things we noted that very quickly, if you are running at a -- a respirator at a moderate air flow, somebody stands up, has to run to the other side of the room, the respirator can go negative very, very quickly. As your breathing rate increases a little bit, it makes a very big difference.

We set up a respirator with a very sensitive thing that could actually monitor the breathing cycle, and you sit down on a low rate, you would be fine. Stand up. If you haven't had a reasonable rate for that thing, you stand up, it would immediately go low.

And, you know, so if you had it at a moderate level and then you started -- you were in a panic situation and had to run, you would immediately go low.

MR. SZALAJDA: Thank you. Actually, we have seen that type of issue as well. And one of the things that we are looking at in terms of our evaluation is trying to capture that in terms of our test parameters, acknowledging that there are instances, well, where a positive pressure type of respirator -- and I hate to use that term, but I don't have a better one to use yet. But where something can go negative, especially in the facepiece.

And one of the historical discussions has been, well, what does that really mean in terms of protection?

You know, and that really has never been completely quantified in terms of what does that mean in terms of protection.

I think one of the things that we are looking at doing as part of our evaluation processes is how do we address that in terms of our testing and allowing those types of incursions to occur, but also limiting the number that occur knowing that that is a situation that will occur.

MR. HOFFMAN: Larry, I want to point out one more thing to you. We have not -- if you read it, we have deliberately not precluded one that can be switchable from one to another. So there could be situations where at one time you want the moderate air flow, and then you need to go to the high air flow, and you switch it over. There is nothing in there to prohibit somebody from making one, or that automatically senses that and changes.

MR. GREEN: I realize that. It was just a comment.

Part of the things my company, we work extensively with medical stuff. And there the option, if it goes low, say if you are in a biological type situation, if it goes low, particles coming in could be potentially deadly. If it gets to typical industrial, the amount of mass that you have coming in is very minimal.

But, you know, if what's out there is hazardous in very, very small concentrations or as individual particles, then that going low becomes a big issue.

And, you know, we when we are doing our fit testing and the TIL testing and things like that, you know, we can note that -- you know, with our -- again, because we test it with a particle counter. And, you know, if we lower the flows, you go a little bit low, you immediately see the spikes on breathing and things like that on the particle levels.

MR. HOFFMAN: That type of industry may be where the ensembles would play in because they are some advantages. For example, in the pharmaceutical industry or even any type of dermal exposure could be hazardous to somebody, especially if it's repeated day after day.

Keep your question in mind when we talk about the ensembles later.

MR. SZALAJDA: I think that's a never -- and I think conceptually, what we have been discussing, I think it's a good discussion to have in these types of forums, but I think it also shows a need that we are trying to take on within the laboratory in terms of being able to develop guides to help people with proper respirator selection.

You know, the fine line that we try to draw is coming up with a set of requirements that everyone has to meet, but the set of requirements may not be appropriate for every application.

So, you know, the art is in determining what those requirements are and making sure that the standard is robust enough that it can it be applied appropriately in different situations.

But your point is well taken.

Mike?

MR. SAVARIN: Yeah, Mike Savarin, Sperian again.

I think, Jon, that that whole thing that you just mentioned there is going to be at the crux of trying to decide what to do with the level of complexity that's now in this part of the standard or proposed standard.

We have a switchover from devices where we just call -- we classify them as a specific device, you know, for a use somewhere, or we just said classification is based on use, and we ended up trying to define parameters for each of those.

And you end up in this kind of quagmire that we are in now.

For example, you know, you look at questions, how does the user determine -- what are the specified air flow rates that they are going to need to use? It sounds like a very simple enough question until you sit down and try and decide what you are going to do.

You know, maybe an approach or a consideration might be to look at how we tabulate the low, medium, and high flow rates, which do still seem to be somewhat arbitrary in my mind here.

You know, when we hear people talking about, oh, well, we think we should just remove the low because low doesn't seem very good. Well, we should remove the high because it's just too high. No one really knows.

Then we look at all the studies, look at peak inspiratory flow rates, and we know things about in excess of 200, 300, 400 liters a minute for very short spikes of time and what does that do with our leakage issue.

Right now, the standard is looking at integrating the TILs, which seem to be based on the respiratory inlet covering, and then talking arbitrarily about low, medium, and high flow rates that might be used in certain applications.

Maybe we try and take a map of the whole thing and correlate the low, medium, high with the

TIL at the inlet covering so that we come up with something that at least there's -- people can draw upon as map or as a framework, as a tabulated framework that puts all of these things together in one visible matrix.

Maybe that's something we should consider so that whenever someone says something, we can say, That's where it is, or that's why it was there, rather than, Well, we seemed to think that was okay today, and then we will drop it in a year because we didn't really look at it properly.

I think it is horrendously complex.

The issue about switchable systems which somebody mentioned just now, that's all well and good.

But if it's going to be NIOSH approved, you are going to have to think about making it so that it provides protection -- whatever that protection is by the way -- at the highest flow rate that that thing is designed for, which means it would run for that maximum length of time. That person may switch it and -- from the word go they may switch it because it's comfortable. Having it at that high flow rate makes you feel good, keeps you cool. You know, trouble is, how long does it last?

So there's a number of issues here in my mind that go beyond just looking at this and picking a place and time and saying, I think we should be there. I'm looking for a more integrated rationale that underpins this work that we are trying to do here.

And I do appreciate how hard this is and why we haven't got a definite answer up to now and how the research is still ongoing and how we incorporate this into ongoing research.

So I think it's certainly leading the way, but I would like us to have a more integrated response and approach to how this is done.

That's all I would like to say.

MR. SZALAJDA: Thank you, Mike. I think that's a good comment.

And I guess the one thing that is encouraging to me is the amount of research and the evolution of these ideas, especially within the past ten years.

I think the knowledge base is so much greater now than where we were, you know, say in 2000, that I think, you know, these are issues, the things that you bring up are issues.

And ultimately, you know, at the end of the day, that we want to make sure our product does what it's supposed to, protect the users for their particular applications, and I think we all share that.

John, do you have a comment?

MR. PERROTTE: Yes. There is two questions via LiveMeeting, one from Michael Klaus from Draeger. I'll have to ask it for him.

It says, We feel this work rate, 25 liters per minute, to be dangerous for the user because there is very -- they are very easy to overbreathe, especially in half-mask versions or demand half-mask. So our proposal would be to delete the low rate.

MR. SZALAJDA: Okay.

MR. PERROTTE: The second one is from Avon, which is Dan. And I can allow him to ask the question here in one second.

MR. ANTUNIS: Yes (unintelligible).

MR. SZALAJDA: Can you repeat that one, please? We didn't quite get the last part of your question.

MR. ANTUNIS: We wanted to know if these work rates are going to be used for filter duration measure or how?

MR. SZALAJDA: So are these going to be used for filter calculations.

UNIDENTIFIED PERSON: Cylinder.

MR. SZALAJDA: Cylinder, okay.

MR. PALCIC: Yes, they will be. And I think right now in the current standard, we reference the high rate, 57 liter.

MR. ANTUNIS: No. The current standard is moderate.

MR. PALCIC: The current proposed draft?

MR. ANTUNIS: No. The current standard in effect, that is.

MR. PALCIC: Right. Yeah, we have to -- we still have to work out the details, how that's going to work together.

MR. ANTUNIS: Thank you.

MR. SZALAJDA: We have just a couple of minutes left at least as far as the items that we had for the first part of the program. I would like to at least cover briefly the last two slides.

One is on the need for hose permeation tests. And I think the issue here is we are looking and hoping to get some feedback regarding what type of blend or what materials we should be considering in the evaluation of hose materials.

I mean, we have historically done gasoline for NIOSH evaluations, and there is also discussions about kerosene and other blends.

And kind of at this point, the question I think is what's appropriate? Or one of the things that we have kicked around internally is should we put together some sort of matrix to identify particular materials for evaluation that the manufacturer or the applicant can tailor a particular device towards a particular hazard, and then we would test it as appropriate.

So we would like to get feedback on this issue, particularly, you know, with regard to what the challenge agent should be in these types of testing.

You guys want to think about that one a little bit?

On the panel, do we have anything we want to add on this slide?

MR. PALCIC: With regard to the challenge agents, if you folks have any information from your distributors or people using your product, any complaints on or off the record as to situations they have seen, or, you know, environments they have been used in and any problems they have had, you know, we would appreciate any data or feedback that you can give us.

MR. SAVARIN: I would just like to know what is the rationale for the proposal for adding the kerosene and the MEK/Toluene blends.

MR. VOJTKO: It's to address what we

conceive as some potential hazards.

The kerosene would be for fueling operations for jet aircraft. The fuel is pretty much kerosene with different additives, so that would cover that.

And we feel that it's sufficiently different from gasoline that there may be some different hazards that we want to address in that it's not as volatile and you may have a longer exposure time to a hose.

The MEK/toluene addresses paint shop applications where most thinners, cleaning solvents, and such incorporate some combination of an aromatic, a ketone, and sometimes an alcohol.

And we feel by using -- the MEK covers a ketone, and probably is aggressive in that family of chemicals and the toluene is the aromatic. And we feel that this would cover that application as well, which is common for supplied-air respirators.

MR. SAVARIN: Have you seen any instances in the field where this has caused a problem with the hose or the respirator?

MR. HOFFMAN: NIOSH does HHE, Health Hazard Evaluation studies, and workers have reported where they have gotten headaches from, for example, airlines that are dragged through jet fuel that is spilled on a floor day after day or body shops where they wipe the hose down at the end of the day, and it tends to degrade the hose.

So yeah, there have been -- there's not an official report where there's been like a death or something that occurred from that. But the fact that people are smelling and getting headaches from it means that there does tend to a problem out there. Since that has been not looked at specifically, it's hard to say how widespread it is, but it does exist.

MS. DEMEDEIROS: Edna DeMedeiros, Honeywell Safety. I was just wondering, have you done any testing with all three or can all three tests be replaced with one custom blend or something.

Have you guys tested any hose hoses that are on the market right now?

MR. PALCIC: We have not.

MS. DEMEDEIROS: You haven't. Because gasoline is not fun to play -- I mean, none of them are fun.

I was just wondering if you have evaluated any of those. But your comments are coming from just people that are sending in things to HHE?

MR. HOFFMAN: Well, no, when NIOSH goes out and does studies for whatever reason, that's one of the things that has been reported.

That wasn't the cause of the investigation, but it's happened on several occasions where we have been told about it.

And as also, as you probably know, in body shops and things like that, it's common practice to wipe the hoses and the equipment and everything down with whatever solvent they happen to be using. And it tends to -- in some cases, it doesn't seem to have any effect. In other cases, it tends to maybe break the outer covering of the hose down where -- maybe to the point that it is being absorbed or permeating through, or in other cases where it's just sort of ruining the hoses and making them unsafe to carry the airline pressure.

So we feel that it ought to be looked at just to address it.

It mean, it is a common practice.

MR. PARKER: I just want to clarify, too, that we are currently running gasoline tests.

MS. DEMEDEIROS: Yeah.

MR. PARKER: I want to make sure that that's clear.

MS. DEMEDEIROS: Yes, it's still gasoline. All right. Thank you.

MR. SZALAJDA: And the last topic, since we are almost out of time, is the CBRN applications.

Initially we considered the challenge concentrations to fall in the range of the SCBA. But it also came to our attention that for other types of applications, it may be appropriate to consider the requirements that we have established for powered-air purifying respirators where you need respiratory protection, but you're not in that crises type of area.

Right now, our initial benchmarking, which we will be conducting probably within the next 30 days or so at Edgewood, is going to look at using the higher challenge concentrations. But we would like to get some feedback on whether it would be appropriate to perhaps consider the lower concentrations, the APR concentrations as well.

Well, it might be something you would like to submit to the docket office.

With that, I think we have run through the gamut of comments. We are right about 11 o'clock, and we will need to move into the air-fed ensemble portion, but I would like to take at least five minutes to take any additional comments or address any questions that you may have that weren't related in any of these topic areas, and we will let the panel have one last shot as well.

MR. HOFFMAN: I have one comment that I want to point out that was asked to me at break.

On these airsource systems, would manufacturers have to submit things like the air vay pitch or piston ring clearances or things like that?

And while I haven't discussed it with certification, I would assume it would be done the same way as it's done now for PAPRs, where all you have is a performance spec that it puts out so much air, and the internals of the compressor or the air handler would not be something NIOSH would want to look at or examine or get the specifications on.

So the way that I would envision, the way that the PAPR is done would carry over.

MR. EASON: Chris Eason with Staubli Corporation.

This is my first venture into this sort of a forum. I work for a manufacturer that develops hoses, fittings, that sort of thing, and one of our product lines is for breathing air.

Now, with that said, since I'm new to this, I hope I don't stick my foot in my mouth too far.

Everybody at NIOSH has been very gracious -- and I have met quite a few of you -- to get me up to speed on how you go to market. But one of the things that I feel that I must say before we go on to another subject is this.

I do see an elephant in the room. And that elephant to me has to do with components.

There are a number of manufacturers of what we call respirators, which is basically what goes on your face or over your body. But other critical components that comprise that are hoses, quick disconnects, and various other pieces that make up the system that you go to great lengths to test to make sure that people are going to be safe and not die.

However, with that said -- and I have been writing this thing as we have been going here a little bit, so excuse me if I look down at my notes.

Because there are connection systems including hose assemblies, safety quick disconnects, manifolds, filters, the tanks, which we discussed earlier, which are continually being updated and technologically advanced, that brings up a problem.

With the current system approval, the best connections quite possibly may never be used. And please know that this is just my opinion.

And why? Once a group of components becomes a system, the respirator manufacturer who has used Hose X, Connector Y, Manifold Z, Tank Z1 doesn't really have, as I see it, an incentive to make the system continually safer because to do so would cost more in testing dollars.

The component manufacturers on the approved system now have apparently no incentive to improve the product because they are already on there.

In addition, everyone involved -- and I have seen this happen -- can charge basically whatever they like to for the components because they are approved, and this also stifles competition and enterprise.

So maybe we are at the point which would require a paradigm change. And I'm glad you mentioned that because I was looking for the right word to use.

Now, I know that this would be a gigantic undertaking that has never been done before. But think it would allow -- if there was a way to work this out, it would allow for systems to be the best they could be all the time.

And there are many suggestions, and I could talk for hours, but I'm not going to, but I have one suggestion. Since NIOSH only approves systems and since you were just talking about testing for permeability of hoses, which is, by the way, a component, why not consider having connectors and hoses and other components go through like a preliminary for flow, Delta P, safety test to make sure they can't be accidentally disconnected, make them as safe as possible, and maybe put them on an approved vendor's list so that the respirator manufacturers can go to this list, and then they can choose who they want to use on their systems.

It would -- I think it would free up the market a bit. It would be a lot more work, but that's my suggestion, and thank you for you time.

MR. SZALAJDA: Thank you for your comment, Chris.

Are there any other comments from the floor at this time regarding supplied-air respirators?

I think at this point, we are about six minutes behind schedule, but what I would like to do is definitely break at noon, and we will make a judgment call based on how the presentations go whether we get all of the air-fed ensemble presentations done this morning, or if we will have to pick any up after lunchtime.

So with that, I would like to thank the SAR panel, if they wanted to go sit and get something to drink or whatnot, but I will march along the next portion of the program, which is air-fed ensembles.

At least with regard to continuing with the flow of the discussion, we have three presentations, one Colleen Miller is the project officer for air-fed ensembles. She will give an overview of what is currently in the concept paper.

Dr. John Williams from the NPPTL Technology Research Branch will give an overview about breathing gas physiological response and potential application to the standard.

And then Heather Farrer will, from Savannah River, will be here to give a DOE perspective on the use of these types of systems. And we will also continue with the panel discussion as well as taking other comments.

What I would like to -- just at this time, because the synapse fired, we do have a survey that will be passed out near the end of the day. And I would really like to get your feedback on what you guys think about this type of presentation between the presentations as well as the panel discussions and the overall approach of this meeting of having the things up on the website. Because we would like to know -- again, we are also trying to continue to improve, you know, how we have this type of dialogue, and any feedback that you have on that subject would be appreciated.

If you attended the December public meeting that we had when we introduced the air-fed concept, you are going to say, well, gee, these are the same slides that Jon presented the last time, and the short answer is you're right.

Again, the standpoint and the position that we have taken as a laboratory is that if there is a system right now that a manufacturer, an applicant wants to bring to us for evaluation, we will evaluate it.

You know, we will use the current provisions that are provided to us under Part 84 for either supplied-air respirators or powered air purifying respirators to evaluate the products.

Where we also will use other criteria such as using the provisions, the policy provisions in there to add additional testing as we see fit to address potential issues regarding the use of the respirator.

And I think the main point is, again, from our perspective, we are looking that these types of ensembles are respirators. But having said that, depending on the application, we may look to other standards, national or international standards, for additional criteria to supplement our evaluation to meet Part 84.

And from that perspective right now, the two tests that we envision that would need to be required would be, one, how do you manage the air within the ensemble, and then the other is an inward leakage test to verify a certain degree of protection. And we would look to other standards such as the recently developed ASTM standard or other standards, EN standards, ISO standards, as appropriate, to augment any types of evaluations that we would need to do.

From that standpoint, a little update on where we are.

We have had some issues, at least in terms of developing the infrastructure. Colleen is going to talk a little bit with regard to some of the benchmarking that was done with looking at the air-management aspect of the standard.

