NATIONAL INSTITUTE
FOR OCCUPATIONAL SAFETY AND HEALTH
NATIONAL PERSONAL PROTECTIVE TECHNOLOGY LABORATORY
PUBLIC MEETING

Tuesday, December 2, 2008

Commencing at 8:32 a.m. at the Hyatt Regency, Pittsburgh International Airport, 1111 Airport Boulevard, Coraopolis, Pennsylvania.

MR. SZALAJDA: Okay. I think we are going to go ahead and begin the meeting today.

Again, welcome. First, I would like introduce Les Boord, the Director of the National Personal Protective Technology Lab, who will have a few opening remarks.

MR. BOORD: Good morning. I would like to welcome everybody to the stakeholder meeting today.

And I think -- could you put it on -- I guess that's as good as it gets. Okay.

Anyway, I would like to thank you for attending the meeting today as we try to live up to the vision and mission that we have identified for the laboratory, which is to -- I want to get it up there.

Anyway, live up to our vision and mission, which is to be a leading provider of personal protective technology information and to prevent work-related injury, accident, and death through the advancement and application of personal protective technology.

And that really does feed right into the

meeting today. On the agenda and as we go through the course of the topics and discussions today, there is actually four key things and four primary topics that we are going to be discussing with you, presenting and discussing with you.

Two of those topics pertain to our efforts, our laboratory and personal protective technology program efforts to update and revise standards, respirator standards in 42 CFR.

Actually, one of them pertains the powered air-purifying respirator requirements currently in 42 CFR. And the second one actually addresses performance requirements for the air fed respirator ensemble suit, which has been a long-standing

discussion that we have had within the program.

So two of the topics are directly related to respirator certification standards.

Another topic that we are going to talk about today is related to the end-of-service-time alarms for self-contained, primarily open-circuit self-contained breathing apparatus. And this is a topic that has generated a lot of interest within

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the fire service industry and touches directly on a requirement in 42 CFR.

And then the fourth topic is more of a strategic topic for us. And it's a discussion that we are going to have relative to the action planning steps that we are taking following a National Academy Institute of Medicine evaluation of our program.

So four very important topics that have an impact on our program and have an impact on you as well, as manufacturers and users of personal protective equipment and respiratory protection products.

Our objectives today in presenting and discussing these issues is really to present the information, present our viewpoints, talk about our logic and our rationale for establishing concept performance requirements, but also to listen and learn.

It's very important for us to hear from you, the stakeholders, manufacturers, users, and other subject matter experts relative to the

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concepts and topics that we are going to talk about.

The format of the meeting today I think is a little unusual in that we are going to have a combination of presentations and posters, which is a repeat of the process that we established in our August meeting.

But in addition, I think we also have a live link with -- the proceedings of the meeting are actually going to be broadcast to several other participants remotely.

So that's new feature for these types of meetings, which really helps us to broaden and expand the reach of what we do.

Again, our objectives are to present, listen, and learn.

In 2008, we have had four meetings of this nature where we have done similar activities. In March we had a meeting to discuss personal protective technology program activities at NIOSH. That was an institute-wide PPT presentation. So we had quite a few posters and discussions relative to research across the Institute.

In August, we had a stakeholder meeting discussing closed-circuit self-contained breathing apparatus, supplied-air respirators, and other topics such as the 40-millimeter thread connecter on our CBRN air-purifying respirator standard.

In the first week in November, we had a no-fit test respirator workshop, which was also of

high interest and had a lot of participation. And then the meeting today to talk about the topics that I have already mentioned.

As we look into the coming year, in 2009, we anticipate and -- we don't anticipate. We have actually identified March the 3rd as the date for a PPT program institutewide stakeholder meeting. That meeting I think is actually scheduled at this location.

So that meeting is on March 3 of 2009 at the Hyatt. Again, an institutewide personal protective technology program stakeholder meeting.

You might ask, well, why March? Well, that actually fits into our strategic planning cycle. So one of the key elements is the

stakeholder input and feedback that we get on our programs, the viability of what we are doing, and new emerging ideas. And we do take that information and factor it into our strategic planning process when we identify our actions to continue programs and institute new start programs.

So March 3.

Additionally, in 2009, I would anticipate that we will have another stakeholder meeting to talk about standards development, again, to help us formulate ideas on respirator standards to revise and update 42 CFR, at least one meeting to do that.

And then there will probably be one or two other public meetings that are geared to those standards that are moving -- have moved a little

further along the line and they are actually in the rulemaking process.

So I think 2009, we can look forward to between three and four stakeholder meetings where we will ask and get your input.

So with that, I told Jon that I wouldn't take too long, and I will wrap it up. I would like

to thank you for being here, and I will turn the meeting back over to Jon.

Thank you.

MR. SZALAJDA: We will get this worked out.

Technology is always -- I think it's the metal stand, so we will try to work through this. Is there still a lot of feedback? All right. How about that? Is that better? All right.

Again, good morning. My name is Jon Szalajda. I am the branch chief for the Policy and Standards Development Branch for NPPTL.

Next slide, please.

As Les had mentioned, we really look to these public meetings to be information sharing opportunities. You know, one, it's a good forum, you know, for us as standards developers to share information with stakeholders and to give you an idea of what our thought process is and where we think we are going, you know, with regard to the evolution of a standard, you know.

And it's very important, you know, when

you look it how we -- John, could I get the second slide and then the public meeting objectives?

There you go. Thank you.

I think it is very important, you know, when you look at the process that we can't develop standards in a vacuum.

You know, and I think the term I have heard lovingly and, having worked for the government for a while, is, you know, a bunch of policy lunks sitting at a table coming up with requirements that nobody can meet.

And I think that's something that we are really trying to avoid, you know, how we address the evolution of personal protective technologies that, you know, the standards are necessary to give manufacturers benchmarks where they can build equipment to.

And it is also important to get the feedback from the user community, you know, the people that actually use the equipment, as least as far as what types of performance attributes are necessary for the equipment and then moving forward

and trying to provide the proper protection.

Next slide, please.

As far as our meeting format today, it is like anything else. I think it's a dynamic process. You know, we try to have a couple of meetings a year, and every time we try to do something a little bit differently because, you know, you people get,

you know, comatose by too many PowerPoints. And sometimes by the end of the day, you are pretty well fried, and the feedback isn't what it should be.

And so what we have tried to do is to come up with a more of an interactive process to encourage feedback and encourage dialogue between the researchers as well as the stakeholders.

And to do that, one of the things that we integrated into the August meeting was the concept of having posters to allow stakeholders to have one-on-one or small-group discussions with the researcher to talk about a specific aspect of the potential standard.

And I think overall, that was very -- the feedback that we got from the last meeting, that was

very well received. But there were some comments, at least as far as how to capture that in relation to the information that is given in the presentation.

So I think with what we will see today is still the same use of the poster format, but the presentations that will be delivered immediately following the poster session will provide an overview of the material that's on the poster and, again, allow an opportunity for dialogue following those types of presentations.

The other thing that we are working with today -- and I hope that you will bear with us on this -- is this the concept of using LiveMeeting. And we have at least eight different sites are

linked into the meeting today with numerous people at each site being able to have to the opportunity to hear the presentations as well as see the presentations as they are delivered.

And we think this is a tool that we are going to try to make more use of in the coming years because of the aspect of the economy and the

restrictions on travel budgets and things of that nature, to be able to allow a remote interface for interested stakeholders that may not have the same opportunity to travel that others may have, but still, you know, provide a forum for their voice to be heard.

Next slide, please.

Some of the housekeeping things that we need to address, hopefully everybody registered on the way in. The registration desk is outside. There's materials, the presentations as well as some other handouts, that are available for your consumption today and to take home with you.

Also, the fact this meeting is being transcribed. The poster discussions are not being transcribed, but the discussions that are taking place in this room will be. That transcript will be available through the NIOSH website in the future.

We were hopeful, I guess, after the August meeting that the information would be posted quickly. And I think, actually, it just came up, the materials that were covered as well as the

transcript were just made available within the past several days. So we can't give you a promise on when the transcript will be available, but it will be available on the website in the near future.

In terms of the agenda, which I will talk about in a minute, we will go through the items as identified in the agenda, and I will spend a little more time on that with the next slide.

We also wanted to address your feedback, at least as far as the format of the meeting as well as the content of the presentations and the location, those types of details. That survey will be provided to you. We will be collecting that this afternoon during the wrap-up at the end of the day.

If you do need to leave early for whatever reason, if you could complete the survey and turn it in at the registration desk, I would appreciate that.

And, again, with the -- the concept with the LiveMeeting, for those meeting participants that are involved remotely, or participating remotely, what we would like to do is to only take questions

at the time when we are having the question-and-answer and public comment period. At least that will make it a little easier for us at this go-round instead of trying to answer the LiveMeeting questions as the meeting is going on.

So those remote participants will have the same opportunity to provide comments as the people that are actually sitting here in the room.

And also, during the meeting, during the public comment periods, there is an opportunity for stakeholders to provide presentations on the topics at hand.

I know at least with the end-of-service-life indicator topic, that there are two individuals who would like to provide presentations. If those people could see me at some point during the meeting, that we can get the -- if you actually have slides, we can get them loaded onto the computer and get a copy of them for the docket, that would be appreciated.

Also, with regard to some of the other logistics that aren't in the slide, for lunch today

there will be an a la carte lunch that will be available for purchase right here outside the door. I'm not sure what the fee is, but I think it is sandwiches and salad and that type of thing, which will be available for purchase. Also, there is a restaurant in the hotel on the other side of the lobby. So there's two options for you to consider.

I think given the time frame, you know, and the location, it may not be feasible for people to get too far off site to go elsewhere. There is at least one other restaurant in the airport that's on this side of security that I'm aware of.

Also, for the local people, there are parking passes for complimentary parking. If you didn't get one when you registered, they are available at the registration desk. So please

either see Tess or Judy at some point during the day so you can get your parking pass.

Next slide, please.

With regard to the agenda, these are the topics that we are going to address. And as Les had mentioned, I think with regard to the activities and

the Policy and Standards Development Branch, you know, we are focusing on using a modular approach to update the Code of -- excuse me, the Federal Regulations Part 84, which provide performance requirements for respiratory protection devices.

I think when you look historically at the evolution of the PAPR, we have been working on this for several years now, beginning with the -- addressing the requirements for the chemical, biological, radiological, and nuclear requirements for Emergency Responders and First Receivers.

And we have been in this process I guess specifically looking at this module for about three-and-a-half years with regard to trying to identify the appropriate performance requirements for this type of system.

And I think, at least with regard to this type of presentation, this will be the last time we talk about the PAPR, at least in this type of forum before we actually get to rulemaking.

Les had mentioned our involvement with the National Academy of Sciences, and our Associate

Director for Science, Maryann D'Alessandro, will give us an overview this afternoon regarding our action planning efforts that have been undertaken to look at response to the National Academy's review of our program.

And I think this is a very critical time with regard to the program because I think, you know, with the current changes that we are seeing in the government, that there may be opportunities coming forward when you look at the evolution of regulations and also this type of technology.

I mean, when you look at issues, you know, with regard to the threat of terrorism, it's still there, as well as concerns in the healthcare industry with regard to preparing for a possible pandemic influenza, that there's a lot of visibility, you know, within the community with regard to the need for personal protective technologies.

And I think as we go forward in sharing with our stakeholders our plan to address the recommendations from the National Academy, it will

provide an opportunity for stakeholders, again, to give us feedback with regard to the path that we would like to go on, at least with regard to being able to address the recommendations for the direction of the PPT program.

Also, this afternoon, we are going to talk about the air-fed ensembles, and this is an evolving area for NIOSH. I think historically when you look

at respiratory protection, and you think -- it is sort of -- I kind of give it the analysis of putting the pegs in the right slot on the board.

When people historically think of what we do, you know, you have certain classes of respirators, and things fall into those classes. Well, the air-fed suits don't have a class, not necessarily. And that -- you know, when you think about respiratory protection, you are thinking about something on your face that protects you from the outside environment.

Well, in this case, for the ensemble, the ensemble is that thing that is protecting your face from the outside environment, which is a little bit

of an evolution for us with regard to how to address the development of those types of requirements.

And we are going to spend some time this afternoon to address things that are going on in other standards development organizations as well as initiatives within NIOSH to develop a specific subpart for this type of technology and also to be able to address or hear from one of our stakeholders, the National Aeronautics and Space Administration, at least with regard to -- as a standards development organization, how they approached the problem in coming up with the standard for an ensemble that they use in their day-to-day operations.

Next slide, please.

So a little bit about the process, and I

think -- it's always worthwhile, I think, for me to note, you know, than when -- as an outsider, when you look at these types of forums, that this is really the precursor to going into the actual rulemaking process.

The more dialogue that we have -- you guys

must going crazy because I can hear the feedback up here.

The more dialogue that we have at this point prior to the rulemaking part of the process, the more efficient we become.

You know, the more problems that we can iron out, the technical questions, technical issues, philosophical, administrative issues that we can iron out ahead of time prior to the rulemaking, the more -- I don't want to say streamlined, but the less problems that we will have with regard to the overall rulemaking process.

You know, because the rulemaking process is lengthy. And when you look at the overall process from the time that we actually start a rule to there's a change in the regulation, you are looking at a period of 18 to 24 months, and that's, you know, after we think we have agreed on what the performance requirements should be.

You know, so I think when you look at how -- the approach that we are taking and cutting up -- in the modular approach and how we are cutting

up Part 84 into sections and then fleshing out these

types of requirements ahead of time, I think that only helps us to try to stay within those rulemaking time frames. And, you know, hopefully it minimizes the amount of dialogue that would have to take place on a more formal basis during the rulemaking process.

So to that end, as you see us developing standards over the next several years, I think you will see this type of process that's on the slide that identifies the types of activities that the branch will undertake in the development of proposed performance requirements.

You know, one of the things that I think has been very effective for us with regard to being able to share our ideas is the concept paper that we have used in the past with other standards development efforts where, you know, we will list performance requirements and occasionally the test procedures as far as, Here's the types of things that we envision that need to go into the standard. And this gives at least a piece of paper for us to

share with the stakeholders so we can get the feedback on those types of topics.

Also, in this type of forum, you know, where we have stakeholders come in and be able to talk with the researchers gives us another opportunity to get that type of feedback.

And, again, I think with the last public meeting and then, as you see, going forward, there's going to be more use of the actual NIOSH webpage,

the docket, which is maintained by our sister division in Cincinnati, as well as the document for comment pages, which gives us a more of a formal repository for the information that is discussed at these meetings as well as the feedback that we get formally, you know, with regard to the performance requirements that are being addressed.

And, again, these are all things that take place prior to the rulemaking.

Les had mentioned we have several things currently going through the process. With regard to the quality assurance module and the closed-circuit escape module, we were optimistic that there would

be something available in the public forum that we could at least mention for you to look at.

But I think at this point, I can safely say that, if you keep attuned to the Federal Register notice, there should be something with regard to those proposed rules coming out in the near term for public discussion.

You know, looking at the process from there, at some point, that once the two proposed rules are published in the Federal Register notice, we will be scheduling public meetings to further discuss and obtain any feedback on the proposed rules during 2009.

One item that isn't an agency review is our Total Inward Leakage requirements for filtering facepiece respirators and half-mask respirators, which is going through the process. And we expect

at some point in 2009, that will be out for public comment as part of the proposed rule as well.

Things that we envision going into the rulemaking process in 2009 are our modules for closed-circuit SCBA, which we discussed at the

August 20th public meeting as well as the proposed rule for the PAPRs, which we are going to be discussing today.

And then in 2010, we expect to introduce modules for supplied-air respirators, also a prior public meeting discussion, as well as the air-fed ensembles.

