

1 NATIONAL INSTITUTE FOR
2 OCCUPATIONAL SAFETY AND HEALTH
3 PERSONAL PROTECTIVE TECHNOLOGY PROGRAM
4 STAKEHOLDER MEETING

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10 Thursday, September 17, 2009
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19 Commencing at 9:00 a.m. at the Hyatt
20 Regency, Pittsburgh International Airport.
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1 MR. SZALAJDA: Good morning. Can everyone
2 take your seats, please, and we will go ahead and
3 get started.

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

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

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

22 I think if you preregistered for the

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

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

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

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

22 So kind of to put it in perspective, there

1 has been a lot of things that have happened since
2 then. As I'm sure all of you aware, we have a new
3 President, President Obama. We have a new Secretary
4 of Health and Human Services, Secretary Sebelius.
5 We have a new Director of CDC, Dr. Tom Frieden, and
6 we have a new, again, Director for NIOSH, who is
7 Dr. Howard. So there's been a lot of change.

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

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

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

1 for the Institute.

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

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

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

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

1 last week.

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

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

16 So H1N1, needless to say, is a topic that
17 consumes a lot of the time and a lot of the
18 resources in the laboratory, in the Institute, in
19 the agency, and in the department. And so much so
20 that I think the H1N1 status and activities and
21 government preparedness is part of the daily
22 briefings to President Obama. So it is a high

1 visibility and priority area.

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

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

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

19 The topics, the types of things that we
20 talk about may be the same, but it's a little
21 different approach for how we conduct those
22 conversations and try to facilitate good exchange

1 with you, our stakeholders.

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

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

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

22 Thank you.

1 MR. SZALAJDA: Thank you, Les.

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

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

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

20 You know, we have tried -- we have had lot
21 of PowerPoint types of discussions and then comments
22 immediately following the PowerPoints, which is just

1 fine for a couple of hours, but then you kind of
2 fall into a coma after seeing PowerPoint after
3 PowerPoint.

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

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

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

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

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

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

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

16 We also are connected with LiveMeeting
17 where people are connected remotely and being able
18 to participate in the discussions with the review of
19 the presentations as well as the opportunity to ask
20 questions. So I think with the format, what we will
21 do is when we begin the panel sessions, we will
22 defer to the LiveMeeting first and see if there are

1 any questions on the LiveMeeting, take those. And
2 then we will have the dialogue with those that are
3 involved -- are physically located here in the
4 auditorium.

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

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

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

21 I would also ask that when you -- during
22 the open comment period, when you come, there's

1 microphones in the aisleway, just to state your
2 name, your affiliation, and state your questions so
3 at least that way we have it captured for the record
4 and also if we do have need to have subsequent
5 dialogue on a particular topic or another.

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

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

15 And, again, I mentioned the agenda.

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

20 I have to laugh just as part of a personal
21 aside. You know, someone had mentioned to me the
22 other day, they said, Boy, it must be a great time

1 to be a federal employee. And I said, Why? And
2 they said, Well, with the changes in the
3 administration, they said, You guys can probably get
4 a lot of stuff down now.

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

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

20 And here we are, you know, 14 years later,
21 and the modular approach I think is finally starting
22 to take hold. And there's a variety of reasons for

1 that, you know, that the laboratory, NPPTL, was
2 established in 2001. There were inherent issues
3 associated with, you know, the development of the
4 infrastructure to go along with the laboratory, and
5 there was also the terrorist attacks, which took a
6 lot of our time and effort looking at the
7 development of the CBRN standards.

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

22 To that extent, we have got a lot of

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

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

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

21 And there's a lot -- there's a lot on the
22 plate, you know. And I think from the opportunities

1 that still exist are to learn from, you know, our
2 experiences in rulemaking with the things that we
3 have learned in the first three and take those
4 lessons and apply them to how we go forward.

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

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

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

1 to commenting on early on in 2010.

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

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

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

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

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

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

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

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

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

21 And with that, does anyone have any
22 general questions with regard to the content of the

1 meeting?

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

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

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

19 Jeff Palcic is our project officer for the
20 supplied-air respirators. And in terms of our
21 dialogue, he will be your point man going forward if
22 you have specific questions regarding the content of

1 the concept paper as well as any discussions that
2 you may like to schedule with him with regard to the
3 performance requirements.

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

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

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

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

1 air-fed ensemble.

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

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

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

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

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

18 UNIDENTIFIED PERSON: Speak up.

19 The volume in the back is very weak.

20 MR. PALCIC: The volume in the back is
21 very weak. Why don't we try a new mic? Is that any
22 better? Can you hear me? I see shaking heads,

1 hands, no, yes.

2 UNIDENTIFIED PERSON: Speak up.

3 MR. PALCIC: Speak up. Okay.

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

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

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

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

1 stakeholder input.

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

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

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

21 And finally, we will be evaluating,
22 acquiring, and securing test capabilities, which

1 will include the evaluation of current test
2 capabilities with regard to the new standard,
3 purchasing and installing new test equipment, and
4 conducting validation tests to the new performance
5 requirements.

6 Once again, a supplied-air standard will
7 remain Subpart J of 42 CFR. And the subpart will
8 contain optional requirements for both IDLH and CBRN
9 applications. And SAR will continue to meet the
10 requirements of Subparts A through G of 42 CFR Part
11 84.

12 We have established two types of
13 supplied-air respirators, airline and airtsource. An
14 airline-type respirator consists of an air supply
15 line, respiratory inlet covering, and a coupling for
16 connection to Grade D or better breathing gas. An
17 optional airtsource-type respirator consists of a
18 portable blower or air compressor, air supply line,
19 respiratory inlet covering certified as a complete
20 system.

21 Bill Hoffman will be presenting the
22 details specific to the airtsource systems in an

1 upcoming presentation.

2 Proposed technical updates for Subpart J
3 Base respiratory requirements.

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

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

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

18 Continuing with base respiratory
19 requirements, exhalation valve leakage. A dry
20 exhalation valve or valve seats will still be
21 subject to a suction of 25 millimeters, but leakage
22 between the valve and valve seat cannot exceed 15

1 milliliters per minute. The old limit was 15 (sic)
2 milliliters per minute.

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

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

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

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

22 These flow rates will be based on a

1 sinusoidal breathing profile.

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

7 As they stand today, the NIOSH proposed
8 air flow rates are a low rate with a 25 liter minute
9 volume, 1.3 liter tidal volume at 19.2 respirations
10 per minute, a moderate rate with a 40 liter a minute
11 volume, 1.67 liter tidal volume at 24 respirations a
12 minute, a high rate with a 57 liter minute volume,
13 1.95 liter tidal volume at 29.1 respirations per
14 minute.

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

19 Proposed technical upgrades for Subpart J
20 base nonrespiratory requirements.

21 Required components, airline systems
22 consist of a respiratory inlet covering, air supply

1 valve or orifice, air supply hose, detachable
2 couplings, flexible breathing tube and harness.

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

8 Continuing with base nonrespiratory
9 requirements, shoulder strap test was increased from
10 250 pounds to 300 pounds for 30 minutes. The belt
11 and rings were increased from 300 pounds to 500
12 pounds for 30 minutes, and the hose attachment to
13 harness remained at 250 pounds.

14 If the harness is designed to act as a
15 safety or rescue harness, it should meet ANSI
16 Z359.1, fall/arrest standard. In addition to the
17 ANSI standards, stakeholder feedback suggested NFPA
18 1983 standard on life safety rope for escape and
19 emergency service as an alternative.

20 And finally, the total length of hose for
21 approval in its heaviest configuration shall permit
22 dragging over the concrete floor without

1 compromising the harness or exerting force on the
2 respiratory inlet covering.

3 Once again, continuing with base
4 nonrespiratory requirements.

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

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

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

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

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

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

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

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

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

22 The system must automatically switch from

1 the supplied air to the air cylinder if the air
2 supply can no longer -- or if the air supply can no
3 longer supply breathing air. An alarm will notify
4 the user when the system is on cylinder air, and
5 these systems require a tight-fitting full
6 facepiece.

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

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

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

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

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

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

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

21 Our plans for benchmark testing include
22 live agent testing. The test setup will be similar

1 to that of the open-circuit Self-Contained Breathing
2 Apparatus.

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

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

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

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

19 Continuing with the benchmark test plans,
20 hose permeation testing. We will be developing a
21 new test apparatus that will allow for a more
22 controlled test and will depend on the finalization

1 of the challenge agents.

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

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

18 Projected timeline. We posted the
19 supplied-air respirator concept standard on the
20 NIOSH web in August. We will be using the comments
21 from this public meeting in the 083B docket to
22 revise the SAR concept standard in November. We

1 will also be using the comments we received to the
2 083A docket and the original 083 docket.

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

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

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

16 So I appreciate it.

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

19 MR. SZALAJDA: Yeah, go ahead.

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

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

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

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

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

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

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

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

12 Discussion slide or hose permeation tests.

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

20 We will talk about that.

21 And a discussion slide for the live agent
22 testing. Should we have two available levels of

1 protection is being considered for the PAPR
2 standard. Right now, we are doing our benchmark
3 testing to the open-circuit SCBA challenge
4 concentrations, but is there a need to have a lower
5 challenge concentration for support activities. You
6 know, warm zone, cold zone. We will also talk about
7 that.

8 That's it.

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

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

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

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

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

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

21 When we are looking at the airtsource
22 requirements, we are looking at a portable source of

1 air. Usually it's a turbine blower or some type of
2 a small air compressor.

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

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

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

22 OSHA, on the other hand, sets the

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

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

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

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

20 Others will take these respirators and
21 combine them with the portable compressors or
22 blowers and sell them as complete respirator

1 systems.

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

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

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

22 Here's some examples of publicity

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

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

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

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

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

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

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

20 The way we are proposing this,
21 manufacturers can have respirators approved both
22 ways. They can have it as an airline or as an

1 aresource, and each of those has an option of CBRN
2 or IDLH or neither if that's the choosing.

3 From the NIOSH perspective, users will be
4 assured that the entire system is approved, whether
5 it be an airline system or a portable aresource
6 system.

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

19 It may not be attached or mounted in any
20 way to a structure or self-propelled vehicle. Like
21 it's mounted in the back of a pickup truck
22 permanently or mounted on an ATV. We are trying to

1 stick with what we consider to be a truly portable
2 system.

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

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

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

21 We are looking at multiple users, but with
22 some stipulations, some criteria there, that it has

1 to permit each hose or each user to be able to use
2 the system regardless of what happens in an adjacent
3 hose. So if an adjacent hose becomes blocked or is
4 cut open, the person that's still wearing the first
5 system still gets the airflow as they need to.

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

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

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

21 Some of the combination SAR/SCBA
22 requirements, we are looking at the airsource to be

1 very much similar to the airline respirators. For
2 example, we are still looking at the five- to
3 ten-minute duration escape bottle, cylinder, so you
4 could be using a portable system, and you still
5 carry the bottle.

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

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

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

22 Automatic switching, again, from supplied

1 air to the air cylinder with the alarm. And the
2 criteria that have been established mirror the
3 airline and the airsource respirators, tight-fitting
4 full facepiece, durability conditioning, and agent
5 testing, which Jeff has already mentioned.

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

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

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

21 Thank you.

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

1 the final correlation test results for
2 implementation of the new CO2 dead space test system
3 at NPPTL.

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

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

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

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

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

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

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

17 In addition to that, we also have a data
18 monitoring/recording system powered by our custom
19 LabVIEW software application, a data recording
20 interval which is 25 milliseconds, which is about 40
21 times per minute -- or excuse me, 40 times per
22 second. And this is four times more frequent than

1 the existing system was using a strip tread recorder
2 (phonetic).

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

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

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

19 Okay. These features have provided for
20 enhanced performance capabilities of the new carbon
21 dioxide dead space test system, and this includes
22 the ability to control the peak carbon dioxide

1 concentration at 5 percent plus or minus
2 .02 percent.

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

6 We are able to obtain consistent blank
7 carbon dioxide levels generally ranging from
8 .39 percent to .44 percent, and it also allows us to
9 precisely determine the start and end of the
10 inhalation phase from the solenoid valve actuation
11 times, and this is corroborated with facepiece
12 resistance data.

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

20 This provided a linear regression that
21 took the form that you see here at the bottom of the
22 slide. The carbon dioxide at the existing system is

1 equal to minus 1.097 plus 1.209 times the carbon
2 dioxide measured at the new system.

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

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

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

1 explained by the variability in the measurements of
2 the existing system.

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

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

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

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

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

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

11 Okay. Going forward, our plans are for
12 respirators that have been previously approved, our
13 procedure is going to be to measure the carbon
14 dioxide dead space level with the new system using
15 the linear regression model, determine the existing
16 test system equivalent carbon dioxide dead space
17 level. And if the existing test system equivalent
18 CO2 dead space level is less than 1 percent, a
19 passing grade will be assigned to the respirator
20 tested.

21 And for all new respirators that are
22 submitted for certification using the new test

1 system, we will use it as it is with some
2 consideration being given to taking a look at,
3 instead of determining the carbon dioxide dead space
4 level based on an arithmetic average of the CO2
5 measured during the inhalation phase, we are going
6 to take a look at using a dead -- a volume weighted
7 average for the future testing.

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

10 Thank you.

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

16 (A recess is taken.)

17 MR. SZALAJDA: All right. Thank you.

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

1 room a little better.

2 One thing, it was brought to my attention,
3 at least on any slide earlier regarding the docket,
4 the comments that you should submit should reference
5 83B. I think one of my earlier slides said 83A, but
6 if you submit comments to the docket office, you
7 should use 83B.

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

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

22 What I would like to do initially, if we

1 are ready with the online part of the meeting, is if
2 there are any questions from the online
3 participants, if they could indicate to John
4 Perrotte that they have questions, and we will go
5 ahead and take them initially.

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

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

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

15 MR. SZALAJDA: I think we are ready now.

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

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

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

22 But relative to the questions and the

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

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

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

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

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

1 The second question is from that from our
2 slide on that topic, what's the reason for the
3 proposal here that one of the three samples is
4 allowed to exceed the CO2 limit? Do you think that
5 it would be better to propose that one of the
6 three -- of the three units tested shall exceed the
7 1 percent level?

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

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

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

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

22 MR. PERROTTE: Let's see here.

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

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

9 MR. PARKER: We are discussing the carbon
10 dioxide?

11 MR. SZALAJDA: Yes.

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

17 MR. HOFFMAN: Yeah. One of the reasons it
18 was proposed to be one out of three passes rather
19 than three out of three is it's not really the --
20 what you are trying to see is if the respirator is
21 capable of holding that level, not that it will do
22 it every time. Because every time you put it on a

1 headform, since it's a nonhuman headform, obviously,
2 it's difficult to get it on the same way every time
3 and to get a repeatable result. So if you do it a
4 couple of times, you are really seeing is the
5 respirator capable of achieving that, not that it
6 will achieve that on a person every time.

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

9 And how do we know if we answer their
10 question?

11 MR. PERROTTE: There are a couple more.

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

19 MR. PERROTTE: Okay. The second question
20 is from Structural Composite Industries, Will. And
21 the question is regarding bullet number five of Jeff
22 Palcic's on Slide 16, is NIOSH approval for the

1 system intended to include the cylinder? If so,
2 why?

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

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

8 MR. SZALAJDA: SAR --

9 MR. PALCIC: Combination SAR/SCBA.

10 What was the question again?

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

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

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

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

5 MR. PALCIC: You meant as an airsource?

6 MR. PARKER: Yes.

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

9 Hello, Will, if you can ask your question.

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

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

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

21 MR. SZALAJDA: Well, I think with -- the
22 concept that's being discussed is that the cylinder

1 would be providing an escape capability.

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

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

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

13 MR. SZALAJDA: No.

14 MR. ANTUNIS: Like from a different
15 manufacturer?

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

19 MR. ANTUNIS: Thank you.

20 MR. SZALAJDA: You're welcome.

21 MR. PERROTTE: The last question is, Does
22 the autoswitch feature in combination SAR/SCBA units

1 have to remain latched?

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

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

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

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

18 MR. SZALAJDA: Okay. Great. Thank you.

19 All right. Well, what we will do at this
20 point is we will go through the discussion slides.
21 And hopefully if you have questions that were --
22 that you identified as part of your review of the

1 material as well as what you heard this morning, if
2 you can integrate those questions into these slides.

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

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

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

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

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

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

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

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

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

20 So when you take it in that scenario,
21 would that system -- would that have to be approved
22 as a system under your airsource requirements, or

1 does it go back to a fixed-point attachment, like a
2 supplied-air respirator.