We are in the process of expanding the LRPL chamber capabilities to include a compressor to allow supplied-air to be evaluated. That not only supports the SAR project but supports the air-fed ensemble project, and Colleen with fill you in on some of the details on where we are with regard to that part of the process.

So with that, formal submittals, the docket number is 148-A. There's a variety of means to submit information to the docket.

And with that I would like to let Colleen come up and give the overview of the current concept paper, and then we will move on through the other presentations.

MS. MILLER: Good morning. It's nice to meet everyone. I am Colleen Miller, and it has been a pleasure to put so many faces with the voices that I have been speaking to on the telephone over the last few months.

Since I am the first woman to speak up here, I wanted to make sure that you all can hear me back there? Yes. Okay.

Well, it was an interesting summer for me, and one of the things that added to it was in the beginning of August, I received a juror summons. And it was one of those things where I received it on a Thursday or Friday afternoon, and I didn't even look at it. And finally Sunday night, it's like, hmmm, I have five days to reply to this thing. I better take a look.

And sure enough, I opened it up, and there it is, the one day that I'm really not available in September is the -- I mean, I have not been summonsed since my children were very, very young, and I had a little bit of fun with Jeff. Oh, you are going to my presentation for me. I won't be there. But fortunately, I was excused.

However, I can tell you that probably on November 2, when I did get reassigned, there will be a horrendous snowstorm or something, as I have to go downtown that day.

Just to give you a little bit of the reminder, in December, I did present the development plan for air-fed ensembles, talked about the fact that we had reviewed internationally and nationally available standards relating to air-fed ensembles, including the NASA standard for propellent handlers ensembles, the DOE standard, EN 1073, ISO 16602.3, and the ANSI standard currently in draft.

Since that time, we have initiated some

benchmark testing. And, as I said at the beginning, we have also -- I really try to encourage and initiate communication with stakeholders.

And of course today, we are presenting an update to the concept. And then on October 19, the docket will close, and I would appreciate if you would please send your comments to 148-A.

Again, reviewing a little bit of what we talked about in December was we talked about whether the development plan should require the ensembles to be certified according to the type of respirator that they are similar to, whether that be a supplied-air or air purifying or even an SCBA.

We also talked about the fact that power air purifying respirators are not certified for IDLH and the fact that in the current update that Jeff just presented, an SAR for that environment would require an escape cylinder, which most ensembles do not have.

So we decided at that time to present that we create a subpart to 42 CFR Part 84 to address the ensembles specifically to better meet the future technological needs and advances of the users and the manufacturers.

And we also last December had presented, we had gone through a big review process with the National Academies where they really said, You know, what? You are doing a great job in your respiratory protection program. We would really like to see NIOSH expand into other types of PPE to meet the needs of more workers. So we felt the new subpart would enable us to do that.

Jon has mentioned that we have initiated contact with OSHA. I'm sure -- I know the manufacturers are well aware and the users that air-fed ensembles are not currently considered respirators by OSHA.

OSHA does have several -- they do give several classifications in a guide that they publish for chemical protective clothing. Two of those classifications would be a fully encapsulating suit. Another one would be irradiation protective suite. They use EPA levels of protection, A, B, C, and D protection. A and B includes an SCBA. C is applied -- excuse me, an APR, and D does not require respiratory protection at all.

OSHA does, however, caution that ensembles must be tailored to the specific situation.

Currently, in the draft that we have posted to the web for this meeting, our subpart whatever it is going to be called -- we have not given it an initial at this point -- would include these subparts to 42 CFR Part 84.

I have purposely not included Subpart F at this point, which is the classifications. I very much look forward to our panel discussion and hearing from you about some of your ideas about how we may approach that. Some of you have already in your comments from the development plan offered some opinions about that, and I would like that conversation to continue.

As Jon stated, we have begun some benchmark testing. Some of the things that we are concerned about at NIOSH, particular preconditioning. The materials sometimes used in these ensembles are what I would call commodity resins. Their properties are very temperature dependent. I think we have to be very aware of that in terms of what we choose as our preconditioning criteria.

We have also begun to do some of the dead space testing, which I will go into in a little bit more detail. Some of the human subject breathing gas concentration, Total Inward Leakage, and we are also looking into the evaluations for the exhaust vent operation, the maintenance of positive pressure and breathing resistance. And so many of these things are interrelated that there may be one test method that may evaluate several of the performance requirements.

For the CO2 dead space testing, as Gary mentioned, we have a new system which he has brought online, and I'm already requiring modifications to it to accommodate the ensembles.

He uses a half torso. We have gone ahead and ordered a Sheffield full torso. We feel that will better accommodate the ensembles, and we will have to make some legs for it.

We are concerned about where we are going to position the sampling tube. We would like to do further benchmarking. Because the hoods are so big on the ensembles, it's very reasonable to expect that a worker could have their head turned to the left or the right for a long periods of time. We want to be sure there's not some CO2 buildup because of that.

We are also looking at what breathing gas flow rate to use. We use a sedentary rate, and there is an ISO standard that calls for a much higher rate. We are trying with our equipment to at least double the rate and do some benchmarking.

We are considering whether or not to include a puncture or a wear abrasion test to see that, for example, if you purpose punctured the suit in an area that affected the respiratory protection, how would the CO2 levels change?

And we have also proposed in this current draft allowing higher CO2 levels for limited periods of time, and that's precedented in 42 CFR Part 84.97, and also the NASA standard has included that as well.

So this is our -- with the new CO2 dead space half torso, we have tried to do some benchmarking with the ensemble.

This half torso is bolted down to the table, so we can't get an ensemble on this Sheffield mannequin. We did however use a brass tube to extend the access to the test method.

We still feel that because of the solenoid valves and the ability to identify the inhalation phase, we think that will be very helpful in terms of doing a test on the ensembles because some of them have such turbulent air flows in the mouth area.

For manned CO2 testing, we are also concerned about proper sampling because these ensembles are different than a traditional facepiece.

We are also looking at the number of test subjects that we would use. At this point, we are thinking that that would be determined by the sizes that are provided by the manufacturer and how the manufacturer specifies whether or not a size is appropriate for a person.

Again, temperature conditioning, very important. And if decontamination methods are recommended and used, we want to look at that. Excuse me, I skipped over the exercises to be included. We would obviously want to include some bending and squatting and reaching and flexing beyond the current standard that we use, which includes standing and brisk walking. We are going to want to be testing those exhaust vents to see if there is any kind of movement that causes CO2 or oxygen changes for the user.

And we are also going to be looking at fogging. And perhaps do some benchmarking when the air supply is off, monitoring the CO2/O2 levels, and, again, looking for fogging there.

Someone put a suit on. I don't know who that is. And we did, as you see, try use a TSI test probe. We felt that was a little bit too far away from my mouth to actually give us an accurate reading of the CO2 and oxygen levels.

For inward leakage, as you know, we have a corn oil aerosol chamber at NIOSH. As Jon said, we are installing a compressor to facilitate testing the ensembles because they do use quite a bit of air through a test period.

There is in the ISO standard for TIL a selection criteria for test agent and method, and for a supplied-air nonporous material, they do indicate that corn oil aerosol can be used.

And again, inward leakage will also help us evaluate exhaust vent evaluation because the ensembles don't tend to have valves. They have vents with a flap over them.

A lot of -- you know that I have spent some time trying to get to know the workers that are using these ensembles currently to help us better understand what their needs are. And I have talked to -- and I'm fortunate enough to have some of the DOE people -- here about radiological workers. And right now the DOE standard is undergoing revision.

And they have concerns, for example, for things about concerning flammability testing. They have very specific doffing requirements for their ensembles. They are looking at, you know, the European standards that are out there and the American standards that they have had to work with for 30 years and trying to decide which would be the better situation for them.

They are also looking at fall arrest ensembles that are used in some of their facilities. And they have a very specific cross-contamination test for their workers.

In terms of Biosafety Level 4, which we hear a lot about, we have spoken with Fort Detrick. And they use the ensembles daily, twice a day for extended work periods. So four hours or more. They are concerned about the ability to decontaminate.

They want to be able to change their gloves easily. They are going to go from one work function to another, and one pair of gloves may be more functioning than another pair, so they want to be able to change them.

They generally have -- sometimes have filter assemblies that they are putting into the suits themselves that are very specific to their needs. And they are making simple repairs onsite to their ensembles, and they are pressure testing them as required.

Chemical workers I would have to say I would really like to hear more from. I would like to get more in touch with the pharmaceutical industry.

The permeation resistance, of course, of the materials used and the method used to construct the ensemble and the hoses used is very important. And because some of these materials are so thick or, you know, specific for permeation resistance, cooling and how warm the worker gets is a big issue. And service life indicators especially -- I know NASA has quite a big section in their standard about that.

I have spoken to someone from -- in the paint industry who is big in the union there, and he said they are concerned about vision clarity. They want to be able to judge mils. So their visors have to be very practical. And the materials themselves that are used to make the ensembles, if they get paint on them, they still to keep painting. So that's a concern for them also.

So, again, as we were in December, we are here because we really want and seek your comments about our draft concept. We would like more information about how the ensembles are currently used, how they intend to be used, and how they are being evaluated.

And, again, as we have said again, it's 148-A since this is the second time around. Please submit your comments to that docket.

Are we going to go through the slides?

Just to give you an idea about some of the topics that we would like to discuss during our panel discussion. As I said, classifications, very important to us. Have some ideas about that.

IDLH keeps coming up again and again. We would like to hear your comments about that.

Use concerns and how we address whether an ensemble is disposable or reusable and what ensures proper functioning for reuse. Storage and use temperature concerns, as I have mentioned.

Flammability, again, the DOE people will probably be talking about that in their presentation as well. And what's a practical requirement for the intended use?

Have some more comments about flammability. And visor, again, is going to come up, as it did in the SAR section.

And I would like feedback about external harnesses. I have learned a lot about the fall arrest, but I would kind of like to know if workers are putting harnesses over these suits and what we need to be concerned about there.

And then, of course, there is so much we could talk about in physical properties of the suits, and I have included that as well.

And now, John Williams is going to speak from our Technology Research Branch.

MR. WILLIAMS: Thank you very much. What I'm going to talk about is a little bit of a departure from what you have been hearing so far, kind of from the human side of things.

And I'm a physiologist with the NPPTL, and we look at lot of different issues regarding the physiological impact from wearing PPE.

And what I would like to talk to you about today is some of the physiological responses, human physiological responses to breathing different concentrations of oxygen and carbon dioxide. And I'll go through a little bit of a physiological primer to kind of get everybody up to speed. I hope everybody can stay awake for the next, you know, half hour or so before lunch.

And then I would like to deliver a little bit of an explanation as to how this might be relevant to respiratory protection.

This observation that all things are poison and nothing is without poison, only the dose makes something a poison by 16th century physician named Paracelsus is actually a running theme through this particular talk, as you will see. Because a lot of the oxygen and carbon dioxide are natural occurring things in your body. You breathe oxygen. You produce CO2. And they are not poisonous in and of themselves except under certain circumstances.

Now we all know that the earth's atmosphere has this particular composition here. It's oxygen, nitrogen, a little bit of CO2, some trace elements.

The oxygen is primarily produced by photosynthesis in plants, but it's also produced chemically through a process photolysis. And CO2 is produced by the oceans, animal respiration, including us, and plant decay and the notorious source of burning of fossil fuels.

But essentially all aerobic life, including human beings, has evolved over the last several million years to deal with a primarily oxidizing environment. And in fact is now dependent upon oxygen for the production of metabolic energy.

Now, if you have variations in the gas concentrations from that which is normally found at sea level under normal atmostpheric conditions, that will have its counterpart in the human physiological response.

So if you have -- if you are exposed to

hypoxia, low oxygen level, or hypercapnia, high CO2 concentration, you will see changes primarily in pulmonary function. You will see some changes in metabolism because you will have changes in blood pH. And there will be some neurological changes that will occur, which I will describe later.

And these ultimately will have some relevance to the use of respiratory protective devices.

Now, gas exchange, as we all know, occurs in the lungs. And air is conducted down the airways to the internal sacs, called the alveoli where gas exchange actually place. And the alveoli are in close proximity to blood capillaries, which are very thin-walled vessels that allow for diffusion down a gradient.

And so oxygen is transported by diffusion from the alveoli into the blood, and it's then immediately transported into red blood cells. And then it attaches itself to hemoglobin.

Now, the reason that's fortuitous is because oxygen has a very, very low solubility in water. And if we didn't have a special transport mechanism, we would not be able to survive aerobically.

And carbon dioxide is also produced, as I said, metabolically in the level of tissues. It gets into the blood. It has a very solubility, about 25 times greater than oxygen.

But it is also transported, not just in solution, but attached to protein molecules. It is attached to hemoglobin itself when the oxygen molecule vacates the hemoglobin. And so it's moved back up into the lungs.

It also diffuses across from the red blood cells in the blood to the alveoli down a diffusion gradient, and it is exhaled into the atmosphere.

And this is an extremely rapid exchange, okay, far more rapid normally than, even at maximal exercise, as your blood moving very rapidly through your lungs during maximal exercise, it will in fact take place unless you have pulmonary disease.

Here's a little bit of a cartoons here where you see these are the airways coming down.

These are the alveoli. They are surrounded by these capillaries. And as the blood comes in from the body tissues and carrying CO2, you can see it goes into the alveoli and is exhaled.

Oxygen that comes in from the air through the alveoli is now transported into the blood.

There's a scanning electron micrograph of a red blood cell.

Now, inside the red blood cells is this very complex molecule called hemoglobin. And you see these little green sites where the binding of oxygen takes place.

Now, there is only four of them, so it doesn't seem like much; right? Until you realize there are about 280 million hemoglobin molecules per red blood cell. And then if you multiply that by 400 billion red cells that are produced daily and that can be ramped up 20-fold in the presence of a low oxygen environment during an adaptation process, that's a tremendous amount of oxygen-carrying capacity.

Your body also has the ability to sense

changes in the level of oxygen and CO_2 through central receptors, and also within specialized areas within the cardiovascular system.

This is the aorta coming off the heart.

And particularly in the common carotid arteries, there is chemoreceptors that can sense changes in the oxygen and CO_2 and deliver a neural signal back to -- it's integrated through the brain and back to the lungs where you have a respiratory or a ventilatory change based on that sensing.

Now, I mentioned that there are changes in gas concentrations under certain circumstances, and one is hyperoxia, which is a concentration or partial pressure of oxygen in the breathing space which is above that found in the normal atmospheric concentration at sea level.

And that can occur under hyperbaric conditions, for instance underwater diving or caisson work, and it can happen under normobaric conditions, just normal atmospheric conditions. But in clinical settings where somebody is being treated therapeutically with a hundred percent oxygen, and that can contribute to an excess of oxygen in the body.

But under mild circumstances, it is well tolerated. Human beings can actually acclimate to mild hyperoxia, and so that's not normally a problem. And that's fortunate because people use oxygen -- physicians use oxygen to treat certain kinds of diseases.

Now, extreme hyperoxia, especially under pressure, can be toxic over time. Now, under normobaric circumstances, what you normally see is a as a response is a mild respiratory depression. You have enough oxygen that you don't need to breathe that frequently in order to get plenty of oxygen for metabolic purposes. And now and again, though, you have an increased ventilation because there's this paradoxical response.

And I mentioned before that CO2 is carried by hemoglobin. And when you have maximal saturation of your hemoglobin with oxygen, there's no sites for occupation by CO2. So there's an elevation of blood CO2, which then stimulates your ventilation when it is sensed by the chemoreceptors in your cardiovascular system.

So you have this paradoxical increase in ventilation because of that, but normally you see a respiratory depression.

Now, because a high level of oxygen creates, as you have probably heard, oxygen free radicals, that can cause a lot of damage if you are exposed to it over a prolonged period of time, days to weeks. And it's probably due to oxidative stress in alveolar cells in response to being exposed to oxygen free radicals.

Now, under hyperbaric or high pressure circumstances, breathing CO2 -- or breathing oxygen, a hundred percent oxygen, even though it's used therapeutically understood normal atmospheric pressures, is toxic under hyperbaric conditions.

And generally speaking, if you go below about two atmospheres absolute -- so that would be wearing diving gear and wearing a hundred percent oxygen rebreather and going below 33 feet, which is one atmosphere, or two atmospheres absolute, you will start to develop seizures. Okay? So there's that neurological component to that.

And the U.S. Navy has determined that the threshold is about 1.3 to 1.5 atmospheres absolute, which is maybe, you know, 12 to 15 feet underwater, 16 feet underwater, and then you start to sense this change in oxygen toxicity.

So the Navy recommends that you don't use a hundred percent oxygen during deep dives or even shallow water diving because of this problem.

And then you also see changes in the cardiovascular system, a decreased heart rate, cardiac output, stroke volume and so forth in response to this hyperbaric exposure to oxygen.

And then you can see also cerebral vasoconstriction and decreased cerebral blood flow.

You have so much oxygen there that you are actually protecting your neural tissues against too much. So you have a reduction in the bore of your cerebral arteries to limit blood flow to that area.

And then you also have a general vasoconstriction of your kidney and gut regions and a decrease in renal blood flow just because you have too much oxygen there.

And these changes are not associated changes in neural activity. They are more local vascular control changes.

Now, the opposite side of this is hypoxia, which is an oxygen concentration or partial pressure in the breathing environment which is lower than that normally found in the atmospheric normal pressures at sea level.