And, again, the approach is to methodically to go to Part 84 and do two modules a year until the regulation has been updated.

And I think that strategically and at some point in the future, we will discuss the framework for how we are going to address the other parts of Part 84, and at least as far as get some stakeholder feedback with regard to priorities on the other aspects of Part 84, that we should be able to address.

Next slide please, John.

Just a couple of things to mention, though, with regard to how to submit -- formally submit input. Each of the topics that we are discussing today has its own specific docket. The

PAPR is a Docket 008 A. And what the "A" specifies

is that it captures the information that we are discussing today as well as any comments that were received to the document for comment that was posted in November on the NIOSH website.

Next slide, please.

For the personal protective technology action planning that you will hear about this afternoon, Docket 0146 is set up for that.

Next, please. For the air-fed ensembles, 0148.

And then for the end-of-service-life indicator for self-contained breathing apparatus, 34 A, again, the "A" signifying the fact that we are capturing the information from this meeting.

And I think just one thing to mention, that if you do go to the NIOSH website, in the upper right-hand quadrant of the webpage, you will see there's a little block, and there's a link that says the docket, or NIOSH docket.

If you click on that, there's a listing of all -- or the majority of the dockets where NIOSH

has collected information, not only on personal protective technologies, but also other technologies where NIOSH is playing a research role in addressing an occupational safety and health issue.

If you were to go to the docket now, there would be a Docket 008 as well as a 034 where NIOSH has posted information that has either been presented at public meetings or has been received from stakeholders with regard to those topics.

And so with that, does anyone have any questions regarding the overview?

At least in terms of taking questions during the course of the day, what we would like you to do is to come to the mic, introduce yourself, who you are with, and then state your question.

And John Perrotte will be collecting questions from the LiveMeeting during the comment periods, so he can address them as well for each of the specific topics.

I think one thing I just wanted to mention in general as John is bringing up the PAPR overview, this afternoon, when we talk about the air-fed

suits, we looked at the volume of information that needed to be presented. And I think the approach that we may take in that forum is let the presenters go through each of their topics.

And then at the end of the four presentations that we are covering for the air-fed ensembles, then we will take questions at that time instead of taking them immediately following the presentations for the individuals.

So any questions on the conduct of the meeting? Okay.

All right. Well, we will move into the powered air-purifying respirator overview.

And one of the things that I thought was interesting in the feedback that we received from the other meetings that kind of led us on to the poster path was it was real nice to get a management

overview on where the associated manager with a particular project sees that project going, that is still having the opportunity talk to, you know, the people who actually do the work, who have actually fleshed out the performance requirement as well as

are working with developing the test procedures for certification, so that when the standard does become part of the regulation, that there's a way to test it, and there's an understanding of the technology that goes behind the equipment as well as the technology that goes into the certification process for the testing.

And so I'm -- at this point I'm really happy to give that top-level overview. And I think with regard to what you are going to hear in the poster session as well as from the researchers, I think you are going to see the culmination to a long road and looking at the evolution of the PAPR standard.

And I think one of the things that is kind of historically when you look at the PAPR, you don't want to say it was forgotten, you know, when Part 84 was updated in 1995. But, again, it wasn't -- there wasn't a strategic emphasis, at least in terms of with regard to those types of requirements, that the focus was more on the requirements for filtering facepieces. And things regarding to the PAPR were

addressed, but not, you know, into a category where the system had its -- at least this type of

protection had its own subpart.

But I think what we will see in 24 months or so from now is that we will have a specific subpart section for the PAPR which addresses this type of technology.

And, you know, from my perspective, having come from an air-purifying respirator type of background, this really looks to be the evolving edge of air-purifying technologies, that there's a lot of things that powered air provides, or powered air-purifying respirators provide with regard to comfort and protection that you don't necessarily get with the traditional gas mask air-purifying respirators technologies.

And I think when we see that going forward, that the -- these requirements will hopefully, you know, be broad enough that it will make the PAPR even more popular in use with the workers that need this type of protection.

In terms of our meeting, following the

overview, I will take a couple of questions. We will break. We will go to the posters next door.

The posters are arranged to talk about the things that we will hear later on this morning with regard to flow rates as well as concepts for gas and vapor testing as well as aerosol testing, especially when we are looking at the high flows, potential high flows for the PAPRs.

And then also to give you an overview of where our research branch has gone with the

end-of-service-life indicators that could be integrated into these types of systems. And I think that has been a very dynamic project over the past several years, which I know some manufacturers may be more aware of than others.

But I think with regard to the potential inclusion of this type of requirement into the standard, I think it is beneficial for all of the stakeholders involved to get an understanding of what that technology entails as well as, you know, some discussion as far as how it can be integrated into the devices. And then prior to lunch, we will

have the public comment period.

So from an overview, these are the types of things that I'm going to spend a few minutes talking about, probably a little more, you know, with regard to the requirement development and the flow rates and a little less with regard to the gas life and aerosol testing and the end-of-service-life testing.

Because I probably would be out of my league in a hurry, and I would sooner defer, you know, detailed discussions on that to my colleagues that know a lot more about those subjects than I do.

Next slide.

I think one of the discussions that we have had internally with regard to the PAPRs is to really try to focus on how we develop requirements that provide the user, provide the worker, the appropriate protection for what they need.

And the thought is that we wanted the PAPR standard, or the concept for the PAPR standard to be specific enough that we established a baseline across the board that all PAPRs would need to meet

certain base requirements, but yet have the standard be dynamic enough that it was going to be able to encompass a wide range of protections that a respirator user could choose an appropriate protection for their specific application.

And historically, when you look at PAPRs -- and some of the user feedback that we have gotten has been along the lines of, you know, the PAPR is great, but some of things that you test for are beyond, you know, the scope of what we need. We don't need to have this Nth level of protection. We can get by with something that's a little bit lower, that's more appropriate for, you know, our particular application.

And along with that, you know, the challenge came along with, Well, if you are looking at trying to make this standard all encompassing to, you know, be able to address the wide range of technologies, how do you develop the requirements so that when people come up with a new idea, that it's something that the standard is amenable to being able to take that new technology and evaluate it and

be able to compare it to that base of requirements that we need to establish but, yet, you know, be

able to provide features that may be desirable for a particular worker, you know, or a particular application.

So that was sort of the overview, at least as far as where we thought we needed to go. And so it really wasn't a simple cut-and-paste of a bunch of requirements or a bunch of aspects from other standards into a new standard, but it was really we tried to think about how we evolve -- you know, what we put in the regulation to the point that we provided a home for the widest possible range of technologies that provide workers with options to choose the protections that they need for their particular site.

Next slide, please.

When you look where we have come, there was -- the last concept paper that we posted was in December of 2007. And I think we kind of realized at that point that we had probably reached a point of saturation in the stakeholder community because

the amount of feedback that we got with regard to that concept paper was very light. I think we actually had three responses to the docket with regard to that particular -- that particular concept paper.

But we have had, you know, discussions on a one-on-one basis with stakeholders at forums such as this or other conferences around the country or people that talk with us on the phone or come into visit us at our site out here in Pittsburgh.

The other aspect that I think that we need to consider and what we have put out on the document for comment pages is I think our last evolution of thought with regard to what we think the performance requirements should entail.

And what we are looking to do from that very brief document is to at least stimulate some thought in the stakeholder community with regard to some of the aspects of the performance of these types of systems that we would like to get your feedback on, not only in the session today, but to give you an opportunity to revisit these things back

in your particular workplace and give us, you know, your ideas, whether you think we are on the right path with these concepts or if there is other things that we should be addressing.

Next slide, please.

And the one thing -- and I always have to laugh because, you know, when -- for those of you who know me, I came primarily out of the Department of Defense before I came to NIOSH.

And with DoD, you know, a widget was a widget, you know, or a mask was a mask. And I never really truly had an appreciation for how critical terminology is until I came to work for NIOSH, at least as far as when you look at how people perceive things and how people look at terminology to provide specific definitions with regard to what particular devices are and what they do.

And so to that extent, I'm apologizing up

front because there's some things I know I'm going to waddle through here in the next five or ten minutes that may not be exactly correct. But at least I wanted to give you my thought on how, you

know, we envision seeing things evolve.

And one is the subject of work rates, which has been a discussion for several years now with regard to the performance of PAPRs.

And I think for the purposes of what you are going to hear today is the translation of work, of an individual worker's work, and speaking of that in terms of respiration flow rates.

So you are going to hear discussions today about expressing work in terms of liters per minute, which is solely focused on looking at how we will test these types of devices once we get to the certification stage.

And, again, we have recognized not only the research that we have done internally within NIOSH, but also research that has been done in the international standard community with ISO and taking a look at this problem -- or taking a look at this topic and looking at the evolution of international standards for respiratory protection and how to address this topic, you know, with regard to expressing work rates.

And, also, we have seen over the years significant comments from stakeholders, not only manufacturers, but also users, with regard to being

able to have capabilities, have respirators that have certain capabilities that may be beyond what an individual worker can sustain over long periods of time.

Also, along with this, as far as looking at the range of potential users and, you know, from the standpoint that, depending on the application, everyone works differently. There's a wide difference between, you know, somebody working in chip manufacturing where you are wearing a respirator to protect the chip from you versus a responder working on a rubble pile wearing this type of respirator that may be doing heavy labor.

So the thought was, Well, how do we leverage all of this information into requirements that manufacturers can build equipment to as well as opportunities for people to select the respirators appropriate for their workplace. And that's what we are looking at in terms of using work rates as a

tool to be able to expand the product market for PAPRs.

Next slide, please.

So one of the things that, again, that I would welcome your comments on is the terminology for how we describe these things. And at least for talking purposes, the way that this was envisioned is that really you could break PAPRs down into two categories. And the focus at this point really was to address how we would evaluate the PAPRs in a laboratory setting.

So when you think of a category, which we call breath-assisted, which is PAPRs which operate at a lower flow rate, you know, 11, 25 or 40 liters per minute that basically provide a degree of powered air, but not necessarily at very high levels, but more of a sedentary, lower type of work rate.

And sort of the vision here, when you look at these types of systems, these are more the -- and, you know, people can laugh. It is also a baseball cap with a blower. It's not necessarily

that you are looking for a high degree of protection, but you are looking to provide a certain degree of protection as well as a certain degree of comfort.

And the thought being, you know, when you look at these types of applications, you know, health care I think is one venue that jumps out, you know, you know, with regard to systems that provide powered air, but maybe not the significant degree of protection that you may want to see in other areas.

We have also looked at the standpoint from what we call positive pressure. And we have talked about this in other forums at least as far as, well, how are you going to measure positive pressure.

I think the thing that we all -- or at least that we have acknowledged internally, is that when you look at the concept of positive pressure, we are focusing on what you can repeat in a laboratory setting.

We acknowledge that probably once you get into use, you know, whether you can maintain positive pressure or not is a whole other issue.

But the thought being that, you know, when you look at the description that this is more of a higher end technically complex type of system where you are looking to actually, you know, operate at a higher flow rate and maintain, you know, positive pressure in a laboratory setting where you are not going negative during the breathing cycle.

I think along with that is, you know, with these type of the scriptures is looking at, you know, linkage of these types of categories with inward leakage.

And I think along with inward leakage, even though I think, you know, we have said in other forums that inward leakage doesn't equal assigned protection factor, we are working with OSHA to look at the recognition of our laboratory respirator protection level testing as a test that applicants can go to and have their systems evaluated and use that data to get an assigned protection factor from OSHA.

And so the thought process is, if you look at these types of -- at this type of categorization for PAPRs, you know, the lesser inward leakage could be addressed for systems that provide lower flow rates, where the higher inward leakage requirement

is for the systems that maintain positive pressure.

And I think the interesting thing is when, you know, when you look at this from a requirements standpoint, I think the technologies that we have today will fit within this type of categorization.

And I think the linkage there is when -- between the two categories is a 40 liters per minute from the standpoint of we know that current technologies that we have evaluated and certified, you know, will meet that type of criteria.

It's the other ends of the spectrum, when you look at the lower flow rates and the higher flow rates, that there may need to be technological evolutions to come up with systems that address those types of requirements.

Next slide, please.

At least as far as with regard to the gas and vapor testing, historically, or at least over the past 15 years or so, when an applicant comes in

for certification, there's a minimum performance requirement that is set that we are going to test the canister at a certain flow rate for a certain amount of time, and we are going to look for a certain amount of breakthrough. And this is the way that all canisters and cartridges are judged.

And while that provides a degree of consistency, you know, with regard to the approach for certification, what does that really tell us with regard to the performance of the canisters or cartridges?

And one of the ideas that has been explored within the ISO community and one of the things that we have been considering over the past several months is an alternate to that type of approach, which is to use the Wheeler relationship for gas and vapor testing to be able to assess the canister capacity and efficiency at multiple flow rates.

And Dr. King will have a poster in the poster room next door as well as a presentation to, you know, discuss this topic in a little bit more

detail, but I think the thing that shows promise with regard to this approach is that it allows the capability to be able to project how a canister or a cartridge will perform at higher flow rates without necessarily having to do the test at those higher flow rates that, you know, you do get a linear relationship by testing at other flow rates, and you can be able to project how the system will perform at very high rates or very low rates. And Bill will discuss that in greater detail later.

Next slide. End-of-service-life indicator, Jay Snyder will be having a poster session talk about research that has been going on, you know, in this area over the past several years.

And one of the things that when you look at this type of technology, it gets into, what does it usually take to take technology to the next level. You know, and to some -- in some instances you can argue, Well, the market will drive that, but

maybe sometimes the market needs a push.

And one of things that -- one way to give that push is through the use of standards. And one

of the things that we have really -- that I would like to get your feedback with -- regarding end-of-service-life indicators is an idea that we have to make this a mandatory requirement for certain types of PAPRs, not for all PAPRs, but for PAPRs that may -- you know, that we consider may be the more technologically advanced when you look at some of the products that are on the market that could be considered in the positive pressure category.

And the focus here really being on looking at two types of protections, one in the organic vapors and then the other acid gases where, you know, over the past several years, not only within NIOSH, but also within other stakeholder organizations, a lot of research has gone into the feasibility of these types of technologies.

And the thought is at this point, you know, that by the time the standards is released, that the technology may be mature enough to be able to consider this as a requirement for these types of systems.

Next slide.

And then you know we are getting serious when we talk about implementation. And I think the long-term aspect of any standard is being able to

see how you put this -- put these requirements into place.

And from a new requirement -- the new-requirement standpoint, I think at least our initial thoughts are this is pretty cut and dry, that, you know, the module will go through the process.

We will have an opportunity to -- the proposed rule will be published in the Federal Register notice. There will be an opportunity for stakeholder feedback. We will have public meetings as necessary to discuss the rule.

And then, you know, following the reconciliation of comments and determination if there's a need to have additional discussions, the process will go into the final stages, and the new rule will be promulgated.

At that point, after the rule is posted

and published in the Federal Register notice, in 30 days we will start accepting applications on a first-in/first-out type of basis.

Other consideration is, well, you know, for a new product, that is I think fairly straightforward. What do we do about things that are already in the field or that may already be in an inventory or a pipeline coming down right before the new rule is introduced.

So the current thought process is that manufacturers and distributors can continue to sell inventory for up to three years after issuance of

the new requirements.

You know, and along with that, you know, we acknowledge there may be changes that might need to be done for a variety of reasons on the existing products so that we will consider modifications and extensions of approval to those products for two years after the issuance of the rule.

And the fact that, you know, if you have a PAPR system that it already meets Part 84 requirements, it can remain in operation as long as

it is still supportable by the manufacturer, that there will be no obsolescence of systems that have already been fielded.

Next slide.