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

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

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

14 So, I mean, where does this fall?

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

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

19 MR. SELL: Correct.

20 MR. HOFFMAN: Okay. I would look more --
21 my initial thought on that is that is more falling
22 on the line of the SCBA. I think we are looking at

1 the aresource as being able to continuously supply
2 ambient air from a remote source.

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

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

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

15 MR. SELL: Correct, right.

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

21 MR. SELL: Okay.

22 MR. PALCIC: -- under the aresource idea.

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

4 MR. PALCIC: That's a new one.

5 I will have to think about that.

6 Les?

7 MR. SELL: Technical Committee Chairman.

8 (Laughter)

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

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

22 MR. SAVARIN: Mike Savarin, Sperian

1 Respiratory Protection. What a nightmare.

2 Mike Savarin, Sperian Respiratory

3 Protection. I have very a brief question today.

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

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

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

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

18 And at this point, we haven't ventured
19 there. We have tried to limit what portable is.
20 Now, whether we would expand that included ones that
21 are cart mounted or pickup truck mounted, we haven't
22 at this point. But a couple of people pointed out

1 that those are commonly used systems, and nobody is
2 looking at that.

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

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

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

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

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

22 SPEAKER: Thank you.

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

3 MR. COLTON: Craig Colton, 3M.

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

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

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

22 MR. PALCIC: It only includes the ones

1 that are packaged that way, Craig.

2 MR. COLTON: Okay. Thank you.

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

11 And, go ahead.

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

15 MR. SZALAJDA: Okay.

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

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

22 Cylinders, as you know, are manufactured

1 by one of two or three companies here in North
2 America. It adds a significant amount of time to
3 the end user's system when they need to buy
4 cylinders from the respirator manufacturer --
5 supplied-air respirator manufacturer's system.

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

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

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

20 The -- you know, the component, at least
21 in terms of the way the CFR is currently structured,
22 is that, you know, the systems are approved -- or

1 respirators are approved as systems, that we don't
2 do the component types of approvals.

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

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

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

1 think would be very worthwhile.

2 MR. ANTUNIS: I agree. Thank you.

3 To make sure I understand it, currently,
4 the goal is to incorporate the aresource system now
5 or moving forward.

6 But currently the aresource system is not
7 part of the rule. Is that correct?

8 MR. HOFFMAN: Yes, that's correct.

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

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

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

19 The question is why include the aresource
20 system as part of the overall approval?

21 MR. HOFFMAN: Okay. If you look at it
22 this way, if you have a stationary air compressor,

1 everybody is assured -- or the user is assured that
2 he is receiving adequate air because the compressor
3 system is supplying Grade D air, and from the
4 connection point on to the respiratory inlet
5 covering has been approved. So the whole system is
6 supplying -- or should be supplying an adequate air
7 supply that has been evaluated.

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

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

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

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

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

11 Does that answer your question?

12 MR. ANTUNIS: It goes to my question.

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

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

22 And the other -- and the SCBAs are being

1 looked at by NIOSH. But it's the portable ones that
2 have that portion of it that nobody is looking at
3 it, and that's where the concern is.

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

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

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

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

20 MR. HOFFMAN: Now, again, the trouble with
21 the separate approval is now it moves into the realm
22 of component approval. And the difficulty with that

1 is knowing how different components with interact
2 with each other.

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

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

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

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

20 MR. BERRYANN: This is Roland BerryAnn
21 from NPPTL.

22 I just -- listening to this, Will, I want

1 to try and summarize in my words what I think
2 addresses your concern. I think it has been said by
3 the panel, but, again, let me try and summarize it.

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

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

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

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

19 Thank you.

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

1 point.

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

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

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

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

22 With this slide, there was a math error

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

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

8 MR. COLTON: Craig Colton, 3M.

9 This gets to be one of my dear topics.

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

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

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

1 calculation.

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

4 MR. PALCIC: The highest APF.

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

7 MR. PALCIC: It was OSHA, NIOSH.

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

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

20 MR. HOFFMAN: I think maybe what is being
21 misunderstood is these aren't the final values.
22 These are sort of the starting values. And the data

1 will dictate what it should be rather than the APF
2 that's currently established dictating it.

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

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

12 MR. HOFFMAN: Right.

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

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

19 MR. SZALAJDA: I appreciate that, Craig
20 because I think with the approach that we have taken
21 is we just wanted to set a target value initially.
22 And, you know, we have made an investment at least

1 in terms of identifying and getting existing
2 technology that we are planning on benchmarking, and
3 then I think between now and the next time that we
4 get together, you know, we will be in a position to
5 present the data that we have accumulated on the
6 laboratory basis and then make adjustments as
7 appropriate to the values.

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

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

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

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

22 MR. FORD: (Garbled question).

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

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

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

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

10 MR. FORD: Thank you.

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

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

1 need a requirement.

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

6 MR. SELL: Bob Sell, Draeger Safety.

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

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

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

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

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

1 NFPA.

2 MR. SZALAJDA: Thank you, Bob.

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

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

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

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

15 MR. HOFFMAN: Okay.

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

22 The eye and face standard actually has a

1 respirator section now, so the -- you know, Z87 does
2 cover respirators. The helmet standard does not.

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

9 MS. FEINER: Lynn Feiner, Honeywell
10 Safety.

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

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

1 MR. SZALAJDA: Thank you, Lynn.

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

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

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

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

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

22 So if you look at these air flow rates,

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

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

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

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

13 If anyone has any comments.

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

16 MR. PERROTTE: No.

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

19 In doing some testing things, say for like
20 the CBRN and things like that, one of the things we
21 noted that very quickly, if you are running at a --
22 a respirator at a moderate air flow, somebody stands

1 up, has to run to the other side of the room, the
2 respirator can go negative very, very quickly. As
3 your breathing rate increases a little bit, it makes
4 a very big difference.

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

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

15 MR. SZALAJDA: Thank you. Actually, we
16 have seen that type of issue as well. And one of
17 the things that we are looking at in terms of our
18 evaluation is trying to capture that in terms of our
19 test parameters, acknowledging that there are
20 instances, well, where a positive pressure type of
21 respirator -- and I hate to use that term, but I
22 don't have a better one to use yet. But where

1 something can go negative, especially in the
2 facepiece.

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

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

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

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

1 one, or that automatically senses that and changes.

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

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

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

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

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

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

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

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

20 So, you know, the art is in determining
21 what those requirements are and making sure that the
22 standard is robust enough that it can it be applied

1 appropriately in different situations.

2 But your point is well taken.

3 Mike?

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

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

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

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

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

1 you are going to do.

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

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

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

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

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

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

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

12 I think it is horrendously complex.

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

16 But if it's going to be NIOSH approved,
17 you are going to have to think about making it so
18 that it provides protection -- whatever that
19 protection is by the way -- at the highest flow rate
20 that that thing is designed for, which means it
21 would run for that maximum length of time. That
22 person may switch it and -- from the word go they

1 may switch it because it's comfortable. Having it
2 at that high flow rate makes you feel good, keeps
3 you cool. You know, trouble is, how long does it
4 last?

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

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

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

18 That's all I would like to say.

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

21 And I guess the one thing that is
22 encouraging to me is the amount of research and the

1 evolution of these ideas, especially within the past
2 ten years.

3 I think the knowledge base is so much
4 greater now than where we were, you know, say in
5 2000, that I think, you know, these are issues, the
6 things that you bring up are issues.

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

12 John, do you have a comment?

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

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

22 MR. SZALAJDA: Okay.

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

4 MR. ANTUNIS: Yes (unintelligible).

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

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

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

13 UNIDENTIFIED PERSON: Cylinder.

14 MR. SZALAJDA: Cylinder, okay.

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

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

20 MR. PALCIC: The current proposed draft?

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

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

4 MR. ANTUNIS: Thank you.

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

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

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

17 And kind of at this point, the question I
18 think is what's appropriate? Or one of the things
19 that we have kicked around internally is should we
20 put together some sort of matrix to identify
21 particular materials for evaluation that the
22 manufacturer or the applicant can tailor a

1 particular device towards a particular hazard, and
2 then we would test it as appropriate.

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

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

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

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

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

22 MR. VOJTKO: It's to address what we

1 conceive as some potential hazards.

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

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

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

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

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

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

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

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

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

1 MR. PALCIC: We have not.

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

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

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

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

14 And as also, as you probably know, in body
15 shops and things like that, it's common practice to
16 wipe the hoses and the equipment and everything down
17 with whatever solvent they happen to be using. And
18 it tends to -- in some cases, it doesn't seem to
19 have any effect. In other cases, it tends to maybe
20 break the outer covering of the hose down where --
21 maybe to the point that it is being absorbed or
22 permeating through, or in other cases where it's

1 just sort of ruining the hoses and making them
2 unsafe to carry the airline pressure.

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

5 It mean, it is a common practice.

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

8 MS. DEMEDEIROS: Yeah.

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

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

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

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

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

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

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

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

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

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

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

10 MR. EASON: Chris Eason with Staubli
11 Corporation.

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

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

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

1 go on to another subject is this.

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

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

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

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

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

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

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

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

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

20 Now, I know that this would be a gigantic
21 undertaking that has never been done before. But
22 think it would allow -- if there was a way to work

1 this out, it would allow for systems to be the best
2 they could be all the time.

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

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

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

21 Are there any other comments from the
22 floor at this time regarding supplied-air

1 respirators?

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

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

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

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

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

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

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

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

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

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

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

22 And from that perspective right now, the

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

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

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

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

1 that part of the process.

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

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

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

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

17 Well, it was an interesting summer for me,
18 and one of the things that added to it was in the
19 beginning of August, I received a juror summons.
20 And it was one of those things where I received it
21 on a Thursday or Friday afternoon, and I didn't even
22 look at it. And finally Sunday night, it's like,

1 hmmm, I have five days to reply to this thing. I
2 better take a look.

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

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

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

22 Since that time, we have initiated some

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

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

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

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

20 So we decided at that time to present that
21 we create a subpart to 42 CFR Part 84 to address the
22 ensembles specifically to better meet the future

1 technological needs and advances of the users and
2 the manufacturers.

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

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

16 OSHA does have several -- they do give
17 several classifications in a guide that they publish
18 for chemical protective clothing. Two of those
19 classifications would be a fully encapsulating suit.
20 Another one would be irradiation protective suite.
21 They use EPA levels of protection, A, B, C, and D
22 protection. A and B includes an SCBA. C is

1 applied -- excuse me, an APR, and D does not require
2 respiratory protection at all.

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

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

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

18 As Jon stated, we have begun some
19 benchmark testing. Some of the things that we are
20 concerned about at NIOSH, particular
21 preconditioning. The materials sometimes used in
22 these ensembles are what I would call commodity

1 resins. Their properties are very temperature
2 dependent. I think we have to be very aware of that
3 in terms of what we choose as our preconditioning
4 criteria.

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

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

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

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

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

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

19 And we have also proposed in this current
20 draft allowing higher CO2 levels for limited periods
21 of time, and that's precedented in 42 CFR Part
22 84.97, and also the NASA standard has included that

1 as well.

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

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

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

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

19 We are also looking at the number of test
20 subjects that we would use. At this point, we are
21 thinking that that would be determined by the sizes
22 that are provided by the manufacturer and how the

1 manufacturer specifies whether or not a size is
2 appropriate for a person.

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

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

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

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

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

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

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

21 And they have concerns, for example, for
22 things about concerning flammability testing. They

1 have very specific doffing requirements for their
2 ensembles. They are looking at, you know, the
3 European standards that are out there and the
4 American standards that they have had to work with
5 for 30 years and trying to decide which would be the
6 better situation for them.

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

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

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

21 They generally have -- sometimes have
22 filter assemblies that they are putting into the

1 suits themselves that are very specific to their
2 needs. And they are making simple repairs onsite to
3 their ensembles, and they are pressure testing them
4 as required.

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

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

18 I have spoken to someone from -- in the
19 paint industry who is big in the union there, and he
20 said they are concerned about vision clarity. They
21 want to be able to judge mils. So their visors have
22 to be very practical. And the materials themselves

1 that are used to make the ensembles, if they get
2 paint on them, they still to keep painting. So
3 that's a concern for them also.

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

10 And, again, as we have said again, it's
11 148-A since this is the second time around. Please
12 submit your comments to that docket.

13 Are we going to go through the slides?

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

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

20 Use concerns and how we address whether an
21 ensemble is disposable or reusable and what ensures
22 proper functioning for reuse. Storage and use

1 temperature concerns, as I have mentioned.

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

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

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

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

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

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

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

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

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

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

1 of themselves except under certain circumstances.

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

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

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

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

22 So if you have -- if you are exposed to

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

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

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

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

21 Now, the reason that's fortuitous is
22 because oxygen has a very, very low solubility in

1 water. And if we didn't have a special transport
2 mechanism, we would not be able to survive
3 aerobically.

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

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

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

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

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

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

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

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

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

13 Now, there is only four of them, so it
14 doesn't seem like much; right? Until you realize
15 there are about 280 million hemoglobin molecules per
16 red blood cell. And then if you multiply that by
17 400 billion red cells that are produced daily and
18 that can be ramped up 20-fold in the presence of a
19 low oxygen environment during an adaptation process,
20 that's a tremendous amount of oxygen-carrying
21 capacity.

22 Your body also has the ability to sense

1 changes in the level of oxygen and CO2 through
2 central receptors, and also within specialized areas
3 within the cardiovascular system.

4 This is the aorta coming off the heart.

5 And particularly in the common carotid
6 arteries, there is chemoreceptors that can sense
7 changes in the oxygen and CO2 and deliver a neural
8 signal back to -- it's integrated through the brain
9 and back to the lungs where you have a respiratory
10 or a ventilatory change based on that sensing.

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

17 And that can occur under hyperbaric
18 conditions, for instance underwater diving or
19 caisson work, and it can happen under normobaric
20 conditions, just normal atmospheric conditions. But
21 in clinical settings where somebody is being treated
22 therapeutically with a hundred percent oxygen, and

1 that can contribute to an excess of oxygen in the
2 body.

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

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

18 And I mentioned before that CO₂ is carried
19 by hemoglobin. And when you have maximal saturation
20 of your hemoglobin with oxygen, there's no sites for
21 occupation by CO₂. So there's an elevation of blood
22 CO₂, which then stimulates your ventilation when it

1 is sensed by the chemoreceptors in your
2 cardiovascular system.

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

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

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

18 And generally speaking, if you go below
19 about two atmospheres absolute -- so that would be
20 wearing diving gear and wearing a hundred percent
21 oxygen rebreather and going below 33 feet, which is
22 one atmosphere, or two atmospheres absolute, you

1 will start to develop seizures. Okay? So there's
2 that neurological component to that.

3 And the U.S. Navy has determined that the
4 threshold is about 1.3 to 1.5 atmospheres absolute,
5 which is maybe, you know, 12 to 15 feet underwater,
6 16 feet underwater, and then you start to sense this
7 change in oxygen toxicity.

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

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

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

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

21 And then you also have a general
22 vasoconstriction of your kidney and gut regions and

1 a decrease in renal blood flow just because you have
2 too much oxygen there.

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

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

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

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

21 So imagine if you got on a treadmill and
22 ran as fast as you could -- and we do this in the

1 laboratory for certain reasons -- get somebody's
2 maximal aerobic capacity, and they say, I can't go
3 any further. They are at their maximum ventilation,
4 and that's at rest is if you were breathing as hard
5 as you could at rest at the top of Mount Everest,
6 you would have barely enough oxygen coming into your
7 body for basic metabolism, and there's not a whole
8 lot left over for muscular work.

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

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

18 So here you have Everest. It's pretty
19 high, over 8,800 meters, more than 29,000 feet. And
20 you can see that as the barometric pressure
21 decreases, you reach a point right here where you're
22 right at the amount of oxygen uptake with maximal

1 ventilation, which is just barely enough to maintain
2 your metabolism -- your aerobic metabolism at base
3 levels.

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

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

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

21 And what happens is you have a high degree
22 of hyperventilation, and so you are blowing off lot

1 of CO₂, and you have the metabolic change. You
2 become more alkalotic. Okay? But you also have
3 resistance to exercise because you're not getting,
4 even with all of that, enough oxygen to exercise in
5 the same manner to the same degree that you would at
6 sea level.

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

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

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

21 And one of the things that happens is they
22 increase the number of those air sacs, the alveoli

1 in your lungs. And so they have a greater surface
2 area for gas exchange, and that happens at birth.
3 That's not something that you and I could, say, go
4 to altitude and suddenly develop more alveoli.
5 That's something that you are born into.

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

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

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

19 Now, remember up at Mount Everest for the
20 unwise person that doesn't go up there with oxygen
21 supplementation, well, they are right in the middle
22 of that. So they are on the edge of losing

1 consciousness because you simply don't have enough
2 oxygen to deliver to the brain and vital organs.