And a lot of this you find in acute exposure. You know, in mountain climbing or aviation. You have the opposite. You have an increase in ventilation because your body senses that it is low on oxygen, and you breathe more rapidly and more deeply to try to get more oxygen into your system for metabolic reasons.

And at the peak of this, at the summit of Mount Everest, coincidentally, you can have your maximum ventilation.

So imagine if you got on a treadmill and ran as fast as you could -- and we do this in the laboratory for certain reasons -- get somebody's maximal aerobic capacity, and they say, I can't go any further. They are at their maximum ventilation, and that's at rest is if you were breathing as hard as you could at rest at the top of Mount Everest, you would have barely enough oxygen coming into your body for basic metabolism, and there's not a whole lot left over for muscular work.

And that's when you are down around 35 millimeters of mercury of partial pressure of oxygen in the alveoli. And below that is you're going to lose consciousness.

And however, you can't always do that in Everest, depending on what time of year, because there's an atmospheric change in pressure which during certain times of year you can't go out there without oxygen supplementation.

So here you have Everest. It's pretty high, over 8,800 meters, more than 29,000 feet. And you can see that as the barometric pressure decreases, you reach a point right here where you're right at the amount of oxygen uptake with maximal ventilation, which is just barely enough to maintain your metabolism -- your aerobic metabolism at base levels.

Now, there is also chronic hypoxia. And that's when people live up in a high altitude environment, and that tends to -- or you go up there and you stay for days to months. That will tend to hypersensitize your chemoreceptors that sense changes in oxygen and CO2 levels in your body so that they are more sensitive.

So even with a mild increase in hypoxia, you will have a greater ventilatory response. And that's protective because you want to get as much oxygen as you can into the lungs.

But you also have an increase in cardiac output because it's not enough to just get the oxygen into your lungs. You have to mobilize it through your body, and that's by getting into the blood and transporting it to all of the tissues in the body.

And what happens is you have a high degree of hyperventilation, and so you are blowing off lot of CO_2, and you have the metabolic change. You become more alkalotic. Okay? But you also have resistance to exercise because you're not getting, even with all of that, enough oxygen to exercise in the same manner to the same degree that you would at sea level.

Now, human beings can adapt. If you live up in these high altitudes, you adapt to it. And there may be 40 million people who live and work at altitudes between 3,000 and 5,500 meters, which is about 10,000, 18,000 feet.

Peruvians work in copper mines at 17,000 feet, okay, and they do it in a manner that would kill any one of us, probably.

They are born, raised, and die this those altitude, and there's a lot of physiological adjustments that start at birth that protect them against that. And none of us would be able to acutely go up to that altitude with a big smile on our face.

And one of the things that happens is they increase the number of those air sacs, the alveoli in your lungs. And so they have a greater surface area for gas exchange, and that happens at birth. That's not something that you and I could, say, go to altitude and suddenly develop more alveoli. That's something that you are born into.

They also have an increased number of hemoglobin molecules and myoglobin molecules in the muscle to carry more oxygen. And also there's a decreased ventilatory response to hypoxia. So they are not constantly jacked up with ventilation. They are desensitized to it, but they can still transport more oxygen.

And they have -- in spite of that, they still have an elevated ventilatory response compared to people living at sea level.

Now, there's a limit to that, and that limit is between to 30 and 40 millimeters of mercury alveolar partial pressure.

Now, remember up at Mount Everest for the unwise person that doesn't go up there with oxygen supplementation, well, they are right in the middle of that. So they are on the edge of losing consciousness because you simply don't have enough oxygen to deliver to the brain and vital organs.

Now, there's a -- people are not as sensitive to hypoxic stimuli in the same way that they are to CO2, okay? So oftentimes, you're not a aware of a progression to unconsciousness. You suddenly go under when there's a hypoxic condition, and it's simply asphyxia.

Now, this can occur in workers exposed to low oxygen environments. I have heard of deaths happening in people that are cleaning chemical storage tanks, which are a low-oxygen environment. The holds of ships that are carrying certain kinds of products that put out CO2, and it displaces the oxygen so it's hypoxic.

And sometimes somebody can go in there wearing an air purifying respirator, and they still die because of hypoxia. And a lot of that is simply the displacement of oxygen by other gases.

Now, shifting to CO2, we call that hypercarbia, it's a normal byproduct of aerobic metabolism.

It is produced in our bodies, so it's not going to kill you normally. And it's a very potent stimulus of minute ventilation. It's extraordinary potent. When your CO2 levels go up, you have to breathe.

And it acts by stimulating the chemoreceptors that I mentioned before. And the change in ventilation in response to CO2 production keeps alveolar PCO2 in a dynamic equilibrium with metabolically produced CO2.

So if you are very active, if you are running very hard, you are producing a lot of CO2 because your metabolism is up, but you are blowing it off into the atmosphere. And so you're getting rid of anything that's produced metabolically under normal circumstances.

And as I mentioned, before, CO2 is also potent stimulus of cerebral vasodilation and blood flow. When you have a lot of CO2, that tells your body, gee, you are not getting enough oxygen. You need more oxygen. So it dilates those blood vessels. You get a lot more blood flow to the brain to carry oxygen to the brain to preserve cerebral function.

Now, hypercarbia can result from hypoventilation, low breathing at a rate that allows a build up of CO2.

So you can see that in skip-breathing by SCUBA divers. You also see it in professional breath-hold divers. And a malfunctioning respirator can lead to rebreathing CO2.

So if you are not completely flushing out CO2 in the breathing space, you rebreathing it each time, but you are also exhaling CO2 into the breathing space. And if it's not completely flushed out, you are going to gradually build it up in the breathing space and rebreathe it.

And if you have a high resistance to say inhalation -- you know, high inhalation resistance, that's going to slow your breathing down. And now you are back to hypoventilation again, and now you are building up CO2.

CO2 can induce visual disturbances at high enough concentrations. A headache, that's a very common one. I have breathed 6 percent CO_2 in a study once, and I had a nice headache afterwards.

It can change your reasoning ability. There's a very strong sense of what we call dyspnea, or air hunger. You literally feel like you can't get enough air because you are stimulating your ventilation so much.

It can act as an anesthetic. 10 percent CO_2 will put you out in very short order and will kill you, probably. You can induce inert gas narcosis similar to nitrous oxide, which is a laughing gas.

And you also have changes in pH, which affects metabolism, and it's probably the mechanism for the inert gas narcosis.

Now, this is a complicated slide, but all you have to do is look on the left here. You see, well, as you increase the CO concentration, you increase the symptoms and the severity of the symptoms, and you decrease the amount of time that you are able to tolerate it. And that's simply aggravated by exercise, so the more active you are -- this is at rest. And if you start exercising, your tolerance is that much less.

Now, respiratory protection, as we all know, is probably not new. This is a plague doctor, Doktor Schnabel von Rom, who is Dr. Beak from Rome. You can see his very fanciful mask there, but that is a respirator.

It has crystal lenses to protect the eyes. It has a filter media, believe it or not, which is aromatic herbs, which they felt were, back in the 16 -- or 17th Century, would block miasma, which they felt was what was transmitting plague through the air. And of course they didn't realize it was -- the vectors were fleas on rats.

This is a productive garment that they are wearing and gloves. And this was waxed, and it also was in continuous -- it was attached to the facepiece here.

This is a stick, not for walking, but to point to the problems of the patient. So for all practical purposes, they were practicing social distancing. They were afraid to touch the patient.

So what they did is they pointed to the family members and said, You touch them. You move them around. You know.

It was ruthless, but it kept them alive.

So now we shift to 21st Century surgeons in an operating room. Well, gee whiz, they have protective garments and hats and, you know, facewear here.

So nothing really changes except fashion. And they are basically doing the same thing that everybody else is doing.

And here's some common respiratory protection, you know, the gas masks, SCSRs for mining, SCBAs for -- you know, that are usually worn by firefighters, and an air-supplied system here.

And what you need to remember is that at rest, we still consume oxygen and put out CO2. And we consume roughly -- you know, you have to realize these are general numbers. You know, it depends on the individual how much they are actually breathing. But on the average, you consume about 250 mL per minute of oxygen, and you put out about 200 mL of

CO_2. Now, that also depends on your diet.

And then at maximal exercise, you are jacking this up, you know, more than 15 times. And so your maximal oxygen consumption in the average individual can be three and a half liters per minute absolute. CO_2 production can be over 4 liters because of the heavily working muscles. And in it athletes, that can be even greater.

So we consume oxygen. We put out CO_2, as I have mentioned.

Now, if you look at these, this is a single breathing cycle in a respirator, kindly provided by Dave Caretti at ECBC.

And this is CO_2 levels here, roughly. And these are O_2 levels. Okay.

So at the end of exhalation, you have exhaled CO_2 into the breathing space. And you can see on this scale on the right, well, you are up about 6 percent, you know, of CO_2.

And down -- and because you are not breathing in, the O_2 levels have dropped down to maybe 15 or 14 and a half percent.

Well, then you breathe in, and you breathe in all of this fresh air, and the oxygen levels go way up, and the CO2 levels go way down because now you are rebreathing that CO2, but you are also in the process bringing in all of this air, which flushes out or removes -- decreases the concentration of CO2. And then the cycle starts over again.

Well, imagine if you know, this line were up here. Let's say you're not really clearing that CO2 from the respirator space.

And so now, with the next round, it goes up maybe a little higher, and the next round after that, next round.

Now, of course this is -- respirator manufacturers go a long way to manufacturing their -- and designing their respirators to make sure that they clear CO2. But if they don't or if there is some sort of malfunction, you can see how CO2 could rise breath by breath fairly quickly.

Now, as I mentioned, if the respiratory protective device, whichever it is, especially a supplied-air system, fails to deliver enough or delivers too much oxygen to match demand or fails to eliminate the carbon dioxide in the breathing space, then you start seeing these issues of hyperoxia or hypoxia or hypercapnia.

This is high O2, low O2 and high CO2.

And that becomes significant for the user. Now, when you -- and here's what I -- a rub, too, is that when you are using a respirator which simply filters air, takes out materials out of the air so that you're not exposed to something but relies upon room air, well, it only takes out vapors or particulates, but it does not protect against any of the hyperoxic or hypoxic atmospheres. And it doesn't protect against high CO2, because you are simply filtering the existing air that's there. And there have been fatalities.

In fact, when there was a group of workers that brought in an order of dry ice, which is frozen CO2, and put it in this confined space that was being used by people, and it was a cold room, but it wasn't designed to ventilate the excess CO2.

And as it sublimates out, and the CO_2 concentration goes up, a researcher went in there and died simply because they displaced all of his oxygen.

And when somebody was doing this in a room designed to hold a Magnetic Resonance Imaging system which had a low atmosphere because a lot of the atmosphere had been displaced by liquid nitrogen to keep the device cold, workers went in there, found dead just from pure asphyxiation.

The air purifying systems will not protect you against that.

So, you know, oxygen is necessary for life and vital for aerobic metabolism. And carbon dioxide is a normal product of aerobic metabolism, and it's an important regulator of physiological function.

But high levels of oxygen, especially under hyperbaric conditions, can be toxic and even fatal. Low levels of oxygen at sea level are at altitude can result in asphyxia and death. And high levels of carbon dioxide can result in asphyxia and death.

So all things are poison, nothing is without poison, only the dose makes something a poison.

And so I developed a lot of this when I was doing some work on the ISO technical specification.

Send your hoots, catcalls, letter bombs and other things to this address, and I will take any questions if there are any.

I guess it's time for lunch.

UNIDENTIFIED PERSON: There is one question.

MR. SZALAJDA: Can we hold it until after lunch when we do the panel session?

I think kind of at this point, since we are pushing 12 o'clock, let's break for lunch and reconvene at 1 o'clock.

If you are interested in the lunch that the hotel is providing, it is $12 cash only. To the right of the door -- I guess it's right out here, so -- and I guess there's also tables and chairs out here that you are welcome to use as well.

So with that, we will reconvene at 1 o'clock.

(A luncheon recess was taken.)

MR. SZALAJDA: At least at this point, we have one person doing a presentation regarding air-fed ensembles. Heather Farrer from Savannah River is going to give us a perspective on their operations and what they do within the Department of Energy.

After Heather is done, we will go ahead and move into the panel discussions at that time and start taking questions. I know I guess we have another least one on LiveMeeting already that we will take first, and we will follow the same type of format we did this morning with the SAR.

So with that, Heather.

MS. FARRER: Good afternoon, like Jon said, my name is Heather Farrer, and I work for Savannah River Nuclear Solutions. I work with Ed Kvartek, who is sitting over here behind Jon, and he works for Savannah River Remediation. And we work at the Savannah River site that's actually not in Savannah. It's in Aiken, South Carolina.

Real quick, I'll just give you a little history about the Savannah River site. It is a DOE facility. It was constructed in the early 1950s to support U.S. defense programs.

Some of our lesser recognized missions include -- we were the first to discover the neutrino particle. We were also the first to operate a nuclear reactor by a computer. We have produced plutonium-238 that's used as a heat source for deep space missions, and we have also created radioisotopes for nuclear medicine and research.

While we continue to support our defense programs, we have got other activities that include radioactive waste solidification, mixed waste soil remediation programs, radioactive waste tank cleaning and closure. And our national lab is currently working on hydrogen fuel cell technology.

And to learn more about the Savannah River site, you can just visit our website I have got listed on the slide.

A quick overview of what I'm going to talk about. Of course, we are here to talk about the SRS, supplied-air suit, and what is a supplied-air suit within DOE facilities. I'll talk about the SRS suit specifically. I will talk about DOE suit usage in the 80's time frame based on a report that was issued in 1984. Then I'll talk about some of our current suit usage, and then discuss some of the unique considerations that you should consider when designing air-supplied suits.

We call them plastic suits, so if I start saying plastic suits, ya'll know that's what I'm talking about.

And then the future.

What is a supplied-air suit?

Currently within the DOE, suits are defined by the DOE tech standard 1167. It was issued in 2003. Suits are constructed for the entire body. They primarily protect the breathing zone. In some cases, they provide skin protection depending upon the contaminant.

Air is supplied to the head and preferably to the body for worker comfort.

Our tech standard also addresses the user program, excuse me, and includes our breathing air hoses, attachments, and accessories. And what a supplied-air suit is not is a NIOSH-approved hood taped to coveralls.

We have many folks that transfer into Savannah River site from other places, and they tell me, Oh, we wear bubble suits -- is what lot of folks call air-supplied suits, bubble suits -- where I came from. And as we talk to them, we will discover, well, no, that's not an air-supplied suit. That's actually a NIOSH-approved hood that they have taped to their coveralls. So -- and I really get that a lot. You guys would be surprised.

The history of the SRS supplied-air suit.

We first started using suits in the 1960s. Initially we used them for tritium, and then their use migrated to other facilities.

Our first suit was a 6-mil PVC suit. Over the years, we have had various versions and modifications. Went from a one-piece suit to a two-piece suit. We improved the durability and tritium protection by adding a 12-mil PVC suit. That suit is actually laying on the counter back here to the right.

We have addressed welding by adding a welding suit. Our welding suit actually has black opaque 20-mil PVC for the helmet, and then the welder would attach a welding adapter to the front of that, and then the dark plate for welding.

We have improved the worker comfort by added a cooling vortex tube, and we also use ice barrels. We have improved the tritium protection by adding a Saranex suit, and we have addressed fall protection by allowing workers to wear full body harness underneath the suit.

We have reduce cross-contamination with what we refer to as shells or oversuits. A shell or an oversuit would be the initial plastic suit. You would wear that first. Then you would have another suit where you cut the helmet off, the cuffs off, and the booties off. And you wear that over the initial suit. And in some cases, we might have to wear two shells, depending on the contamination level and the work area.

This is a photograph of our 12-mil supplied-air suit. It is single use. It is two piece. It consists of pants and a top, constructed of 12-mil material.

Our helmet portion is 20-mil PVC. Our suit requires an airflow of 16 to 24 CFM. It's an air hog. Air is distributed to the helmet and of course the pants for worker comfort. Like I said while ago, we allow them to wear vortex tubes for cooling, and we also use an ice barrel.

Typically our suits are worn with two pair of coveralls underneath.

This is the Saranex suit that I mentioned earlier. We call it is tritium suit. It is a single-use suit. It's also two pieces.

The material is actually constructed of a series of films layered together. They consist of the chlorinated polyethylene, the Saranex polyester scrim, and then those are bonded together with EVA. This suit provides superior breakthrough and permeation characteristics for tritium.

These are the key steps in production of the SRS suit.

The first photograph is of our air distribution assembly. The second photograph is the suit being removed from the packaging box from our supplier.

They come four to a box, and the jacket portion is actually folded up into the helmet. The air distribution is inserted into the suit.

And then in the third paragraph, we have a worker who is doing what we refer to as our integrity test. That's where he runs his hands along all of the seams looking for pinholes or any kind of imperfections.

What you can't quite see in the photograph, there is actually a sound level meter mounted on the test stand that's in the helmet portion of our suit, and we take a measurement of the noise level of the air flowing into the helmet. We do this process for a hundred percent of the suits that we use at the Savannah River site.

The last photograph is of the packaging. We package them four to a box or five to a box, depending on the size.

What's not pictured here is the integrity test that we do on our plastic pants. We do the same thing that he is doing here on the third picture, is just runs his hand.

They inflate them. They run their hands along all of the seams, and they check for any pinholes.