And then these are the types of things that we are hopeful to get feedback from you today.

Again, you know, the concept as far as the three categorization of PAPRs and whether or not, you know, breath-assisted or positive pressure is the right way to categorize these things. You know, is there a better way to categorize it if we talked about it in terms of inward leakage, say, for example, that -- and using that as a measuring stick that differentiates one type of system from the other.

Also, you are going to hear in the poster discussion as well in the presentation how we are going to address work rates in terms of the process for evaluation.

The linkage of the categories of

breath-assisted and positive pressure with LRPL testing and inward leakage requirements, what do you think about this, the approach of using the Wheeler relationship for gas and vapor testing in lieu of the traditional approach for our canister and cartridge evaluation.

And then also feedback on the development of the end-of-service-life indicator for organic vapors and acid gases.

Next slide, please.

And then as far as the information to formally submit it, you know, the formal comments to the docket using 008 A, and that will focus us on the things that we are discussing today. And what I would like to do, at least as far as this point, to take any questions.

I would rather, at least at this point, leave it on the implementation, take questions on the implementation strategy for the system and any of the administrative types of questions regarding this.

If you have specific questions with regard to the work rate discussion or the things that you will see in the poster room, I would prefer to take those questions after you have had a chance to either participate in the poster session or hear the presentations from the researcher.

So with that, if there are any

administrative questions with regard to PAPR or, you know, with regard to the implementation, I would be happy to try to address those right now.

Bob, there's a little switch.

MR. SELL: Bob Sell, Draeger Safety.

One question concerning, would you be issuing a final written concept document at some point in time so people can review the exact text?

MR. SZALAJDA: That's debatable, I guess. And I think a lot of it is going to depend on the nature of the comments that we receive.

You know, from the standpoint that, you know, we got -- we received so few comments, you know, with regard to the December paper, and depending on the nature of the feedback that we get today, we may issue another -- not a full concept paper, but maybe an additional flesh-out of what we discuss today on the document for comment page. But

in terms of a comprehensive update of all of the requirements, we are probably not going to do that.

MR. SELL: Okay. From our opinion, or from Draeger's opinion, we would like to at least see something fleshed out like that.

MR. SAVARIN: Mike Savarin, SPERIAN.

We would just like some clarification on the implementation.

We had in the first -- in the second bullet there, where you had product approvals under previous requirements, manufacturers can sell the product for three years after the rule is

promulgated, but then PAPRs with current approvals will not be obsoleted.

You clarified that by saying the manufacturer could still support them. What exactly do you mean by support?

MR. SZALAJDA: Well, I think -- I'm sorry. At least, let me take that one first.

I think when you look at support as with regard to logistics, spare parts, maintenance, you know, those types of parameters --

MR. SAVARIN: So you couldn't sell another blower to the person then, to the -- you know.

MR. SZALAJDA: I think if you are looking at it from the standpoint of it's a spare part, okay, if -- you know, if you have a system that's under warranty, for example, when you have a component that fails and can be replaced under warranty, that, you know, that would be conceivable.

I think the thought is at some point, when you look at the application of these types of systems in the workplace, you know, there's -- at some point, there's going to be a line which the economics get out off whack, at least with regard to whether it's cost effective for the manufacturer to continue to support items that may have been in the field for ten, 12 years versus, you know, let's try to move people into a new technology and whether or not users are willing to pay, you know, for that premium.

You know, so we figure that's probably an

area where the market is going to kind of determine, you know, how long a manufacturer may want to, you know, support a particular product versus, you know, how long a user is willing to pay for it.

MR. SAVARIN: Thank you.

MR. SZALAJDA: All right. I think at this point what we will do is -- it's about 9:35. We are about ten minutes ahead of schedule.

We will break. The posters are adjacent -- in the room adjacent to us. If the -- I guess if the researchers can go and man their posters, we will run the poster session until 10:15.

At 10:15, we will reconvene in this room, and then we will go through the individual presentations with regard to the topics on the posters.

All right? Thank you.

(A recess was taken while stakeholders viewed the posters in the Poster Room.)

MR. SZALAJDA: Okay. I think we are going to start in about a minute, once we get the speakers up here. We are going to go ahead and get started again.

At this point, we will move through several presentations that are going to cover the information that was in the poster session. So at this point, if you didn't get a chance to get to a particular poster, you will have an opportunity to hear the information that was contained on the

poster.

When you go through the topics, the first presentation will be by Rich Vojtko, who is a relatively new engineer within our laboratory. He has been with us, at least as far as a federal employee, since the earlier part of this year, but he has supported the program as a support contractor for several years prior to joining NPPTL.

So with that, Rich will talk about the evolution of the work rates to where we are today.

MR. VOJTKO: Thank you. As Jon said, I'm going to be covering the PAPR work rate revolution -- or evolution. Nothing so drastic.

We have broken down the evolution into three stages. First of all is the method that we currently use to approve PAPR for flow in which we measure the flow within a sealed chamber. And this

is at a constant flow, and it either passes or fails.

During the December 21, 2007 draft of the PAPR standard, we developed three work rates and a positive pressure requirement that is measured at the maximum manufacturer specified work rate. And that's specified by the manufacturer out of a discrete number of work rates that we have already defined within the draft.

The final stage is the additional work rates that Jon has already brought up, and the idea of breaking that down into the breath-assisted and positive pressure classifications.

We also aren't sure what approval requirements would be used to determine pass/fail for flow or pressure or whatever for breath-assisted class, so that's something else we would appreciate input on.

Next, John.

Beginning with the current requirements, that's basically the laboratory setup that is used to measure flow for a PAPR. The respiratory inlet

covering is mounted on the headform within the chamber, and the blower is located on the outside with the hose sealed around the chamber. A vacuum blower then removes air from the chamber, and that flow is monitored on the dry test meter showing there.

Not yet, John.

We then monitor the pressure differential using the electronic manometer on top of the box to determine that we have a constant -- not yet.

That we have constant -- or a balanced flow between the PAPR blower going in and the vacuum blower on the outlet. And that way we know that the flows are even, and we have measured the flow.

Now the next slide.

The flow rates that have been established are 115 liters per minute for a tight-fitting PAPR and 170 liters for the loose-fitting.

Based on the work that I'm going to continue to describe here, these flows are capable in most cases of maintaining positive pressure in

the breathing zone of a PAPR respiratory inlet covering at the -- what we have defined in the current draft as the moderate work rate, which corresponds to a breathing rate of 40 liters a minute.

Next one, John.

Moving along to the work rates that were proposed in last December's concept paper, we had an original objective in proposing multiple work rates in terms of improved protection so that we would have sufficient air flow for the user to not have to overbreathe a PAPR and would then maintain positive pressure in the breathing zone and have a higher level of protection without any negative pressure differentials across components to the atmosphere.

It would also have greater flexibility so that we could establish comfort for the user, both at the high end so that there would be enough air so the user, again, doesn't overbreathe, and also at the low end. If someone has a fairly light duty task, they would have something that's not cumbersome, easy and light to wear, and they would be willing to wear to afford them the protection. And it would also afford cost savings for employers who would then be more willing to implement this protection.

This is a table that's based on one that's in that December concept. It's got a little added

because it is just taken here out of context of the standard itself.

We are saying here that the work rates are sinusoidal wave form, and we are expressing the work rate as respiration rates. And I have also shown the peak flow, which is based on, again, the sinusoidal work rate.

And as before, we have broken these down into 25, 40, and 57 liters per minute for the low, moderate, and high work rates respectively. And we have defined tidal volumes and respirations for this as well.

Next one, John.

The test protocol that we have envisioned for this is having, again, the manufacturer specify the highest work rate from the table for the intended use of the PAPR and then using a variable

breathing machine that can accommodate that.

The one we have been using for some of our benchmark testing is illustrated in the picture there.

The PAPR has to maintain positive pressure in the breathing zone while it is properly mounted on the headform coupled to that breathing machine at the work rate.

In addition to that, we feel that there's some additional criteria that must be met for fully evaluating the PAPR when we have a variable work rate allowable. And the one I would like to discuss here is identifying the appropriate air flow for

particulate and gas vapor challenge testing.

We would like to have a minimum constant air flow rate that we would use to test canisters, cartridges, and filters. And something that we think would, in a worse case for a constant flow PAPR, maintain positive pressure in the breathing zone during a machine test.

We went on to determine these required flows experimentally, and we did this for the

moderate and high work rates for the tight-fitting PAPR and for all three work rates for the loose-fitting PAPR because last December, when we issued that draft, we were envisioning not allowing a tight-fitting PAPR to be approved at the low work rate. But we can certainly go beyond that with future work, but -- go onto the next slide.

These are the constant flows that we came up with as a result of that work. And this was, again, based on positive pressure tests with single-speed units. And this corresponds to Table 2 in the draft standard.

As I stated, there is no low work rate applicable for the tight-fitting PAPR, and the flows associated with each work rate are given in the table there.

And we can go on to the next slide.

In order to do this evaluation and experimental determination, we needed to operate PAPRs at flow rates that aren't commercially available. So we obtained several samples of two

different PAPR blowers and both tight and loose

respiratory inlet coverings that are designed for those PAPRs. And we varied the input voltage to control the flow from the blower motor rather than using the battery packs that were originally designed for those PAPRs.

We began by establishing that we could operate these over a range without doing any damage to the PAPRs, and then we varied the voltage and recorded air flow for each sample.

And we did this several times to prove repeatability. And then we used two different mask flow -- or air flow measurement techniques, one, the dry test meter that we currently use for the flow test, and we used an electronic mass flow meter as the other, just to eliminate any systematic error that may be the result of the type of the system that we are using. And we eliminated that as a possible source of error.

We then plotted the data and correlated it and found that a second order polynomial fit worked real well. And we actually used both voltage and flow as the independent variables so that we could

both predict the voltage needed to obtain our starting value for flow when we did the experiments, and then the other way so that we could find a flow at the voltage we finally settled on that seemed to give us a little safety margin for positive pressure throughout the test.

This is an example of the calibration curves that we generated with -- in this case, we have voltage as an independent variable on the X axis, and we have the mass flow curve, the dry test meter curve, and then a composite curve. And these are actual data points, so you can see there's a little wiggle in there. But they actually correlated very well, and we were able to obtain very good, repeatable data.

Once we had the calibration curves for the voltage versus flow and vice versa, we were ready to actually do the breathing tests to determine what flows were required to maintain positive pressure.

For this portion of the test, we mounted a PAPR respiratory inlet covering on a torso, and we coupled this with the variable frequency and tidal

volume breathing machine that I had shown before.

And then we used -- here in the picture, these are Validyne fast response transducers coupled with the signal processing units there that can convert the signals they get from the transducers to an analog voltage output that we were able to capture with our LabView software, and we were obtaining data at the rate of ten points per second.

We then monitored and recorded the breathing zone pressure and the canister pressure drop.

In the previous presentation, we have shown that we have correlated canister pressure drop with flow and have been able to use canisters

themselves as a pressure element in the system to measure the flow dynamically of the system as we would go.

And we obtained that correlation at constant flows using a vacuum blower and established the flow at each point with a mass flow meter. But then we can get instantaneous flows at these ten-per-second intervals to establish a nice curve.

We were able to plot a pressure profile, a flow profile that we calculated again from the canister pressure drops. And we averaged all of those discrete points in the flow to get an average flow. And the next slide has an example of that.

We have time as the X axis. And on top, the dark blue curve is -- the actual flow is that sine curve which varies based on the resistance caused by the breathing machine simulating a wearer of the PAPR.

And the scale for that is on the left, and then the red curve is our pressure profile and facepiece. And the scale for that is on the right. You can see in this case, we stayed above zero.

This sample is for a tight-fitting PAPR, and, as you can see, we had about 110 liter per minute average here where we were predicting about 115, so I considered that pretty good repeatability as well.

Next slide, John.

The conclusions from this testing with PAPRs on breathing machines at varying work rates,

we found that the flow versus voltage correlations were similar, regardless of whether we used the dry test meter or the mass flow meter to determine flow.

We had excellent repeatability between samples of the same model and repeat tests of the same sample as well. And we had excellent agreement, again, between the predicted flow with those calculated from the canister pressure drop.

Going on with conclusions, the flow required to maintain positive pressure at both work rates that we tested for the tight-fitting PAPR were similar for both PAPR models that we tested. And the same held true when we tested the loose-fitting models for all three work rates.

Moving on to the material that Jon started out with earlier, and that's the work rates that we are now considering for inclusion in the PAPR standard and the separation into two classes, that, for discussion sake, we are calling breath-assisted and positive pressure.

We have within that additional work rates. And, again, these are expressed as respiration

rates. We have inserted the sedentary rate at 11 liters per minute and extremely high work rate possibilities at 78 and 99. These are based on the ISO technical specification listed there for their Classes 1, 7, and 8 for a standard body with that 1.8 meter squared surface area.

Again, we are open to suggestion for what would be acceptable or good specifications to use for additional rates.

ISO has other suggestions in terms of having both the smaller and a larger body size that they have done work with, and also they have looked at a two standard -- a span of an increase in respiration rate well.

So any of these things are something that we would be considering -- we think would be worthy of consideration if someone gave us reasonable argument for any of that.

Next, John.

As far as characterizing those work rates, the sedentary rate would probably, if we have one, be a sinusoidal ventilation profile. And we have

not defined a tidal volume or frequency because, again, we not sure of where exactly we want to be. And we will wait until we have something more defined before we get something that is physiologically reasonable in terms of something that we can simulate on a breathing machine that is a reasonable test for human activity.

With the extremely high work rates, we are not even sure what sort of ventilation profile we would like to use. And, again, we are open to suggestion for all of this.

This diagram more or less summarizes this section. We have taken the PAPR Subpart P and divided it into that breath-assisted category,

which, in addition, as Jon pointed out, would have an LRPL of around 250.

And the positive pressure monitored, I call it because we may not maintain it consistently. But one of the things that we want to include in the positive pressure models is a pressure monitor to alarm the user when they consistently overbreathe the unit. And that would have a 10,000 LRPL value.

In the middle range there, we have 40 liters per minute falling into both, and I think that's good place for it to be in terms of -- as I stated before, most of the units out there now would pass under this 40 liter per minute rate. But in the positive pressure side of things, they would have to meet some of our other requirements, like a pressure monitor. And then in the breath-assisted side of things, they could probably pass as is but with a different protection factor than perhaps they have now.

We have lowered the 25 down into the breath-assisted category. And we also, you can see on here, have not said anything about either tight- or loose-fitting units.

So, as I stated before, we may change what we did in terms of defining a flow rate that correlates to a 25 liter per minute tight-fitting PAPR, for instance. Again, we are looking for input on this and on the other end, what we should do with the very high work rates.

Any questions?

MR. BARD: (Not speaking into microphone) Brent Bard, Supplied Air Monitoring Systems.

Has the testing taken into the account CO2 at different temperature cycles as well as (not audible to court reporter.)

MR. VOJTKO: None of this testing has.

We do have -- in a separate section of the draft standard, we do have CO2 dead space testing defined, tentatively.

And what was the other --

MR. BARD: The temperature of --

MR. VOJTKO: Oh, the battery.

MR. BARD: -- operational range as well as -- (inaudible).

The reason why I ask is because, of course, when we get into (inaudible).

MR. VOJTKO: We have done some environmental chamber testing with batteries, and we have found inconsistent results to be honest when we have gone to the lowest temperature recommended by the manufacturer for the units.

And we didn't follow up because of -- in

some cases, because we didn't have enough access to the environmental chamber for a while as far as -- and we had other tasks to complete.

But we did start to see some patterns in terms of our recharge cycles in terms of letting the batteries return to room temperature naturally before we did them and cold soaking them before they

were used versus not cold soaking.