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

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

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

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

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

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

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

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

1 to carry oxygen to the brain to preserve cerebral
2 function.

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

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

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

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

21 CO₂ can induce visual disturbances at high
22 enough concentrations. A headache, that's a very

1 common one. I have breathed 6 percent CO₂ in a
2 study once, and I had a nice headache afterwards.

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

8 It can act as an anesthetic. 10 percent
9 CO₂ will put you out in very short order and will
10 kill you, probably. You can induce inert gas
11 narcosis similar to nitrous oxide, which is a
12 laughing gas.

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

16 Now, this is a complicated slide, but all
17 you have to do is look on the left here. You see,
18 well, as you increase the CO concentration, you
19 increase the symptoms and the severity of the
20 symptoms, and you decrease the amount of time that
21 you are able to tolerate it. And that's simply
22 aggravated by exercise, so the more active you

1 are -- this is at rest. And if you start
2 exercising, your tolerance is that much less.

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

8 It has crystal lenses to protect the eyes.
9 It has a filter media, believe it or not, which is
10 aromatic herbs, which they felt were, back in the
11 16 -- or 17th Century, would block miasma, which
12 they felt was what was transmitting plague through
13 the air. And of course they didn't realize it
14 was -- the vectors were fleas on rats.

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

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

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

4 It was ruthless, but it kept them alive.

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

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

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

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

1 CO2. Now, that also depends on your diet.

2 And then at maximal exercise, you are
3 jacking this up, you know, more than 15 times. And
4 so your maximal oxygen consumption in the average
5 individual can be three and a half liters per minute
6 absolute. CO2 production can be over 4 liters
7 because of the heavily working muscles. And in it
8 athletes, that can be even greater.

9 So we consume oxygen. We put out CO2, as
10 I have mentioned.

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

14 And this is CO2 levels here, roughly. And
15 these are O2 levels. Okay.

16 So at the end of exhalation, you have
17 exhaled CO2 into the breathing space. And you can
18 see on this scale on the right, well, you are up
19 about 6 percent, you know, of CO2.

20 And down -- and because you are not
21 breathing in, the O2 levels have dropped down to
22 maybe 15 or 14 and a half percent.

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

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

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

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

21 Now, as I mentioned, if the respiratory
22 protective device, whichever it is, especially a

1 supplied-air system, fails to deliver enough or
2 delivers too much oxygen to match demand or fails to
3 eliminate the carbon dioxide in the breathing space,
4 then you start seeing these issues of hyperoxia or
5 hypoxia or hypercapnia.

6 This is high O2, low O2 and high CO2.

7 And that becomes significant for the user.

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

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

1 And as it sublimates out, and the CO2
2 concentration goes up, a researcher went in there
3 and died simply because they displaced all of his
4 oxygen.

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

11 The air purifying systems will not protect
12 you against that.

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

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

1 death.

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

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

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

11 I guess it's time for lunch.

12 UNIDENTIFIED PERSON: There is one
13 question.

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

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

19 If you are interested in the lunch that
20 the hotel is providing, it is \$12 cash only. To the
21 right of the door -- I guess it's right out here,
22 so -- and I guess there's also tables and chairs out

1 here that you are welcome to use as well.

2 So with that, we will reconvene at
3 1 o'clock.

4 (A luncheon recess was taken.)

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

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

17 So with that, Heather.

18 MS. FARRER: Good afternoon, like Jon
19 said, my name is Heather Farrer, and I work for
20 Savannah River Nuclear Solutions. I work with Ed
21 Kvartek, who is sitting over here behind Jon, and he
22 works for Savannah River Remediation. And we work

1 at the Savannah River site that's actually not in
2 Savannah. It's in Aiken, South Carolina.

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

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

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

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

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

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

14 And then the future.

15 What is a supplied-air suit?

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

22 Air is supplied to the head and preferably

1 to the body for worker comfort.

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

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

16 The history of the SRS supplied-air suit.

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

20 Our first suit was a 6-mil PVC suit. Over
21 the years, we have had various versions and
22 modifications. Went from a one-piece suit to a

1 two-piece suit. We improved the durability and
2 tritium protection by adding a 12-mil PVC suit.
3 That suit is actually laying on the counter back
4 here to the right.

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

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

16 We have reduce cross-contamination with
17 what we refer to as shells or oversuits. A shell or
18 an oversuit would be the initial plastic suit. You
19 would wear that first. Then you would have another
20 suit where you cut the helmet off, the cuffs off,
21 and the booties off. And you wear that over the
22 initial suit. And in some cases, we might have to

1 wear two shells, depending on the contamination
2 level and the work area.

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

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

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

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

18 The material is actually constructed of a
19 series of films layered together. They consist of
20 the chlorinated polyethylene, the Saranex polyester
21 scrim, and then those are bonded together with EVA.
22 This suit provides superior breakthrough and

1 permeation characteristics for tritium.

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

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

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

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

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

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

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

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

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

19 There is a three on his back and on his
20 shoulder. And you can't see it, but there is also a
21 number 3 on his forearm. And that's to identify the
22 breathing air hose that's connected to the back of

1 that suit to the manifold that could be in another
2 room or down the hall.

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

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

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

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

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

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

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

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

18 In the second photograph, it's the same
19 thing, the PSSD. And it has actually cracked at the
20 inlet supply bar where the air comes into the suit.
21 And we have learned through many investigations that
22 during the molding process, the part can develop a

1 void that can then lead to a crack. And then this
2 is like a catastrophic failure when it actually
3 cracks.

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

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

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

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

22 And then lastly, the noise level is below

1 80 decibels in our suit, but we would like to have
2 it lower.

3 Suit status within the DOE facilities. In
4 1984, according to a report that was issued at that
5 time, Rocky Flats was using a two-piece 12-mil PVC
6 suit, required 6 CFM to the helmet. It was
7 manufactured by JJ Avery, and it had an assigned
8 protection factor of 20,000.

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

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

16 At SRS, we used the 6-mil suit that I
17 mentioned earlier. It required 6CFM to the helmet.
18 It had an assigned protection factor of 10,000. And
19 since then we have upgraded, and we have four
20 styles. And those were the welder suit I mentioned,
21 the tritium suit, and the 12-mil, and of course the
22 6-mil.

1 Los Alamos National Lab used a two-piece
2 6-mil PVC suit. Required 6 CFM, had an assigned
3 protection factor of 10,000. And in that particular
4 suit, they had two different versions of air
5 distribution to distribute the air throughout the
6 suit. That suit was manufactured by Fab Ohio.

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

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

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

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

22 Los Alamos National Lab uses the SRS

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

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

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

10 I think this is why we are here.

11 Considerations when designing suits: The four most
12 important is avoiding an oxygen-deficient or an
13 elevated CO2 condition in your suit helmet.

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

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

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

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

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

10 NIOSH-approved mask and hoods require 4 to
11 10 CFM. Suits generally require much more volume of
12 air to address cooling, worker comfort, and of
13 course the protection factor.

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

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

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

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

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

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

21 Another thing would be your
22 self-extinguishing characteristic. We do have a

1 welding suit, so that is important to us. Within
2 the DOE, our suits have to comply with NFPA 701, the
3 1989 version.

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

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

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

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

22 Then there's heat stress. Our workers

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

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

8 Then there's chemical permeation. In the
9 2003 technology standard, it addressed chemical
10 permeation. We have had our suit material tested
11 for tritium, organics, and a couple of acids.

12 And then there's additional equipment.

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

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

21 And then there's body harnesses. When you
22 design your suit, you want to keep body harnesses in

1 mind. We have got a lot of work going on where our
2 workers are at elevated heights.

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

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

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

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

21 The third picture is just a poor guy
22 hanging. It's not an air-supplied suit, but it's

1 the same mechanism that's in the single-use suit,
2 and it's just to demonstrate and show that it does
3 work.

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

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

13 And that's it.

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

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

20 We have our presenters, Colleen, Heather,
21 and Jon. They are going to be joined by Bill
22 Haskell, who has a wealth of experience in personal

1 protective technologies, came to us from Natick Labs
2 in previous lives before then, but is very actively
3 involved, not only with our program, but also with
4 NFPA and ASTM standards development committees.

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

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

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

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

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

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

21 MR. PERROTTE: No, he did not.

22

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

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

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

7 The first was on the issue of
8 classification.

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

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

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

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

15 Thank you, Gary.

16 MR. ZIMMERMANN: Gary Zimmermann, Sperian
17 Protection Clothing.

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

21 Typically all these suits are
22 overpressurized, so that's the key in concept

1 regarding these suits.

2 And the majority of the designs from
3 manufacturers hopefully are such that if -- this
4 overpressure being maintained is helping a situation
5 where if there's a breach in the envelope of the
6 suit itself, the protection factor is maintained at
7 least -- it may not be to the elevation in which the
8 suit is protected or certified to, but it is
9 definitely maintained because the overpressure is
10 maintained.

11 So in some of the standards existing in
12 Europe, for instance, there is an overpressure
13 concept there that is taken into account. And if
14 you are developing standards for that, maybe making
15 sure that overpressure measurement is taken in suits
16 when they are being submitted for certification will
17 certainly help you generate a suit that is reliable
18 from a health-and-safety perspective, even there is
19 a breach in the envelope.

20 Because we find in the field a lot of
21 tears and a lot of rips that do happen as far as
22 people using suits.

1 So definitely that overpressure is going
2 to solve a lot of people's problems.

3 MR. SZALAJDA: Okay. Thank you.

4 MR. GIANFORCARO: Can you hear me okay?
5 George Gianforcaro, IndutexUSA.

6 I have a question for Heather, who just
7 presented, if that's okay?

8 MR. SZALAJDA: Uh-huh.

9 MR. GIANFORCARO: May I?

10 You have different workers, I think you
11 said 3,500 suits a year, approximately, according to
12 your numbers.

13 How many different pairs of gloves are the
14 workers wearing? Is everybody wearing the exact
15 same pair of gloves, or are they different styles,
16 different materials, et cetera?

17 MS. FARRER: They are generally wearing
18 the type of glove. They may have layers of the same
19 kind of glove.

20 MR. GIANFORCARO: For instance, is someone
21 wearing a nitrile glove, someone wearing a
22 leather-palm glove, someone wearing an inspection

1 glove or a surgical glove or something?

2 MS. FARRER: Yes. Yes.

3 MR. GIANFORCARO: So you will have
4 different workers wearing different types --

5 MS. FARRER: Different gloves for the
6 different applications.

7 MR. GIANFORCARO: So if I were to go into
8 your storage area, approximately how many different
9 pairs of gloves or styles of gloves would I find?

10 MS. FARRER: Oh, I don't know.

11 MR. GIANFORCARO: More than ten?

12 MS. FARRER: No. I think probably about
13 six.

14 MS. FERRAR: Six, okay. Which leads to my
15 question or comment to the panel which we spoke
16 about at lunchtime, is the way that the
17 certification -- the direction that they are going
18 right now in America, is that each time the worker
19 has a different pair of gloves, they would need a
20 different certification, and the manufacturer would
21 have to submit a different garment for the testing.

22 Whereas in Europe, we manufacture air-fed

1 suits in Europe, and the European standard, it stops
2 at the cuff.

3 It's for a number of reasons. One is it's
4 positive pressure. And number two is because if
5 Organization A wears five or you said maybe six
6 different pairs of gloves, and then maybe another
7 division within your company has another six
8 different pairs of gloves, right now, the
9 manufacturer, the way that the US is writing the
10 standard would require 12 different submittals for
11 each different ensemble because it's a different
12 pair of gloves.

13 And my concern is that I think that if we
14 are writing the standard this way is that it's going
15 to become either -- we are going to outprice the
16 product just because of testing, or I don't really
17 think -- or what we are going to do is cause the end
18 users to say, Well, just test it with one pair of
19 gloves, but the other nine guys, we will wear a
20 different pair of gloves, and it's good enough.

21 So then they are going to be wearing a
22 suit or ensemble that has not been certified. So I

1 think that's something that the panel, I would like
2 them to address prior to finishing this up because I
3 think we are going down an area which is a dangerous
4 area.

5 MR. HASKELL: George, I have a quit
6 question on your concept, the way they use them in
7 Europe. Do they not worry about the hazard getting
8 under the glove?

9 Because you are overpressure is, I assume,
10 ending at the cuff; right?

11 MR. GIANFORCARO: It's my understanding
12 what we do -- it's my understanding that they
13 have -- when they do run the tests, there is a
14 glove. And then they tape the glove.

15 Now, the tape that they have comes with
16 the suit.

17 MR. HASKELL: But there's really no
18 certification process that you know you have a
19 good -- a vapor-tight seal under the glove?

20 MR. GIANFORCARO: I can't speak -- I don't
21 consider myself an expert on that.

22 MR. HASKELL: Because one thought I have

1 is what if the gloves had a mandatory attached glove
2 with a minimum level of protection, physical
3 durability and chemical. And then for other things
4 like welding or other more aggressive operations,
5 you then put another glove on top of that, but you
6 are maintaining your physical protection barrier
7 between the arm and the glove with an attached inner
8 glove.

9 Does that make sense?

10 That's the way it is done with a lot of
11 hazmat suits. You will have an attached glove, and
12 then you will have an overglove depending on what
13 additional protection you need.

14 MR. GIANFORCARO: Well, what I would like
15 the panel to do is possible -- at least -- now, I
16 don't have the European standards here. I could
17 brush up on it for the next meeting.

18 But it's my understanding that the testing
19 or -- they call it a suit standard and not an
20 ensemble standard, and that the suit is certified.

21 But I will for the next meeting, I could
22 follow up to find out exactly how they word it in

1 Europe.

2 MS. FARRER: I would like to add a
3 comment.

4 On the gloves, what we found, when the
5 glove is sealed to the cuff, that when you are
6 ordering suits, they don't fit everyone. So then
7 you get into you need a suit size, and then you need
8 a glove size. So I'm kind of like with George, stop
9 that at the cuff and address the glove separately.

10 MR. SZALAJDA: Okay. Do we have a
11 LiveMeeting?

12 MR. PERROTTE: Yeah, it's from Draeger,
13 Michael Klaus.

14 It says, We totally agree with the AFS
15 should be under the scope of NIOSH/NPPTL. Colleen
16 explained the standard is limited to suits without
17 exhalation valves. We would propose to open
18 standard also for gas-tight suit ensembles with
19 exhalation valves since this gives additional
20 safety.

21 MR. SZALAJDA: Okay. Thank you.

22 I think with -- I think just to kind of

1 wrap the classification question up, unless we have
2 one more comment, I think the challenge for us is
3 when you -- from my perspective, anyway, that we are
4 looking at this initially in terms of it being a
5 respirator.

6 You know, and I think it's -- part of our
7 definition needs to be where does the respirator end
8 in terms of the definition of the ensemble, whether
9 it's the complete ensemble, and you have attached
10 gloves or you have attached boots.

11 I think the challenge for us and where the
12 feedback and discussion like this is important is
13 trying to find that limitation. Because from the
14 one -- the one standpoint -- and I can appreciate
15 the issue in terms of the certification testing and
16 the cost and the times -- the time that goes along
17 with that.

18 But, you know, again, as Bill had
19 discussed, it's, you know, where do we make sure
20 that we are assuring the protection that if you are
21 wearing multiple gloves, how is that accommodated as
22 part of the specification?

1 So it's a good discussion.

2 MR. CARDINALE: Mike Cardinale, NASA.

3 This discussion on the gloves I think is
4 interesting. It looks like there's two different
5 strategies here. There's suits with attached gloves
6 and boots, if you want to call them that. And then
7 there's apparently suits where the gloves or
8 footwear are separate from the primary garment.

9 And I think that what you need to be
10 looking at is the boot/glove interface and that's
11 what you are certifying as opposed to the different
12 size gloves that might come with the suit.

13 You know, if you engineer an interface
14 between the suit and the glove, that defines how
15 airtight, you know, the unit is. And perhaps that's
16 a way around this little dilemma here.

17 MR. SZALAJDA: Thank you, Mike.

18 All right. Well, I think we would like to
19 go and move into the IDLH type of discussion.

20 I think part of the concept that we have
21 been kicking around was the inclusion of an escape
22 type of capability for these type of systems to

1 allow for egress from a certain environment.

2 And any comments on these questions? Or
3 anything in light of potentially having combination
4 types of units where it might be supplied-air as
5 well as some sort of air purifying type of device?

6 MS. MILLER: Jon, if I could just add to
7 that.

8 Heather did make a point in her
9 presentation of saying that they have done some
10 measurement of oxygen level -- or CO2 levels when
11 the air is shut off.