These three photographs are a picture of a one-piece suit that we recently started using. In the first photograph, you will see the back of the suit. And this particular suit has two zippers in the back, and we have applied duct tape over the zipper to keep that zipper clean while the worker is cleaned from contamination while he is in the work area.

There is a three on his back and on his shoulder. And you can't see it, but there is also a number 3 on his forearm. And that's to identify the breathing air hose that's connected to the back of that suit to the manifold that could be in another room or down the hall.

So when he gets to the doffing process, once he is removed from the suit, either he himself or the worker assisting in the removal will tell the manifold attendant, Turn off the valve for No. 3.

In the second photograph, you can't quite tell, but we have actually taken and spray painted the duct tape. And that's to affix any contamination that the worker encountered during the work activity.

Once the spray painting application has taken place, then they peel the duct tape off. And then they would unzip the suit. The worker would turn around, which is in the third picture, and the suit would be peeled forward. And at that time, he would hold his breath, lean back, and be dunked in a NIOSH-approved hood.

So that's on -- on the third picture you can kind of tell the suit is kind of hanging down, and he is wearing a NIOSH-approved hood at that point.

What the worker will do then is they will finish the suit removal process. He will step back into a lower contamination area. He will be surveyed. If he is clean, then they will remove the hood.

The two-piece SRS suit has served us well. Like I say, we have used this suit for many years, and there are plenty of opportunities for improvement.

The first photograph is the center part of our air distribution. We call that the Plastic Suit Silencer Distributor, or PSSD. It's a mouthful.

And in that particular photograph -- well, let me tell you. That is a mold-injected spin-welded part. And in that particular photograph, the spin weld has failed, and the media inside the PSSD has come out the side.

In the second photograph, it's the same thing, the PSSD. And it has actually cracked at the inlet supply bar where the air comes into the suit. And we have learned through many investigations that during the molding process, the part can develop a void that can then lead to a crack. And then this is like a catastrophic failure when it actually cracks.

What happens when that happens with the worker in the suit is they don't lose breathing air, but the air is redistributed throughout the suit. So you might get a little bit less in the helmet.

And when that happens, our workers are to immediately move to the exit.

The third photograph is the pinholes that I mentioned. We have sprayed some soap on there so you can see it. We are considering alternative materials right now. We are thinking of changing possibly from PVC to polyethylene or a polyurethane blend.

The fourth picture is a picture of the cuff on our suit. Our cuffs are stitched and then taped over. Sometimes they will get a little bit of a pucker and you will get a leak in the cuff. So we are considering going from a stitched cuff to a heat-sealed cuff.

And then lastly, the noise level is below

80 decibels in our suit, but we would like to have it lower.

Suit status within the DOE facilities. In 1984, according to a report that was issued at that time, Rocky Flats was using a two-piece 12-mil PVC suit, required 6 CFM to the helmet. It was manufactured by JJ Avery, and it had an assigned protection factor of 20,000.

That particular suit was a one-piece suit in use. It is believed that they used tape to tape two pieces together.

During the doffing process, rather than wearing a hood or being dunked in a hood is what we call that, the worker would don a half-face respirator.

At SRS, we used the 6-mil suit that I mentioned earlier. It required 6CFM to the helmet. It had an assigned protection factor of 10,000. And since then we have upgraded, and we have four styles. And those were the welder suit I mentioned, the tritium suit, and the 12-mil, and of course the 6-mil.

Los Alamos National Lab used a two-piece 6-mil PVC suit. Required 6 CFM, had an assigned protection factor of 10,000. And in that particular suit, they had two different versions of air distribution to distribute the air throughout the suit. That suit was manufactured by Fab Ohio.

Fab Ohio also manufactured a suit for Oak Ridge. It was two-piece, 6-mil PVC, required 8 CFM, and had an assigned protection factor of 10,000.

Also at that time, Rich Industries, who is the manufacturer of the suit we use today, had a one-piece, 20-mil PVC suit. It required 6 CFM, had an assigned protection factor of 10,000. And as far as we know, there was no DOE facility using that suit.

Suit usage today within the DOE facilities. At SRS, we use four styles, and we have recently added the one-piece suit that you saw.

Our annual usage is approximately 3,500. In 1990, we peaked at 67,000. That is not a typo, ya'll. We used quite a few suits back then.

Los Alamos National Lab uses the SRS

tritium suit, one or two per year. Idaho uses a suit that evolved from Rocky Flats after that 1984 report was issued.

It was limited to an assigned protection factor of 1,000. That's because there was actually an airline respirator worn underneath the suit, and the suit did not have an approval.

At Y-12, they use supplied-air suits for product protection rather than worker protection.

I think this is why we are here. Considerations when designing suits: The four most important is avoiding an oxygen-deficient or an elevated CO2 condition in your suit helmet.

We have learned at SRS that the oxygen can fall to 19.5 percent in less than 20 seconds and 16 percent within 40 to 70 seconds. And that's depending upon conditions.

Another consideration is how you address loss of air. Unassisted removal, can the worker get out of the suit by themselves? Does the suit have a built-in escape cartridge or an emergency evacuation strip.

Then there's egress air. At SRS our breathing air systems typically provide five minutes of egress air.

And then of course the assigned protection factor: Historically within the DOE, we have had an assigned protection factor of 10,000.

The volume of air required may impact your breathing air systems. Ya'll might remember I said that our suit was an air hog.

NIOSH-approved mask and hoods require 4 to 10 CFM. Suits generally require much more volume of air to address cooling, worker comfort, and of course the protection factor.

Donning and removal. One-piece suits, some of them have zippers in the back. Two-piece suits can -- you know, these workers, can they get in and out of these suits without assistance?

Typically, there's an additional person required. And then of course, body types, height, girth, and inseam. And I have got some suit pants back there for you guys to see the variety of suit sizes that we have.

And you will learn real quick, and I think you guys already know, there's no such thing as one size fits all.

Another thing to consider is your suit materials. At SRS, we use PVC, and it is a balancing act. In cold weather, the PVC film becomes rigid and can break. In hot weather, it can sag and distort the worker's vision.

In the first photograph, that's me standing there holding up a pair of pants at room temperature. You can't quite tell, but the pants are actually kind of just folded over there where my fingers are. In the second photograph, I'm in an environmental chamber where it has been chilled down to 25 degrees Fahrenheit. It's kind of why I'm not smiling because it's pretty cold in there.

And you can see how the pants become pretty rigid, and it makes it very difficult for the workers to don the pants and the suit jacket as well when it gets that cold.

Another thing would be your self-extinguishing characteristic. We do have a welding suit, so that is important to us. Within the DOE, our suits have to comply with NFPA 701, the 1989 version.

It states that the material will self-extinguish when the flame is removed, and the film will not drip during the burn.

And if you look in the photograph there, you can see the material does burn. Okay? Now, it does self-extinguish when you remove the flame, which is a good thing, and that's what we want. And that's -- part of that standard requires us to measure the amount of char, so that's what they are doing there.

Okay. Couple of other things to consider would be your noise level. Suit noise level is usually higher than what you have in hoods.

Your suit design can affect your noise level, be it where the air enters the helmet, the top of the helmet, the back of the helmet, up underneath the chin. You know, a higher volume of air generally increases your noise.

Then there's heat stress. Our workers

wear what we call modesty clothing, which would be shorts and a T-shirt and then two pair of coveralls.

So you might need supplemental air for cooling. In South Carolina it's not warm, ya'll, it's very hot. And most of our workers always want cooling. So the majority of our workers are wearing the vortex tube.

Then there's chemical permeation. In the 2003 technology standard, it addressed chemical permeation. We have had our suit material tested for tritium, organics, and a couple of acids.

And then there's additional equipment.

Hard hats is a big one for us. A lot of the work areas that our workers enter require hard hats. Our 12-mil PVC suit will accommodate a hard hat.

Communication devices. Our workers wear communication devices underneath the suit because it's very difficult to communicate with handheld radio when wearing a plastic suit.

And then there's body harnesses. When you design your suit, you want to keep body harnesses in mind. We have got a lot of work going on where our workers are at elevated heights.

You do not want your worker wearing that body harness over the suit because in an emergency situation or an air-off situation, they need to be able to get out of that suit, and the body harness definitely can limit that.

Improper use of the body harness can reduce your assigned protection factor, and it can also affect how the fall arrest mechanism is designed to work.

And the first photograph is the one-piece suit. This worker actually has the body harness underneath. You can kind of see it.

In the second photograph is the side profile of the one-piece suit, and you can see the how the fall arrest feature comes through the back of the helmet and then attaches to the D-ring in between the worker's shoulder blades. That's the single-use suit at SRS.

The third picture is just a poor guy hanging. It's not an air-supplied suit, but it's the same mechanism that's in the single-use suit, and it's just to demonstrate and show that it does work.

And then lastly, the future. Other DOE sites are expressing an interest in using suits. Then there's a PAPR suit on the market. We would consider using PAPR suits, but right now they lack approval. And also did I tell you it was hot in South Carolina?

We would have to limit their use to some of the air conditioned areas. And then of course, there's efforts beyond the DOE, like ASTM and NIOSH.

And that's it.

MR. SZALAJDA: Yeah. I think we will go head and move into the panel discussion at this point. Excuse me for a second. Sometimes you need the prompter.

I guess what we would like to is I would like to introduce the panel.

We have our presenters, Colleen, Heather, and Jon. They are going to be joined by Bill Haskell, who has a wealth of experience in personal protective technologies, came to us from Natick Labs in previous lives before then, but is very actively involved, not only with our program, but also with NFPA and ASTM standards development committees.

And also Terry Thornton from the Technology Evaluation Branch. And Terry has been very instrumental in the establishment of our LRPL capabilities at NPPTL.

So with that, you know, again, just reiterate the document information. The submittal of comments.

What I would like to do initially, since I know we have at least one LiveMeeting question, John, if we to can guy ahead and line --

MR. PERROTTE: Sure. Draeger, Michael Klaus. Give me a minute to unmute him.

Go ahead, Mike. Hello, Mike. He's not there.

MR. SZALAJDA: It's getting late. Did he happen to write the question by any chance?

MR. PERROTTE: No, he did not.

MR. SZALAJDA: Do we have anything else on LiveMeeting right now?

MR. PERROTTE: That's all we had, just that one.

MR. SZALAJDA: Well, let's move into the different topics for the panel discussion.

The first was on the issue of classification.

And actually this is a very interesting topic that we have had internally in terms of where do these things fit into the puzzle. And in my simplistic thought patterns, I was thinking, well, you know, I can kind of conceive of a couple of different situations. One is, you know, you have -- you truly have the ensemble where, if the ensemble is ruptured or compromised in some way, it affects the whole body, that there's no possibility that your breathing air is controlled. And then I thought, well, there's another possibility depending ping on the innovation of the design is, well, if something did happen to the suit, the individual's breathing zone is still protected.

And I think what we are looking for at this point, since this is a new area for us, one of things that we would rather not do is invent something if there's already preexisting language or preexisting classifications, you know, in the industry or in the user community for addressing this type of topics.

So we were hopeful to get feedback on the classification aspect as far as is there a language that we should be using? And if so, what is it? Or if not, what do you think we should call these things?

I don't think you guys had enough cake at lunchtime.

Thank you, Gary.

MR. ZIMMERMANN: Gary Zimmermann, Sperian Protection Clothing.

I'm not quite sure on that question regarding intrinsic safety, but maybe I can give you a little bit of information.

Typically all these suits are overpressurized, so that's the key in concept regarding these suits.

And the majority of the designs from manufacturers hopefully are such that if -- this overpressure being maintained is helping a situation where if there's a breach in the envelope of the suit itself, the protection factor is maintained at least -- it may not be to the elevation in which the suit is protected or certified to, but it is definitely maintained because the overpressure is maintained.

So in some of the standards existing in Europe, for instance, there is an overpressure concept there that is taken into account. And if you are developing standards for that, maybe making sure that overpressure measurement is taken in suits when they are being submitted for certification will certainly help you generate a suit that is reliable from a health-and-safety perspective, even there is a breach in the envelope.

Because we find in the field a lot of tears and a lot of rips that do happen as far as people using suits.

So definitely that overpressure is going to solve a lot of people's problems.

MR. SZALAJDA: Okay. Thank you.

MR. GIANFORCARO: Can you hear me okay? George Gianforcaro, IndutexUSA.

I have a question for Heather, who just presented, if that's okay?

MR. SZALAJDA: Uh-huh.

MR. GIANFORCARO: May I?

You have different workers, I think you said 3,500 suits a year, approximately, according to your numbers.

How many different pairs of gloves are the workers wearing? Is everybody wearing the exact same pair of gloves, or are they different styles, different materials, et cetera?

MS. FARRER: They are generally wearing the type of glove. They may have layers of the same kind of glove.

MR. GIANFORCARO: For instance, is someone wearing a nitrile glove, someone wearing a leather-palm glove, someone wearing an inspection glove or a surgical glove or something?

MS. FARRER: Yes. Yes.

MR. GIANFORCARO: So you will have different workers wearing different types --

MS. FARRER: Different gloves for the different applications.

MR. GIANFORCARO: So if I were to go into your storage area, approximately how many different pairs of gloves or styles of gloves would I find?

MS. FARRER: Oh, I don't know.

MR. GIANFORCARO: More than ten?

MS. FARRER: No. I think probably about six.

MS. FERRAR: Six, okay. Which leads to my question or comment to the panel which we spoke about at lunchtime, is the way that the certification -- the direction that they are going right now in America, is that each time the worker has a different pair of gloves, they would need a different certification, and the manufacturer would have to submit a different garment for the testing.

Whereas in Europe, we manufacture air-fed suits in Europe, and the European standard, it stops at the cuff.

It's for a number of reasons. One is it's positive pressure. And number two is because if Organization A wears five or you said maybe six different pairs of gloves, and then maybe another division within your company has another six different pairs of gloves, right now, the manufacturer, the way that the US is writing the standard would require 12 different submittals for each different ensemble because it's a different pair of gloves.

And my concern is that I think that if we are writing the standard this way is that it's going to become either -- we are going to outprice the product just because of testing, or I don't really think -- or what we are going to do is cause the end users to say, Well, just test it with one pair of gloves, but the other nine guys, we will wear a different pair of gloves, and it's good enough.

So then they are going to be wearing a suit or ensemble that has not been certified. So I think that's something that the panel, I would like them to address prior to finishing this up because I think we are going down an area which is a dangerous area.

MR. HASKELL: George, I have a quit question on your concept, the way they use them in Europe. Do they not worry about the hazard getting under the glove?

Because you are overpressure is, I assume, ending at the cuff; right?

MR. GIANFORCARO: It's my understanding what we do -- it's my understanding that they have -- when they do run the tests, there is a glove. And then they tape the glove.

Now, the tape that they have comes with the suit.

MR. HASKELL: But there's really no certification process that you know you have a good -- a vapor-tight seal under the glove?

MR. GIANFORCARO: I can't speak -- I don't consider myself an expert on that.

MR. HASKELL: Because one thought I have

is what if the gloves had a mandatory attached glove with a minimum level of protection, physical durability and chemical. And then for other things like welding or other more aggressive operations, you then put another glove on top of that, but you are maintaining your physical protection barrier between the arm and the glove with an attached inner glove.

Does that make sense?

That's the way it is done with a lot of hazmat suits. You will have an attached glove, and then you will have an overglove depending on what additional protection you need.

MR. GIANFORCARO: Well, what I would like the panel to do is possible -- at least -- now, I don't have the European standards here. I could brush up on it for the next meeting.

But it's my understanding that the testing or -- they call it a suit standard and not an ensemble standard, and that the suit is certified.

But I will for the next meeting, I could follow up to find out exactly how they word it in

Europe.

MS. FARRER: I would like to add a comment.

On the gloves, what we found, when the glove is sealed to the cuff, that when you are ordering suits, they don't fit everyone. So then you get into you need a suit size, and then you need a glove size. So I'm kind of like with George, stop that at the cuff and address the glove separately.

MR. SZALAJDA: Okay. Do we have a LiveMeeting?

MR. PERROTTE: Yeah, it's from Draeger, Michael Klaus.

It says, We totally agree with the AFS should be under the scope of NIOSH/NPPTL. Colleen explained the standard is limited to suits without exhalation valves. We would propose to open standard also for gas-tight suit ensembles with exhalation valves since this gives additional safety.

MR. SZALAJDA: Okay. Thank you.

I think with -- I think just to kind of

wrap the classification question up, unless we have one more comment, I think the challenge for us is when you -- from my perspective, anyway, that we are looking at this initially in terms of it being a respirator.

You know, and I think it's -- part of our definition needs to be where does the respirator end in terms of the definition of the ensemble, whether it's the complete ensemble, and you have attached gloves or you have attached boots.

I think the challenge for us and where the feedback and discussion like this is important is trying to find that limitation. Because from the one -- the one standpoint -- and I can appreciate the issue in terms of the certification testing and the cost and the times -- the time that goes along with that.

But, you know, again, as Bill had discussed, it's, you know, where do we make sure that we are assuring the protection that if you are wearing multiple gloves, how is that accommodated as part of the specification?

So it's a good discussion.

MR. CARDINALE: Mike Cardinale, NASA.

This discussion on the gloves I think is interesting. It looks like there's two different strategies here. There's suits with attached gloves and boots, if you want to call them that. And then there's apparently suits where the gloves or footwear are separate from the primary garment.