So we saw a wide variety of performance in those batteries. And we will define some testing, and any suggestions you have in terms of pretreatment -- or preconditioning would certainly be welcome and something that we could follow up on with some benchmark testing.

MR. BARD: Thank you.

MR. SAVARIN: Mike Savarin, SPERIAN, again.

The whole idea here seems to be to offer enhanced options and classifications of work rate and, therefore, protection to the users.

But I could see that under the additional work rates expressed as respiration rates, there is

the proposition to use what they call the ISO standard man. As you can see, I'm a fine example of an ISO standard man.

What I would like to know is, how does that compare to the USA standard man? And from that, from what is quite obviously a case where USA people have may have a significantly different body size mass index, what does that do for the intended protection?

MR. VOJTKO: That was, as we stated before, a starting point for discussion.

And as I mentioned, there is a larger man in the ISO definition. I'm not sure what the actual definition of it is. But I understand that it is closer to both Northern European and American -- or

North American standard.

And perhaps the two standard errors would serve us well to hit the high end of the range as well.

MR. SAVARIN: Yeah. We should consider strongly including that. Because I don't think we are doing that here at the moment in the

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proposition.

MR. SZALAJDA: I guess -- yeah, let me help out. Rich here, I guess, kind of went from a philosophical standpoint.

I think when we looked at the flow rates, you know, from a conceptual standpoint, we felt that the 25, the 40, and the 57 were probably going to encompass 90 to 95 percent of where we anticipated that was where the majority, the vast majority of the potential applicants would submit their devices.

You know, and I think in looking at the ISO criteria, given, you know, the nature of the people that have been involved in the process, you know, when you look at the -- you know, from the worldwide perspective, you know, a lot of the major players that have been supporting our standards effort are also supporting the ISO effort.

So, again, it was sort of the leveraging of, you know, the body of knowledge, you know, and the fact that, you know, while we think, you know, for the most part we can cover almost all of the applications with 25, 40, or 57, we wanted to have,

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you know, some of the outer ranges identified.

So, you know, for whatever reason, if somebody wanted to produce something that they felt they could sell or protection that was needed, you know, at those extremes, you know, there was a target of opportunity and the certification criteria in place where, you know, an applicant could come in, and then the worker could get the protection they were looking for.

You know, again, as Richard said, you know, kind of at this point, we want to know what people think about, you know, using those numbers, you know, that -- you know, the fact that, you know, there has been another standards development organization go through the process, identify that in the specification, you know.

And where possible, we love to use other people's stuff because it helps make our life easier and then, you know, develop things as we need to. And this was a convenient opportunity to, you know, grasp that information now.

MR. SAVARIN: That's fine. Thank you very much.

MR. PERROTTE: There is a question via LiveMeeting.

MR. SZALAJDA: We will wait on that a moment.

MR. BLAKE: John Blake, Safety Tech International.

My question is in regard to the new categories as to whether or not under the breathing machine testing, the requirement for it to remain positive during the test is still applicable.

MR. SZALAJDA: You mean for the breath-assisted?

MR. BLAKE: Yeah, just in general, this entire new category.

You know, what I -- I guess what I'm thinking about is depending on, perhaps if it were loose fitting, that you may not be able to maintain positive pressure under a loose-fitting situation.

MR. SZALAJDA: Yeah. That's a good question. I think that's something that we would really like to get some stakeholder feedback on when

you look at the concept because the thought is with the breath-assisted types of technologies, we are looking at it from the aspect of a lower degree of protection, you know, and I think acknowledgment of the fact that you are not always going to maintain positive pressure. So I think that opens up a couple of opportunities.

You know, one is the fact that you do have technologies that, you know, people may be more willing to use. But then it's also incumbent on us, you know, from the standpoint of educating the user on what that protection really means, you know, and the fact that they don't get a false impression that this is providing the same level of protection as another device that may be hundreds of dollars more

expensive, but it provides a higher degree of protection.

So I see, you know, as the standard evolves, you know, there is probably a couple of layers of responsibility that go on that. You know, one is, you know, how the applicants develop the user instructions to specifically identify, you

know, the capabilities of the units as well as the guidance types of products that NIOSH will need to develop to reflect this categorization, whatever the terminology may end up being.

MR. BLAKE: So you think it is dependent on the user to make sure the application is appropriate?

MR. SZALAJDA: Right. And I think that's part of -- you know, that really hasn't changed the mindset now, at least in terms of a user's respiratory selection criteria.

But I think with the evolution of the requirement, you know, that it almost has a degree of responsibility I think in terms of being able to explain, you know, what this categorization means.

MR. BLAKE: Okay. That answers the question. Thanks.

MR. SZALAJDA: I guess we will take one more, and I guess the LiveMeeting people can either submit something in writing at this point in time or in general on, I guess, over the phone.

So we have one more question in-house, and

then we will take the LiveMeeting questions.

MR. WELLS: Jesse Wells, NOVA Chemicals. It is kind of a follow-up on a previous question.

For the end user, are you developing or have you developed any kind of guidances that links activities to these work rates, or is there going to be a standard model that we apply to determine, you know, for our application, you know, what flow rate do we need?

MR. SZALAJDA: Yeah. I think the short answer to the first question is, no, we haven't done that yet. But long term, I think part of where we are looking in terms of -- you know, I will go off on a tangent for a second because I have the floor.

Yeah. Part of what our branch does is not only does the standards, but also trying to develop guidance documents to help the people understand what we mean, you know, in terms of CBRN respirators or, you know, the criteria that we are trying to develop.

And I think when you look at where we are going with this, is I really see this being a --

causing philosophical changes in looking at the system because now, you know, with trying to open up the standard to embrace a variety of technologies, I think there is going to be a need to include, you know, and capture that information so people understand that for certain types of applications, depending on what I do, these types of respirators may be appropriate and help them with that selection

process, you know, for the respirators.

I think the ISO work is a good start in that direction because, as part of the development of that standard, they looked at particular work activities and used that in terms of building the different flow rates that are identified in the work specifications.

I think from our standpoint, we would look at that as a building block. And then, you know, once we come to some sort of agreement on what we are going to call these things, then be able to start building this product.

So at the time when the standard is issued, you know, we will have the support system in

place to help the users understand what the different protections mean.

I guess with that, John, can you -- my vision is not good. If you can read the question, that would be great.

MR. PERROTTE: Larry Janssen's question was: You used the term "more protection" when talking about PAPR with more air flow, and also implied that maintaining positive pressure assures more protection.

What data do you have to support these assumptions?

The literature does not support and there was no extensive discussion of this at the OSHA APF hearing. Neither air flow nor positive pressure have been shown to correlate with protection.

MR. SZALAJDA: Yeah, I think that's a good comment. Let me kind of, I guess, address it from the standpoint of, you know, when we are looking at defining the capabilities of the system, I think that's where we are going in the introduction of an inward leakage requirement.

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Because the fact is, you know, when you are wearing these types of systems, you know, your protection, the protection you are getting afforded may vary depending on what you are doing, and we appreciate that.

I think it is -- it falls into the area, though, when you look at the, you know, coming up with an inward leakage requirement that hopefully can be used to translate into an APF, that will be the decision making part of the process for a user in trying to determine what the protection is that they need, whether it's in, you know, with a lower APF or a lower inward leakage value versus a higher inward leakage value.

And I think that's kind of where we want to go because, I mean, part of the issue that we need to resolve is the comparison between, you know, how things are done in the laboratory versus how things are done in the workplace.

And, you know, part of the process is when you look at doing the certification test, trying to come up with repeatable criteria that, you know,

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give us confidence that the device will perform as intended.

But I think when you look at the evolution of the inward leakage requirement, I think that's where, you know, we can start, you know, helping develop information which leads us to supporting developing APF criteria that OSHA can assign for a particular technology.

Any other LiveMeeting questions?

Okay. I think we will move on to the next presenter, which will Bill King.

And while they are exchanging the mic, I didn't want to say it was like a coming-out party for the Policy Branch, but I think historically, if you have been coming to these meetings, you have seen a lot of the same faces over the years.

And one of the things that came out of our National Academy recommendations was, you know, looking at re -- our process was looking at resourcing the Policy and Standards Development Branch, you know, to help us develop the modules and bring them, you know, forward in the rulemaking

process. So today you are going to see a lot of the new faces in the Policy branch.

And Bill King has been with us for about a year and a half at this point in the Branch, and he is going to discuss the Wheeler relationship and some thoughts with gas and vapor testing.

MR. KING: Can you hear me? Sounds pretty good.

Good morning. Yeah, what I wanted to do was really first go over the proposed changes for the PAPR gas/vapor test requirements. Because in addition to the flow dependence, there are a couple of other important things we proposed.

The first is to discontinue equilibration, that is preconditioning requirements. That is we will only carry out as-received cartridge tests or canisters, tested.

We did these at two levels, that is the RH of the challenge air. Three tests at 25 percent RH and three samples at 80 percent RH for a total of six.

And of course, one additional item is we

want to propose using cyclohexane for the organic vapor test.

Most of you probably recognize the initial assumptions, basically following the lead of the CBRN test plan that was previously used.

What we want to do here, however, as well, is specify minimum test capacities along with maximum breakthrough concentrations for efficiency and the challenge concentration for each gas and vapor.

One thing you will notice if you inspect our poster out there is that these are generally unchanged from the as-received service life requirements that are currently in effect.

One thing we are proposing to change is to discontinue the current allowance for multiple gas

type approvals where the minimum test requirement currently specified in terms of time is halved for a multi-type gas approval. And there's the paragraph in the CFR that you can refer to.

So those are changes unassociated with variable flow rate.

The last one is tests performed to assess multiple work rates.

And so what we are proposing is we can, if we choose, to test the different test flow rates as opposed to specifying a specific flow rate, as is done in the current test.

Here are some examples for cartridges. The corresponding larger tables are out on the poster, but currently, this is where we are at.

A couple of things you can see here is for -- in this column here for a gas. We have specified, again, a challenge concentration, a maximum breakthrough, and a minimum test capacity.

That is in liters at room temperature and pressure for the gas concerned.

So that's -- of course you can calculate from the -- what these are, by the way, to reflect the current -- is calculated from the current test concentrations, the -- to the minimum test time, what those volumes were.

What I have included here in the last column is the testing at 170 liters per minute.

This test is carried out at 170 liters per minute

under these conditions. You would achieve a capacity of 8.16 liters for ammonia in 60 minutes.

Well, I include this to reflect the fact that we have -- more for internally, we have adjusted these concentrations and conditions such that we have consistent service lives at set conditions.

One last thing, there is a bottom line for unlisted contaminants. This is in the current draft that you see. I include it here for your comment, is to -- for one that's not listed in the table, you would calculate the challenge concentration by taking four times the IDLH, which, again, there are some issues, which IDLH. We will cover that later.

The REL. And, again, this would be for a 60-minute test, here simply multiplying by .0408 times the IDLH will give you the capacity in liters for this proposed contaminant.

In the next slide, I have the corresponding examples of canister test capacities and maximum breakthrough and challenge

concentrations for canisters.

As you -- of course, we have preserved, again, the standard half percent per 12-minute capacity, which is -- runs throughout all of the current regulations. So you can see that is applied here, again, probably -- with the exception of carbon monoxide, which there is a specific extant test requirements for it.

So we see that the capacities are

generally 6.9 liters throughout.

Okay. So the next slide, we cover the three test flow rates that were called out in the December draft, that is low, moderate, and high rate. The test rates would be 115, 170, and 235 liters per minute.

So as it was originally proposed, that these work rates, you would -- the tests would be carried out at one of those flow rates depending on the maximum work rate that you would specify in the approval.

What we are looking at here has -- based on work that has been done -- well, it is a pretty

well-accepted relationship.

We go to the next slide, we see that -- what we find is that the time to breakthrough, that is to a given breakthrough -- and I didn't include all of the meanings of these. It is actually on the poster.

But breakthrough to a given set of conditions of challenge and breakthrough concentration -- that's the time to breakthrough -- is in inversely proportional to the test flow rate, Q.

So we say that time to breakthrough is inversely proportional. And that's fairly well understood. It has been fairly well characterized for a lot of systems.

And if we take a look at that, what we have done here is look at some -- using organic

vapor tests, the next slide. I have some data for current PAPR cartridges, where we have done just that.

What we have done is taken -- now, remember, we are talking about doing three samples

at each -- three as-received samples at each of the two humidities, challenge humidities.

So what we can do is, instead of doing each one of those at one flow rate, what we have done here is, in this test, this is, I believe it's 235, 170, and 115 liters a minute. Remember, this an inverse relationship here.

So what we see is that we have a relationship with service life that's directly proportion to the inverse of that flow rate.

So what it allows us to do is to take data obtained from these three done at three different flow rates.

Of course, now we can extrapolate that. And that's what I have done with this third sample. I took it to higher flow rates to show that this does carry down. Again, .2 here would be 300 liters a minute, and you can look at higher flow rates.

Again, we can certainly test there, but as a convenient way of consistently looking at this data, running of these three tests gives us reliable assessment of where -- the maximum flow rates that

this cartridge or canister can perform as we don't

see immediate penetration. That's what this tells us here.

When we have zero service life, that is this line intersects the X-axis here. If it's on the positive side here -- which I don't have the origin. I apologize -- it would mean that there's flow rate at which you would get instantaneous breakthrough with this cartridge.

So it allows us to assess the higher flow rates without too much effort from one -- so when you have multiple approvals and things like that for different flow rates, we can get a consistent basis on which to judge them all.

If we go to the next slide, again, what we really wanted to do was assess capacity. And if we take that data from that previous slide and assess the capacity, we see that we can get consistent -- even though we have done it with different flow rates, they are reasonable estimates of the capacity for these.

And, again, remember, these are run to a

fixed penetration under fixed conditions.

So it's one way we can certainly do this and not do them at specific flow rates. We can do two or more different flow rates and still get capacity data.

Okay. The next slide, I believe -- yeah. One thing I have assessed as well was taking a look at the tests -- again, these are the tests we are proposing.

We have done them with cyclohexane and with carbon tetrachloride on three different current PAPR canisters.

And what we see is -- I didn't include it, but the average difference here is about a minus 5.8 percent. And that's pretty much in line -- that is -- the cyclohexane tends to run 5, 6 percent of service life shorter than the carbon tet test, which is very consistent with all of the data that exists.

Terry and Murray did a survey of that a couple of years ago, and their -- that was right in line with the average difference that they found for all of the studies they looked at. So that's what

we are seeing here, is roughly a 5 percent difference.

On the next slide, I think I have summarized things. Yeah, the current requirements are conserved as proposed capacities. Okay. That is we have gone from specifying the service life by challenge, concentration, and service time to simply a capacity, again, at a fixed concentration and penetration to give us efficiency.

Cartridge/canister test plan reflects current respirator use as compared to the equilibration approach. I would like your thoughts on that.

And can we -- we can apply an accepted method -- again, the Wheeler Relationship, which I didn't reiterate there, apply this method of assessing the effect on flow rates so that we can,

if we choose, to look at multiple flow rates as opposed to single flow rates in repetitions of the as-received test.

And, of course, we can do cyclohexane in place of carbon tetrachloride. In fact, if you are

looking at capacity, I think we are proposing about a 4 or 5 percent lower capacity to reflect that difference in the behavior of cyclohexane.

And with that, again, these findings are nowhere near formal. They are for your consideration.

Any questions?

MR. SELL: Bob Sell with Draeger Safety.

You identified four times IDLH for unlisted gases for a cartridge. What about for canisters?

MR. KING: No. The canister would remain at the -- or at least as we have -- the 5 point -- or 6.9 liters. That would be the maximum capacity.