12 I guess what I was hoping is that if there
13 are any other users out there who had done similar
14 work or manufacturers and you have, you know, some
15 information that you could share, we would
16 appreciate it.

17 Thanks, Chrissy.

18 MS. DUQUESNE: Hi, my name is Chrissy
19 DuQuesne. I work at KSC-NASA.

20 We did do testing when we shut the air off
21 inside of our suits. We had two minutes worth of
22 air to egress if we didn't have cylinders to use,

1 but we do have cylinders to use as well.

2 So we have done that CO2 testing for
3 leaving an area. We actually have over two minutes
4 of air just from -- time just from the air inside
5 the suit.

6 MS. MILLER: And that was a manned test?

7 MS. DUQUESNE: That was a manned test.

8 MR. ZIMMERMANN: Gary Zimmermann again.

9 We have done a lot of testing actually on
10 CO2 with air off because we got some applications
11 where they actually use suits to that effect.
12 Moving around in pharmaceutical applications,
13 sometimes they will unplug, replug.

14 And the key again is design of the suit
15 systems whereabouts the exhaust valves have to be
16 able to shut down when you unplug.

17 So an encapsulating suit that's airtight
18 is very effective. So once you unplug, you
19 literally have an individual living in a suit's
20 microenvironment where the CO2 levels will rise a
21 lot slower if you are literally exhausting air from
22 the suit.

1 So if you train an individual to move
2 quietly to the area where he has to leave, for
3 instance, in emergency situations, you can get CO2
4 levels inside 3 percent for as long as two to three
5 minutes, very easily.

6 But, again, suit design is critical on
7 that side.

8 MS. MILLER: Thank you, Gary.

9 MR. SZALAJDA: Any other comments on this
10 topic? Okay, use concerns, the concept of
11 disposable versus reusable.

12 One of the things I know that we have been
13 sensitive to is with regard to the storage and use
14 temperature considerations. I think the picture
15 that Heather showed us with holding the PVC suit and
16 being able to see the bend in it because the -- you
17 know, it seized up in the cold I think is pretty
18 telling.

19 And I think that, again, part of the
20 challenge here is looking at, you know, with these
21 types of systems, is, you know, providing the range
22 of capabilities to address the appropriate user

1 scenario, that for some situations, that type of
2 material, that PVC material, may be appropriate.
3 But to build requirement completely around that may
4 not be appropriate for addressing other
5 applications.

6 So any comments on these questions?

7 MR. WILLIAMS: On thing I thought was a
8 little interesting was when Heather mentioned with
9 her suits, that you would be hypoxic within 70
10 seconds or so.

11 And that's presumably when you are not
12 panicking, you are not moving around that much. And
13 CO2 levels are going up, you know, maybe you can
14 maintain, you know, CO2 at 3 percent for a couple of
15 minutes if you train somebody to move very quietly
16 across, but circumstances don't always allow for
17 that.

18 And if you're in a more of a panic
19 circumstance, you are not going to have that much
20 time to -- when there's air off -- to get to a safe
21 place. And, you know, if the oxygen concentration
22 is down to 19 and a half percent in 20 seconds,

1 well, 20 seconds goes by pretty quick.

2 So I think it's an important consideration
3 when you are talking about these encapsulating suits
4 that have essentially a bag of air, a
5 microenvironment of atmosphere around you. And,
6 yet, once that is no longer regulated by an external
7 source, you don't have that much time.

8 And I'm glad to hear that there's some
9 training out there to say, okay, just move slowly
10 and you might get out of here. You might have two
11 minutes.

12 But it's not that long of a period of
13 time. It's an interesting concern.

14 MS. FARRER: Jon, what we do at SRS is we
15 train our workers how to doff the suit by pulling it
16 over their head like a shirt, and they have to be
17 able to demonstrate that they can do that within 15
18 seconds.

19 MR. WILLIAMS: But are they going to do
20 that in a dangerous environment?

21 MS. FARRER: We don't send our workers
22 into an oxygen deficient or an IDLH area, so yes.

1 That is their instruction, that if you
2 lose air, that means there is no air going to the
3 suit, then you remove the suit top and proceed to
4 the exit.

5 And even though we have egress air, egress
6 air doesn't help you if I cut off the wrong valve, I
7 cut Jon's air off or I cut his hose when I'm
8 supposed to be cutting Terry's hose.

9 MR. WILLIAMS: There are people who would
10 like to do that, by the way.

11 MS. MILLER: And now it's on the record.

12 MR. WILLIAMS: Yeah, now it's on the
13 record.

14 Because if somebody is in an IDLH, or if
15 you are working in a BSL-4 facility where you can't
16 afford the exposure because some of these
17 biologicals have no known cure and you get exposed,
18 that's a shame, you know. You know, it's a
19 consideration if the air goes off.

20 MS. DUQUESNE: Just a comment on that
21 really quick.

22 We have what we -- we converted some SCBA

1 cylinders into what we call ventilator bottles.

2 They are the 30-minute ISI little bottles that we
3 have, the aluminum ones, 30-minute cylinders.

4 They supply 10 to 12 minutes of emergency
5 breathing air. Our users can disconnect their hose
6 and connect to that bottle and emergency egress out
7 of the area. So that's one thing you could put on
8 there.

9 And it has a high enough flow rate to keep
10 that CO2 wash out, and it is 10 to 15 minutes of
11 breathing air.

12 But I have comments on the questions --

13 MS. MILLER: Before we go on, can I just
14 ask, do you have any kind of a filter system that
15 you are using with that cylinder so that if the
16 gloves are dirty, you are not contaminating when you
17 are connecting to that cylinder?

18 MS. DUQUESNE: We have quick disconnects
19 that --

20 MS. MILLER: But there's no like HEPA
21 filter on it or anything?

22 MS. DUQUESNE: No.

1 UNIDENTIFIED PERSON: You have actually
2 tested that?

3 MS. DUQUESNE: Yeah, we have actually
4 tested that, and no contaminants. Actually, even if
5 you do have contaminants on your gloves, like
6 oxidizer, we have had guys who have oxidizer on
7 their gloves because we have had a spill, liquid
8 oxidizer go all over the down the suit.

9 No contaminants got in through the quick
10 disconnect that we have.

11 MS. MILLER: Okay. Thank you. Go ahead,
12 Chrissy. You had another comment?

13 MS. DUQUESNE: On question 2, what methods
14 are used to ensure proper functioning prior to use
15 if you do reuse the suits?

16 At KSC, we have really high safety
17 standards. I have a lot of documents to prove it,
18 but for our suits what we do after every use, they
19 are not assigned to a user. We get them after they
20 are used every time, and it goes through a huge
21 recycle process where the outside is washed, the
22 inside is washed. We have what looks kind of like a

1 car wash. It is dried. The suits are inflated,
2 bubble checked, bubble leak checked over the whole
3 entire suit.

4 We do a light inspection test where you
5 stick the light up inside the suit to find thin
6 areas and pinholes in a dark room. Then it's
7 visually inspected by a technician. He fixes
8 whatever he finds, and then it goes to a pressure
9 check, exhaust valve check, comm check, quick
10 disconnect, the manifold check. And then it goes to
11 a quality inspector after that.

12 MR. HASKELL: Jon, may I ask her a
13 question?

14 MR. SZALAJDA: Sure.

15 MR. HASKELL: Do you actually have a way
16 to prove that you are disinfecting, or is it just
17 some sort of soap solution?

18 MS. DUQUESNE: We have a sea wash that we
19 put on the outside of the suit. It's hand washed.
20 And if there's like scuffs or something that we
21 can't really get off, we use toulene.

22 Our guys have to use respirators if they

1 do that.

2 And then on the inside of the suit, we
3 have an actual -- it's heat washed on the inside and
4 outside of the suit with hot water. It's at 110
5 degrees Farenheit. Soap is used and then a
6 clean-water rinse.

7 The suits, after every time they are used
8 out in the field, they are sniff checked before the
9 technicians are allowed to leave the area.

10 After every time that they use a suit in
11 the area, they take a five-minute shower.

12 So, yeah, it's a lot of soap, I guess.

13 MR. SZALAJDA: Thank you.

14 MS. MILLER: Could you also say your name?

15 MR. GIANFORCARO: I'm sorry. George
16 Gianforcaro, IndutexUSA.

17 Not everybody -- I believe not everybody
18 has the budget that NASA has. And what we have
19 found in the European marketplace, a lot of
20 pharmaceuticals are mixing chemotherapy drugs and
21 they can't have the worker exposed to chemotherapy
22 for four, eight hours a day every day.

1 So they always take the suit off. They
2 shower, decon, and then they throw the suit away.

3 And we asked them about a reusable versus
4 disposable, and they said it's not worth it, the
5 risk, to put a worker -- have a worker exposed just
6 in a case that maybe they didn't decon it properly
7 or there was a trace or something. It's not worth
8 it to them.

9 And in specifically one application, I
10 remember speaking to them, a worker will wear the
11 suit for only two minutes, run a quick test, then
12 they step out, they shower, and then they throw the
13 suit away.

14 And they said again, it is cost
15 prohibitive for them to go to the decon and open
16 themselves up to a risk. So...

17 MS. MILLER: So, as a follow-up, is there
18 ever a concern that you are selling something that
19 is considered disposable and it is being deconned
20 and reused?

21 MR. GIANFORCARO: Well, we recommend -- we
22 always say it's a disposable suit. But when I'm

1 talking to the customers, I was asking them, Do they
2 have any use or any desire for a reusable? And all
3 of the customers hands down are saying, no, we do
4 not want a reusable suit. We want a disposable.

5 So we have kind of -- it was a happy
6 marriage there.

7 MS. MILLER: So you have chosen that.
8 Okay.

9 MR. SZALAJDA: Okay. Any other comments
10 on this topic?

11 The next topic -- actually, the next two
12 slides relate to flammability and the need for a
13 flammability requirement in the standard.

14 I think we saw Heather's -- again, I think
15 her slide was good at least with regard to how they
16 conduct the flammability and self-ignition -- or
17 self --

18 MS. FARRER: Extinguishing.

19 MR. SZALAJDA: Extinguishing, thank you.

20 MS. FARRER: You're welcome.

21 MR. SZALAJDA: For the flame on the suit.

22 And, again, we would like to get input on

1 what would be a valid criteria to include with the
2 standard.

3 Bill.

4 MR. HASSELL: One thing we discussed prior
5 to the meeting was I think the NASA tester used an
6 NFPA 701, which is --

7 MS. FARRER: DOE.

8 MR. HASSELL: DOE, excuse me. And I think
9 that was a test originally developed for wall
10 coverings and drapes.

11 In some of the other consensus standards
12 out there, there is requirements for both material
13 flame propagation tests and even full systems-level
14 tests.

15 So maybe as we address what are the
16 different classifications you need, we need to
17 figure out do we need something more advanced than a
18 materials test? Do you need some sort of like a
19 flash fire test or something like that.

20 You know, we are looking for input along
21 those lines.

22 MR. SZALAJDA: And I think just to follow

1 up on Bill's -- Bill's comments, especially when you
2 look at the wide range of wearers, these suits can be
3 used -- you know, we have heard from the last public
4 meeting as well as the comments today about the NASA
5 experiences. You know, we have heard insight -- or
6 gotten insight today into the DOE applications when
7 you look at dealing with radiological issues.

8 You know, we haven't really touched into
9 or delved into the chemical aspect in terms of the
10 pharmaceuticals and gotten the feedback from how
11 things are used in pharmaceuticals or paints, other
12 applications like that.

13 Or the biological, you know, the biosafety
14 level requirements.

15 So I think, again, with this topic as well
16 as the others, again we are walking that balancing
17 act between, you know, specifying meaningful
18 performance requirements, but yet trying to be able
19 to encompass a wide range of applications.

20 MS. MILLER: Actually, to add to that,
21 looking at EN 1073, the flammability requirement is
22 EN 1146, the single burner test.

1 It actually does not relate to the
2 classification, whereas the other physical
3 properties, like the abrasion, puncture resistance,
4 flex cracking and tear resistance do.

5 So if anyone has any comments about how we
6 may approach relating the flammability or the
7 ability to ignite to the classification, that would
8 also be of interest to us, if not today, on the
9 formal docket as well.

10 MR. GIANFORCARO: George Gianforcaro,
11 IndutexUSA.

12 Is there a flame requirement for a hood, a
13 loose-fitting hood today?

14 MS. MILLER: No.

15 MR. SZALAJDA: I don't think so.

16 MR. GIANFORCARO: No? Then with that same
17 thought process, maybe there should not be a flame
18 resistance test.

19 Because really the suit is really just --
20 the way I explained, it's an extension of a hood.
21 Instead of a hood stopping at your chest, it goes
22 all the way to your feet.

1 So if there is no requirement for a flame
2 test on a hood, I don't see why we would want to
3 have a flame test for a suit.

4 MS. MILLER: Thank you, George.

5 MR. HASKELL: What if you have an IDLH
6 environment, but the IDLH is related to a lower
7 exposure limit for that particular work environment?

8 See, I think it's so complex, we have got
9 to figure out what are all of the different
10 classifications and then figure out, do you need
11 different requirements depending on a particular
12 classification.

13 MR. GIANFORCARO: Right. And my concern
14 is that if we try and take on so much, we are going
15 to get nothing done.

16 And so I like the process of keeping it
17 simple. And whatever we are doing for the hoods,
18 just apply that to the suit. And we will keep it
19 very simple, and we will get a standard written, and
20 then possibly a revision two or three years later,
21 or six months later.

22 MR. HASKELL: Well, don't we have a

1 requirement for some minimum level of flammability
2 for the escape hoods? CBRN?

3 MR. SZALAJDA: Yes.

4 MR. HASKELL: So we do have that for that
5 type of respiratory protective product.

6 MR. GIANFORCARO: Well, then my suggestion
7 would be whatever that requirement is, put that on
8 the suit, make the same requirement.

9 MR. KVARTEK: Ed Kvartek with Savannah
10 River. Most people there think I work for Heather.

11 We use the NFPA test for both our hood and
12 our suit, but we do consider them a little
13 different. The reason being that you can remove
14 that hood unassisted. If you have got a suit that
15 is difficult to get off, I think a performance-based
16 approach for this at least should be considered.

17 There was an incident several years ago --
18 time flies -- a welder -- not at Savannah River --
19 but a welder was working. He was wearing PPE. It
20 was not a supplied-air suit, but his protective
21 clothing caught on fire. He did realize it because
22 he did not feel the heat. He subsequently died.

1 So I think you are on the right track on
2 looking at flammability.

3 I think you have to consider the
4 application of course, but I think you are on the
5 right mark.

6 MR. SZALAJDA: Thank you, Ed.

7 I would like to move on to the
8 visor/harness topic. We had a little bit this
9 morning, we had some discussion about the marking
10 issues.

11 I think the one thing there, the one
12 discussion I have heard is why is NIOSH in the
13 business of specifying harness requirements, you
14 know, and how do they relate to respiratory
15 protection?

16 I think we would like to hear some more
17 feedback with regard to that issue, not only how it
18 applies to the air-fed ensembles in the pictures
19 that we saw in the DOE presentation, but also how it
20 applies across the board with SAR as well.

21 Comments?

22 Panel?

1 MS. FARRER: It says on your slide
2 external harnesses used with ensembles.

3 If you wear the harness on top of your
4 supplied-air suit and the workers is in an air-off
5 situation, you have now reduced the amount of time
6 that it is going to take -- you have added time for
7 them to be able to get all of that off so they can
8 get the suit off, and they may, like Jon said, be in
9 a panic situation.

10 So I mean, I think the harness -- the
11 suits, ensembles, should be designed where that
12 harness is either integral with the suit or it is
13 underneath the suit so that the worker can get out
14 of it.

15 MR. SZALAJDA: Thank you, Heather.

16 MR. ZIMMERMANN: Gary Zimmermann.

17 On the visors, that's a tough one. I
18 think I just want to mention some practical
19 approaches on visors and overall penetration
20 resistance.

21 Again, it is so application related, even
22 on the flame resistance side of things. It's very

1 application oriented.

2 And I'm actually for that on the flame
3 resistance, by the way, but I just didn't want to
4 dominate these type of things.

5 But in a sense of the visors and
6 penetration, we have a lot of situations where on
7 our disposable garments, for instance, the visors
8 are quite thin, but they are practical for the
9 application.

10 So I don't know the relevancy of
11 penetration resistance testing there.

12 Ideally, of course you want the suit to
13 work well, but also if there's a little puncture in
14 a hood, for instance, again, the overpressure is
15 supposed to take care of things, especially in a
16 particulate resistant environment.