And I think that what you need to be looking at is the boot/glove interface and that's what you are certifying as opposed to the different size gloves that might come with the suit.

You know, if you engineer an interface between the suit and the glove, that defines how airtight, you know, the unit is. And perhaps that's a way around this little dilemma here.

MR. SZALAJDA: Thank you, Mike.

All right. Well, I think we would like to go and move into the IDLH type of discussion.

I think part of the concept that we have been kicking around was the inclusion of an escape type of capability for these type of systems to allow for egress from a certain environment.

And any comments on these questions? Or anything in light of potentially having combination types of units where it might be supplied-air as well as some sort of air purifying type of device?

MS. MILLER: Jon, if I could just add to that.

Heather did make a point in her presentation of saying that they have done some measurement of oxygen level -- or CO2 levels when the air is shut off.

I guess what I was hoping is that if there are any other users out there who had done similar work or manufacturers and you have, you know, some information that you could share, we would appreciate it.

Thanks, Chrissy.

MS. DUQUESNE: Hi, my name is Chrissy DuQuesne. I work at KSC-NASA.

We did do testing when we shut the air off inside of our suits. We had two minutes worth of air to egress if we didn't have cylinders to use, but we do have cylinders to use as well.

So we have done that CO_2 testing for leaving an area. We actually have over two minutes of air just from -- time just from the air inside the suit.

MS. MILLER: And that was a manned test?

MS. DUQUESNE: That was a manned test.

MR. ZIMMERMANN: Gary Zimmermann again.

We have done a lot of testing actually on CO_2 with air off because we got some applications where they actually use suits to that effect. Moving around in pharmaceutical applications, sometimes they will unplug, replug.

And the key again is design of the suit systems whereabouts the exhaust valves have to be able to shut down when you unplug.

So an encapsulating suit that's airtight is very effective. So once you unplug, you literally have an individual living in a suit's microenvironment where the CO_2 levels will rise a lot slower if you are literally exhausting air from the suit.

So if you train an individual to move quietly to the area where he has to leave, for instance, in emergency situations, you can get CO2 levels inside 3 percent for as long as two to three minutes, very easily.

But, again, suit design is critical on that side.

MS. MILLER: Thank you, Gary.

MR. SZALAJDA: Any other comments on this topic? Okay, use concerns, the concept of disposable versus reusable.

One of the things I know that we have been sensitive to is with regard to the storage and use temperature considerations. I think the picture that Heather showed us with holding the PVC suit and being able to see the bend in it because the -- you know, it seized up in the cold I think is pretty telling.

And I think that, again, part of the challenge here is looking at, you know, with these types of systems, is, you know, providing the range of capabilities to address the appropriate user scenario, that for some situations, that type of material, that PVC material, may be appropriate. But to build requirement completely around that may not be appropriate for addressing other applications.

So any comments on these questions?

MR. WILLIAMS: On thing I thought was a little interesting was when Heather mentioned with her suits, that you would be hypoxic within 70 seconds or so.

And that's presumably when you are not panicking, you are not moving around that much. And CO2 levels are going up, you know, maybe you can maintain, you know, CO2 at 3 percent for a couple of minutes if you train somebody to move very quietly across, but circumstances don't always allow for that.

And if you're in a more of a panic circumstance, you are not going to have that much time to -- when there's air off -- to get to a safe place. And, you know, if the oxygen concentration is down to 19 and a half percent in 20 seconds, well, 20 seconds goes by pretty quick.

So I think it's an important consideration when you are talking about these encapsulating suits that have essentially a bag of air, a microenvironment of atmosphere around you. And, yet, once that is no longer regulated by an external source, you don't have that much time.

And I'm glad to hear that there's some training out there to say, okay, just move slowly and you might get out of here. You might have two minutes.

But it's not that long of a period of time. It's an interesting concern.

MS. FARRER: Jon, what we do at SRS is we train our workers how to doff the suit by pulling it over their head like a shirt, and they have to be able to demonstrate that they can do that within 15 seconds.

MR. WILLIAMS: But are they going to do that in a dangerous environment?

MS. FARRER: We don't send our workers into an oxygen deficient or an IDLH area, so yes.

That is their instruction, that if you lose air, that means there is no air going to the suit, then you remove the suit top and proceed to the exit.

And even though we have egress air, egress air doesn't help you if I cut off the wrong valve, I cut Jon's air off or I cut his hose when I'm supposed to be cutting Terry's hose.

MR. WILLIAMS: There are people who would like to do that, by the way.

MS. MILLER: And now it's on the record.

MR. WILLIAMS: Yeah, now it's on the record.

Because if somebody is in an IDLH, or if you are working in a BSL-4 facility where you can't afford the exposure because some of these biologicals have no known cure and you get exposed, that's a shame, you know. You know, it's a consideration if the air goes off.

MS. DUQUESNE: Just a comment on that really quick.

We have what we -- we converted some SCBA cylinders into what we call ventilator bottles. They are the 30-minute ISI little bottles that we have, the aluminum ones, 30-minute cylinders.

They supply 10 to 12 minutes of emergency breathing air. Our users can disconnect their hose and connect to that bottle and emergency egress out of the area. So that's one thing you could put on there.

And it has a high enough flow rate to keep that CO2 wash out, and it is 10 to 15 minutes of breathing air.

But I have comments on the questions --

MS. MILLER: Before we go on, can I just ask, do you have any kind of a filter system that you are using with that cylinder so that if the gloves are dirty, you are not contaminating when you are connecting to that cylinder?

MS. DUQUESNE: We have quick disconnects that --

MS. MILLER: But there's no like HEPA filter on it or anything?

MS. DUQUESNE: No.

UNIDENTIFIED PERSON: You have actually tested that?

MS. DUQUESNE: Yeah, we have actually tested that, and no contaminants. Actually, even if you do have contaminants on your gloves, like oxidizer, we have had guys who have oxidizer on their gloves because we have had a spill, liquid oxidizer go all over the down the suit.

No contaminants got in through the quick disconnect that we have.

MS. MILLER: Okay. Thank you. Go ahead, Chrissy. You had another comment?

MS. DUQUESNE: On question 2, what methods are used to ensure proper functioning prior to use if you do reuse the suits?

At KSC, we have really high safety standards. I have a lot of documents to prove it, but for our suits what we do after every use, they are not assigned to a user. We get them after they are used every time, and it goes through a huge recycle process where the outside is washed, the inside is washed. We have what looks kind of like a car wash. It is dried. The suits are inflated, bubble checked, bubble leak checked over the whole entire suit.

We do a light inspection test where you stick the light up inside the suit to find thin areas and pinholes in a dark room. Then it's visually inspected by a technician. He fixes whatever he finds, and then it goes to a pressure check, exhaust valve check, comm check, quick disconnect, the manifold check. And then it goes to a quality inspector after that.

MR. HASKELL: Jon, may I ask her a question?

MR. SZALAJDA: Sure.

MR. HASKELL: Do you actually have a way to prove that you are disinfecting, or is it just some sort of soap solution?

MS. DUQUESNE: We have a sea wash that we put on the outside of the suit. It's hand washed. And if there's like scuffs or something that we can't really get off, we use toulene.

Our guys have to use respirators if they do that.

And then on the inside of the suit, we have an actual -- it's heat washed on the inside and outside of the suit with hot water. It's at 110 degrees Farenheit. Soap is used and then a clean-water rinse.

The suits, after every time they are used out in the field, they are sniff checked before the technicians are allowed to leave the area.

After every time that they use a suit in the area, they take a five-minute shower.

So, yeah, it's a lot of soap, I guess.

MR. SZALAJDA: Thank you.

MS. MILLER: Could you also say your name?

MR. GIANFORCARO: I'm sorry. George Gianforcaro, IndutexUSA.

Not everybody -- I believe not everybody has the budget that NASA has. And what we have found in the European marketplace, a lot of pharmaceuticals are mixing chemotherapy drugs and they can't have the worker exposed to chemotherapy for four, eight hours a day every day.

So they always take the suit off. They shower, decon, and then they throw the suit away.

And we asked them about a reusable versus disposable, and they said it's not worth it, the risk, to put a worker -- have a worker exposed just in a case that maybe they didn't decon it properly or there was a trace or something. It's not worth it to them.

And in specifically one application, I remember speaking to them, a worker will wear the suit for only two minutes, run a quick test, then they step out, they shower, and then they throw the suit away.

And they said again, it is cost prohibitive for them to go to the decon and open themselves up to a risk. So...

MS. MILLER: So, as a follow-up, is there ever a concern that you are selling something that is considered disposable and it is being deconned and reused?

MR. GIANFORCARO: Well, we recommend -- we always say it's a disposable suit. But when I'm talking to the customers, I was asking them, Do they have any use or any desire for a reusable? And all of the customers hands down are saying, no, we do not want a reusable suit. We want a disposable.

So we have kind of -- it was a happy marriage there.

MS. MILLER: So you have chosen that. Okay.

MR. SZALAJDA: Okay. Any other comments on this topic?

The next topic -- actually, the next two slides relate to flammability and the need for a flammability requirement in the standard.

I think we saw Heather's -- again, I think her slide was good at least with regard to how they conduct the flammability and self-ignition -- or self --

MS. FARRER: Extinguishing.

MR. SZALAJDA: Extinguishing, thank you.

MS. FARRER: You're welcome.

MR. SZALAJDA: For the flame on the suit.

And, again, we would like to get input on what would be a valid criteria to include with the standard.

Bill.

MR. HASKELL: One thing we discussed prior to the meeting was I think the NASA tester used an NFPA 701, which is --

MS. FARRER: DOE.

MR. HASKELL: DOE, excuse me. And I think that was a test originally developed for wall coverings and drapes.

In some of the other consensus standards out there, there is requirements for both material flame propagation tests and even full systems-level tests.

So maybe as we address what are the different classifications you need, we need to figure out do we need something more advanced than a materials test? Do you need some sort of like a flash fire test or something like that.

You know, we are looking for input along those lines.

MR. SZALAJDA: And I think just to follow up on Bill's -- Bill's comments, especially when you look at the wide range of wearer, these suits can be used -- you know, we have heard from the last public meeting as well as the comments today about the NASA experiences. You know, we have heard insight -- or gotten insight today into the DOE applications when you look at dealing with radiological issues.

You know, we haven't really touched into or delved into the chemical aspect in terms of the pharmaceuticals and gotten the feedback from how things are used in pharmaceuticals or paints, other applications like that.

Or the biological, you know, the biosafety level requirements.

So I think, again, with this topic as well as the others, again we are walking that balancing act between, you know, specifying meaningful performance requirements, but yet trying to be able to encompass a wide range of applications.

MS. MILLER: Actually, to add to that, looking at EN 1073, the flammability requirement is EN 1146, the single burner test.

It actually does not relate to the classification, whereas the other physical properties, like the abrasion, puncture resistance, flex cracking and tear resistance do.

So if anyone has any comments about how we may approach relating the flammability or the ability to ignite to the classification, that would also be of interest to us, if not today, on the formal docket as well.

MR. GIANFORCARO: George Gianforcaro, IndutexUSA.

Is there a flame requirement for a hood, a loose-fitting hood today?

MS. MILLER: No.

MR. SZALAJDA: I don't think so.

MR. GIANFORCARO: No? Then with that same thought process, maybe there should not be a flame resistance test.

Because really the suit is really just -- the way I explained, it's an extension of a hood. Instead of a hood stopping at your chest, it goes all the way to your feet.

So if there is no requirement for a flame test on a hood, I don't see why we would want to have a flame test for a suit.

MS. MILLER: Thank you, George.

MR. HASKELL: What if you have an IDLH environment, but the IDLH is related to a lower exposive limit for that particular work environment?

See, I think it's so complex, we have got to figure out what are all of the different classifications and then figure out, do you need different requirements depending on a particular classification.

MR. GIANFORCARO: Right. And my concern is that if we try and take on so much, we are going to get nothing done.

And so I like the process of keeping it simple. And whatever we are doing for the hoods, just apply that to the suit. And we will keep it very simple, and we will get a standard written, and then possibly a revision two or three years later, or six months later.

MR. HASKELL: Well, don't we have a

requirement for some minimum level of flammability for the escape hoods? CBRN?

MR. SZALAJDA: Yes.

MR. HASKELL: So we do have that for that type of respiratory protective product.

MR. GIANFORCARO: Well, then my suggestion would be whatever that requirement is, put that on the suit, make the same requirement.

MR. KVARTEK: Ed Kvartek with Savannah River. Most people there think I work for Heather.

We use the NFPA test for both our hood and our suit, but we do consider them a little different. The reason being that you can remove that hood unassisted. If you have got a suit that is difficult to get off, I think a performance-based approach for this at least should be considered.

There was an incident several years ago -- time flies -- a welder -- not at Savannah River -- but a welder was working. He was wearing PPE. It was not a supplied-air suit, but his protective clothing caught on fire. He did realize it because he did not feel the heat. He subsequently died.

So I think you are on the right track on looking at flammability.

I think you have to consider the application of course, but I think you are on the right mark.

MR. SZALAJDA: Thank you, Ed.

I would like to move on to the visor/harness topic. We had a little bit this morning, we had some discussion about the marking issues.

I think the one thing there, the one discussion I have heard is why is NIOSH in the business of specifying harness requirements, you know, and how do they relate to respiratory protection?

I think we would like to hear some more feedback with regard to that issue, not only how it applies to the air-fed ensembles in the pictures that we saw in the DOE presentation, but also how it applies across the board with SAR as well.

Comments?

Panel?

MS. FARRER: It says on your slide external harnesses used with ensembles.

If you wear the harness on top of your supplied-air suit and the workers is in an air-off situation, you have now reduced the amount of time that it is going to take -- you have added time for them to be able to get all of that off so they can get the suit off, and they may, like Jon said, be in a panic situation.

So I mean, I think the harness -- the suits, ensembles, should be designed where that harness is either integral with the suit or it is underneath the suit so that the worker can get out of it.

MR. SZALAJDA: Thank you, Heather.

MR. ZIMMERMANN: Gary Zimmermann.

On the visors, that's a tough one. I think I just want to mention some practical approaches on visors and overall penetration resistance.

Again, it is so application related, even on the flame resistance side of things. It's very application oriented.

And I'm actually for that on the flame resistance, by the way, but I just didn't want to dominate these type of things.

But in a sense of the visors and penetration, we have a lot of situations where on our disposable garments, for instance, the visors are quite thin, but they are practical for the application.

So I don't know the relevancy of penetration resistance testing there.

Ideally, of course you want the suit to work well, but also if there's a little puncture in a hood, for instance, again, the overpressure is supposed to take care of things, especially in a particulate resistant environment.

Now, it may be, again, different for chemical resistance. That may be a different requirement altogether. So, again, we have to take things into account from an application point of view.

Regarding external harnesses, I agree with

Heather. We are talking the heat stress issue, never wear them on top, always inside. So that's fine by me.

MR. SZALAJDA: Thank you, Gary.

MR. PERROTTE: There is one question from LiveMeeting.

There is one question from LiveMeeting from JSJ and Associates, Jim Johnson.

MR. SZALAJDA: Go ahead, Jim.

MR. JOHNSON: Hello.

MR. SZALAJDA: You're on, Jim.

MR. JOHNSON: Oh, thank you.

After listening to this discussion, it seems to me that there are so many questions and so many different applications for a suit, either a chemical protective suit, a physical protective suit, and components of the suit, that I was looking at this standard to deal with the respiratory protection provided to the wearer of the suit, possibility the cooling effect provided by the air that comes through the suit, and any of the obvious hazards that we have talked about just recently, there is a flammability, presenting a minimum flammability for a suit to pass. And unless the demand or the market puts the other standards together that match what the suit finally comes to be, when you think about putting gloves, boots, various materials on it, exhalation valve, the type of lens, looking at a respirator inside; do you need a harness, safety harness?

I mean, it becomes a phenomenally complicated topic. And my thought is respiratory protection is where we ought to start.

MR. SZALAJDA: Thank you, Jim. I think that's kind of what we are trying to get our arms around when you can look at the generation of the standard with regard to the performance.

And I think I had said this morning, first and foremost, it's a respirator. And I think regardless of how the standard evolves, you know, right now if we were to get a submittal, we would evaluate it, and we would evaluate it as a respirator.

I think the intent of what we are trying to do is to fill the gaps with the development of this standard and looking, you know, leaning on other existing national and international standards to look at physical properties and other properties of the -- you know, that may lean towards the dermal protection.

But I think it sort of falls within our purview when you look at the aspects of the standard that, you know, we reserve the right to look at other parameters if we feel it's going to have an impact on the performance of the respirator.

And I think that's when we start talking a about physical properties as well as flammability and some of these other issues, that you are blurring the line in between the respirator and the ensemble.

Because of the fact that, you know, at the end of the day, you know, we may guarantee a certain level of protection. But the performance, the other factors associated with the respirator, the physical parameters, the flammability, the other topics that may impact on how well the ensemble actually performs as a respirator.

So I think that's kind of where we walk the line in looking at the development of the standard. Yeah, what's appropriate to include and what's not.

I think at this point, given the nature of where we are in the development cycle of the standard, nothing is really off limits.

So at this point, we need to go through and vet all of the potential issues. And then at the end of the day, in another 18 months or so, we will hopefully come to some sort of position that people will be able to understand and is backed by, you know, have a good scientific basis for why we are doing what we are doing.

And with that, the last topic for discussion is the physical properties that I had mentioned. There are two slides associated that.