Now, the efficiency would require the REL. And I apologize. I didn't include that. We did do that in a draft, and I don't recall what it is offhand.

The capacity is fixed by the half percent, 12-minute consistency there.

MR. SELL: Okay. So it is going to be considered?

MR. KING: Yeah.

MS. DeMEDERAS: Edna DeMederas, North

Safety Products.

I don't have a problem with the different recommendations that you have made as far as cyclohexane, carbon tet, and all of those different things.

BY cutting the service time, getting rid of it, cutting it in half, I think the end users would be affected by that because people are used to using canisters and cartridges for a certain amount of time.

And if -- especially if you have high flow rates, they are not going to have as much time. So at this point, please take that into consideration.

MR. KING: Okay. Thank you.

MS. SWANSON: Hi. Meghan Swanson from MSA.

I didn't really have a question. I just wanted to comment that you mentioned we were using this Wheeler method for the ISO gas test. I just wanted to clarify that, for ISO, we were considering

using this for test houses for manufacturers who did not have the resources to test at the high flow rates.

So certainly, you know, it is very interesting and it's good to run the test out and see what the breakthrough times are instead of just, you know, cutting things off a couple of minutes past the required service time. Maybe it's a good reality check to make sure that your service lives at the high flow rates are going to lie on that

line.

But I just wanted to say the manufacturer, you know, we would be happy to see NIOSH just running at the actual high flow rates instead of using this method to extrapolate the service life.

MR. SAVARIN: Mike Savarin, SPERIAN.

In looking at the examples of canister test capacities and breakthrough concentrations, I see we have four gases there.

How does this relate to all of the other gases, the list of gases? Are you seeing any -- are you seeing any variances arise from using cartridges

that rely heavily on chem absorption versus straightforward absorption, you know, organic versus acid gas?

What happens when you use very basic and -- low boilers for example? What are you seeing when you are using the other agents?

MR. KING: Well, to clarify, that these are minimum test capacities based on the current test requirements for NIOSH approval. So that's where those values in that table come from. So they don't really have a basis in experimental results. Okay.

Now, one thing that we do see is, as you say, for the cyclohexane, a slight difference associated with that.

We really haven't assessed the effect of low boilers, so that's pretty well understood for issues of -- I think there is a minimum vapor

pressure or a minimum boiling point that you should not consider organic vapor cartridges for, for that reason, which has nothing to do with our capacities here.

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These are for the standard tests that have already been laid out by NIOSH.

MR. SAVARIN: Okay. Which are you seeing for sulfur dioxide or formaldehyde?

MR. KING: Well, if -- I don't know them offhand.

What I did was -- and I didn't talk about here. It's on my poster. I did do -- take three current PAPR multitype cartridges, you know, acid gas, organic vapor, and some of ammonia, and tested them according to the conditions as were proposed in this -- the table here. And I have the service lives out there just to see.

One thing you do see, of course, is that -- in the case of -- I believe it is organic vapor -- no. I think it's SO-2, but under dry conditions, some of the cartridges may have difficulty in meeting what we are proposing, that is cutting -- not cutting in half for a multigas approval that minimum service life.

So some of that data is in there if you look at it. But I haven't made a specific study of

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looking at all of those aspects with regard to how they would be considered, but they certainly are

considerations. I agree.

One thing I would share with you, as we talked in our discussion, is that we would probably not apply this flow rate relationship to every approval for one cartridge or canister. We want to assess the efficiency of that bed.

Again, considerations of kinetics and the like, taking that into account, there is some you would test. There is some you certainly wouldn't because of service life and things like that, it would be impractical to do that.

MR. SAVARIN: So you could see a situation where this proposal could be adopted for just the few of the gas/vapor --

MR. KING: (Speaking simultaneously) Yes, I agree.

And in fact, I think they have done that a little because they have only seen that it really -- they know that it works well for organic vapors and A, B, and K and the like.

So I think this same thing we are thinking about here does not necessarily apply in that relationship because it doesn't make sense to reiterate that every time once we have established it for one set.

If you have multiple approvals, again.

MR. SAVARIN: I just wasn't sure everybody understand that here. Thanks.

MR. KING: Yeah. I'm certainly glad you asked the question.

MR. SAVARIN: That's fine. Thank you.

MR. BLANK: George Blank with Draeger Safety.

Maybe I'm not seeing something, but my original understanding was that a CBRN was going to be a subset of the PAPR standard, but I don't see any mention specifically of CBRN in anything we have talked about here.

MR. KING: That is true.

MR. SZALAJDA: I guess I will try to address that.

The thought process with going forward

with CBRN and the approach that we took with the, you know, with the implementation of the standard in 2006 were that the requirements were set in a way such that when the new PAPR standard evolved, the CBRN requirements weren't going to change. So that the requirements that you would have to meet now for CBRN will be the same if you submit something now versus five years from now.

Does that answer your question?

MR. BLANK: I'm not sure. I'm still a little confused as to -- because --

MR. SZALAJDA: Well, I guess things -- what we have defined -- what we have currently defined for CBRN for the chemical warfare agent testing, the LRPL, the gas and vapor testing, and also the environmental conditioning, that's part of your application. Those tests are not going to change.

MR. BLANK: So they would be written into the standard and also be part of it?

MR. SZALAJDA: Yes. But it won't be a requirement. It will be if you want to get that

specific protection, but it will part of the standard. We just weren't going to talk about it because the requirements aren't going to change.

MR. PERROTTE: There's a LiveMeeting question.

MR. SZALAJDA: I guess we will take, I guess, one more, the LiveMeeting question, and then we will move on since we are a little bit behind schedule.

MR. PERROTTE: This question is from Simon Smith. It says: Thanks for a great presentation.

Is there any consideration for low boiling organic vapor cartridge as a standard item, not as a special requirement in parallel with European AX or ISO's direct standards?

MR. KING: No. We haven't considered it at that point. Certainly, if -- I haven't really weighed that issue, so I'm a little flat-footed there.

I will certainly look into it.

MR. SZALAJDA: All right. We are going to move ahead to the last -- the next-to-last subject

we are going to discuss is Gary Walbert, who has been with us about a year now in terms of being a NIOSH employee.

And with regard to the work he has done over the past several years with looking at the particulate testing associated with high flows. And he spent a lot of time and effort in looking at the development of the technologies necessary to be able to evaluate the filters in these types of settings.

So once Gary is set up, we will be good to go.

MR. WALBERT: Okay. Just to reiterate, I have come to discuss recent work performed at NPPTL to evaluate high flow filter efficiency testers for PAPR applications.

The planned activities for this project include evaluating two filter testers, an ATI Model TDA-500P and a TSI Model 3120 High-Flow Filter Efficiency Testers for use in PAPR95 and PAPR100 particulate filter efficiency level determination testing.

Through these efforts, we hope to identify

the high flow filter testers acceptable for the required testing, and then formulate standard test procedure for particulate filter efficiency level determination testing for PAPR and operating procedures for the acceptable high flow filter efficiency testers.

Next slide, please, John.

Okay. The specific testing that will be performed on each filter tester includes verifying that high-flow filter efficiency testers conform to advertised specifications and the PAPR standard.

Also determining DOP aerosol loadings as a function of time at flow rates ranging from 100 to 500 liters per minute, determining the time required to load 1000 milligrams of DOP aerosol.

Determining the DOP aerosol particle size, distribution at flow rates ranging from 100 to 500 liters per minute. And also identifying lab technician issues.

Next side, please, John.

Okay. The operating requirements for the ATI and TSI high-flow filter testers were different

than the standard filter tester that is being used right now for low flow testing.

We require additional compressed air due to the higher flow rates. And for the ATI unit, that is 18 scfm at 80 psig. And for the TSI unit, we require 25 scfm at 100 psig.

In addition, larger vacuum pumps are required to overcome the higher pressure drop across the filter test bed and the DOP discharge filter due to the higher flow rates.

These were taken from the vacuum pump curves for both units. For the ATI unit, 22.5 acfm at 19 inches of mercury are required. And for the TSI unit, 25 acfm at 7 and a half inches of mercury are required.

Next slide, please, John.

Higher exhausting capabilities are also required due to higher flow rates. For the ATI unit, we require 48 scfm. And for the TSI unit, 25

scfm.

And the higher flow rates -- the higher exhausting requirements for the ATI unit are due to

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a special DOP aerosol carryover venting system that they have incorporated into their system.

This next slide shows a photograph of the ATI TDA-500P High-Flow filter tester.

On the bottom enclosure, you can see the vacuum pump that is close-coupled to the unit. In the center of the picture is the filter checks. Let me go back one slide, John, please.

This shows the filter check area where we set our filters -- canisters for testing.

The next slide shows the TSI 3120 high-flow filter tester. And beside that, located on the floor, is the vacuum pump close-coupled to the unit.

Next slide, please, John.

Okay. Determination of DOP aerosol loadings required an enlargement of the filter test bed to approximately eight-and-a-half inches in diameter. And this was done to reduce the pressure drop at the higher flow rates and also to collect sufficient DOP aerosol to obtain accurate change in weight measurements in measuring the loading

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generated by these two units.

We are also using a glass -- Type A/E glass fiber filters for the one micron four size,

265 millimeters in diameter, to collect of the aerosol for the loading tests.

And also a support grid with a one-half inch by one-half inch openings and a one-quarter inch thick lattice is being used to support the filter to prevent filter blowout at the higher flow rates.

Next slide, please, John.

This photograph shows the eight-and-a-half-inch diameter filter test bed with the support grid that we use for the loading tests.

Next slide, please, John.

There is a flow rate effect on the DOP aerosol loading, as we observed with our initial testing. Initial testing indicates that DOP aerosol loading is dependent on the flow rate.

We have done some recent testing employing, using a hand valve to control the flow rate through the test bed, and this has resulted in

an improvement in repeatability and consistency of the DOP aerosol loading measurements from run to run.

Also, we would recommend using mass flow controllers in place of the existing mass flow meters to improve the aerosol loading stability to take the human element of controlling the flow rates.

This next slide shows a -- this is for the ATI high-flow filter tester at 300 lpm. This was done back on July 29.

And as you can see here, there was no flow control employed. The flow rate drops off very sightly from about 300 lpm down to about 296 lpm. And during that time, the loading increases from 140 up to almost 190 milligrams per meter cubed.

Next side, please, John.

The next slide shows testing done just recently where we were controlling the flow rate with a hand flow control valve that's on a make-up airline that goes into the vacuum pump.

And, as you can see, the flow rate is

maintained very steadily between 300 and 302 lpm. And the aerosol loading during that time -- this is, again, a seven-hour test -- varied from 145 to about 155 milligrams per meter cubed.

The units we have on site, they are sized up to 500 lpm because that would mean a larger vacuum pump.

The vacuum pumps are close-coupled to the high-flow filter testers. Therefore, the noise level in test lab is high.

The vacuum pumps for any commercial models that are this large in size should be located remotely to mitigate the noise.

Also, vacuum pump noise may be mitigated by sizing the vacuum pump to the final PAPR standard gas flow rate requirements and also for the particular PAPR test application.

Waste gas venting is an issue. The higher flow rates result in higher waste gas flow rates

that have to be exhausted from the test area through a controlled ventilation system, such as a ventilated hood.

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The ATI high-flow filter efficiency tester requires a secondary exhaust system to balance excess DOP aerosol generation from an aerosol generator vent, resulting in higher waste gas venting requirements.

Whereas, a TSI high-flow filter tester vents directly from the aerosol generator.

And that should be it. I will take any questions at this point.

Thank you.

MR. SZALAJDA: All right. I guess, John, did we have any LiveMeeting questions?

MR. PERROTTE: No.

MR. SZALAJDA: We will move on to the last PAPR presentation, which is going to address the work done by Jay Snyder of the Technology Research Branch with the end-of-service-life indicator.

Jay had a couple of posters next door. I hope you had the opportunity to look at them. The posters -- just in general, the posters will be up, you know, throughout the course of the day. And, of course, you are welcome to peruse them. And also,

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if you see the associated researcher, to ask them questions as time permits.

So with that, if Jay -- well, he was just back there. If Jay can come forward, and we will

get him miked up, and he can give his presentation.

MR. SNYDER: Well, good morning. I want to talk to you about something near and dear to me, end-of-service-life programs at NPPTL.

And specifically, I would like to talk about our current work on cartridge sensor integrations and the testing and evaluation we have done, and this has to do with the electronic system.

I also want to talk about the future work in the area of the electronic system as well as describe to you some of the efforts that are going into an optical system. So we have two approaches to developing an end-of-service-life system currently going on.

Slide, John. And, again, John.

Hit it again.

Yeah. This is an animated slide to give you an idea of what we have in mind here. This is

our ultimate system where we can produce a sensor that is sufficiently inexpensive that we can have multiples of in it a carbon bed.

We also incorporate some electronics in with the sensor and an antenna so that we have a wireless device. I'm playing with the laser. Technical issue.

So we have multiple sensors in the bed that are powered by RF transmission. We have RF coming in. It powers the device. It takes some readings. That information then is transmitted back to some central processing unit, which then provides

the user with an indication of the condition of the respirator cartridge.

That's our ultimate goal. We are not there yet.

Next slide, please.

I would like to extend a big thank you to these companies who have volunteered to work with us on integrating sensors. We have just gone through a first round. Just this month, we will be completing the testing.

I would like to do some evaluations on the results of that. And one of the things in particular I'm doing is a post-mortem evaluation of the sensors after they have been run through a cartridge test.

And then in the first quarter of next year, getting together with the participants and reviewing the information that we have accumulated.

Now, we did several things in this test. We tried to design this round-robin system so that we could maximize our information.

Next slide, John.

Here are some examples of some of the cartridges, APR cartridges that had sensors integrated into them. You can see we had multiple arrangements, had them where the sensor was located in the side wall as well as in the very center of the carbon bed.

We also had a variation in sizes of cartridge. They went anywhere from a 50-gram bed to

a 300-gram bed. So we have been finishing up on that work, and, as I said, doing some post-mortem work on the sensors to see how well they survived.

One of the things we did in that work was to send both a fully completed sensor to the manufacturer as well as just a cap which they integrated both types. They came back to NIOSH, and then the one -- the cartridges that had just caps, we inserted a sensor. So that gave us some information of how well the sensor would survive the manufacturing transportation process, and it's proven to be quite interesting.

Just to give you a brief background of where this system has come from and where we are at, we have had multiple generations of the device. We started out with this one up here on top first.

It was a chip, a silicon chip with gold electrodes imprinted on it. And in this case, they were interdigitated electrodes, which we then placed on a conductive film. And that conductive film interacted with environmental contaminants, water vapor as well as organic vapors.

Following that, we went to a parallel plate system where we just had two parallel plates with a three-micron gap. Again, filling that gap was a conductive material. That's this device.

Then we moved on. And by the way, these two had 24 sensors on the silicon chip.

Then we moved on to a spiral electrode arrangement, which gave us much greater service area. And that's the electrode arrangement we are currently using, but we have made several modifications.

We reduced the 24 system down to six, and ultimately we have paired the six sensors in three groups of two, covering three of the sensors, or one of each of those pairs so that we use that as a reference.

What we find to be the challenge in this system is keeping that reference device hermetically sealed. It is very difficult to do that without affecting the performance of the sensor itself. It is under this cover plate you see in these two models.

So this round-robin we have just completed, we used a Generation 5 device. From some

of the information we have gleaned from that, we have begun to develop a Gen 6 device, which has gone through the development process. It has gone out to the foundry. They have produced the mask.

It is back. And so in this next quarter, we will be producing sensors and evaluating them in considerably different format. It will only have a single sensor in this new format, but it will be -- have a pre-concentrator up front, which will significantly affect its performance in terms of sensitivity and we think eliminating some of the background problems with humidity.