17 Now, it may be, again, different for
18 chemical resistance. That may be a different
19 requirement altogether. So, again, we have to take
20 things into account from an application point of
21 view.

22 Regarding external harnesses, I agree with

1 Heather. We are talking the heat stress issue,
2 never wear them on top, always inside. So that's
3 fine by me.

4 MR. SZALAJDA: Thank you, Gary.

5 MR. PERROTTE: There is one question from
6 LiveMeeting.

7 There is one question from LiveMeeting
8 from JSJ and Associates, Jim Johnson.

9 MR. SZALAJDA: Go ahead, Jim.

10 MR. JOHNSON: Hello.

11 MR. SZALAJDA: You're on, Jim.

12 MR. JOHNSON: Oh, thank you.

13 After listening to this discussion, it
14 seems to me that there are so many questions and so
15 many different applications for a suit, either a
16 chemical protective suit, a physical protective
17 suit, and components of the suit, that I was looking
18 at this standard to deal with the respiratory
19 protection provided to the wearer of the suit,
20 possibility the cooling effect provided by the air
21 that comes through the suit, and any of the obvious
22 hazards that we have talked about just recently,

1 there is a flammability, presenting a minimum
2 flammability for a suit to pass. And unless the
3 demand or the market puts the other standards
4 together that match what the suit finally comes to
5 be, when you think about putting gloves, boots,
6 various materials on it, exhalation valve, the type
7 of lens, looking at a respirator inside; do you need
8 a harness, safety harness?

9 I mean, it becomes a phenomenally
10 complicated topic. And my thought is respiratory
11 protection is where we ought to start.

12 MR. SZALAJDA: Thank you, Jim. I think
13 that's kind of what we are trying to get our arms
14 around when you can look at the generation of the
15 standard with regard to the performance.

16 And I think I had said this morning, first
17 and foremost, it's a respirator. And I think
18 regardless of how the standard evolves, you know,
19 right now if we were to get a submittal, we would
20 evaluate it, and we would evaluate it as a
21 respirator.

22 I think the intent of what we are trying

1 to do is to fill the gaps with the development of
2 this standard and looking, you know, leaning on
3 other existing national and international standards
4 to look at physical properties and other properties
5 of the -- you know, that may lean towards the dermal
6 protection.

7 But I think it sort of falls within our
8 purview when you look at the aspects of the standard
9 that, you know, we reserve the right to look at
10 other parameters if we feel it's going to have an
11 impact on the performance of the respirator.

12 And I think that's when we start talking a
13 about physical properties as well as flammability
14 and some of these other issues, that you are
15 blurring the line in between the respirator and the
16 ensemble.

17 Because of the fact that, you know, at the
18 end of the day, you know, we may guarantee a certain
19 level of protection. But the performance, the other
20 factors associated with the respirator, the physical
21 parameters, the flammability, the other topics that
22 may impact on how well the ensemble actually

1 performs as a respirator.

2 So I think that's kind of where we walk
3 the line in looking at the development of the
4 standard. Yeah, what's appropriate to include and
5 what's not.

6 I think at this point, given the nature of
7 where we are in the development cycle of the
8 standard, nothing is really off limits.

9 So at this point, we need to go through
10 and vet all of the potential issues. And then at
11 the end of the day, in another 18 months or so, we
12 will hopefully come to some sort of position that
13 people will be able to understand and is backed by,
14 you know, have a good scientific basis for why we
15 are doing what we are doing.

16 And with that, the last topic for
17 discussion is the physical properties that I had
18 mentioned. There are two slides associated that.

19 Some of these topics are indicated or
20 covered or have tried to have been addressed by
21 other standards, the ASTM standards as well as
22 international standards.

1 The second slide, I think when you get
2 into the discussion, is how do we apply -- and I
3 think this is a good follow-on to Jim's comment --
4 is the follow-on is how these properties should be
5 classification or use-specific.

6 I mean, where do we draw the line in terms
7 of defining these types of properties with regard to
8 the performance of the respirator?

9 With that, I would like to take comments.

10 Any comments from the panel first?

11 LiveMeeting?

12 No, okay. Any comments?

13 MS. MILLER: Well, I guess I would just
14 like to, again, let the manufacturers know that if
15 you don't want to get up and speak to the
16 performance levels of the ensembles today, that we
17 certainly do welcome your comments on the docket or,
18 you know, you are always free to call. I think you
19 know that.

20 This is the informal part of the process,
21 and that's the nice part about it, is we are allowed
22 to talk at this point.

1 MR. SZALAJDA: At this point, are there
2 any other comments or questions that you may have
3 that haven't been addressed during the course of the
4 discussion?

5 MR. CARDINALE: Mike Cardinale, NASA.

6 Something that I hadn't seen that's of
7 interest to us, of course, is the use of internal
8 air supplies as part of air-fed suits.

9 I hadn't seen it as part of the
10 discussion, but it is an integral component to the
11 type of suits used by NASA for ground operations for
12 spacecraft fueling.

13 And I would hope that, you know, whatever
14 approach you take to establishing this would allow
15 us to include other types of air supplies than those
16 are currently -- you know, that are usually
17 available in the industry now.

18 MR. SZALAJDA: Thank you, Mike.

19 MR. CARDINALE: Sure.

20 MR. SZALAJDA: Are there any other
21 comments at this time?

22 MS. NEWLAND: Michelle Newland from ILC

1 Dover.

2 I just wanted to make a brief comment that
3 actually wasn't brought up in this meeting, but the
4 meeting last year in December. Colleen brought up
5 the point with the ASTM standard that the suit may
6 have to be recertified each year.

7 And that's kind of a concern to me because
8 it could be kind of cost driven if, you know, the
9 customers know that this has to be resubmitted every
10 year, that the cost of the suit might go up. And
11 people -- customers might be not wanting it
12 certified then if they know it is going to be cost
13 driven. It has a direct effect.

14 MR. SZALAJDA: Thank you.

15 Any other comments at this time?

16 Okay. What I would like to do is we are
17 about ten after 2. I would like to take about ten
18 minutes, and we will get ready to do the Total
19 Inward Leakage part of the presentations.

20 So we will reconvene at 2:20. Thank you.

21 (A recess was taken.)

22 MR. SZALAJDA: The last topic for today is

1 Total Inward Leakage for respirators other than
2 Filtering Facepieces and Half-masks.

3 And we have three presentations that you
4 will be hearing. One is Gary Walbert will be
5 introducing the concept for the project with you
6 today. And I think the other opportunity today,
7 which I'm pretty excited about, is you are going to
8 get an opportunity to hear about some pretty
9 innovative research that is ongoing, not only at
10 NPPTL, but also National Institute for Standards and
11 Technology.

12 And Kathy Butler is going to be providing
13 a presentation on a couple of research projects that
14 they have ongoing related to ultimately improving
15 respirator fit.

16 And the other project that I'm pretty
17 excited about because somehow Bill King has linked
18 me to it, is using ultrasound as a method for
19 evaluating respirator fit.

20 And with this project, NIOSH has an
21 initiative called Research 2 Practice and the
22 ultrasound testing project is something that we

1 would like to partner with someone in industry that
2 may be interested in taking the concept that Bill is
3 going to talk about this afternoon and possibly
4 bringing it to fruition as a marketable device.

5 So from that standpoint, you know, after
6 the meeting, if you would be inclined to either
7 submit something to the docket or to contact me or
8 Bill King to discuss about partnerships in terms of
9 being able to develop -- this is part of the NIOSH
10 Research 2 Practice initiative, I would appreciate
11 hearing back from you.

12 And so with that, the docket, it's a new
13 docket for this. It's Docket 168. And I would like
14 to introduce Gary Walbert, who is going to be the
15 project officer for bringing these concepts to
16 fruition.

17 John, we seem to have a problem with the
18 slide progressing.

19 MR. PERROTTE: Hang on.

20 MR. WALBERT: Okay, thank you, Jon.

21 As Jon indicated, I'm going to be cover
22 the concept plan for the Total Inward Leakage

1 program, and this is for respirators other than the
2 filtering facepieces and half-masks.

3 The current project under the TIL program
4 is the characterization of other classes of
5 respirators that are associated with standards that
6 presently in the rulemaking process or whose
7 standards are currently being developed.

8 And that includes the closed-circuit SCBA
9 and the PAPR, whose standards are currently in a
10 rulemaking process, and the supplied-air respirators
11 and the air-fed ensembles standards updates you
12 heard from Jeff Palcic and Colleen miller.

13 Our approach is going to be determine
14 benchmark testing variables and then set pass/fail
15 requirements based on the results of the benchmark
16 testing.

17 Our initial project under the TIL program
18 was TIL characterization of the half-mask and
19 filtering facepieces.

20 Lessons learned during these tests will
21 provide valuable information for benchmark testing
22 of other classes of respirators, and this is in the

1 areas of test protocol development, test agent
2 applicability, and test subject panel size
3 selection.

4 Okay. We have identified what we feel are
5 the sources of inward leakage, and these are listed
6 here. Particles passing through filter media of
7 particulate respirators, contaminants passing
8 through respirator component connections that did
9 not seal properly, and contaminants passing through
10 the respirator-human interface when respirator
11 internal pressure is negative.

12 And the bottom line is that the TIL test
13 is intended to measure inward leakage from all
14 sources combined.

15 Okay. We would like to present options
16 for consideration for TIL benchmark testing. And
17 the first area is in the selection of test subjects.

18 For tight-fitting facepiece assemblies, we
19 propose to use the panel-based -- we proposed to use
20 the NIOSH bivariate panel based on the 2003 NIOSH
21 anthropometric survey. This panel is expected to
22 cover greater than 97 percent of the US civilian

1 workforce. This is in contrast to the LANL panel,
2 which excludes 15.3 percent of the NIOSH survey
3 subjects.

4 For loose-fitting assemblies containing
5 hoods and helmets and tight-fitting neck-dam
6 assemblies, we propose to develop test panels based
7 on the 2003 NIOSH anthropometric database containing
8 head and neck circumference measurements.

9 We also propose that the test panel size
10 be specified through statistical analysis of
11 benchmark test data. And this would be done by
12 determining the number of tests that are sufficient
13 to yield statistically reliable data, as was done
14 for the half-mask and the filtering facepieces TIL
15 project.

16 In area of the test configurations, the
17 number of respirator configurations we need to be
18 tested will be determined on a case-by-case basis at
19 the discretion of NIOSH, and this is in terms of
20 what accessories will be included when testing a
21 respirator.

22 Considerations for respirator probe

1 specifications will include the probe type and probe
2 location. It is likely that these specifications s
3 will be respirator-class dependent.

4 A lot of information available only this
5 subject and available probe technology will be
6 reviewed and implemented based on what makes sense
7 and through benchmark testing.

8 Okay. The draft ISO TIL standard is one
9 such reference that includes TIL probing
10 specifications that we have looked at so far.

11 Okay. In the area of test agent
12 selection, we are proposing to use corn oil aerosol
13 for all four respirator classes that are listed in
14 this concept plan.

15 Corn oil aerosol is a currently recognized
16 and accepted test agent. And with current
17 technology, a TIL level of -- a minimum TIL level of
18 .001 percent can be measured.

19 Other test agents salt aerosol, for which
20 a minimum measurable TIL level of less than .0005 is
21 possible using flame photometry.

22 Another test agent that we have considered

1 is use of ambient particulates. However, a
2 consideration for its use will be whether sufficient
3 particle concentration exists. In addition, the
4 minimum measurable TIL level for the ambient
5 particulates were based on the maximum ambient
6 particle concentration.

7 Also considering isoamyl acetate vapor.
8 We are considering whether it can be quantitatively
9 evaluated or used for particulates.

10 The use of dioctyl phthalate aerosol will
11 require addressing its associate health effects. A
12 minimum measurable TIL level of .001 percent is
13 possible for dioctyl phthalate with current
14 technology.

15 The final test agent that we were
16 considering is a sulfur hexafluoride gas. The draft
17 ISO TIL standard indicates that this gas is
18 applicable to non-particulate filtering respirators
19 containing materials that are porous to gases and
20 vapors. Suitable detection systems for sulfur
21 hexafluoride include IR absorption and electron
22 capture detection. And we use the combination that

1 can provide minimum measurable TIL levels less than
2 .0005 percent.

3 There are a number of protocols that are
4 currently available that could be modified for TIL
5 testing. They include the LRPL corn oil test
6 protocol, and the references for that are -- we find
7 are the NIOSH LRPL STP and also the draft ISO TIL
8 standard.

9 So the sodium chloride test protocol, and
10 we find reference for that in the draft ISO TIL
11 standard.

12 Sulfur hexafluoride test protocol. The
13 draft ISO -- in reference for that is the draft ISO
14 TIL and NFPA 1994 standards.

15 And in addition, the OSHA quantitative fit
16 test protocol for the selection of test exercises
17 and the industrial fit test isoamyl acetate vapor
18 test protocol measured quantitatively.

19 Test protocol issues would include, under
20 test performance, test performance requirements
21 should be established through benchmark testing.
22 Also test performance requirements would be

1 determined for the respirator configuration
2 submitted for approval.

3 Okay. Other protocol issues would include
4 test exercises where we propose to follow the OSHA
5 fit test exercises with some additional criteria
6 added to ensure that exercise motions are performed
7 more consistently by human test subjects.

8 Also, the OSHA fit test exercises
9 represent typical movements where leakage could
10 occur. Other exercises may be identified to add to
11 this list, or one or more of these exercised may be
12 eliminated depending on benchmark test results.

13 Respirator class-specific exercised may
14 also be identified through benchmark testing.

15 Okay. This relationship, TIL is equal to
16 100 percent divided by the fit factor, which was
17 presented previously for the half-mask and filtering
18 facepieces TIL project.

19 Assuming that the measured fit factor
20 approximates the protection factor, a TIL of .001
21 percent would be approximately equal to a protection
22 factor of 100,000 on down to a TIL of 20 percent

1 would be approximately a protection factor of 5.

2 It is anticipated that the pass/fail TIL
3 values will approximate 100 percent over the fit
4 factor where the fit factor is a minimum tenfold
5 multiple of current OSHA assigned protection
6 factors.

7 Pass/fail criteria will be based on
8 benchmark performance test results, not on the
9 current APF.

10 Benchmark testing will be also be
11 performed to gauge state-of-the-art technology
12 capabilities, including instrument sensitivities.

13 And finally, we feel that as the TIL
14 project and development of the TIL module
15 progresses, LRPL requirements will ultimately be
16 replaced by the inward leakage requirements in the
17 TIL program.

18 Any comments that aren't submitted here
19 verbally can be submitted to our NIOSH docket
20 office, and reference Docket 168.

21 Okay. These are question that will be
22 considered for consideration during our panel

1 discussion.

2 I'll read them off here.

3 Should a TIL pass/fail criteria be based
4 on the type of respirator inlet covering, the
5 intended use of the respirator, or other factors?

6 Are there any other test agents that can
7 be used which will work for some or all types of
8 respirators that are safe, environmentally friendly,
9 and can be accurately measured at the desired
10 concentration?

11 Is there test equipment available that can
12 reliably measure the concentration of the test
13 agents of choice that are not overly expensive to
14 own, operate, or maintain?

15 Should NIOSH consider accepting TIL test
16 results from independent laboratories. Should the
17 standard set of exercises employed by the fit
18 testing process be used for all TIL testing, or
19 should it be different for various types, and why?

20 Do the options for available respirators
21 dictate what exercises can be done?

22 And what will be the strategy for the

1 placement of sample ports for other classes of
2 respirators? Where will the sample point terminate
3 with respect to the test subject for each class of
4 respirator.

5 That's all I have.

6 MS. BUTLER: Hello everybody. I'm Kathy
7 Butler at NIST. I'm in the Fire Research Division
8 there, so our main interest is with firefighters and
9 the types of protection they need.

10 I'll be talking today about two of our
11 projects, both of which are dealing with respirator
12 modeling.

13 We also have two other projects that we
14 are doing for the Department of Homeland Security.
15 One of them has to do with respiratory hazards
16 during the cleanup from a fire. And the other one
17 has to do with what happens to the respirator
18 materials when they are heated up, as with a
19 firefighter going into a highly heated situation.
20 And for that I will introduce Amy Mensch, who will
21 be working on that.

22 Wave your hand, Amy. So if you have any

1 questions having to do with that project, please see
2 her afterwards.

3 Okay. So the two projects that I have
4 been working on for the Department of Homeland
5 Security are characterizing the respirator fit for
6 real faces and masks. And the second one is looking
7 at respirator sensor placement for accurate readings
8 inside of a respirator.