Some of these topics are indicated or covered or have tried to have been addressed by other standards, the ASTM standards as well as international standards.

The second slide, I think when you get into the discussion, is how do we apply -- and I think this is a good follow-on to Jim's comment -- is the follow-on is how these properties should be classification or use-specific.

I mean, where do we draw the line in terms of defining these types of properties with regard to the performance of the respirator?

With that, I would like to take comments.

Any comments from the panel first?

LiveMeeting?

No, okay. Any comments?

MS. MILLER: Well, I guess I would just like to, again, let the manufacturers know that if you don't want to get up and speak to the performance levels of the ensembles today, that we certainly do welcome your comments on the docket or, you know, you are always free to call. I think you know that.

This is the informal part of the process, and that's the nice part about it, is we are allowed to talk at this point.

MR. SZALAJDA: At this point, are there any other comments or questions that you may have that haven't been addressed during the course of the discussion?

MR. CARDINALE: Mike Cardinale, NASA.

Something that I hadn't seen that's of interest to us, of course, is the use of internal air supplies as part of air-fed suits.

I hadn't seen it as part of the discussion, but it is an integral component to the type of suits used by NASA for ground operations for spacecraft fueling.

And I would hope that, you know, whatever approach you take to establishing this would allow us to include other types of air supplies than those are currently -- you know, that are usually available in the industry now.

MR. SZALAJDA: Thank you, Mike.

MR. CARDINALE: Sure.

MR. SZALAJDA: Are there any other comments at this time?

MS. NEWLAND: Michelle Newland from ILC

Dover.

I just wanted to make a brief comment that actually wasn't brought up in this meeting, but the meeting last year in December. Colleen brought up the point with the ASTM standard that the suit may have to be recertified each year.

And that's kind of a concern to me because it could be kind of cost driven if, you know, the customers know that this has to be resubmitted every year, that the cost of the suit might go up. And people -- customers might be not wanting it certified then if they know it is going to be cost driven. It has a direct effect.

MR. SZALAJDA: Thank you.

Any other comments at this time?

Okay. What I would like to do is we are about ten after 2. I would like to take about ten minutes, and we will get ready to do the Total Inward Leakage part of the presentations.

So we will reconvene at 2:20. Thank you.

(A recess was taken.)

MR. SZALAJDA: The last topic for today is

Total Inward Leakage for respirators other than Filtering Facepieces and Half-masks.

And we have three presentations that you will be hearing. One is Gary Walbert will be introducing the concept for the project with you today. And I think the other opportunity today, which I'm pretty excited about, is you are going to get an opportunity to hear about some pretty innovative research that is ongoing, not only at NPPTL, but also National Institute for Standards and Technology.

And Kathy Butler is going to be providing a presentation on a couple of research projects that they have ongoing related to ultimately improving respirator fit.

And the other project that I'm pretty excited about because somehow Bill King has linked me to it, is using ultrasound as a method for evaluating respirator fit.

And with this project, NIOSH has an initiative called Research 2 Practice and the ultrasound testing project is something that we would like to partner with someone in industry that may be interested in taking the concept that Bill is going to talk about this afternoon and possibly bringing it to fruition as a marketable device.

So from that standpoint, you know, after the meeting, if you would be inclined to either submit something to the docket or to contact me or Bill King to discuss about partnerships in terms of being able to develop -- this is part of the NIOSH Research 2 Practice initiative, I would appreciate hearing back from you.

And so with that, the docket, it's a new docket for this. It's Docket 168. And I would like to introduce Gary Walbert, who is going to be the project officer for bringing these concepts to fruition.

John, we seem to have a problem with the slide progressing.

MR. PERROTTE: Hang on.

MR. WALBERT: Okay, thank you, Jon.

As Jon indicated, I'm going to be cover the concept plan for the Total Inward Leakage program, and this is for respirators other than the filtering facepieces and half-masks.

The current project under the TIL program is the characterization of other classes of respirators that are associated with standards that presently in the rulemaking process or whose standards are currently being developed.

And that includes the closed-circuit SCBA and the PAPR, whose standards are currently in a rulemaking process, and the supplied-air respirators and the air-fed ensembles standards updates you heard from Jeff Palcic and Colleen miller.

Our approach is going to be determine benchmark testing variables and then set pass/fail requirements based on the results of the benchmark testing.

Our initial project under the TIL program was TIL characterization of the half-mask and filtering facepieces.

Lessons learned during these tests will provide valuable information for benchmark testing of other classes of respirators, and this is in the areas of test protocol development, test agent applicability, and test subject panel size selection.

Okay. We have identified what we feel are the sources of inward leakage, and these are listed here. Particles passing through filter media of particulate respirators, contaminants passing through respirator component connections that did not seal properly, and contaminates passing through the respirator-human interface when respirator internal pressure is negative.

And the bottom line is that the TIL test is intended to measure inward leakage from all sources combined.

Okay. We would like to present options for consideration for TIL benchmark testing. And the first area is in the selection of test subjects.

For tight-fitting facepiece assemblies, we propose to use the panel-based -- we proposed to use the NIOSH bivariate panel based on the 2003 NIOSH anthropometric survey. This panel is expected to cover greater than 97 percent of the US civilian workforce. This is in contrast to the LANL panel, which excludes 15.3 percent of the NIOSH survey subjects.

For loose-fitting assemblies containing hoods and helmets and tight-fitting neck-dam assemblies, we propose to develop test panels based on the 2003 NIOSH anthropometric database containing head and neck circumference measurements.

We also propose that the test panel size be specified through statistical analysis of benchmark test data. And this would be done by determining the number of tests that are sufficient to yield statistically reliable data, as was done for the half-mask and the filtering facepieces TIL project.

In area of the test configurations, the number of respirator configurations we need to be tested will be determined on a case-by-case basis at the discretion of NIOSH, and this is in terms of what accessories will be included when testing a respirator.

Considerations for respirator probe

specifications will include the probe type and probe location. It is likely that these specifications s will be respirator-class dependent.

A lot of information available only this subject and available probe technology will be reviewed and implemented based on what makes sense and through benchmark testing.

Okay. The draft ISO TIL standard is one such reference that includes TIL probing specifications that we have looked at so far.

Okay. In the area of test agent selection, we are proposing to use corn oil aerosol for all four respirator classes that are listed in this concept plan.

Corn oil aerosol is a currently recognized and accepted test agent. And with current technology, a TIL level of -- a minimum TIL level of .001 percent can be measured.

Other test agents salt aerosol, for which a minimum measurable TIL level of less than .0005 is possible using flame photometry.

Another test agent that we have considered is use of ambient particulates. However, a consideration for its use will be whether sufficient particle concentration exists. In addition, the minimum measurable TIL level for the ambient particulates were based on the maximum ambient particle concentration.

Also considering isoamyl acetate vapor. We are considering whether it can be quantitatively evaluated or used for particulates.

The use of dioctyl phthalate aerosol will require addressing its associate health effects. A minimum measurable TIL level of .001 percent is possible for dioctyl phthalate with current technology.

The final test agent that we were considering is a sulfur hexafluoride gas. The draft ISO TIL standard indicates that this gas is applicable to non-particulate filtering respirators containing materials that are porous to gases and vapors. Suitable detection systems for sulfur hexafluoride include IR absorption and electron capture detection. And we use the combination that can provide minimum measurable TIL levels less than .0005 percent.

There are a number of protocols that are currently available that could be modified for TIL testing. They include the LRPL corn oil test protocol, and the references for that are -- we find are the NIOSH LRPL STP and also the draft ISO TIL standard.

So the sodium chloride test protocol, and we find reference for that in the draft ISO TIL standard.

Sulfur hexafluoride test protocol. The draft ISO -- in reference for that is the draft ISO TIL and NFPA 1994 standards.

And in addition, the OSHA quantitive fit test protocol for the selection of test exercises and the industrial fit test isoamyl acetate vapor test protocol measured quantitatively.

Test protocol issues would include, under test performance, test performance requirements should be established through benchmark testing. Also test performance requirements would be determined for the respirator configuration submitted for approval.

Okay. Other protocol issues would include test exercises where we propose to follow the OSHA fit test exercises with some additional criteria added to ensure that exercise motions are performed more consistently by human test subjects.

Also, the OSHA fit test exercises represent typical movements where leakage could occur. Other exercises may be identified to add to this list, or one or more of these exercised may be eliminated depending on benchmark test results.

Respirator class-specific exercised may also be identified through benchmark testing.

Okay. This relationship, TIL is equal to 100 percent divided by the fit factor, which was presented previously for the half-mask and filtering facepieces TIL project.

Assuming that the measured fit factor approximates the protection factor, a TIL of .001 percent would be approximately equal to a protection factor of 100,000 on down to a TIL of 20 percent would be approximately a protection factor of 5.

It is anticipated that the pass/fail TIL values will approximate 100 percent over the fit factor where the fit factor is a minimum tenfold multiple of current OSHA assigned protection factors.

Pass/fail criteria will be based on benchmark performance test results, not on the current APF.

Benchmark testing will be also be performed to gauge state-of-the-art technology capabilities, including instrument sensitivities.

And finally, we feel that as the TIL project and development of the TIL module progresses, LRPL requirements will ultimately be replaced by the inward leakage requirements in the TIL program.

Any comments that aren't submitted here verbally can be submitted to our NIOSH docket office, and reference Docket 168.

Okay. These are question that will be considered for consideration during our panel discussion.

I'll read them off here.

Should a TIL pass/fail criteria be based on the type of respirator inlet covering, the intended use of the respirator, or other factors?

Are there any other test agents that can be used which will work for some or all types of respirators that are safe, environmentally friendly, and can be accurately measured at the desired concentration?

Is there test equipment available that can reliably measure the concentration of the test agents of choice that are not overly expensive to own, operate, or maintain?

Should NIOSH consider accepting TIL test results from independent laboratories. Should the standard set of exercises employed by the fit testing process be used for all TIL testing, or should it be different for various types, and why?

Do the options for available respirators dictate what exercises can be done?

And what will be the strategy for the

placement of sample ports for other classes of respirators? Where will the sample point terminate with respect to the test subject for each class of respirator.

That's all I have.

MS. BUTLER: Hello everybody. I'm Kathy Butler at NIST. I'm in the Fire Research Division there, so our main interest is with firefighters and the types of protection they need.

I'll be talking today about two of our projects, both of which are dealing with respirator modeling.

We also have two other projects that we are doing for the Department of Homeland Security. One of them has to do with respiratory hazards during the cleanup from a fire. And the other one has to do with what happens to the respirator materials when they are heated up, as with a firefighter going into a highly heated situation. And for that I will introduce Amy Mensch, who will be working on that.

Wave your hand, Amy. So if you have any

questions having to do with that project, please see her afterwards.

Okay. So the two projects that I have been working on for the Department of Homeland Security are characterizing the respirator fit for real faces and masks. And the second one is looking at respirator sensor placement for accurate readings inside of a respirator.

My standard introductory slide, all of you know this. We need respirators to protect us against many hazards. For firefighters, we don't have any idea of what kind of threat they are going into, so we really need to provide adequate protection for any threat, a wide range of situations. We need to account for high stress situations, high exercise, and possibly long duration, short duration being fire suppression.

And we have issues with imperfect fit, with leaks, with what's happening while people are talking, while people are coughing. These are some of the things that we hope to address with this project.

So the question that comes up is an annual fit test good enough, what kinds of variations do you see over time, what are the consequences of an imperfect fit? And then do leaks happen and under what conditions? Is a sensor for real-time monitoring a good idea? Do we have the technologies availability to us now, and where would you put that inside of a mask so that you could actually read something that's of value to the person who wants to be monitored?

So I have taken to approach that -- using a computational model to supplement the work that's been done by NIOSH, very good experimental work. But there are some things that a computational model can do for you, which is that you can visualize the results throughout the mask and not just at a location of a sensor, looking at velocity, pressure, particle traces, gas concentrations. And you can set up problems that test a variety of conditions and look at what if this and that.

The first thing that you need to do, as I found out, is actually the most time consuming task, which is to define the complex geometry. So the first thing I started with was my own head.

NIOSH was kind enough to let us use their 3D scanner. And this results in a point cloud that you then bring into a program that allows you to come up with a surface for that and close that surface, all of the holes.

And for projects that I have been doing, I wanted to have my mouth open, so I was breathing through my mouth. So I manipulated this model to do that.

Actually, what we plan to do with our project is to take various scans of people with their mouths open, with their mouths closed, in various states of various expressions.

For mask geometry, we can use a 3D scanner. We can also use mechanical drawings, which I have done. Both of those take a good deal of time to close up. The geometry is pretty complex and there are a lot of points that -- well, you come to a point within the geometry, so it's a little bit tough to get those right. And I'm grateful to

Draeger for providing us with a set of CAD files so that I can have a good set of accurate measurements for a mask to use in this experiment.

One of the things that -- one of the obvious things that I found out early in the testing is that if you take this rigid face and you combine it with a rigid mask and you put them together, well, you have problems with the mask hitting the cheeks and cutting through them. And at the same time, the forehead and the chin do not quite touch the head. And, you know, if you take a mask and you try to push it on, of course that's the way it's going to work.

So part of this testing also will supply us with a respirator being fit over a person and, therefore, having the correct geometry for that.

So the first question that we are addressing with these two projects is how to characterize fit and discomfort for a given individual and a given respirator.

And after I had thought of this technique, I found out I wasn't the first person. There was a study that was done for Aberdeen in 1997 in which these people, Piccione and Moyer, also did this project with putting a seal and fitting it over a face.

So the idea is that you take a respirator geometry, you put material properties to it. You are dealing with a seal. You don't need to deal with the solid parts. And then you deal with a face, with the actual material properties of skin over bone.

Once you look at the contact pressures of the contact region in between the two, you find regions that are of a lower pressure where you might expect there to be leaks appearing first in the mask, and there are also regions where you would have a high pressure.

And you might expect those to be regions where you would end up with a red mark if you really tightened it down to make sure that you were well protected.

So some of the questions that we can deal with with this is how good is a rigid 3D scan for predicting fit?

If manufacturers are using headforms to look at respirator fit, how good are those when you consider that these are rigid bodies as compared to you have got a face with a cheek thickness, very different from forehead thickness, very different from opening your mouth wide and having your cheeks.

So these are the kinds of questions that I would like to deal with. And perhaps a bit farther down the road a question would be can you customize the seal for an individual?

Could you go into somebody's office, as you do now with the dentist, and come up with a seal that's customized for your own face.

So the project is called characterizing respirator fit for real faces and masks. And the issue is for emergency responders, they work very hard, and they can overbreathe the respirator.

You know, we are not certain how much loss of protection there is from that, but that's one thing that we would like to contribute to.

And the other thing is that if the

respiratory equipment is not comfortable, then it's already been shown that if a first responder is convinced that they can't do their job while wearing it, they will take them off. And so discomfort is an important thing as well.

So the purpose of this project is to enhance respirator fit and sizing procedures by improving our knowledge of the relationship between the human and the respirator features and the respirator effectiveness. So, yeah, I already described the approach.

So here are the steps that are involved in this.

I have already prepared some three-dimensional representations. We have got three human heads. We have got a set of respirator masks.

And then starting with a rigid head and a single piece of the seal, push it on, do a contact problem and find an element analysis. And plot the stresses on the surface, find those locations where you might expect leaks and fit comfort.

And then to complicate it a little bit more, put skin, represent a thickness of skin over the face. And finally I would like to move to medical scans and actually do some real situations with actual face properties.

Second thing, well, also we want to animate the face or at least, you know, have different representations of somebody yawning, somebody coughing, somebody speaking, then assess the sensitivity to how the mask is positioned to design factors and find out what is the ability of a fixed head scan to fully represent the fit of a respirator in comparison with the actual material properties.

So here is a set of what we have now in our little library. The respirator seal geometry. I have started out on the left of this with the full geometry. What I would like to end up doing is a full seal geometry so that you have rigid edges that are represented by the contact with the visor and fixed properties of the -- of the facepiece.

What you start out with is a simple

geometry is just taking a single seal on this multiple seal unit, and then take this and push it onto a face. And I have to admit, I chose unwisely.

I have had a couple of finite element programs that I have tried. Both of them said they could do contact problems. Neither of them could actually do it, and I'm now moving to ellstina (phonetic), which is something that -- Ziquing Zhuang also has a person working on this from Texas Tech University work is working on a half-mask project. And they have had success with ellastina. So at the moment, I'm learning how to use it. And I expect at the next one of these meetings, I will have some very interesting work.

In the meantime, let me show you what Jingzhou Yang -- is that correct? -- has been doing with Ziquing to do this same type of problem, starting out with the geometry of a half facepiece mask, applying forces to each strap and pushing that onto the head and looking at the pressures.

On the respirator first, this is with two and a half newtons for each strap, and then the pressures on the face. And you can see that there are different properties there.

You have to push it on hard enough, of course, to have a contact all around this area.

And here is a test where they did five newtons for each strap. So one of the things that you need to understand is how much pressure it takes to actually fit this thing so that all of the conditions are met so that you have a good fit.

So that's the first project that I'm working on.

The second one is what kind of possibilities do we have now for looking at real-time respirator monitoring. And the question that I will look at numerically is where are the best positions for placing a sensor to look at flow pressure or gas? How is that flow affected by a leak? And what kind of breathing resistance? There are other kinds of questions that I can do once I know the flow field.