Next slide, John.

This is a further breakdown of the Generation 5 device that we have used in the round-robin system.

You can see the silicon wafer here in the center. It is approximately two millimeters on the side. And on that, there are six sensors and bond pads to attach wire bonds that brings the information out to the outside world.

This all incorporated onto the top of a

TO-5 package, a very common electronics package found in the electronics industry.

And covering that, then we have placed a metal cap which has a hole, which is covered with a Teflon filter to permit vapors to permeate through into the sensor, but prevent contaminants from entering, such as carbon dust.

Next slide, John.

We are applying nanotechnology to this application, and I wanted to talk a little bit about it.

By nanotechnology, in our case, we are using materials from the two-nanometer range down to a fraction of a nanometer, or several angstroms. The interesting thing about nanotechnology and materials that are used and formed in the nano region is that their characteristics change significantly from what you would normally expect them to do.

Even the color. For example, I have shown

here a gold nugget, and we all know the color of gold. As you transition down to the smaller and

smaller sizes, the color you see in reflectance actually changes.

So the material we are using for this round-robin was a monolayer protected gold nanoparticle. And it's pictured here. What it consists of is an approximately two-nanometer gold core onto which a chemically bonded organic film is applied. And that's about seven-tenths of a nanometer in thickness.

And what that does is if you had pure gold touching pure gold modules or nuggets, particles, touching, it would be a perfect conductor, very good conductor. When we add the film to it, it becomes a semiconductor. And this semi-conductance characteristic changes as it interacts with its environment, such as when there are organic vapors present.

Okay, John.

Here is a summary slide of some of the work we went through before we went into the round-robin.

You see here is what we call our C8

nanoparticle. The reason we call it a C8 nanoparticle is because that's the film we have surrounding the two-nanometer gold particle. It's a C8 material.

And some of the early testing we did, we

have a cartridge simulator in the laboratory. We can fill it with 50 grams of carbon, place a sensor inside the carbon bed as well as a gas chromatographic probe. We can monitor what the sensor sees.

And here you see a plot. In this case, we ran a thousand parts per million of toluene into a carbon bed of 50 grams at 32 liters a minute and relative humidity of approximately 25 percent.

So at the bottom, you see the response of the sensor, and this is time.

And -- I'm sorry. At the bottom you see, this is the response of the GC, the yellow. This is the sensor response, and you can see both are nearly the same in terms of when they see the contaminant, the difference being the actual location.

It's difficult to locate the GC probe and

the sensor at precisely the same location in the cartridge. But we did get decent correlation.

Some of the things that we like about these nanoparticles is they are easy to handle, quite stable in air, soluble in organics, so it permits us to dissolve them and apply them to our sensors quite easily. And so we can do that in a number of ways, by inkjetting, just plain old dropping, drop casting, spinning, spraying.

And sometimes the way in which you apply these materials affects the performance of the material because you can get different morphologies.

Some of the other things that we like

about them is we can easily modify them in terms of shape and size. And the functional group that -- in this case, the C8, we can modify either the C8 or put a totally different functional group on as a film. And it gives you different performance characteristic.

And we also like the fact that it's reusable. And that is we were able to expose them numerous times to solvent vapors and get some more

performance out of them.

This is our setup in the laboratory. And I have summarized the types of tests we did the round-robin experiments with.

You see at the top here, we used toluene at 500 parts per million and 200 parts per million. We also used a DuPont enamel reducer at 500 parts per million. And the reason I like that is because it is a mixture, a blend of numerous compounds. It has got over 19 different groups of organic compounds, several hundred compounds total.

We had aldehydes, ketones, aliphatics, aromatics, substituted aromatics, and branched aliphatics. So quite of variety of different types of compounds, numbering in the hundreds.

We also did trichloroethylene at 500 parts per million, and we varied these at 25 percent and 80 percent relative humidity.

This is our laboratory test setup done in a hood. This is the actual chamber, which we have a cartridge. And this is a little larger. You can

see the sensor connection here on the side.

Here is a summary of just some of the results. In this case, 500 parts per million toluene.

Now, one of the things we learned as we were building these sensors for this round-robin is that there was a significant difference in performance depending upon the film thickness of that conductive layer over the electrodes.

And the conclusion we came to was that, after evaluating a number of them and seeing the responses, came to the conclusion that we were able to produce a more uniform device with a thicker film. These are all thicker films to the left of this area, and these are the thinner films.

Now, with the thinner films, we did get some performance similar to the maximum performance we saw with the thick film, but they just weren't as consistent. And these were in terms of microvolts per part per million.

John.

Here's a summary of the results we got from one brand's integration. And I wanted to show

you the results of all of the tests. Here we have toluene at 500 parts per million, 25 percent relative humidity. 500 parts per million at 80 percent humidity. 200 parts per million toluene, 25 humidity. The Dupont solvent at 500 parts per

million, 25 humidity. Trichloroethylene at 500 and 25 and 80 percent relative humidity.

And you can see, we got decent responses, in the order of 60 to a hundred microvolts per part per million, which was really quite good.

So some of the preliminary conclusions that we have arrived at based on we have seen in this round-robin of tests is the uniform film thicknesses were more sensitive than the thinner film devices. That is something I just talked to you about at length.

The detection of the contaminates at high humidity I would term as unacceptable, and that is something we will be concentrating on this Gen 6 device, to improve upon that effort.

Here is an interesting one. The location is centered. It didn't seem to make much difference

in performance whether the sensor was located in the side wall of the cartridge or out in the center of the bed.

I have marked no failures due to handling and transportation, and that was an early conclusion. Now that we are doing the post-mortem work, I'm not entirely sure that's the case. I may have more to say about that later.

And we have been using these devices for about year, and we haven't seen any aging effects yet. But we do have some longevity tests ongoing to further evaluate that.

So here are some of the tasks that we have

got upcoming for '09. In the materials area, we want to a develop some nanomaterials, nanoparticles, particularly the gold nanocrystals and clusters.

And we want to also look at incorporating other devices. I have been talking to you today solely about a chemiresistive device. This silicon wafer MEMS device is capable of other types -- of incorporating other types of systems. And one which considerable work has been done is a gravimetric

device. So we would like to incorporate that into a single MEMS unit.

These are all really important. Just some are more so than others. Next one, John.

In the areas of system integration, we are really excited to start testing the pre-concentrator. The design has been completed and implemented. And, as I have said, we will expect to begin testing in the first quarter.

We also want to look at that integration of multiple types of sensors as well as testing various analytes in a passive system.

And of course, the humidity effort will be ongoing through the year to improve performance and be able to better discriminate between analyte and humidity.

And finally, I have identified the wireless task. This year we will begin looking at the feasibility of making it all wireless, and that is taking electronics, integrating it into the chip via CMOS, the sensor chip, and adding an antenna and

making it wireless.

Okay, John.

And this is a concept slide of what we think we need to do in the area of wireless work. Start out with something rather large, a flexboard approximately an inch across, which we have got the Chemsensor system in the center.

Later, we think we can shrink that down further and incorporate the Chemsensor and power and communications to the point where we reach this very small device. Hopefully it will be in the order of two-tenths of an inch, which will have the antenna, the sensor, as well as the electronics to operate the sensor.

And I have included a block diagram of our Generation 6 device, a couple of important features of it that we will bring in the sample into a pre-concentrator which will then flash that sample periodically onto various types of sensors, the chemiresistive device as well as the gravimetric device. And that data then can be collected and analyzed.

We also will be putting a humidity sensor

on this new chip. We think that having that information available, we can better decipher responses between the humidity and organic contaminants.

One of the other things I wanted to talk to you about was this core silicon work, or our

optical system.

Could you back up just one slide, John?

It is, again, applying nanotechnology to an optical sensing system. Some of the advantages are very low power, can be produced in mass quantities at low cost. Tuneable optics. And really quite high sensitivity for the amount of surface area. So we can put a very, very small device in a carbon bed that would be totally unobtrusive in the performance of the bed.

Okay. Next one.

Again, we are working down here in the couple-of-nanometer range, and I'll describe the way in which this works with our next slide.

Yeah. We take a silicon wafer and etch nanometer channels into it. And these channels, of

course, can be very well controlled in terms of size and length.

And we attach this wafer, this etched wafer, onto a piece of optical fiber and transmit some light into it so that it impinges the surface and is transferred through the wafer.

As it passes through these channels, the walls cause a reflection to occur. And the reflection can be monitored. And if we then continue the monitoring and expose the wafer to an organic vapor, these vapor molecules accumulate in those channels, and they cause a change in the reflectance. So we get a band shift.

And if we do some calibrations, we can

equilibrate that band shift to a concentration.

Next one.

This is a further breakdown. Here we have the film, the filament, optical fiber filament, which we have attached a photonic crystal to it. This is a multitude of filaments down here, but we can take just one of those, or we could take several of them and place them at different locations inside

of that and monitor them for the performance of the bed and determine the condition of the bed.

Next slide.

So just to describe this a little further, if we have a bed. We insert a carbon -- or an optical fiber with a photonic crystal on the end. We provide a broad spectrum of light. It then penetrates the photonic crystal.

We get some reflection back. We monitor that reflection with a spectrophotometer, and we can see this differentiation in a band. And we can then equilibrate or relate that shift to some contaminant and concentration.

Next slide, John.

Here's a simplified version. The problem with the other version I just showed you, we have got you pretty large supporting devices, like the light source and spectrophotometer. So we wanted to reduce that down. We could do that by simply using an LED.

The difference here is now we have a single band of light will be transmitting. And so

we can't look for that shift any longer, but what we can do is look for a reduction or change in absorption. And this thing can be equated to concentration.

Next one, John.

I would like to acknowledge some of the folks that I have worked with on this program. Quite a number at Carnegie-Mellon University, specifically, Lee Weiss and Gary Fedder, who have been the principal investigators at CMU.

Next one.

Other, Tony Rozzi, EG&G, is working at NIOSH. Michael Sailor, Anne Ruminski, and Brian King from the University of California at San Diego. They have been the principal investigators on the optical system.

And finally, you know, we have been funding the work. We have been taking advantage of a number of funding sources.

Of course, CDC/NIOSH has put money into this effort. Another agency is the U.S. Air Force Office of Scientific Research. They put in an equal

amount of money in under their Multidisciplinary University Research Initiative Program.

CMU, Carnegie-Mellon, received an earmark from the Defense Department for a program called Sensors for a Safer America, which had a lot of the same interests and goals incorporated into it as did

our program. So we have been able to leverage that work, and that was really quite significant funding.

And then the University of California, who has been providing the research funding so far for the optical system.

Questions or comments?

MR. BARD: Brent Bard from Supplied Air Monitoring Systems.

With the managing the humidity is one of your larger problems with the sensors, do you perceive it beneficial to increase the humidity level that you are going to the testing at given the fact that a lot of the end users, for example, Gulf Coast, are going to require it be exposed to a higher than 80 percent relative humidity on a daily basis?

MR. SNYDER: I will be real happy if we can get the 80 percent.

I think once we get to that, no reason why we can't look at higher concentration, recognizing the situation you just identified.

MR. BARD: Thank you.

MR. SNYDER: Just to comment one thing further, one of the issues you begin to get into is just total condensation, and then discrimination really becomes quite difficult.

A couple of the things that we are doing in that area that I didn't mention was that in the optical system, we have been looking at treatments of a surface that tend to affect its performance in

the presence of water vapor really quite significantly, and we think that offers some real potential.

As well as the concentration system that I mentioned on the chemiresistive device. We are using a single sensor and actually pulsing the contaminant in along with having the separate humidity sensor.

We think both of those will be of significant advantage for future work.

MR. SZALAJDA: Do we have anything from the LiveMeeting?

MR. PERROTTE: No.

MR. SNYDER: Thank you.

MR. SZALAJDA: Thank you.

At this point, we do not have any requests to make specific PAPR presentations, so for the next few minutes, I would like to open up the floor for any general questions and also any comments regarding the standards development program for PAPR.

MR. COLTON: Craig Colton, 3M.

I have a -- sort of going back to some of the earlier things that were said, and you have got this classification of a breathing assist and the positive-pressure PAPR.

Has NIOSH given consideration as to then how these devices will be approved, let's say, and then labeled or identified? Or are they all going to be different, or are they going to be approved

just as NIOSH PAPRs?

Today, you have got loose-fitting and tight-fitting, but they are all powered air-purifying respirators.

MR. SZALAJDA: That's a good question.

Sort of what I envisioned, you know, with the classification is that this next generation of PAPR will have their own specific -- I don't want to say 14G, but I will call it like PP1, PP2, whatever that, for each, to tie it in with the performance characteristics that each -- if you get it approved at, say, 25 liters per minute, that will be a PP2 classification. If you get it approved at a higher flow rate, it's a PP3 or a PP4.

That's something we still need to flesh through, but I think part of what we want to do is show a separation between -- yeah, not to ignore the systems that are out there, but show that they are different.

You know, and if you have any ideas as far as how to do that, we would love to hear them. But I think there's a need -- there's a definite need to

show that there is a difference between where the approval came from, whether it was from, you know, Part 84 circa 1995 or, you know, Part 84, 19 -- or 2010, but if there is a difference between that in the systems.

MR. COLTON: Yeah. Because I think that has implications then for the users, especially when

you have got a standard that OSHA that has set that has APFs and tells how to select PAPRs, but it just identifies PAPRs in the category based on their respiratory inlet covering, not these different flow rates.

MR. SZALAJDA: Yeah. That's a good comment, Craig. It is something that we are continuing to work through and that, you know, I think we will have to address that as part of the development in the rule.

(Someone talking while sitting down where the court reporter couldn't hear.)

MR. SZALAJDA: Oh, okay.

MR. COLTON: The follow-up sort of to that is, did I hear you indicate that NIOSH was going to

set APFs for these devices?

MR. SZALAJDA: No.

MR. COLTON: Okay. I heard that word used and --

MR. SZALAJDA: Well, I think the thought is what we have been working with -- I guess the question for LiveMeeting, is NIOSH going to set APFs.

And I think the answer there is no, that thought is -- and we have been talking with OSHA now for several years -- is that with the corn oil capability that we have established and others have, is to have OSHA recognize that as a means of being able to use the test results to recognize and set an APF for a particular system.

And, you know, I guess, for example, when you look at the testing that's been done on different models over the years, the applicant has gone on and had simulated workplace studies done, and that data had been used to go back to OSHA and request an assignment of an APF.

What we have done is -- with our

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discussions with OSHA, is having -- is working for them to recognize our testing as data that can be used for them to assign an APF. And the linkage there being by -- through doing the LRPL type of testing, to develop that data where a determination can be made.

MR. COLTON: Is that then for hoods and helmets, or are you considering that for -- or is that sort of what has been talked about for all?

MR. SZALAJDA: I think that's where -- we are in the area of all, any system.

And I think that's where we are curious to get feedback from when you look at trying to categorize the systems that we know, you know, in looking at an inward leakage test with the different categories, you know, with being able to determine what is reasonable, you know, for what a specific piece of equipment may be able to do.

You know, and, you know, for example, I think I used the baseball cap with the blower, you know, example, that, you know, there may be a home for that somewhere, but you don't want to give the

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impression that you can use that baseball cap with a blower if you are working in a high workload, intensive, you know, type of environment.

So depending -- I mean, it all gets into the respiratory -- gets into the selection of your respiratory device.

I think that's where, you know, I see a need, you know, in going forward here over the next -- you know, with the generation of the rule, of being in a position to be able to talk about this with the users and increase the user knowledge, at least as far as what does this new PAPR standard mean to them, you know, and how they can use the standard and use the information coming, you know, out of the certification program and in our guidance to help them select the appropriate respiratory device where they need the protection.