9 My standard introductory slide, all of you
10 know this. We need respirators to protect us
11 against many hazards. For firefighters, we don't
12 have any idea of what kind of threat they are going
13 into, so we really need to provide adequate
14 protection for any threat, a wide range of
15 situations. We need to account for high stress
16 situations, high exercise, and possibly long
17 duration, short duration being fire suppression.

18 And we have issues with imperfect fit,
19 with leaks, with what's happening while people are
20 talking, while people are coughing. These are some
21 of the things that we hope to address with this
22 project.

1 So the question that comes up is an annual
2 fit test good enough, what kinds of variations do
3 you see over time, what are the consequences of an
4 imperfect fit? And then do leaks happen and under
5 what conditions? Is a sensor for real-time
6 monitoring a good idea? Do we have the technologies
7 availability to us now, and where would you put that
8 inside of a mask so that you could actually read
9 something that's of value to the person who wants to
10 be monitored?

11 So I have taken to approach that -- using
12 a computational model to supplement the work that's
13 been done by NIOSH, very good experimental work.
14 But there are some things that a computational model
15 can do for you, which is that you can visualize the
16 results throughout the mask and not just at a
17 location of a sensor, looking at velocity, pressure,
18 particle traces, gas concentrations. And you can
19 set up problems that test a variety of conditions
20 and look at what if this and that.

21 The first thing that you need to do, as I
22 found out, is actually the most time consuming task,

1 which is to define the complex geometry. So the
2 first thing I started with was my own head.

3 NIOSH was kind enough to let us use their
4 3D scanner. And this results in a point cloud that
5 you then bring into a program that allows you to
6 come up with a surface for that and close that
7 surface, all of the holes.

8 And for projects that I have been doing, I
9 wanted to have my mouth open, so I was breathing
10 through my mouth. So I manipulated this model to do
11 that.

12 Actually, what we plan to do with our
13 project is to take various scans of people with
14 their mouths open, with their mouths closed, in
15 various states of various expressions.

16 For mask geometry, we can use a 3D
17 scanner. We can also use mechanical drawings, which
18 I have done. Both of those take a good deal of time
19 to close up. The geometry is pretty complex and
20 there are a lot of points that -- well, you come to
21 a point within the geometry, so it's a little bit
22 tough to get those right. And I'm grateful to

1 Draeger for providing us with a set of CAD files so
2 that I can have a good set of accurate measurements
3 for a mask to use in this experiment.

4 One of the things that -- one of the
5 obvious things that I found out early in the testing
6 is that if you take this rigid face and you combine
7 it with a rigid mask and you put them together,
8 well, you have problems with the mask hitting the
9 cheeks and cutting through them. And at the same
10 time, the forehead and the chin do not quite touch
11 the head. And, you know, if you take a mask and you
12 try to push it on, of course that's the way it's
13 going to work.

14 So part of this testing also will supply
15 us with a respirator being fit over a person and,
16 therefore, having the correct geometry for that.

17 So the first question that we are
18 addressing with these two projects is how to
19 characterize fit and discomfort for a given
20 individual and a given respirator.

21 And after I had thought of this technique,
22 I found out I wasn't the first person. There was a

1 study that was done for Aberdeen in 1997 in which
2 these people, Piccione and Moyer, also did this
3 project with putting a seal and fitting it over a
4 face.

5 So the idea is that you take a respirator
6 geometry, you put material properties to it. You
7 are dealing with a seal. You don't need to deal
8 with the solid parts. And then you deal with a
9 face, with the actual material properties of skin
10 over bone.

11 Once you look at the contact pressures of
12 the contact region in between the two, you find
13 regions that are of a lower pressure where you might
14 expect there to be leaks appearing first in the
15 mask, and there are also regions where you would
16 have a high pressure.

17 And you might expect those to be regions
18 where you would end up with a red mark if you really
19 tightened it down to make sure that you were well
20 protected.

21 So some of the questions that we can deal
22 with with this is how good is a rigid 3D scan for

1 predicting fit?

2 If manufacturers are using headforms to
3 look at respirator fit, how good are those when you
4 consider that these are rigid bodies as compared to
5 you have got a face with a cheek thickness, very
6 different from forehead thickness, very different
7 from opening your mouth wide and having your cheeks.

8 So these are the kinds of questions that I
9 would like to deal with. And perhaps a bit farther
10 down the road a question would be can you customize
11 the seal for an individual?

12 Could you go into somebody's office, as
13 you do now with the dentist, and come up with a seal
14 that's customized for your own face.

15 So the project is called characterizing
16 respirator fit for real faces and masks. And the
17 issue is for emergency responders, they work very
18 hard, and they can overbreathe the respirator.

19 You know, we are not certain how much loss
20 of protection there is from that, but that's one
21 thing that we would like to contribute to.

22 And the other thing is that if the

1 respiratory equipment is not comfortable, then it's
2 already been shown that if a first responder is
3 convinced that they can't do their job while wearing
4 it, they will take them off. And so discomfort is
5 an important thing as well.

6 So the purpose of this project is to
7 enhance respirator fit and sizing procedures by
8 improving our knowledge of the relationship between
9 the human and the respirator features and the
10 respirator effectiveness. So, yeah, I already
11 described the approach.

12 So here are the steps that are involved in
13 this.

14 I have already prepared some
15 three-dimensional representations. We have got
16 three human heads. We have got a set of respirator
17 masks.

18 And then starting with a rigid head and a
19 single piece of the seal, push it on, do a contact
20 problem and find an element analysis. And plot the
21 stresses on the surface, find those locations where
22 you might expect leaks and fit comfort.

1 And then to complicate it a little bit
2 more, put skin, represent a thickness of skin over
3 the face. And finally I would like to move to
4 medical scans and actually do some real situations
5 with actual face properties.

6 Second thing, well, also we want to
7 animate the face or at least, you know, have
8 different representations of somebody yawning,
9 somebody coughing, somebody speaking, then assess
10 the sensitivity to how the mask is positioned to
11 design factors and find out what is the ability of a
12 fixed head scan to fully represent the fit of a
13 respirator in comparison with the actual material
14 properties.

15 So here is a set of what we have now in
16 our little library. The respirator seal geometry.
17 I have started out on the left of this with the full
18 geometry. What I would like to end up doing is a
19 full seal geometry so that you have rigid edges that
20 are represented by the contact with the visor and
21 fixed properties of the -- of the facepiece.

22 What you start out with is a simple

1 geometry is just taking a single seal on this
2 multiple seal unit, and then take this and push it
3 onto a face. And I have to admit, I chose unwisely.

4 I have had a couple of finite element
5 programs that I have tried. Both of them said they
6 could do contact problems. Neither of them could
7 actually do it, and I'm now moving to ellstina
8 (phonetic), which is something that -- Ziquing
9 Zhuang also has a person working on this from Texas
10 Tech University work is working on a half-mask
11 project. And they have had success with ellastina.
12 So at the moment, I'm learning how to use it. And I
13 expect at the next one of these meetings, I will
14 have some very interesting work.

15 In the meantime, let me show you what
16 Jingzhou Yang -- is that correct? -- has been doing
17 with Ziquing to do this same type of problem,
18 starting out with the geometry of a half facepiece
19 mask, applying forces to each strap and pushing that
20 onto the head and looking at the pressures.

21 On the respirator first, this is with two
22 and a half newtons for each strap, and then the

1 pressures on the face. And you can see that there
2 are different properties there.

3 You have to push it on hard enough, of
4 course, to have a contact all around this area.

5 And here is a test where they did five
6 newtons for each strap. So one of the things that
7 you need to understand is how much pressure it takes
8 to actually fit this thing so that all of the
9 conditions are met so that you have a good fit.

10 So that's the first project that I'm
11 working on.

12 The second one is what kind of
13 possibilities do we have now for looking at
14 real-time respirator monitoring. And the question
15 that I will look at numerically is where are the
16 best positions for placing a sensor to look at flow
17 pressure or gas? How is that flow affected by a
18 leak? And what kind of breathing resistance? There
19 are other kinds of questions that I can do once I
20 know the flow field.

21 So there were a couple of things that I
22 thought of initially with this problem. One of them

1 is if you could provide the immediate warning of a
2 leak, and something that goes on for more than --
3 for more than a very short period of time. Say
4 somebody hits their head against the wall and it
5 doesn't quite adjust properly for them, and they are
6 continuing to have some problems with this
7 respirator. Then you could say that that worker
8 needs to be removed or needs to be adjusted somehow.

9 And you need to have that sensor placed in
10 a region that actually sees the flow, actually sees
11 what's going on within the mask over time, but won't
12 be disturbed while you are putting the respirator
13 on, while you are taking it off.

14 And the other thing that we want to know
15 is what is the need for this kind of work? So we
16 have looked at that question as well.

17 So the purpose is to evaluate the need and
18 what are the potential technologies for real-time
19 monitoring of emergency responder respiratory intake
20 and what kind of criteria and recommendations for
21 placement of sensors in respirator masks can we
22 make?

1 So with this problem, we started out this
2 year. On May 1, we conducted a workshop to discuss
3 the need and potential solutions for real-time
4 monitoring, and the report on that should be coming
5 out within the next few weeks for -- at least for
6 review by the people who have been there. And it
7 will come out in the next couple of months for the
8 general public.

9 And then as far as the computations go,
10 well, first of all we have to represent the
11 three-dimensional geometries of the masks and the
12 faces, and I intend to use the results of the first
13 problem where I'm pushing masks onto the face to
14 give me an initial geometry for looking at these
15 flows and then take a look, what is the flow field,
16 what is the pressure field? What happens when you
17 have low and high work rates?

18 And, you know, perhaps you could take it
19 on further to say, what if I -- well, I'm looking at
20 concentrations of various gases within. I can also
21 represent those in a finite element model, and I
22 also do a thermal problem to look at temperatures of

1 breathing, of gases coming in, and what their effect
2 is on the properties of -- well, on what the user is
3 breathing.

4 We also intend to have some experiments to
5 validate this and to determine some criteria and
6 potential locations to make recommendations for.

7 So our workshop consisted of firefighters,
8 researchers, academia, and government manufacturers,
9 representatives from the NFPA Standards Committee.

10 And we looked at the question, What is the need?

11 And, well, we found out that there were
12 more than one potential use. You can use some
13 information from a sensor mounted within the mask to
14 ask not only is there a leak, but also to collect
15 data from somebody in the field rather than --
16 rather than in a laboratory while they are doing
17 actual work to monitor the physiological capability
18 of the person and to ask the question -- mounting a
19 sensor also on the outside, one could ask can the
20 respirator be removed at this point. Is it a safe
21 environment?

22 So there were a number of possible

1 approaches that were discussed, mount the sensor
2 inside and outside. Should there be multiple
3 measurements of various kinds of gases, of pressure,
4 and how should it be mounted that were addressed in
5 this workshop.

6 We also looked at some sensor
7 technologies. We had about five different groups
8 come in and present what technologies they have now
9 to measure gas and particulates and pressure.

10 The sensors, of course, are getting
11 smaller, so this becomes a real possibility.

12 And then looking at some of the challenges
13 that we must meet with this, which are, first of
14 all, confounding factors, temperature and humidity
15 being important there. And having an unknown
16 environment is certainly an issue.

17 And of course, any time you are thinking
18 of introducing anything to first responders, you
19 need to consider that you need to gain their trust
20 in the equipment.

21 And we did find that there was a
22 firefighter community that very much likes to try

1 out new things. So we have people that would be a
2 possible stable of people to do some testing for us.

3 I will show this from a half-facepiece
4 mask. I'm working on the full-facepiece mask.

5 But here's an example for what can be
6 done, put the mask on the face. You have got
7 enclose the surface so that you have a single space
8 within. And then in this case, I have the air
9 coming in through the filters on the side during
10 inhalation, going out through the center valve
11 during exhalation. I made some assumptions about
12 the breathing rate. And I had a very simple
13 sinusoidal breathing rate, and I think I will make
14 that a little more proper the next time I run this
15 model.

16 Refine the mesh, and this is what we found
17 with the gas flow. During exhalation, what happened
18 with this particular mask is that breathing out, the
19 gases smack against the back wall and then kind of
20 spread out over the mask. And, you know, some of
21 the gases go directly down.

22 But you have got a high pressure region

1 that is right across from where you are breathing.
2 There is a lot going on in the space during
3 exhalation as compared to inhalation, where you have
4 got a pretty direct flow between the side valves and
5 the mouth.

6 We will see. No. I think you can see.
7 Yeah. I can animate it. It all depends on the
8 laptop that I'm using whether it looks really pretty
9 or not.

10 I can then take a look at what happens
11 under different breathing and workload conditions.
12 I can look at various sizes, various placements of
13 leaks.

14 And that's all I have. So I thank you
15 very much for your time.

16 MR. KING: Hi. I'm Bill King. I'm in the
17 Policy and Standards Group with Jon and the others
18 that are here today. And what I would like to talk
19 about is ultrasound respirators, our concepts and
20 initial results.

21 I guess I have got this -- hold on here.
22 I have got to learn something. How do you do this,

1 page down, next. There we go.

2 Yeah, an overview of what I'm talking
3 about. Ultrasound and its uses, primarily
4 associated with leak detection. We are looking at a
5 couple of ways ultrasound is used, and then, again,
6 kind of redundant.

7 This initial assessment of respirators,
8 there's the preliminary results I have developed to
9 support the concept.

10 Why do this? The objective here was --
11 going in long detail in an aside, but, you know, you
12 can think of a lot of reasons why you might want to
13 have a device, a nondestructive method of monitoring
14 fit or leakage in situ. And what I mean by in situ
15 is an actual respirator that is unprobed, you know,
16 that is -- while you are wearing the darn thing,
17 real-time during use. That is you get data out of
18 this thing while you are wearing it.

19 And I think that would be -- I can think
20 of several things. I won't elaborate, but leave
21 that to your own thoughts.

22 I kind of stuck this in. It's about

1 ultrasound because that was the general concept. As
2 I thought about ways of doing this, ultrasound came
3 to my attention. And this kind of just was actually
4 was written for a plan for a project proposal some
5 time ago characterized ultrasound associated with
6 leaks in respirators, correlated -- so I won't go
7 over all of these details.

8 But anyway, what I'm going to look at is
9 could we use ultrasound basically to detect leaks.
10 I'm sorry. I'm jumping around. Is that driving you
11 crazy or what? I'm going to stay a little closer
12 here.

13 While I'm thinking, the results will
14 provide a basis for determination of the most
15 effective strategies for monitoring respirator fit
16 using ultrasound. I will try to go back and cover
17 that here. It's a little out of place in my view.

18 Anyway, ultrasound, what is it?

19 You all know -- you think about when you
20 think about ultrasound is ultrasound images
21 generated by ultrasonic used primarily for looking
22 at internal structure in a body and stuff like that.

1 That's ultrasound.

2 And what it is is -- there's a little
3 graph. I don't know if you see it here -- but it's
4 basically cyclic pressure above -- here's the
5 acoustic range, what we can hear, up to 20 kilohertz
6 typically. And everything above that is considered
7 ultrasound, basically, at a higher frequency than
8 that. And so that's where we are at.

9 And, again, we have -- there's medical --
10 medical diagnostic, they run a couple of megahertz
11 and the like -- we won't get into what.

12 Anyway, what I'm interested in here is
13 airborne ultrasound, okay, distinctly different only
14 that it's sound transmitted through the air as
15 opposed to through aqueous media, what is basically
16 what you and I are.

17 So what's that typically used for? Things
18 like SONAR, tracking, positioning, its main use.
19 And of course one of -- one of the people -- unless
20 you are an engineer or something, you are not aware
21 of leak detection, ultrasound use for leak
22 detection, which, hey, why not?

1 So another salient feature is exposure to
2 airborne ultrasound is not a big human health risk.
3 And there is the TLVs for -- out of the ACGIH there.
4 I notice they have TWAs for sound. Ultrasound, they
5 don't have any, but their ceiling value is 110 dBA.
6 So hopefully everything we do would be well below
7 that.

8 And of course, it's inaudible. They say
9 why not use sound. Well, you know, you can hear
10 that stuff. You can't hear this.

11 So what we see here is ultrasonic range.
12 I just want to -- how is it used for some of these
13 things, and hopefully can I get this work.

14 You have a transceiver. That's a device
15 that can send and hear ultrasound. And you send it
16 out, a pulse -- hopefully it will work. Yeah,
17 there's ultrasound going out. It hits an object,
18 reflects back, radar; right, just like they do in
19 electromagnetic stuff, except you are using
20 ultrasound.