So there were a couple of things that I thought of initially with this problem. One of them is if you could provide the immediate warning of a leak, and something that goes on for more than -- for more than a very short period of time. Say somebody hits their head against the wall and it doesn't quite adjust properly for them, and they are continuing to have some problems with this respirator. Then you could say that that worker needs to be removed or needs to be adjusted somehow.

And you need to have that sensor placed in a region that actually sees the flow, actually sees what's going on within the mask over time, but won't be disturbed while you are putting the respirator on, while you are taking it off.

And the other thing that we want to know is what is the need for this kind of work? So we have looked at that question as well.

So the purpose is to evaluate the need and what are the potential technologies for real-time monitoring of emergency responder respiratory intake and what kind of criteria and recommendations for placement of sensors in respirator masks can we make?

So with this problem, we started out this year. On May 1, we conducted a workshop to discuss the need and potential solutions for real-time monitoring, and the report on that should be coming out within the next few weeks for -- at least for review by the people who have been there. And it will come out in the next couple of months for the general public.

And then as far as the computations go, well, first of all we have to represent the three-dimensional geometries of the masks and the faces, and I intend to use the results of the first problem where I'm pushing masks onto the face to give me an initial geometry for looking at these flows and then take a look, what is the flow field, what is the pressure field? What happens when you have low and high work rates?

And, you know, perhaps you could take it on further to say, what if I -- well, I'm looking at concentrations of various gases within. I can also represent those in a finite element model, and I also do a thermal problem to look at temperatures of breathing, of gases coming in, and what their effect is on the properties of -- well, on what the user is breathing.

We also intend to have some experiments to validate this and to determine some criteria and potential locations to make recommendations for.

So our workshop consisted of firefighters, researchers, academia, and government manufacturers, representatives from the NFPA Standards Committee. And we looked at the question, What is the need?

And, well, we found out that there were more than one potential use. You can use some information from a sensor mounted within the mask to ask not only is there a leak, but also to collect data from somebody in the field rather than -- rather than in a laboratory while they are doing actual work to monitor the physiological capability of the person and to ask the question -- mounting a sensor also on the outside, one could ask can the respirator be removed at this point. Is it a safe environment?

So there were a number of possible

approaches that were discussed, mount the sensor inside and outside. Should there be multiple measurements of various kinds of gases, of pressure, and how should it be mounted that were addressed in this workshop.

We also looked at some sensor technologies. We had about five different groups come in and present what technologies they have now to measure gas and particulates and pressure.

The sensors, of course, are getting smaller, so this becomes a real possibility.

And then looking at some of the challenges that we must meet with this, which are, first of all, confounding factors, temperature and humidity being important there. And having an unknown environment is certainly an issue.

And of course, any time you are thinking of introducing anything to first responders, you need to consider that you need to gain their trust in the equipment.

And we did find that there was a firefighter community that very much likes to try out new things. So we have people that would be a possible stable of people to do some testing for us.

I will show this from a half-facepiece mask. I'm working on the full-facepiece mask.

But here's an example for what can be done, put the mask on the face. You have got enclose the surface so that you have a single space within. And then in this case, I have the air coming in through the filters on the side during inhalation, going out through the center valve during exhalation. I made some assumptions about the breathing rate. And I had a very simple sinusoidal breathing rate, and I think I will make that a little more proper the next time I run this model.

Refine the mesh, and this is what we found with the gas flow. During exhalation, what happened with this particular mask is that breathing out, the gases smack against the back wall and then kind of spread out over the mask. And, you know, some of the gases go directly down.

But you have got a high pressure region

that is right across from where you are breathing. There is a lot going on in the space during exhalation as compared to inhalation, where you have got a pretty direct flow between the side valves and the mouth.

We will see. No. I think you can see. Yeah. I can animate it. It all depends on the laptop that I'm using whether it looks really pretty or not.

I can then take a look at what happens under different breathing and workload conditions. I can look at various sizes, various placements of leaks.

And that's all I have. So I thank you very much for your time.

MR. KING: Hi. I'm Bill King. I'm in the Policy and Standards Group with Jon and the others that are here today. And what I would like to talk about is ultrasound respirators, our concepts and initial results.

I guess I have got this -- hold on here. I have got to learn something. How do you do this, page down, next. There we go.

Yeah, an overview of what I'm talking about. Ultrasound and its uses, primarily associated with leak detection. We are looking at a couple of ways ultrasound is used, and then, again, kind of redundant.

This initial assessment of respirators, there's the preliminary results I have developed to support the concept.

Why do this? The objective here was -- going in long detail in an aside, but, you know, you can think of a lot of reasons why you might want to have a device, a nondestructive method of monitoring fit or leakage in situ. And what I mean by in situ is an actual respirator that is unprobed, you know, that is -- while you are wearing the darn thing, real-time during use. That is you get data out of this thing while you are wearing it.

And I think that would be -- I can think of several things. I won't elaborate, but leave that to your own thoughts.

I kind of stuck this in. It's about

ultrasound because that was the general concept. As I thought about ways of doing this, ultrasound came to my attention. And this kind of just was actually was written for a plan for a project proposal some time ago characterized ultrasound associated with leaks in respirators, correlated -- so I won't go over all of these details.

But anyway, what I'm going to look at is could we use ultrasound basically to detect leaks. I'm sorry. I'm jumping around. Is that driving you crazy or what? I'm going to stay a little closer here.

While I'm thinking, the results will provide a basis for determination of the most effective strategies for monitoring respirator fit using ultrasound. I will try to go back and cover that here. It's a little out of place in my view.

Anyway, ultrasound, what is it?

You all know -- you think about when you think about ultrasound is ultrasound images generated by ultrasonic used primarily for looking at internal structure in a body and stuff like that.

That's ultrasound.

And what it is is -- there's a little graph. I don't know if you see it here -- but it's basically cyclic pressure above -- here's the acoustic range, what we can hear, up to 20 kilohertz typically. And everything above that is considered ultrasound, basically, at a higher frequency than that. And so that's where we are at.

And, again, we have -- there's medical -- medical diagnostic, they run a couple of megahertz and the like -- we won't get into what.

Anyway, what I'm interested in here is airborne ultrasound, okay, distinctly different only that it's sound transmitted through the air as opposed to through aqueous media, what is basically what you and I are.

So what's that typically used for? Things like SONAR, tracking, positioning, its main use. And of course one of -- one of the people -- unless you are an engineer or something, you are not aware of leak detection, ultrasound use for leak detection, which, hey, why not?

So another salient feature is exposure to airborne ultrasound is not a big human health risk. And there is the TLVs for -- out of the ACGIH there. I notice they have TWAs for sound. Ultrasound, they don't have any, but their ceiling value is 110 dBA. So hopefully everything we do would be well below that.

And of course, it's inaudible. They say why not use sound. Well, you know, you can hear that stuff. You can't hear this.

So what we see here is ultrasonic range. I just want to -- how is it used for some of these things, and hopefully can I get this work.

You have a transceiver. That's a device that can send and hear ultrasound. And you send it out, a pulse -- hopefully it will work. Yeah, there's ultrasound going out. It hits an object, reflects back, radar; right, just like they do in electromagnetic stuff, except you are using ultrasound.

And over here I just have a plot of what you would see in time.

There's your -- we call it a pulse. You send out a pulse. It goes off and it bounces back, and you listen for it coming back. And this distance is a way, of course, is a function -- you know, it's two times the transit time divided by the speed of sound in that medium.

So you can tell how far away something is using this approach, and that's typically what it's used for. You know, things that open your -- automatic doors for you typically are ultrasound sensors, or the burglar alarms in people's homes, that's an ultrasound, looking for this kind of thing.

What we see on the next one.

For leak detection, now it's interesting, fluid flow, when you have a fluid flow through a leak where you get turbulent flow, the condition is such that you have turbulent flow associated with that fluid, that is the source of ultrasound.

So what you can do very conveniently is just simply look for the ultrasound. You can detect it. And that's what I just show here.

Typically you don't qualify and say if you don't have a leak -- your goal is if you detect ultrasound, you got a leak. Get rid of the leak, you don't have any ultrasound. And that's typically -- it works well, even in industrial environments because of, you know, the immunity to the sound is because you are way out of the frequency of sound, so it is kind of interesting.

Anyway, that's generally what's done.

However, in another approach here, leak detection, what if you don't have a flow, and what if your flow isn't generating ultrasound. Well, another thing you can do is just stick a generator in.

You stick a generator on one side of the container or area that you want to look for a leak in, and then you put your detector on the other side, and you look for the ultrasound coming through.

It is only transmitted -- again, this thing has got to be rigid enough. It doesn't allow for transmission through it, you know, like a drumhead or something like that. It only lets what's conducted through a leak path.

And so, again, the same situation, it's not -- typically not quantified. But that's the kind of stuff that you can do with ultrasound for leak detection.

Now, just a little bit on the technology again. This might be trite, but it's a low power and size. That is you can -- the technology is such that -- you know, you don't need very big devices. This is something you can buy in Radio Shack here. It's actually -- it sends and receives, and you stick it on the top of your little robot for, you know, when you have a chainsaw on so it will cut the other robot in half kind of thing. Well, you can tell where the other robot is by using that device right there.

Well, it has a logic in it right there. You have to run power to it and stuff like that.

There's a transducer right there. That's what they -- they are very small. Actually, the element itself is right inside there, but you need that housing, but they are very small.

And you can see that same thing down here in this thing. This is the device that I actually used in the work I will show you in a minute.

It looks like a gun because it's -- you know, you just aim it. Actually, the element is in the end of this thing, so you point your basically microphone at where you think the ultrasound is and listen for it.

And it shows up as a reading on the back there. There's a series of bar LEDs that tell you the dBA level to come out.

By the way, this is the source here. The same element is in here. You notice there's a little source there, so you can generate it. You know, it's got it's own battery in it and stuff like that. And there's the microphone -- or the earphones for hearing.

It heterodynes into the audible so you can hear it in a set of headphones.

The other things you can do with this -- well, and this unit here is a little pricey, like

800 bucks, 900 bucks, but you can get them for 50 bucks, you know, real simple devices.

Not that that's too big an issue, but I mean it's relatively low cost. It's not -- in fact, I should bring up some spectroscopic techniques, I think of photoacoustic spectroscopy. They pulse their light interrogation of objects in the ultrasound region so they can detect -- instead of using a sophisticated optical detector, you use a ultrasound microphone, or sonic, actually, so you can hear it with a microphone as opposed to, you know, a device for detecting light, which you can argue those are getting simpler and cheaper anymore, anyway.

But anyway, my point made.

Anyway, you can -- plus you can apply sound techniques. Everything you do -- this just shows the front end of some software where they have the power spectrum for some -- actually, those are chirps from a bat because bats use ultrasound, and they are interested -- a lot of people are interested in studying the nature of them. But the point is you can record this data and look at it and look at the spectral properties, you know, power, spectrum, things like that.

So all of the elements are there for what? Looking at it in respirators.

So then we have to ask ourselves some questions, ultrasound source -- and this is really back to that original plan slide, there. Ultrasound sources, do leaks give off ultrasound? How about respiration? That's fluid flow, and are there other sources of ultrasound we would have to deal either as noise or things like that?

And then if you can get ultrasound information, can you relate, for instance, the amplitude. The easiest thing you do, and that's what you typically measure here with this is the simplest thing to do, you know, what's the dBA level of the sound coming through.

Can you relate that to fit factor?

And some related things, how about temporal? And that's one I'm interested. Can you follow that change over the course of time and, you know, and how fast can you respond to changes in the fit factor associated with wearing this device, wearing a respiratory device. And also could you do a spatial -- this -- can you see -- can you divine out where it is leaking?

And of course, then using the spectral techniques, then, can you -- I won't get into that. Using -- instead of just a relatively simple approach, like we are doing now, could you maybe go to a more sophisticated analysis of behavior of different wavelengths and kind of get that information above in different ways.

So those are kind of the things that I wanted to assess for this.

First thing, source assessment, back to that point, it has to be -- in order to generate ultrasound, you have to have turbulent flow, so what do you get? You have to look at the Reynolds number you might be aware of.

Reynolds number is a way of -- associated with the nature of flow in a system -- I just have the variables here. I won't go into it. But anyway, it depends on the -- like the characteristic diameter is flowing through the velocity and kinematic viscosity, or the dynamic fluid viscosity, I should say.

So I just had these up here so you can look at it and tell me I calculated it wrong, if you care to. Whatever. But we will recalculate it if you want.

But anyway, what's -- you want to be do -- calculate the Reynolds number because there's this issue of critical Reynolds number. That's kind of the region -- that's the -- well, if it's below that, you don't have turbulent flow. If it's above it, you will have turbulent flow, or you tend to -- a higher level of turbulent flow as you are above the Reynolds number for this, and this is a flow through -- so the range for that, that is the boundary, is between 10 to the 3, 10 to the 4.

So what I did here next is took a look at -- oop, there it is.

Here's the numbers I plugged in if you want to go through those. But -- well, you have had time to do it, but basically, it's over here. I looked at three things. The leak -- a normal leak of -- detection factor of a hundred at a relatively low breathing rate, 20 liters a minute -- I used the average value, so it's at the root mean square of it, so -- and calculated the Reynolds number under these different conditions.

I looked at a leak. I looked at a nostril, breathing through your nose and breathing through your mouth. And what's really important here is the Reynolds number, of course.

Notice the Reynolds number for leak and mouth are really low, 10 to the 2, 10 to the 1.

The only thing that goes above our criteria or our boundary, 10 to 3, 10 to 4, is breathing through your nose.

So there we have a source of ultrasound is in breathing through your nostril. Now, that could be a problem because it could be an interference or whatever. So the fact -- well, let me show you. I don't know if this will work or not. I doubt it. I can't get my -- oh, here.

I put some wave files on here -- now, well, I should say, yeah, I mentioned earlier that recording with this device, what you get is -- this thing has a heterodyning circuit on it, so it shifts the ultrasound frequency down into the audible so that you can hear it through the headphones. So that's what I have got recorded here.

So you breathe through your nose -- well, let's hear breathe through your mouth first. Well, it doesn't work. Forget it. Well, it sounds like this.

Okay? You don't hear anything.

So it confirms what I calculated -- my prediction there.

Nasal, though, you do hear. And you hear this (sniffing sound). You hear -- well, you hear -- you can definitely tell somebody is breathing through their nose. In fact, you can't hear it audible, but you can hear this distinct, 20, 30 dB -- well, it's high for the exhale, about 30 dB, and it's about half to a quarter of that for inhalation. But you have a distinct ultrasound generated associated with nasal breathing.

So -- well, okay. So much for that.

Another question was -- and I didn't put it as a point -- but what about this issue of amplitude versus leakage for detected ultrasound.

So I did a little experiment here. There's a diagram for us, take another slide. Put the -- again, it was what I had before, and that would have the generator sound on it if I could play it.

But, anyway, it's squeaking away, and I have a receiver over here. And I put different hole -- I just got a set of drill bits, actually two. That's why I have two types of points, one small set and one big set. And I drilled different holes in my barrier and looked at the -- keeping all of that configuration the same.

And there's, again, you get a real good correlation with leak size. That is the ultrasound amplitude in decibels over here is proportional to the diameter of the leak.

So what do I have? I have a technique

that I can predict the -- I can have a good way of telling how big the hole is in a system.

So let's go to the next. Well, back to that point before I came to this one.

One of the problems I realized was -- because I wanted to do this in a mask, a respirator. That generator is too big to stick in a mask, and I didn't want to -- I don't think Jon would have appreciated me carving holes in a headform or anything like that, so I got the idea to say, Well, wait a minute. Let's measure the nose.

So that's what I did. I used the nose. I basically did the same experiment except I used the nose in place of the generator. And I repeated the experiment. I didn't have the diagram, but, you know, there's a those there.

And did the same thing, and I get the same thing. The only difference is I looked at the peak, you know, that -- because it's kind of sinusoidal, there's a lopsided sinusoidal profile there that you get -- or not -- it's humps, whatever that is.

Anyway you get a fairly linear response

with the inhalation, peak inhalation, peak exhalation ultrasound. Going through the leak, you get a fixed configuration.

So what do I have? Now I have a technique I could use in a respirator I think. So that's what I did next.

I took, again, nasal breathing as the ultrasound source in a single object. I just breathed through my mouth while I'm wearing respirators, measure the ultrasound level -- the point is, it could leak several places, so I chose five points around the perimeter of the mask, you know, left nose, right nose, left chin, right chin, and under the chin here.

And simultaneously, by using probed respirators, I measured the fit factor with a PortaCount. Okay. So this all happens over a single exercise period, one minute. I think they are one minute on those things; right?

Anyway, whatever it is, that's what I did.

And what I wanted to do, of course, is modulate the fit factor as much as I could. So each respirator, I did three times with -- you know, they all have the adjustable straps, so I did a very loose -- which it's -- it's not an approved configuration, appropriate, but it's very loose to get a very low fit factor, normal, and then very tight, trying to get some modulation in that, and at the same time measuring the ultrasound leakage.

Now, what I measured here -- actually, what's important here is this.

Here are the five points I did. Again, I measured the peak ultrasound again because what I'm doing is measuring through a mirror there. It's tricky to read the back of the meter, so I'm pointing this thing around. So it's a little tricky.

But, anyway, what I did here was each of the five measurements, both at the peak of the inhale and peak of the exhale. And I also looked at background.

And then I correct these values if there's any background -- for any background. And that's what I record. As well as the fit factor I measured from the PortaCount.