MR. COLTON: Well, then the last comment I would have is that I would urge NIOSH to listen to the comment that was made earlier by Mr. Janssen. Because when you started talking about the inward leakage, that's never been really correlated to the

flow, as he indicated.

In fact, we have shown it to be even more related to the type of respiratory inlet covering since we have currently got PAPRs, for example, that are approved with the same air flow rate. But in field tests in the workplace, we know that they give different performance based on the type of

loose-fitting respiratory inlet coverings.

MR. SZALAJDA: Yeah, that is a good point. I appreciate you clarifying that because I didn't want to misstate, you know, at least as far as the development of the inward leakage requirement because there a lot of -- as well as the other factors that need to be considered in going into development of a standard.

But, again, it's part of the whole suite of requirements that need to be considered.

MR. MCKEE: Tony McKee, ILC Dover. I wrote a little speech here, Jon, a little commentary relative to PAPR technology. A lot of Rich's work on establishing flow rates.

It appears that flow rates are established

for basic specific work rates or based on conventional existing loose- and tight-fitting PAPR technologies.

It seems like -- it seems to me that this may limit -- tend to limit innovation from the aspect that in future products, since the ultimate goal should be to maintain positive pressure in the breathing zone regardless of the flow rates provided by the system.

Excessively high flow rates encumber the user by requiring large batteries, multiple canisters, have a negative impact on canister service life.

My question would be, is it possible to consider an addition to the standard that provides a

placeholder for lower flow technologies while still providing those high levels of protection at moderate and high work rates?

MR. VOJTKO: The flow rates are not for approval of the PAPR itself, but for canisters, cartridges, and filters.

If you have a more efficient PAPR in terms

of the amount of air it requires to maintain a positive pressure, then maybe we have a little bit of a heavier filter. But I don't think we are in any way blocking development of something that will maintain positive pressure because that's the standalone test as far as for the positive pressure unit.

What we were looking at is just a basic capacity for the filters and such so that we don't have immediate breakthrough.

And in some cases, some of these devices that have lower overall flow rates may have higher peaks to compensate.

So we want to be able to accommodate that, and we are looking at a safe value for the sizing.

If you find that you are putting less air through a canister, I think it's a marketing tool for a longer life because you have a capacity there kind of based on some of Bill's statements, and you're not using it up as quickly.

MR. COLTON: I notice -- because I notice most of your testing was based on, you know,

conventional tight-fitting and loose-fitting PAPRs.

MR. VOJTKO: Well, we thought that would be the worst case in terms of developing these cartridge/canister capacities.

We feel anything else would probably be better and would stand it in good stead to -- so that a user would feel safe in using it and possibly have a longer life from that equipment.

MR. COLTON: Great. Thanks, Rich.

MR. PERROTTE: The LiveMeeting question is from David Spelce. I believe I pronounced that right.

It says: Since there is an STP in place to perform LRPL testing of neck sealing hooded CBRN PAPRs, are these hooded CBRN PAPRs covered in all draft PAPR standards, and can they receive NIOSH tight-fitting CBRN PAPR approval?

MR. SZALAJDA: Okay. I think I'm going to -- and maybe Dave can clarify this.

I think I'm going to assume that this is looking forward, you know, from the standard. Because right now, I mean, you would -- you know,

for submission you would have to meet Part 84 as it exists plus the CBRN criteria. And I think in going forward, you know, it looks at -- for CBRN, as long as you met the performance requirement, we are not necessarily going to be looking at the -- whether it's tight or loose fitting, but rather that you meet the performance requirements that are identified.

So I don't know if that answers Dave's question or not.

MR. SPELCE: Well, I don't think it does, but --

MR. SZALAJDA: Dave, I guess if you have voice capability, if you can restate the question.

MR. SPELCE: Well, I was just wondering -- boy, I'm getting a lot of feedback in my headset.

Are -- a tight sealing PAPR is going to be able to receive tight-fitting CBRN approval.

MR. SZALAJDA: Well, right now, you would have to meet the criteria as far as being -- if you had a hooded system, you would have to meet the tight-fitting criteria where it needs to seal to the

neck.

MR. SPELCE: Right.

MR. SZALAJDA: So if you had a hooded system now, as long as you had a neck dam or some sort of means to seal the neck, you could get a CBRN approval as a tight-fitting device.

MR. SPELCE: Thanks.

MR. SZALAJDA: Okay.

All right. Since we are at 12:13, we will take one more question from Edna.

MS. DeMEDERAS: Edna DeMederas, North Safety.

Do you still have a requirement for low flow/low battery?

MR. SZALAJDA: The question, I guess, for LiveMeeting, do we still have the requirement for

low flow and low battery, and that is yes.

MS. DeMEDERAS: For everything? For breath-assisted and --

MR. VOJTKO: We will have a low battery requirement, and we are not measuring flow. So we are going to have a positive pressure requirement in

the positive pressure.

And for the breath-assisted, we really haven't developed anything yet, so we are open to suggestion on that. And we may just be looking at the inward leakage on that, or maybe flow.

But we haven't established that yet.

MS. DeMEDERAS: Okay. Thanks.

MR. SZALAJDA: Okay. I think with that, what we will do is we will take an hour break for lunch.

If we could reconvene at 1:15, and we will resume with the program.

(A luncheon recess was taken.)

MR. SZALAJDA: We are going to go ahead and get started with the afternoon portion of the program.

And we are about I think 15 minutes behind schedule, and we will just try to at least operate within the timeline, even if -- or the timeline with regard to the amount of time for each topic, even if we end up going a little bit later than planned.

But the next item on the agenda is the --

is Maryann D'Alessandro is going to be discussing the PPT planning efforts in response to the National Academy of Sciences' review of the Personal Protective Technology program.

MS. D'ALESSANDRO: Can you hear me?

Is that better? Good afternoon. I'm going to provide a brief overview of the PPT program action planning. First, I'll talk a little bit about how we got to where we are today, and then I'll give you an overview of the National Academies' recommendations. And then I'll talk a little bit about how you can help.

Stay on this slide, John, please.

First of all, in this era of program evaluations and when the government is being held accountable for what it is doing, NIOSH decided to conduct a series of evaluations through the National Academies.

They believed that the National Academies would provide the most scientifically rigorous review of NIOSH programs. So they identified eight programs that would be reviewed over a three-year

period that started in 2005, and there were three NIOSH sectors reviewed and five NIOSH cross-sectors reviewed. We have talked about those in the past in our program, public meetings, so we won't get into those today.

The PPT program was one of those evaluations that was reviewed.

Now, all eight of these reviews now are

being addressed through each particular program. Now, the PPT program is managed by NPPTL, and NPPTL is the primary component of the PPT program, and that's why we are reporting on this to you today.

So the next slide, please, John.

So who reviewed the PPT program?

The National Academies identified a committee of esteemed scientists, medical researchers, and doctors, and subject matter experts to reviewed the committee. Now, these handouts are in your notebook that you were provided. It is hard to read here. But you will be to identify some of these names.

Now, the chair of the committee, John

Gallagher, is an emergency medical doctor, and he did not have any knowledge of PPT.

Although he knew people in health care used PPT, he had never really used it himself. So this was a very enlightening experience for him, but he really was an excellent chair of this committee and really managed it very well.

You will also notice that there are some esteemed scientists there who are involved in protective clothing. There is Roger Barker. There is Jimmy Perkins. Also some stakeholders, scientists, Howard Cohen and Janice Comer-Bradley.

There will be some names that you cannot identify there who are not familiar with PPT that are esteemed scientists and researchers, perhaps in program evaluation and other areas who are on the

National Academies.

Next slide, please.

So what did the committee review? The PPT program had to put together what we called an evidence package. And that evidence package encompassed everything that the PPT program, not just NPPTL, but what the PPT program had done since NPPTL's creation is when we started.

And we had 12 goals and objectives that were identified. And they were based on our strategic goals, which were to reduce exposure to inhalation hazards, dermal hazards, and injury hazards.

So of those 12 objectives that were reviewed, they were categorized into three what the Committee called was PPT domains, which are essentially the NPPTL branches of research, policy and standards, and respirator certification. So that's the way they had broken down everything to evaluate our activities.

So then how it was reviewed is by looking at relevance, impact, emerging issues, and recommendations.

The Academies had to review the program based on relevance based on a scale of 1 to 5, and the details regarding what each of those means can be looked at -- you can download that on the website. And impact, a scale of 1 to 5 as well, with five being the highest.

And then they also had to look at what emerging issues we should be addressing in the activities that we are conducting today and moving into the future. And then they had to provide recommendations based on what we have been doing over the past year since 2001 and where we are headed for the future.

And this resulted in 144 different cells, if you -- cells that they had to categorize.

Next slide, John.

So the relevance score that we received and the impact scores were both 4. And you can see what those scores of 4 actually mean. Five being the highest, we could not -- they said that we are working in priority areas and engaged in transferring research, but there is room for improvement.

Now, those two scores of four do not really do the evaluation report justice because you really have to dig into the details of the report to see what was recommended. And what was recommended

was really that we continue with what we are doing, but that we expand in a number of areas in all of our domain activities and in our outreach and transfer as well.

Next slide, please.

So what was recommended? The Committee had five recommendations that they provided to the PPT program. After reviewing the evidence, it was clear to the program that our focus was in

respiratory protection, and that we were moving into protective garments.

But they wanted to really see that NPPTL was actually living up to what it was charged to do, which was to have a comprehensive PPT program addressing not only respiratory and dermal hazards, as we are addressing now, but moving into all PPE areas.

And also, most of our activities have been focused in areas where there are stakeholder interests, such as mining and in emergency response. And we are now moving into healthcare with the PPE -- with the pandemic influenza threat.

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So they wanted to see that we are addressing all of the industry sectors that NIOSH has, not just those specific areas. And that we also are focused more in all PPE areas, not just in respiratory protection.

And then in the second recommendation, they recommend that Centers of Excellence be established.

Now, this is -- I'm sure many of you or all of you have heard of -- the Center of Excellence concept has been around. There many ways that people perceive what that should be, and we were trying to see what exactly they wanted to see from that, but they left that wide open.

And they said to us that, what they see is there are a number of -- especially in academia, a number of test facilities that exist and academia

researchers who are out there who have a capability that we don't have in house, but that we could actually provide them directed research. So we don't necessarily have to build up that capability in house, but we could manage all of those

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activities.

So that's the way they saw it. And so that is what Recommendation 2 is, and I will talk about how we are trying to address that.

Third, the committees have a lot of opportunity for enhancing the respirator certification program. So they left that as a separate recommendation. And that stood out, that being the foundation of NPPTL.

They wanted that to be addressed and figured that there are a number of ways that our activities could be enhanced in that program.

Fourth, they wanted to see research on use and usability of PPE.

While we have a good respiratory research program and an evolving program in garments, they wanted to see more research on how do we know that the PPE that is out there in the field is actually -- actually working as it is designed to work.

So the use and usability of that PPE that is out there, and how do we address the barriers to

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using that PPE. So more workplace studies, they

wanted to see. And also they had a specific focus on the comfort issue as well, and on the integration and interoperability.

So those were the three key areas in this recommendation.

And finally, assessing the PPT use and effectiveness using a lifecycle approach. And this boils down to having effective surveillance in the program and ensuring that all of the work that we conduct is not just based on the squeaky wheel and those stakeholders' interests, but on surveillance data that demonstrate that this is what we need to be doing. So we should have surveillance as a key input into evidence into everything that we are doing.

So how are we addressing the recommendations? We prepared the evidence package in August and submitted it to the Academies, and we received their evaluation in June of this year.

And then what we did is the PPT program leadership developed a strategy for moving forward

with this approach. And what we decided to do is to have a team approach in addressing these recommendations.

So we solicited both NPPTL and all of NIOSH for participants in teams to assist us in identifying strategies for moving forward with these recommendations.

So the three individuals that you see up here volunteered to lead those teams. Actually,

Colleen led Recommendations 4 and 5. Tom was the assistant lead to Lynn Rethi, who couldn't be here today due to a family emergency. And 14.3, the respirator certification, he and Ed Fries on the end led Recommendations 1 and 2.

And they were assisted by five to ten people in NIOSH in developing the recommendations and really providing a lot of detail. You will not see that detail today.

The briefing that they gave was three and a half hours, just on their recommendations, and that was not the detail that provided all of the resources. So it is a very detailed plan, and you

are just going to see the surface today.

And also, could I just see a show of hands of other people who participated? Ziqing Zhuang was also an assistant lead. And if you participated on our team, could you just raise your hand so they realize that this was a team approach? Thank you.

Okay. This happened over -- this is a very intense process. It happened over a six-week time frame, in August and September. And then the teams provided us their reports in September, and we then presented it to our National Academies Committee on PPE in October.

And now, the leadership is in the process of synthesizing these recommendations with what we are doing now and how we move forward.

The next slide.

So the way the action plan is put

together -- and you will see this on the website when it is posted this month -- is that we have the National Academies' recommendations.

And then these recommendations are broken down into issues that are associated with each of these recommendations and desired outcomes.

And then each of those has associated activity output goals, which is a NIOSH term in identifying typically what project level goals are.

So our project activity is the activities you heard about today. These would be activity output goals that we intend to do. And then what action steps need to be achieved to achieve those goals.

The thing that is missing in this hierarchy is the intermediate goal step, which I will talk to you about at the end of the presentation.

And this is what others do with the information with our outputs. And that's where the we need your assistance in what intermediate output protocols should we incorporate in the plan.

Next slide.

Okay. Now I'll briefly go over all five of the recommendations. And then if you have any questions, you could ask the team leaders while I'll answer the questions that I can.

So the first recommendation was to implement and sustain the comprehensive National

Personal Protective Technology program. And this was broken down into four issues. And the Academy was pretty clear with what they wanted to have addressed in these -- under this recommendation.

And those essentially fall into our three branch activities, which are the research area, policy and standards, and the certification activities. And then they added a fourth one, which is the integration and interoperability of PPT components and ensembles.

Next slide.

So the first one is to manage and conduct research across all types of PPT and across all occupations and workplaces. And the desired outcome that we would like to achieve with this recommendation is that we have a comprehensive PPT research program that addresses PPT needs in all industry sectors.

As I mentioned, we have been focused in particular sector areas based on those stakeholders

that are most vocal, and also the national interests. And also we have been focused in respiratory protection and evolving into dermal.

Now, there are other NIOSH divisions who are focused in other areas of PPE and PPT, such as hearing protection, and also in fall protection harnesses.

But what the PPT program wants to do is provide oversight of all of these activities and identify where the gaps are and what activities need

to be conducted and researched and where could we add some areas in the Centers of Excellence and extramurally as well.

So be more active in identifying those gaps across all PPT and all industry sectors.

The second issue is to participate in policy development and standards setting across all types of PPT. And the desired outcome is that PPT policy and standards development effort is in place and gaps identified and addressed.

And you have heard a lot about the policy and standards efforts today, which are headed in the

near term and that the -- we want to have notices of proposed rulemaking, two every year to address 42 CFR Part 84.

But what we also want to do is ensure that we are effectively involved in all those consensus standards that are applicable to PPE and PPT where we should be involved, and also that we are using those consensus standards most effectively in 42 CFR.

So how can we actually leverage existing standards to update 42 CFR? And also in addition to -- can you please go back to the next slide?

In addition to the respirator certification, respirator policy and standards activity, also, what other activities should we be involved with in policy and standards?

So not just moving from respiratory protection to include other areas. We are in the

garment area as well, but we need to identify what other areas in the PPT.

Next slide.