21 And over here I just have a plot of what
22 you would see in time.

1 There's your -- we call it a pulse. You
2 send out a pulse. It goes off and it bounces back,
3 and you listen for it coming back. And this
4 distance is a way, of course, is a function -- you
5 know, it's two times the transit time divided by the
6 speed of sound in that medium.

7 So you can tell how far away something is
8 using this approach, and that's typically what it's
9 used for. You know, things that open your --
10 automatic doors for you typically are ultrasound
11 sensors, or the burglar alarms in people's homes,
12 that's an ultrasound, looking for this kind of
13 thing.

14 What we see on the next one.

15 For leak detection, now it's interesting,
16 fluid flow, when you have a fluid flow through a
17 leak where you get turbulent flow, the condition is
18 such that you have turbulent flow associated with
19 that fluid, that is the source of ultrasound.

20 So what you can do very conveniently is
21 just simply look for the ultrasound. You can detect
22 it. And that's what I just show here.

1 Typically you don't qualify and say if you
2 don't have a leak -- your goal is if you detect
3 ultrasound, you got a leak. Get rid of the leak,
4 you don't have any ultrasound. And that's
5 typically -- it works well, even in industrial
6 environments because of, you know, the immunity to
7 the sound is because you are way out of the
8 frequency of sound, so it is kind of interesting.

9 Anyway, that's generally what's done.

10 However, in another approach here, leak
11 detection, what if you don't have a flow, and what
12 if your flow isn't generating ultrasound. Well,
13 another thing you can do is just stick a generator
14 in.

15 You stick a generator on one side of the
16 container or area that you want to look for a leak
17 in, and then you put your detector on the other
18 side, and you look for the ultrasound coming
19 through.

20 It is only transmitted -- again, this
21 thing has got to be rigid enough. It doesn't allow
22 for transmission through it, you know, like a

1 drumhead or something like that. It only lets
2 what's conducted through a leak path.

3 And so, again, the same situation, it's
4 not -- typically not quantified. But that's the
5 kind of stuff that you can do with ultrasound for
6 leak detection.

7 Now, just a little bit on the technology
8 again. This might be trite, but it's a low power
9 and size. That is you can -- the technology is such
10 that -- you know, you don't need very big devices.
11 This is something you can buy in Radio Shack here.
12 It's actually -- it sends and receives, and you
13 stick it on the top of your little robot for, you
14 know, when you have a chainsaw on so it will cut the
15 other robot in half kind of thing. Well, you can
16 tell where the other robot is by using that device
17 right there.

18 Well, it has a logic in it right there.
19 You have to run power to it and stuff like that.

20 There's a transducer right there. That's
21 what they -- they are very small. Actually, the
22 element itself is right inside there, but you need

1 that housing, but they are very small.

2 And you can see that same thing down here
3 in this thing. This is the device that I actually
4 used in the work I will show you in a minute.

5 It looks like a gun because it's -- you
6 know, you just aim it. Actually, the element is in
7 the end of this thing, so you point your basically
8 microphone at where you think the ultrasound is and
9 listen for it.

10 And it shows up as a reading on the back
11 there. There's a series of bar LEDs that tell you
12 the dBA level to come out.

13 By the way, this is the source here. The
14 same element is in here. You notice there's a
15 little source there, so you can generate it. You
16 know, it's got it's own battery in it and stuff like
17 that. And there's the microphone -- or the
18 earphones for hearing.

19 It heterodynes into the audible so you can
20 hear it in a set of headphones.

21 The other things you can do with this --
22 well, and this unit here is a little pricey, like

1 800 bucks, 900 bucks, but you can get them for 50
2 bucks, you know, real simple devices.

3 Not that that's too big an issue, but I
4 mean it's relatively low cost. It's not -- in fact,
5 I should bring up some spectroscopic techniques, I
6 think of photoacoustic spectroscopy. They pulse
7 their light interrogation of objects in the
8 ultrasound region so they can detect -- instead of
9 using a sophisticated optical detector, you use a
10 ultrasound microphone, or sonic, actually, so you
11 can hear it with a microphone as opposed to, you
12 know, a device for detecting light, which you can
13 argue those are getting simpler and cheaper anymore,
14 anyway.

15 But anyway, my point made.

16 Anyway, you can -- plus you can apply
17 sound techniques. Everything you do -- this just
18 shows the front end of some software where they have
19 the power spectrum for some -- actually, those are
20 chirps from a bat because bats use ultrasound, and
21 they are interested -- a lot of people are
22 interested in studying the nature of them. But the

1 point is you can record this data and look at it and
2 look at the spectral properties, you know, power,
3 spectrum, things like that.

4 So all of the elements are there for what?
5 Looking at it in respirators.

6 So then we have to ask ourselves some
7 questions, ultrasound source -- and this is really
8 back to that original plan slide, there. Ultrasound
9 sources, do leaks give off ultrasound? How about
10 respiration? That's fluid flow, and are there other
11 sources of ultrasound we would have to deal either
12 as noise or things like that?

13 And then if you can get ultrasound
14 information, can you relate, for instance, the
15 amplitude. The easiest thing you do, and that's
16 what you typically measure here with this is the
17 simplest thing to do, you know, what's the dBA level
18 of the sound coming through.

19 Can you relate that to fit factor?

20 And some related things, how about
21 temporal? And that's one I'm interested. Can you
22 follow that change over the course of time and, you

1 know, and how fast can you respond to changes in the
2 fit factor associated with wearing this device,
3 wearing a respiratory device. And also could you do
4 a spatial -- this -- can you see -- can you divine
5 out where it is leaking?

6 And of course, then using the spectral
7 techniques, then, can you -- I won't get into that.
8 Using -- instead of just a relatively simple
9 approach, like we are doing now, could you maybe go
10 to a more sophisticated analysis of behavior of
11 different wavelengths and kind of get that
12 information above in different ways.

13 So those are kind of the things that I
14 wanted to assess for this.

15 First thing, source assessment, back to
16 that point, it has to be -- in order to generate
17 ultrasound, you have to have turbulent flow, so what
18 do you get? You have to look at the Reynolds number
19 you might be aware of.

20 Reynolds number is a way of -- associated
21 with the nature of flow in a system -- I just have
22 the variables here. I won't go into it. But

1 anyway, it depends on the -- like the characteristic
2 diameter is flowing through the velocity and
3 kinematic viscosity, or the dynamic fluid viscosity,
4 I should say.

5 So I just had these up here so you can
6 look at it and tell me I calculated it wrong, if you
7 care to. Whatever. But we will recalculate it if
8 you want.

9 But anyway, what's -- you want to be do --
10 calculate the Reynolds number because there's this
11 issue of critical Reynolds number. That's kind of
12 the region -- that's the -- well, if it's below
13 that, you don't have turbulent flow. If it's above
14 it, you will have turbulent flow, or you tend to --
15 a higher level of turbulent flow as you are above
16 the Reynolds number for this, and this is a flow
17 through -- so the range for that, that is the
18 boundary, is between 10^3 to 10^4 .

19 So what I did here next is took a look
20 at -- oop, there it is.

21 Here's the numbers I plugged in if you
22 want to go through those. But -- well, you have had

1 time to do it, but basically, it's over here. I
2 looked at three things. The leak -- a normal leak
3 of -- detection factor of a hundred at a relatively
4 low breathing rate, 20 liters a minute -- I used the
5 average value, so it's at the root mean square of
6 it, so -- and calculated the Reynolds number under
7 these different conditions.

8 I looked at a leak. I looked at a
9 nostril, breathing through your nose and breathing
10 through your mouth. And what's really important
11 here is the Reynolds number, of course.

12 Notice the Reynolds number for leak and
13 mouth are really low, 10 to the 2, 10 to the 1.

14 The only thing that goes above our
15 criteria or our boundary, 10 to 3, 10 to 4, is
16 breathing through your nose.

17 So there we have a source of ultrasound is
18 in breathing through your nostril. Now, that could
19 be a problem because it could be an interference or
20 whatever. So the fact -- well, let me show you. I
21 don't know if this will work or not. I doubt it. I
22 can't get my -- oh, here.

1 I put some wave files on here -- now,
2 well, I should say, yeah, I mentioned earlier that
3 recording with this device, what you get is -- this
4 thing has a heterodyning circuit on it, so it shifts
5 the ultrasound frequency down into the audible so
6 that you can hear it through the headphones. So
7 that's what I have got recorded here.

8 So you breathe through your nose -- well,
9 let's hear breathe through your mouth first. Well,
10 it doesn't work. Forget it. Well, it sounds like
11 this.

12 Okay? You don't hear anything.

13 So it confirms what I calculated -- my
14 prediction there.

15 Nasal, though, you do hear. And you hear
16 this (sniffing sound). You hear -- well, you
17 hear -- you can definitely tell somebody is
18 breathing through their nose. In fact, you can't
19 hear it audible, but you can hear this distinct, 20,
20 30 dB -- well, it's high for the exhale, about 30
21 dB, and it's about half to a quarter of that for
22 inhalation. But you have a distinct ultrasound

1 generated associated with nasal breathing.

2 So -- well, okay. So much for that.

3 Another question was -- and I didn't put
4 it as a point -- but what about this issue of
5 amplitude versus leakage for detected ultrasound.

6 So I did a little experiment here.

7 There's a diagram for us, take another slide. Put
8 the -- again, it was what I had before, and that
9 would have the generator sound on it if I could play
10 it.

11 But, anyway, it's squeaking away, and I
12 have a receiver over here. And I put different
13 hole -- I just got a set of drill bits, actually
14 two. That's why I have two types of points, one
15 small set and one big set. And I drilled different
16 holes in my barrier and looked at the -- keeping all
17 of that configuration the same.

18 And there's, again, you get a real good
19 correlation with leak size. That is the ultrasound
20 amplitude in decibels over here is proportional to
21 the diameter of the leak.

22 So what do I have? I have a technique

1 that I can predict the -- I can have a good way of
2 telling how big the hole is in a system.

3 So let's go to the next. Well, back to
4 that point before I came to this one.

5 One of the problems I realized was --
6 because I wanted to do this in a mask, a respirator.
7 That generator is too big to stick in a mask, and I
8 didn't want to -- I don't think Jon would have
9 appreciated me carving holes in a headform or
10 anything like that, so I got the idea to say, Well,
11 wait a minute. Let's measure the nose.

12 So that's what I did. I used the nose. I
13 basically did the same experiment except I used the
14 nose in place of the generator. And I repeated the
15 experiment. I didn't have the diagram, but, you
16 know, there's a those there.

17 And did the same thing, and I get the same
18 thing. The only difference is I looked at the peak,
19 you know, that -- because it's kind of sinusoidal,
20 there's a lopsided sinusoidal profile there that you
21 get -- or not -- it's humps, whatever that is.

22 Anyway you get a fairly linear response

1 with the inhalation, peak inhalation, peak
2 exhalation ultrasound. Going through the leak, you
3 get a fixed configuration.

4 So what do I have? Now I have a technique
5 I could use in a respirator I think. So that's what
6 I did next.

7 I took, again, nasal breathing as the
8 ultrasound source in a single object. I just
9 breathed through my mouth while I'm wearing
10 respirators, measure the ultrasound level -- the
11 point is, it could leak several places, so I chose
12 five points around the perimeter of the mask, you
13 know, left nose, right nose, left chin, right chin,
14 and under the chin here.

15 And simultaneously, by using probed
16 respirators, I measured the fit factor with a
17 PortaCount. Okay. So this all happens over a
18 single exercise period, one minute. I think they
19 are one minute on those things; right?

20 Anyway, whatever it is, that's what I did.

21 And what I wanted to do, of course, is
22 modulate the fit factor as much as I could. So each

1 respirator, I did three times with -- you know, they
2 all have the adjustable straps, so I did a very
3 loose -- which it's -- it's not an approved
4 configuration, appropriate, but it's very loose to
5 get a very low fit factor, normal, and then very
6 tight, trying to get some modulation in that, and at
7 the same time measuring the ultrasound leakage.

8 Now, what I measured here -- actually,
9 what's important here is this.

10 Here are the five points I did. Again, I
11 measured the peak ultrasound again because what I'm
12 doing is measuring through a mirror there. It's
13 tricky to read the back of the meter, so I'm
14 pointing this thing around. So it's a little
15 tricky.

16 But, anyway, what I did here was each of
17 the five measurements, both at the peak of the
18 inhale and peak of the exhale. And I also looked at
19 background.

20 And then I correct these values if there's
21 any background -- for any background. And that's
22 what I record. As well as the fit factor I measured

1 from the PortaCount.

2 And then to -- well, I looked at this. I
3 said, Well, how am I going to come up with one value
4 I can plot. Well, I did a very crude thing. I just
5 averaged these all together.

6 And so I plotted all of the values I did
7 for these several variations of each respirator. I
8 think I had five or -- you will even count them here
9 in a minute -- and plotted them versus fit factor,
10 and this is what I got.

11 Notice that what we see is -- here's peak
12 dB. That is the ultrasound -- again, the average of
13 the ultrasound inhalation and exhalation for all of
14 those points for each respirator. Each point is an
15 average value for one respirator, versus the fit
16 factor I read from the PortaCount.

17 And it stands out here that it -- if you
18 have a very high ultrasound leakage, the average
19 leakage level, that corresponds to a very low fit
20 factor, and vice versa.

21 And it's is fairly linear. I get fairly
22 good correlation with that.

1 So I have first technique I think of
2 anybody -- and I challenge anybody, does anybody
3 have a technique that has correlated, other than the
4 fit factor, with the fit factor, that can tell you
5 the average leakage, and I would say likely not.

6 So I'm kind of proud of that.

7 UNIDENTIFIED PERSON: Negative pressure.

8 MR. KING: Say what?

9 UNIDENTIFIED PERSON: Negative pressure.

10 MR. KING: Oh, yes, I take that back.

11 Willeke's work, he patented that about 15,
12 20 years ago, but he is not standing there breathing
13 normally. He has to stop and draw it negative and
14 then follow the decay of the leak.

15 So, yeah, I agree it does correlate with
16 leak. However, could Willeke do that with a FFR was
17 my next question? And the answer would be no.

18 And so I repeated this with about 13 FFRs.
19 I did it a little differently. I did six points
20 around here, and here's what I got.

21 That is, I get -- essentially -- well, the
22 slope's a little bit different, and I think there's

1 reasons for that. Go into more detail here, too. I
2 looked at a little more degraded. Now you are on
3 the edge of being settled, but I think that's
4 reasonable for a relatively simple experiment. It
5 wasn't very highly controlled because I didn't
6 control the distance and everything and the points
7 around this thing.

8 But what I get is the intimation that I --
9 the concept itself, with some refinement, I could
10 predict the fit factor in a nondestructive way
11 without a probe, and I like the thought of that.

12 So here we go, what did I find?

13 Well, the summary, face seals, I don't
14 think there's any nascent ultrasound associated with
15 that from my predictions. I haven't been able to do
16 the experiments because, again, the interference of
17 my nasal breathing, what will have to be done is we
18 will have to do some flow experiments on masks, you
19 know, either with an arbitrary flow or remove the
20 ultrasound in some way, mouth breathing probably the
21 way to go. But I haven't done that yet -- to see if
22 there is some nascent ultrasound that I could use.

1 I suspect it won't happen until you get to
2 very high -- much higher flow rates.

3 Respiration is a significant source.
4 There are others. The interesting thing, you have
5 friction. By the way, that's what it's used for,
6 you can detect bearing wear and electrical discharge
7 with these the devices, but you can also detect the
8 sound of an FFR sliding around on your face, which I
9 thought was interesting. I thought that might have
10 some potential as well.

11 And electrical discharge. Actually, the
12 ones I recorded for you, there's a high pitched ring
13 in it, and that's actually my phone in my office
14 giving off all of this ultrasound, the high pitched
15 ring.

16 Anyway, assessment of the information,
17 what I conclude here so far is there is a definite
18 correlation with fit factor. That is I can -- I
19 think ultimately I could get a very good -- much
20 better correlation even than what I get there with
21 FFRs. I think it's pretty clear in half mask.

22 Temporal, I didn't do anything to really,

1 you know, do an experiment, but in working with it,
2 it looks like it would follow it over the course of
3 seconds, the changes in it.

4 Spatial, likewise. Although if you go
5 back and look at that data, you can see there are
6 high leaks. I didn't correlate it with looking at
7 the leak around the perimeter as well. That's what
8 would have to be done, but I think I can correlate
9 that, again, as indicated over the correct
10 configuration.

11 And I haven't done anything on spectral
12 stuff yet, either, so that's yet to be done.

13 Anyway, what I plan to do with this yet in
14 the immediate future is to -- what I'm limited by
15 and things we have discussed is that probably you
16 need a good controlled source on the inside. So I
17 want to develop a small enough source and some
18 transceivers that I can put together some prototypes
19 and put them in and on and around the mask and
20 repeat this kind of stuff and improve my data
21 acquisition, do it on computer so I can just get it
22 easier and do more sophisticated data analysis of

1 this.