And then to -- well, I looked at this. I said, Well, how am I going to come up with one value I can plot. Well, I did a very crude thing. I just averaged these all together.

And so I plotted all of the values I did for these several variations of each respirator. I think I had five or -- you will even count them here in a minute -- and plotted them versus fit factor, and this is what I got.

Notice that what we see is -- here's peak dB. That is the ultrasound -- again, the average of the ultrasound inhalation and exhalation for all of those points for each respirator. Each point is an average value for one respirator, versus the fit factor I read from the PortaCount.

And it stands out here that it -- if you have a very high ultrasound leakage, the average leakage level, that corresponds to a very low fit factor, and vice versa.

And it's is fairly linear. I get fairly good correlation with that.

So I have first technique I think of anybody -- and I challenge anybody, does anybody have a technique that has correlated, other than the fit factor, with the fit factor, that can tell you the average leakage, and I would say likely not.

So I'm kind of proud of that.

UNIDENTIFIED PERSON: Negative pressure.

MR. KING: Say what?

UNIDENTIFIED PERSON: Negative pressure.

MR. KING: Oh, yes, I take that back.

Willeke's work, he patented that about 15, 20 years ago, but he is not standing there breathing normally. He has to stop and draw it negative and then follow the decay of the leak.

So, yeah, I agree it does correlate with leak. However, could Willeke do that with a FFR was my next question? And the answer would be no.

And so I repeated this with about 13 FFRs. I did it a little differently. I did six points around here, and here's what I got.

That is, I get -- essentially -- well, the slope's a little bit different, and I think there's reasons for that. Go into more detail here, too. I looked at a little more degraded. Now you are on the edge of being settled, but I think that's reasonable for a relatively simple experiment. It wasn't very highly controlled because I didn't control the distance and everything and the points around this thing.

But what I get is the intimation that I -- the concept itself, with some refinement, I could predict the fit factor in a nondestructive way without a probe, and I like the thought of that.

So here we go, what did I find?

Well, the summary, face seals, I don't think there's any nascent ultrasound associated with that from my predictions. I haven't been able to do the experiments because, again, the interference of my nasal breathing, what will have to be done is we will have to do some flow experiments on masks, you know, either with an arbitrary flow or remove the ultrasound in some way, mouth breathing probably the way to go. But I haven't done that yet -- to see if there is some nascent ultrasound that I could use.

I suspect it won't happen until you get to very high -- much higher flow rates.

Respiration is a significant source. There are others. The interesting thing, you have friction. By the way, that's what it's used for, you can detect bearing wear and electrical discharge with these the devices, but you can also detect the sound of an FFR sliding around on your face, which I thought was interesting. I thought that might have some potential as well.

And electrical discharge. Actually, the ones I recorded for you, there's a high pitched ring in it, and that's actually my phone in my office giving off all of this ultrasound, the high pitched ring.

Anyway, assessment of the information, what I conclude here so far is there is a definite correlation with fit factor. That is I can -- I think ultimately I could get a very good -- much better correlation even than what I get there with FFRs. I think it's pretty clear in half mask.

Temporal, I didn't do anything to really, you know, do an experiment, but in working with it, it looks like it would follow it over the course of seconds, the changes in it.

Spatial, likewise. Although if you go back and look at that data, you can see there are high leaks. I didn't correlate it with looking at the leak around the perimeter as well. That's what would have to be done, but I think I can correlate that, again, as indicated over the correct configuration.

And I haven't done anything on spectral stuff yet, either, so that's yet to be done.

Anyway, what I plan to do with this yet in the immediate future is to -- what I'm limited by and things we have discussed is that probably you need a good controlled source on the inside. So I want to develop a small enough source and some transceivers that I can put together some prototypes and put them in and on and around the mask and repeat this kind of stuff and improve my data acquisition, do it on computer so I can just get it easier and do more sophisticated data analysis of this.

And then I will evaluate these other strategies and configurations. There's about -- to even -- just using the approach I'm talking about here, there's about six configurations that are possible. So one of them is probably the best, but I don't know what it is right now.

So that's it, I believe.

MR. SZALAJDA: With that, I would like to move into the last stage of the TIL discussion, which is the panel discussion. Who am I missing? Oh, Bill. That's okay.

I think what I would like to do is -- these questions that Gary indicated in the slides were provided as part of the concept plan, and hopefully you have had an opportunity to check or read those before the meeting.

And I think I would like to take at least these three in the next slide in total, at least with regard to some of the considerations with regard to the pass/fail agents, the development of -- or identification of the test agents that would be used in evaluating inward leakage, and then the equipment considerations to go along with that.

And one of the things that I did want to note from Gary's presentation was the consideration or at least the decision logic that goes behind where we are, where our current status is with the use of the corn oil chamber and those capabilities that we have established within NIOSH, that the initial approach is, until we do our due diligence on looking at other potentials, will continue to evolve the corn oil concept. And you will see that reflected in standards. You will see that in the PAPR. You will see that in the supplied-air respirator. You will see that in the closed-circuit SCBA.

But we are going to do our due diligence in looking at other potentials, potential test methods that are commercially available.

I mean, obviously at this point, you know, we are looking at test setups and methodologies and protocols that already exist, you know, to go and try to establish a new criteria, new protocols are really beyond the capabilities of what we have right now.

So we are trying to work within the framework of existing technologies when we look at these types of protocols. So at least initially, until we do our due diligence in looking at the other types of evaluation techniques, our focus is going to be on the corn oil.

With that, I would like to -- John, do we have any LiveMeeting questions?

MR. PERROTTE: None.

MR. SZALAJDA: None? Okay. Any questions or comments regarding the criteria in this slide?

I can tell it is 3:30.

MS. FEINER: I just wanted -- Lynn Feiner, Honeywell.

I just wanted to comment on your first one, should TIL be based on the type of respirator or the intended use.

If they have my vote, it would be the type of inlet covering. There is just so many different uses and types of applications out there that I don't think we would be able to quantify them all.

MR. SZALAJDA: Okay, thank you.

MR. SAVARIN: Mike Savarin, Sperian.

I think in a perfect world, what the TIL should be bringing to us is the ability to characterize the system, period. On the basis of that ability, we should be able to determine configurations which are then used, no matter what those configurations are, whether they are comprised of the loose-fitting, as we call them now, neck, hands, whatever they are. It shouldn't matter anymore.

The number that we get from that test should be able to do this. But I do side with Lynn here in that the complexity with going the applications route means we may never get a standard out of this. So sometimes we are maybe forced to consider expedient methods to get something out of there rather than ideal.

MR. SZALAJDA: Okay. Thank you, Mike.

Any other comments?

And then the remainder of the questions

are related to focusing on third-party evaluations, the exercises that are used for consideration, and the placement of the ports for sampling.

Any insights that you may have or that you would like to share with us on these topics?

MR. SAVARIN: If I could say something about the first one.

MR. SZALAJDA: Mike, the mic is not on.

MR. SAVARIN: Usually I don't need one.

Should NIOSH accept TIL results from independent laboratories.

I don't think there is any problem with this as long as certain criteria are met, that that independent laboratory is qualified, approved. Typically the A2LA type process, which looks at lab accreditation, can make an adjudication as to whether that lab is capable with doing the test prescribed and doing that in conjunction with being an ISO 17025 type organization, shouldn't really prevent that lab being able to fulfill those requirements in conjunction with the NIOSH test protocols in my opinion.

So I don't think there's a problem with accepting TIL results from independent labs that meet that kind of criteria.

The same would go for the exercises. You know, we say a standard set of exercises because, you know, we have done it in the past.

There isn't any reason why we shouldn't have different exercise regimes that relate to different performance criteria.

In all of the things we have heard today seem to indicate that the performance criteria are so different for different configurations that maybe what we have learned from the different exercise regimes that have been modified these last five or ten years, we can put those together and have those as classifications or groupings so that we can have a set of standard exercises rather than one where we scratch all day and modify it.

You know, some of these exercises require quite some contortion, lying prone, excessive bending, and others are quite sedentary, and there is no reason why they should be adjudged the same.

So maybe we should have a standard set of exercises rather than just one set.

I think that's it from me for now. Thanks.

MR. SZALAJDA: Thank you, Mike.

MR. GREEN: Larry Green, Syntech International.

And on the types of exercises and things, I know the others, if you tried to do a standard set, that you would get a lot of different applications and things like that. As we are doing these, we typically try to be creative on our exercises and try to find out what actually makes the respirators fail. It doesn't matter if it -- if somebody is doing a standard it works fine, but the actual users never -- he's not going to do those type of things.

And if you try to provide information to them, then you try to do some things that are extreme, possibly, and maybe 99 percent of the people aren't going to ever do those.

But if somebody does have those types of things that they experience them, you know, there's -- you know, if you can give them that information, it's good for them.

You get -- if you are doing standard exercises, you don't do things. We do jumping jacks with a loose-fitting hood, and it's pretty tough to get a loose-fitting hood to pass on jumping jacks because you drive -- as you go up and down, you drive the air up under it. You generate high respiratory rates, push the system into a negative pressure and things like as your respiratory goes up, and you challenge the systems.

And I think it's good to, as we are looking at these, to say, Well, in a standard situation, this is fine. But what happens if you do try to challenge the systems.

MR. SZALAJDA: Thank you, Larry. That's a good point.

I think kind of -- you know, in looking at it from the perspective of ultimately defining criteria that could be used for certification, I think part of the focus that -- of what the standard is going to need look at is, you know, coming up with things that are repeatable, you know, at least with regard to the criteria: Is this something that we have confidence in, that we are going to get repeatable results. But that's not to say that there aren't other things that should be considered in terms of exercises that could be considered.

So in this type of area, I'm going to encourage people that have an interest to submit comments to the docket, at least as far as other things to consider that normally aren't or may not be part of the protocols that are in place today.

Any other comments?

Okay. I think with that, again, anything that you would like to formally submit goes to the docket office, Docket No. 168. And so with that, I think we are ready for the wrapup.

There is a survey that I would like Charlene and Dawn to pass out for the non-NIOSH -- or at least the non-NPPTL participants to fill out and submit.

You can either -- once you have completed it, there's a box out on the table outside the door. You can drop them in the box or you can pass them towards the center aisle, and we will go through the aisle at the end of the meeting and collect them there. It's your choice for what you would like to do.

And, again, I will give everyone a couple of minutes to fill it out, but we would be particularly interested in hearing back from you, you know, with regard to the format that we tried today, any areas for improvement.

I think one of the things that we will try to continue going forward that I think was beneficial for the participants was to get the presentations up on the website ahead of time. And hopefully that, you know, helped with your preparation for the meeting.

Since they are brief, and I figured you guys -- everybody is good at multitasking these days, I would like go ahead and at least run through my concluding slides.

First I would like to thank all of you for attending. You know, we value getting your input. You know, not necessarily that we accept everything you say, but when you go through -- that doesn't sound quite right, so let me rephrase that.

But it's part of -- when you look at the standards development process, it is an iterative process. And the challenge to us comes when you have to look at the balance from things -- and someone has told me, you have to look at the balance in things.

And when you define the performance requirements, it's a combination of looking at the determining the right balance and what goes into the criteria that ultimately is going to be used for certifying respiratory protective devices.

And from that extent, everything -- we seriously consider everything that is said to us, you know. And at the end of the day, we have to a make a decision, you know, which way to proceed.

And sometimes, you know, like life, you can't satisfy everybody, but we end up making a choice to determine a requirement that we feel is appropriate for addressing a particular need.

So, you know, if you think that we are ignoring your comments or not considering them, please don't -- try not to feel that way.

If there is things that you really feel strongly about, you know, come and talk to us. We are very agreeable to meet with you or come and visit you or have additional discussions with you on issues that you may feel passionate about.

And one thing that I have learned in my career so far is when you get into personal protective technologies, anybody that's involved in this field is really passionate. So from that standpoint, don't be Afraid to pick up the phone and call us, send us an email. You know, continue the dialogue that we started today with regard to the program.

I also would like to thank the NPPTL presenters and panelists. I think they did a find job in preparing this, and they were under the gun from me to get things done in time that we were able to get them up on the website in advance to allow you time for review prior to the meeting, and I appreciate their efforts in the support of the meeting.

And I would also like to thank Heather and Kathy for providing some very pertinent information relative to how they see things outside of the NIOSH world. And I think, you know, the information, getting information like that from stakeholders I think shows a couple of things.

One, that personal protective technology isn't limited to NPPTL. It's NIOSH. It's NIST. It's DOE. It's NASA. It's manufacturers. It's users. It's a collective effort to make the standard as best as we possibly can.

The other thing that I think these types of discussions add to is it improves our overall knowledge base.

And I think for those who have been involved with this effort over the past several years, I think there has been a lot of efforts that have gone on that we capture in these types of forums, and that only improves how we do business going forward.

I'm very excited about the efforts that we have ongoing, and I think, you know, as we move through, you know, these initial stages of promulgating or codifying rules for quality assurance for the closed-circuit escape respirator, for Total Inward Leakage, it's only adding to our knowledge base.

And the things that we have learned together going forward in the process are only going to make our jobs easier as we go forward.

So with that, what I wanted to do was to give everyone a last chance. You know, because of the time frame and trying to get things done within the schedule, there wasn't a lot of opportunity at the end, excuse me, at the end of each of the sessions for comments. And I know Dave Spelce -- see, that's the great thing about having Blackberries now because you get instantaneous feedback. And Dave Spelce, who was on LiveMeeting, had sent me a couple of comments, and I didn't know if he wanted to bring up one right now on the supplied-air respirators if he is still on the line.

MR. PERROTTE: If you give me a moment, I have just got to get his -- I have got to get his phone number there.

MR. SZALAJDA: While John is doing that, does anyone in the audience have any additional points that they would like to raise regarding the supplied-air respirators?

MS. FARGO: Can I ask an unrelated question?

MR. SZALAJDA: Sure.

MS. FARGO: With regard to the TIL --

MR. SZALAJDA: I'm sorry. Can you introduce who you are?

MS. FARGO: I'm sorry. Christine Fargo with the ISEA.

Can you give us a brief update or a timeframe as to what the TIL for the filtering facepiece process is looking like?

MR. SZALAJDA: Yes.

MS. FARGO: Would you?

MR. SZALAJDA: Yeah. I don't know if the

lawyers have left the room or not. No, it's okay.

Actually, we are in agency review. We have had meetings within our review process, and I probably expect that you will see something within the next couple of months that will be posted on web.

We will go through the similar type process that was done with the CCER and the QA module, having an opportunity for public comment.

MR. PERROTTE: Okay, I'm ready now.

MR. SZALAJDA: All right. Dave, go ahead.

MR. SPELCE: Thank you, Jon. I didn't think you could hear me.

I wanted to address again markings. I don't believe NIOSH should require marking lenses to indicate that they are not impact resistant.

That's mainly because it might cause confusion with the manufacturers T87.1, such marking if it was put on there to indicate that the lenses do meet ANSI impact and optical requirements.

I think it would be better to label compliant or impact-resistant lenses than to label those that are not compliant. It is causing a problem right now because the (unintelligible) as they pass both the high impact and optical requirements under T87.1.

So during respirator selection right now, respirator users really have to end up calling the manufacturer if they want to make sure the lenses have high -- pass the high impact testing, they have to call the manufacturer to find out if a particular respirator they are interested in has passed that test or not.

MR. SZALAJDA: Okay, Dave.

Then I'll make sure I take the email that you sent to me, and we will provide that to the docket as well.

MR. SPELCE: Thanks, Jon.

MR. SZALAJDA: And I understand that you had an additional, moving on to the next subject with the air-fed ensembles, you had an additional comment regarding hoses.

MR. SPELCE: Oh, I was just going to ask if the supplied-air hoses also pass an agent permeation test. It was not on the slide.

MR. SZALAJDA: Oh, okay. I think just in short, when you look at the CBRN application, that we are going to be evaluating the hose as part of the evaluation with the Smartman testing.

I think the other aspect is when -- that we will be looking for feedback on is when you look at the hoses for chemical permeation, the gasoline, the kerosene, those types of things. I think we will be looking for impact -- or input from stakeholders with regard to what's the best test representative agents that we should consider in those areas.

MR. SPELCE: Thank you, Jon.

MR. SZALAJDA: Thank you, Dave.

Any comments regarding air-fed ensembles? We are almost done.

And the last is Total Inward Leakage. Any comments regarding the concept paper or the presentations that you heard today?

I would like to put another plug in regarding the ultrasound topic. And then Bill's presentation, again, was part of our Research 2 Practice initiative. We are looking to partner with someone to help bring this technology to fruition.

So if you are interested, please contact myself or Bill or submit something to the docket office, and we will consider it.

And the last slide. We finally made it, and thank you for bearing with us. The Personal Protective Technology Program is going to have a stakeholder meeting or March 2 and 3. It will be in this venue.

We are currently in the process of developing the agenda associated with the stakeholder meeting. But in light of current world events, it appears that the stakeholder meeting is going to focus on the service sector and also healthcare.

So keep -- if you're listed, or if you get our listserv messages, try to save the date and plan to attend. The meeting will be held at the hotel. It will probably be in one of the bigger rooms down the hall.

And so with that, thank you very much for your participation. We will look forward to seeing you at future NPPTL meetings.

(Whereupon, the public meeting was concluded at 3:50 p.m.)

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

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Joseph A. Inabnet
Court Reporter