2 And then I will evaluate these other
3 strategies and configurations. There's about -- to
4 even -- just using the approach I'm talking about
5 here, there's about six configurations that are
6 possible. So one of them is probably the best, but
7 I don't know what it is right now.

8 So that's it, I believe.

9 MR. SZALAJDA: With that, I would like to
10 move into the last stage of the TIL discussion,
11 which is the panel discussion. Who am I missing?
12 Oh, Bill. That's okay.

13 I think what I would like to do is --
14 these questions that Gary indicated in the slides
15 were provided as part of the concept plan, and
16 hopefully you have had an opportunity to check or
17 read those before the meeting.

18 And I think I would like to take at least
19 these three in the next slide in total, at least
20 with regard to some of the considerations with
21 regard to the pass/fail agents, the development
22 of -- or identification of the test agents that

1 would be used in evaluating inward leakage, and then
2 the equipment considerations to go along with that.

3 And one of the things that I did want to
4 note from Gary's presentation was the consideration
5 or at least the decision logic that goes behind
6 where we are, where our current status is with the
7 use of the corn oil chamber and those capabilities
8 that we have established within NIOSH, that the
9 initial approach is, until we do our due diligence
10 on looking at other potentials, will continue to
11 evolve the corn oil concept. And you will see that
12 reflected in standards. You will see that in the
13 PAPR. You will see that in the supplied-air
14 respirator. You will see that in the closed-circuit
15 SCBA.

16 But we are going to do our due diligence
17 in looking at other potentials, potential test
18 methods that are commercially available.

19 I mean, obviously at this point, you know,
20 we are looking at test setups and methodologies and
21 protocols that already exist, you know, to go and
22 try to establish a new criteria, new protocols are

1 really beyond the capabilities of what we have right
2 now.

3 So we are trying to work within the
4 framework of existing technologies when we look at
5 these types of protocols. So at least initially,
6 until we do our due diligence in looking at the
7 other types of evaluation techniques, our focus is
8 going to be on the corn oil.

9 With that, I would like to -- John, do we
10 have any LiveMeeting questions?

11 MR. PERROTTE: None.

12 MR. SZALAJDA: None? Okay. Any questions
13 or comments regarding the criteria in this slide?

14 I can tell it is 3:30.

15 MS. FEINER: I just wanted -- Lynn Feiner,
16 Honeywell.

17 I just wanted to comment on your first
18 one, should TIL be based on the type of respirator
19 or the intended use.

20 If they have my vote, it would be the type
21 of inlet covering. There is just so many different
22 uses and types of applications out there that I

1 don't think we would be able to quantify them all.

2 MR. SZALAJDA: Okay, thank you.

3 MR. SAVARIN: Mike Savarin, Sperian.

4 I think in a perfect world, what the TIL
5 should be bringing to us is the ability to
6 characterize the system, period. On the basis of
7 that ability, we should be able to determine
8 configurations which are then used, no matter what
9 those configurations are, whether they are comprised
10 of the loose-fitting, as we call them now, neck,
11 hands, whatever they are. It shouldn't matter
12 anymore.

13 The number that we get from that test
14 should be able to do this. But I do side with Lynn
15 here in that the complexity with going the
16 applications route means we may never get a standard
17 out of this. So sometimes we are maybe forced to
18 consider expedient methods to get something out of
19 there rather than ideal.

20 MR. SZALAJDA: Okay. Thank you, Mike.

21 Any other comments?

22 And then the remainder of the questions

1 are related to focusing on third-party evaluations,
2 the exercises that are used for consideration, and
3 the placement of the ports for sampling.

4 Any insights that you may have or that you
5 would like to share with us on these topics?

6 MR. SAVARIN: If I could say something
7 about the first one.

8 MR. SZALAJDA: Mike, the mic is not on.

9 MR. SAVARIN: Usually I don't need one.

10 Should NIOSH accept TIL results from
11 independent laboratories.

12 I don't think there is any problem with
13 this as long as certain criteria are met, that that
14 independent laboratory is qualified, approved.
15 Typically the A2LA type process, which looks at lab
16 accreditation, can make an adjudication as to
17 whether that lab is capable with doing the test
18 prescribed and doing that in conjunction with being
19 an ISO 17025 type organization, shouldn't really
20 prevent that lab being able to fulfill those
21 requirements in conjunction with the NIOSH test
22 protocols in my opinion.

1 So I don't think there's a problem with
2 accepting TIL results from independent labs that
3 meet that kind of criteria.

4 The same would go for the exercises. You
5 know, we say a standard set of exercises because,
6 you know, we have done it in the past.

7 There isn't any reason why we shouldn't
8 have different exercise regimes that relate to
9 different performance criteria.

10 In all of the things we have heard today
11 seem to indicate that the performance criteria are
12 so different for different configurations that maybe
13 what we have learned from the different exercise
14 regimes that have been modified these last five or
15 ten years, we can put those together and have those
16 as classifications or groupings so that we can have
17 a set of standard exercises rather than one where we
18 scratch all day and modify it.

19 You know, some of these exercises require
20 quite some contortion, lying prone, excessive
21 bending, and others are quite sedentary, and there
22 is no reason why they should be adjudged the same.

1 So maybe we should have a standard set of
2 exercises rather than just one set.

3 I think that's it from me for now.

4 Thanks.

5 MR. SZALAJDA: Thank you, Mike.

6 MR. GREEN: Larry Green, Syntech
7 International.

8 And on the types of exercises and things,
9 I know the others, if you tried to do a standard
10 set, that you would get a lot of different
11 applications and things like that. As we are doing
12 these, we typically try to be creative on our
13 exercises and try to find out what actually makes
14 the respirators fail. It doesn't matter if it -- if
15 somebody is doing a standard it works fine, but the
16 actual users never -- he's not going to do those
17 type of things.

18 And if you try to provide information to
19 them, then you try to do some things that are
20 extreme, possibly, and maybe 99 percent of the
21 people aren't going to ever do those.

22 But if somebody does have those types of

1 things that they experience them, you know,
2 there's -- you know, if you can give them that
3 information, it's good for them.

4 You get -- if you are doing standard
5 exercises, you don't do things. We do jumping jacks
6 with a loose-fitting hood, and it's pretty tough to
7 get a loose-fitting hood to pass on jumping jacks
8 because you drive -- as you go up and down, you
9 drive the air up under it. You generate high
10 respiratory rates, push the system into a negative
11 pressure and things like as your respiratory goes
12 up, and you challenge the systems.

13 And I think it's good to, as we are
14 looking at these, to say, Well, in a standard
15 situation, this is fine. But what happens if you do
16 try to challenge the systems.

17 MR. SZALAJDA: Thank you, Larry. That's a
18 good point.

19 I think kind of -- you know, in looking at
20 it from the perspective of ultimately defining
21 criteria that could be used for certification, I
22 think part of the focus that -- of what the standard

1 is going to need look at is, you know, coming up
2 with things that are repeatable, you know, at least
3 with regard to the criteria: Is this something that
4 we have confidence in, that we are going to get
5 repeatable results. But that's not to say that
6 there aren't other things that should be considered
7 in terms of exercises that could be considered.

8 So in this type of area, I'm going to
9 encourage people that have an interest to submit
10 comments to the docket, at least as far as other
11 things to consider that normally aren't or may not
12 be part of the protocols that are in place today.

13 Any other comments?

14 Okay. I think with that, again, anything
15 that you would like to formally submit goes to the
16 docket office, Docket No. 168. And so with that, I
17 think we are ready for the wrapup.

18 There is a survey that I would like
19 Charlene and Dawn to pass out for the non-NIOSH --
20 or at least the non-NPPTL participants to fill out
21 and submit.

22 You can either -- once you have completed

1 it, there's a box out on the table outside the door.
2 You can drop them in the box or you can pass them
3 towards the center aisle, and we will go through the
4 aisle at the end of the meeting and collect them
5 there. It's your choice for what you would like to
6 do.

7 And, again, I will give everyone a couple
8 of minutes to fill it out, but we would be
9 particularly interested in hearing back from you,
10 you know, with regard to the format that we tried
11 today, any areas for improvement.

12 I think one of the things that we will try
13 to continue going forward that I think was
14 beneficial for the participants was to get the
15 presentations up on the website ahead of time. And
16 hopefully that, you know, helped with your
17 preparation for the meeting.

18 Since they are brief, and I figured you
19 guys -- everybody is good at multitasking these
20 days, I would like go ahead and at least run through
21 my concluding slides.

22 First I would like to thank all of you for

1 attending. You know, we value getting your input.
2 You know, not necessarily that we accept everything
3 you say, but when you go through -- that doesn't
4 sound quite right, so let me rephrase that.

5 But it's part of -- when you look at the
6 standards development process, it is an iterative
7 process. And the challenge to us comes when you
8 have to look at the balance from things -- and
9 someone has told me, you have to look at the balance
10 in things.

11 And when you define the performance
12 requirements, it's a combination of looking at the
13 determining the right balance and what goes into the
14 criteria that ultimately is going to be used for
15 certifying respiratory protective devices.

16 And from that extent, everything -- we
17 seriously consider everything that is said to us,
18 you know. And at the end of the day, we have to a
19 make a decision, you know, which way to proceed.

20 . And sometimes, you know, like life, you
21 can't satisfy everybody, but we end up making a
22 choice to determine a requirement that we feel is

1 appropriate for addressing a particular need.

2 So, you know, if you think that we are
3 ignoring your comments or not considering them,
4 please don't -- try not to feel that way.

5 If there is things that you really feel
6 strongly about, you know, come and talk to us. We
7 are very agreeable to meet with you or come and
8 visit you or have additional discussions with you on
9 issues that you may feel passionate about.

10 And one thing that I have learned in my
11 career so far is when you get into personal
12 protective technologies, anybody that's involved in
13 this field is really passionate. So from that
14 standpoint, don't be Afraid to pick up the phone and
15 call us, send us an email. You know, continue the
16 dialogue that we started today with regard to the
17 program.

18 I also would like to thank the NPPTL
19 presenters and panelists. I think they did a find
20 job in preparing this, and they were under the gun
21 from me to get things done in time that we were able
22 to get them up on the website in advance to allow

1 you time for review prior to the meeting, and I
2 appreciate their efforts in the support of the
3 meeting.

4 And I would also like to thank Heather and
5 Kathy for providing some very pertinent information
6 relative to how they see things outside of the NIOSH
7 world. And I think, you know, the information,
8 getting information like that from stakeholders I
9 think shows a couple of things.

10 One, that personal protective technology
11 isn't limited to NPPTL. It's NIOSH. It's NIST.
12 It's DOE. It's NASA. It's manufacturers. It's
13 users. It's a collective effort to make the
14 standard as best as we possibly can.

15 The other thing that I think these types
16 of discussions add to is it improves our overall
17 knowledge base.

18 And I think for those who have been
19 involved with this effort over the past several
20 years, I think there has been a lot of efforts that
21 have gone on that we capture in these types of
22 forums, and that only improves how we do business

1 going forward.

2 I'm very excited about the efforts that we
3 have ongoing, and I think, you know, as we move
4 through, you know, these initial stages of
5 promulgating or codifying rules for quality
6 assurance for the closed-circuit escape respirator,
7 for Total Inward Leakage, it's only adding to our
8 knowledge base.

9 And the things that we have learned
10 together going forward in the process are only going
11 to make our jobs easier as we go forward.

12 So with that, what I wanted to do was to
13 give everyone a last chance. You know, because of
14 the time frame and trying to get things done within
15 the schedule, there wasn't a lot of opportunity at
16 the end, excuse me, at the end of each of the
17 sessions for comments. And I know Dave Spelce --
18 see, that's the great thing about having
19 Blackberries now because you get instantaneous
20 feedback. And Dave Spelce, who was on LiveMeeting,
21 had sent me a couple of comments, and I didn't know
22 if he wanted to bring up one right now on the

1 supplied-air respirators if he is still on the line.

2 MR. PERROTTE: If you give me a moment, I
3 have just got to get his -- I have got to get his
4 phone number there.

5 MR. SZALAJDA: While John is doing that,
6 does anyone in the audience have any additional
7 points that they would like to raise regarding the
8 supplied-air respirators?

9 MS. FARGO: Can I ask an unrelated
10 question?

11 MR. SZALAJDA: Sure.

12 MS. FARGO: With regard to the TIL --

13 MR. SZALAJDA: I'm sorry. Can you
14 introduce who you are?

15 MS. FARGO: I'm sorry. Christine Fargo
16 with the ISEA.

17 Can you give us a brief update or a
18 timeframe as to what the TIL for the filtering
19 facepiece process is looking like?

20 MR. SZALAJDA: Yes.

21 MS. FARGO: Would you?

22 MR. SZALAJDA: Yeah. I don't know if the

1 lawyers have left the room or not. No, it's okay.

2 Actually, we are in agency review. We
3 have had meetings within our review process, and I
4 probably expect that you will see something within
5 the next couple of months that will be posted on
6 web.

7 We will go through the similar type
8 process that was done with the CCER and the QA
9 module, having an opportunity for public comment.

10 MR. PERROTTE: Okay, I'm ready now.

11 MR. SZALAJDA: All right. Dave, go ahead.

12 MR. SPELCE: Thank you, Jon. I didn't
13 think you could hear me.

14 I wanted to address again markings. I
15 don't believe NIOSH should require marking lenses to
16 indicate that they are not impact resistant.

17 That's mainly because it might cause
18 confusion with the manufacturers T87.1, such marking
19 if it was put on there to indicate that the lenses
20 do meet ANSI impact and optical requirements.

21 I think it would be better to label
22 compliant or impact-resistant lenses than to label

1 those that are not compliant. It is causing a
2 problem right now because the (unintelligible) as
3 they pass both the high impact and optical
4 requirements under T87.1.

5 So during respirator selection right now,
6 respirator users really have to end up calling the
7 manufacturer if they want to make sure the lenses
8 have high -- pass the high impact testing, they have
9 to call the manufacturer to find out if a particular
10 respirator they are interested in has passed that
11 test or not.

12 MR. SZALAJDA: Okay, Dave.

13 Then I'll make sure I take the email that
14 you sent to me, and we will provide that to the
15 docket as well.

16 MR. SPELCE: Thanks, Jon.

17 MR. SZALAJDA: And I understand that you
18 had an additional, moving on to the next subject
19 with the air-fed ensembles, you had an additional
20 comment regarding hoses.

21 MR. SPELCE: Oh, I was just going to ask
22 if the supplied-air hoses also pass an agent

1 permeation test. It was not on the slide.

2 MR. SZALAJDA: Oh, okay. I think just in
3 short, when you look at the CBRN application, that
4 we are going to be evaluating the hose as part of
5 the evaluation with the Smartman testing.

6 I think the other aspect is when -- that
7 we will be looking for feedback on is when you look
8 at the hoses for chemical permeation, the gasoline,
9 the kerosene, those types of things. I think we
10 will be looking for impact -- or input from
11 stakeholders with regard to what's the best test
12 representative agents that we should consider in
13 those areas.

14 MR. SPELCE: Thank you, Jon.

15 MR. SZALAJDA: Thank you, Dave.

16 Any comments regarding air-fed ensembles?
17 We are almost done.

18 And the last is Total Inward Leakage. Any
19 comments regarding the concept paper or the
20 presentations that you heard today?

21 I would like to put another plug in
22 regarding the ultrasound topic. And then Bill's

1 presentation, again, was part of our Research 2
2 Practice initiative. We are looking to partner with
3 someone to help bring this technology to fruition.

4 So if you are interested, please contact
5 myself or Bill or submit something to the docket
6 office, and we will consider it.

7 And the last slide. We finally made it,
8 and thank you for bearing with us. The Personal
9 Protective Technology Program is going to have a
10 stakeholder meeting on March 2 and 3. It will be in
11 this venue.

12 We are currently in the process of
13 developing the agenda associated with the
14 stakeholder meeting. But in light of current world
15 events, it appears that the stakeholder meeting is
16 going to focus on the service sector and also
17 healthcare.

18 So keep -- if you're listed, or if you get
19 our listserv messages, try to save the date and plan
20 to attend. The meeting will be held at the hotel.
21 It will probably be in one of the bigger rooms down
22 the hall.

1 And so with that, thank you very much for
2 your participation. We will look forward to seeing
3 you at future NPPTL meetings.

4 (Whereupon, the public meeting was
5 concluded at 3:50 p.m.)

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Joseph A. Inabnet
Court Reporter