And then in the certification area, the

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desired outcome is a comprehensive certification program is in place. And with regard to this, the Committee was very vocal that other PPE and PPT, apart from respirators, is not certified. And the committee thought that that's something that we should be doing.

Now, NIOSH doesn't necessarily want to take that on. So what we need to do is conduct a feasibility assessment regarding, Does it make sense for us to go beyond respirator certification? Does it make sense for us to manage the overall certification of all PPE and PPT? So we have some way to go in actually developing this concept and addressing this issue.

Next slide.

And then finally, promoting the development, standards, and certification of integrated PPT components and ensembles.

And with this desired outcome, we want to ensure we have a strategy in place to ensure that users have the confidence that their PPT works together as it is certified to work. So the

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respirator, when it is used in conjunction with goggles or hearing protection or an ensemble is

actually working as it is certified to work.

So how can we get more involved in that type of testing and in whole body and whole ensemble testing? And that's what this recommendation addresses.

So then onto Recommendation No. 2.

The second recommendation addresses establishing PPT research Centers of Excellence and increasing the extramural PPT research.

And two issues were identified in this recommendation: Establishing and managing Research Centers of Excellence, and coordinating with the NIOSH Office of Extramural Programs.

Next slide, please.

So the first issue, establishing and managing the Research Centers of Excellence, the outcome under this issue would be that we have centers of the excellence identified that are targeted in addressing those areas that are not addressed with our intramural program, and also

synchronized with our activities that are going on intramurally.

And we produce a stronger and ever-improving research base. And also we see some area of involvement in certification and standards in this Center of Excellence concept as well.

Right now, the thought is that we will have a -- the next committee on PPE meeting that will be held in March, the day after our stakeholder meeting. We will be focused on addressing this

issue and how we better establish the Centers of Excellence concept.

So the National Academies, through our committee on PPE, will be bringing in experts in Centers of Excellence and other experts to help us refine this concept better and look at how we can move forward with addressing this issue.

Right now, what we are looking at is that we would have two components of Centers of Excellence. One would be an area to address research, technology translation, technology research activities, research and development

activities. And the second concept or components of the Center of Excellence, to address technology translation issues.

So once the research is conducted, the standards are out there, how do we ensure that effective training and interventions are taking place?

And that's the division that we have at this time, but that will be evolved more in the March time frame.

Next slide.

And the next component of this recommendation is effectively working with the Office of Extramural Programs.

The Office of Extramural Programs leads the NIOSH grant activities and leads the education and research centers, which some of you are familiar with, and also the agriculture centers.

Now, they all operate independently to our intramural PPT program, and the objective is to have these Centers of Excellence that have one extramural component, the Office of Extramural Programs and our

intramural program all working in harmony.

So the next slide, please.

And this is a visual that would show what that might look like in the future.

So we would have intramural activities that may be independent of the other two areas, Center of Excellence, directed research activities, OEP grant, ERC activities, and then some areas of overlap among all three of them.

Next slide, please.

The next recommendation focused on enhancing the respirator certification program. And under this recommendation, the National Academies came up with four issues that were clearly identified in the report, and they are -- we had broken those out into six, and you can see the red outline in the two that we have broken out.

The first, expediting the respirator certification regulations and updating certifications fees, we split into two because we believe they are separate issues.

And then registering the purchase of NIOSH

certified respirators, the third. And the audit program we broke into the product audit and the site audit. And then finally, the sixth recommendation

was that respirator certification test results be disseminated.

So under the first recommendation, expediting revision of respirator certification regulations, you heard Jon talk about that today and his efforts to move forward with that and address this recommendation.

We were already headed down that path prior to this recommendation, but we believe that the approach the Policy and Standards Branch has and the activities that we have outlined in the plan will help us most effectively address this recommendation.

And under enhancing -- updating the certification fees, and with the exception of CBRN respirators, all of you know that the respirator certification fees have not been updated since 1972. The committee was very adamant that we recover a hundred percent of those fees and that all of the

excess be put into research activities.

They don't realize that it doesn't quite work that way, that there are a lot of other components and external factors that are associated with how we recover fees and what is done with that money once those fees are recovered.

So our approach now is that we attempt to recover 60 percent of the fees. That is what we are leaning towards now. So we have to conduct an assessment of exactly how much is being spent now and then move toward that 60 percent fee recovery.

And then our vision is that those fees would then go into improving the respirator certification activities by upgrading the certification test equipment and the facilities to ensure that when your products are certified, that they are using state-of-the-art equipment to certify those activities.

So everything would be -- go into that program and the fee recovery. They would not be able to be put out into a research program.

But what we would envision then is that

then would free up other resources that are now taken out of our base budget to actually do the respirator certification activities.

So we hope that in a way, it will address what they were trying to address with its recommendation, but also we think that it will also improve activities for manufacturers as well as the stakeholders in the end and internally for us as well.

Next slide, please.

So the third recommendation was that we register the purchase of NIOSH-certified respirators. And with the exception of SCSRs, there is no respirator certification program, no respirator registration program in place at this time.

And what we need to do is -- our desired outcome is that we have registration across multiple classes of respirators to enable a better

understanding of respirator deployment, distribution of other data and knowledge leading to reduced injuries and fatalities.

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What we need to do is identify which respirators make the most sense to register and which approaches make the most sense.

For filtering facepiece respirators, for example, it does not make sense to have each user register those respirators with the numbers that are out there and because of they are disposable, et cetera.

But there may be another venue that may be more appropriate, such as having something on the web when different -- when product audits occur and different findings occur. Updating the web more regularly may be something more appropriate in that area.

So right now, we need to conduct a feasibility assessment for all respirators and also get a good handle on the products that are actually out there on the market. Because now, although the numbers that we have certified are great, right now we don't have a good handle on which of those are actually being fielded at this time.

So we are going through a process now to

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identify which respirators are actually out there in the field, and then moving forward with trying to determine the best way to look at registering the

respirators.

Next slide.

The next recommendation was expanding the product audit program. We separated this from the site audit because the two programs are conducted in separate manners.

Currently, because of our resource constraints, the product audit focus is mostly on the filtering facepiece respirators.

And in order to have an effective and statistically valid program, as they would like to see, we really need to increase our resources.

So this recommendation we are addressing, and it's really based on resources both from a manpower standpoint and a financial standpoint in the purchasing of the respirators to conduct those audits.

Next slide.

Then expanding the site audit program.

The desired outcome is that a site audit program that uses valid methodology is properly managed, monitored, and the program is recognized as statistically valid.

This recommendation we believe came from the National Academies because they didn't quite understand the way our product audit program was conducted.

We do audit sites every two years and believe that that is definitely a statistically valid program and believe that they just didn't have

the information to really understand that they were merging the product and the site audit programs.

So we think we just need to get the information out there regarding how we conduct the site audits, how sites are selected. And once that information is out there, we don't believe that this will have to be addressed in the way they wanted to.

We did, however, believe that there were some ways that we could enhance the site audit program. And that is by more effectively integrating the site and the product audit program.

So when findings are -- and the CPIP, the Certified Product Investigation Program.

So when there are findings that come out of the CPIPs or the product audits, then using a lot of those findings to feed that into those who are conducting the site audits.

So while that information is available to them, it would be a more deliberate approach to addressing those issues.

Next recommendation.

And the final recommendation under this -- the final issue under this recommendation is disseminating the respirator certification test results.

The Committee was adamant about getting more than just a pass/fail information out there regarding respirator certifications, and they would like to see all of the data that manufacturers provide.

Now, we disagree with this recommendation, but we have identified other approaches where we believe we can address how this information could

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get out, but not through the respirator certification program, but through something like the -- a research program or a Center of Excellence could actually conduct some comparative analysis. But we did not believe that this should be part of the respirator certification program.

So if you read about this in the action plan, you will see how we intend to approach it, and there are three activities that we have identified as potential ways to address this.

Next slide.

And the fourth recommendation, Increasing the research on the use and usability of PPT. There were four issues that were identified in this recommendation, and they boiled down to those that I mentioned earlier, the defining the barriers to and facilitators of PPT use.

The comfort and fit issue, which we are currently addressing through our anthropometrics action plan, which our technology and research branch has placed on the web over, I believe, about two years ago now it was put out there.

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And that's the basis for that 4.2 at this point. And also that branch also has just conducted a no-fit workshop, and the output from that workshop will go into better defining how we address the

issues under this recommendation.

So we think we are on a good path for addressing 4.2. We believe we do have a lot of work to do in addressing 4.1 and the barriers to use and having an effective workplace studies out there that are identifying what those barriers are and how we can address interventions to get at those barriers.

And then finally, in this area also developing the systems integration strategies for PPT and their components.

Now, this overlaps with the recommendation under Issue 1.4, and this, primarily Recommendation 4 addresses that research on use and usability of PPT component of the integration and interoperability issue.

In 1.4, it addresses more how do we manage those activities in all of -- through all of PPT.

Next slide.

And then finally under Recommendation 5, assessing PPT use and effectiveness in the workplace using a life-cycle approach. This recommendation boils down to having an effective surveillance program in place and conducting random periodic field testing of PPE.

Right now, we do have a surveillance strategy that we have developed, and that is a component of this overall plan.

And we have been moving forward with that with the best that we can with our resources that we do have available. But it primarily focuses on

using what secondary data sources are out there and what other surveillance activities are being conducted throughout the institute and nationally and trying to collaborate with the state-based surveillance programs, which are part of the Office of Extramural Programs.

Next slide.

So this slide is something that the committee on PPE put together to show what -- and we like the way that they presented what our future

visions should be. So of course, we would have to have our enablers of our resources, our human and financial resources, and then our organizational structure.

Right now, if we were to have this foundation set up as it is today, I think it would probably be about one-fourth the size that you see it there.

So I think we would see this expanding, not just intramurally at NPPTL, but also more involvement from all NIOSH divisions and also the Centers of Excellence as part of that overall infrastructure.

And then, we have our science and engineering of PPE, the standards and the testing. But how else do we need to -- what other roles do we need to take on to address the recommendations to complete this building and have the foundation set up so we can have this group of these Center of Excellences in PPT in all that we do?

Next slide.

So what do we need to do? We need to

take -- that left-hand cover is the cover from our evidence package, which is all of the information regarding the activities we were doing up until August 2007.

And we need to take all of those, what we are doing now in FY '08 and '09 activities, what the recommendations were from the National Academies, and the recommendations -- the ways to address those put together by the teams, and also the COPPE assessment and other inputs, such as inputs from you and other stakeholders and the inputs, once we post this on the web, that we receive to develop what the future PPT program should be.

Next slide.

So how can you help?

One is by helping us -- providing recommendations for intermediate -- and actually that should say goals, intermediate goals. And I have the definition of intermediate goals there.

And as I mentioned, the intermediate goals are those activities that other organizations conduct by using the outputs that we produced. And

I have an example there.

So filter capacity as identified in NIOSH standards are incorporated in manufacturer design specifications as evidenced by NIOSH-approved

respirators.

So that's an example of what we actually have to put in our action plan are, What are the things you are going to do to use what we create? That's something that -- the way NIOSH has structured the way we need to define our goals now.

So what are -- we need to define what you are going to do. So it would be helpful if you could help us define what you are going to do rather than us doing it for you.

The next slide.

So the way, again, you can help is by providing the feedback on the action plan. We have the current activities are at that URL identified.

The program evaluation can also be downloaded from the web. And then the action plan will be available later this month, and you can respond to that through Docket 146, and it will be

posted before Christmas-time.

So the steps to finalizing the plan are now that we will post it in December, and then we will address all of the comment, public comments in the January time frame. And then we have to submit it to the NIOSH higher headquarters in the March time frame and present it to the NIOSH Board of Scientific Counselors in April time frame.

Now, regardless of what comes out of all of those activities, the feedback that we get and the action plan as it stands today with comments incorporated from the feedback will be incorporated

in our strategic planning.

So this is the way we are defining how we are moving forward from what we are doing today.

So are there any questions? Questions of me or any of the team leads who put together the detail that you haven't seen yet, but ...

Dr. Schwerha, Joe, could you raise your hand? He was one of the members of the committee on PPE. You weren't on our evaluation team, though, were you?

MR. SCHWERHA: I was on both of them.

MS. D'ALESSANDRO: You were on both of them? Okay.

So he was on the evaluation team and the committee on PPE. Now he is no longer on the committee on PPE, but he is here today as well. So he -- if you have any questions on what the committee was looking for, if I haven't effectively relayed it, he could help you as well.

MR. BARD: Brent Bard from Supplied Air Monitoring Systems.

I would like to start by applauding the efforts of the Academy. I think that this is a good first initial step into really understanding how and why all of the components have to fit together.

I do believe, though, that one of the areas that you are missing is to consider a type of standardization that will analyze really what PPT is, and that's -- there's a lock of engineering controls that results in the use of it, and then I

think that you have to have some sort of methodology of evaluation of the environment in which the

apparatuses will be combined and used to really determine the interoperability of them.

I think that is kind of paramount because you are going to have to look at, you know, doing some air analysis. You are going to have to look at doing some abrasion requirements. There's just a whole bunch of other things that you have to look at for the end use.

And I think that your field testing audit that you have there kind of addresses that. But to really fully understand whether or not it is going to work together properly as intended would be to come up with some sort of standardized assessment program that the end users can turn to to help figure that out on their behalf.

MS. D'ALESSANDRO: I'm glad you said that. Good recommendation.

Anything else? Thank you.

MR. SZALAJDA: (Speaking without the microphone on.)

Is that better? It helps to turn the on switch on.

I guess to start, I'm going to use my prerogative as a moderator to kind of structure this portion of the meeting a little bit differently.

And I think what -- for the purposes of time, I think it is kind of important to at least

get through the three topics as a block to sort of give everyone a perspective on what the NIOSH approach to developing standards for air-fed ensembles is.

And along with that, we wanted to have the opportunity to have another organization discuss their approach in identifying performance criteria for one of their particular applications. We are very fortunate to have some representation from NASA today to be able to discuss how they addressed the development of performance requirements for the propellant handlers ensemble.

So at least at this point in the meeting, what I would like to do is we will go ahead and cover the NIOSH portion, take questions at the time when we are done with the three NIOSH presentations, and I will introduce my NASA colleagues, and they

will be able to go through their presentation. And then we will have an open comment period following that presentation.

When you look at the -- let's go to the next slide, please, John.

The development of air-fed ensemble standard, there are some things that have become apparent to us as an organization. And seeing that there was a gap in identifying performance criteria for this type of system on a national basis.

You know, the fact that different agencies had taken different approaches to trying to identify performance criteria for these type of systems as

well as, you know, internationally and other standards organizations trying to address the development of performance criteria for air-fed ensembles.

And to that end, what we have done internally is try to take a look at the problem, both on a respiratory performance need as well as a dermal performance need. And what you are going to hear in the following presentations by Angie

Shepherd and Colleen Miller are the approach that's been undertaken to actually do that. The ASTM method is identifying and addressing performance criteria for providing protection against dermal hazards. And what we are looking to do with the NIOSH portion is to address performance criteria for respiratory protection.

Now, having said that, I think in looking at this type of product, with the -- from a standpoint of the fact that NIOSH will issue a certification for these types of the devices as respiratory protection devices, you know, how are we going to do that?

And I think the first point to make is the fact that if we were to get an application today, you know, we would look at it from two different perspectives.

One is the standpoint of the system being a respirator alone, you know, as far as when you look at the second bullet, looking at it from the aspect of with and without the ensemble, the dermal

protection evaluation.

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You know, we get the application. We look at it. We evaluate it in accordance with the requirements that are already in 42 CFR Part 84, as well as being able to use the policy provisions that are given to us in the respirator standard.

Along with that, though, is an acknowledgement of looking at the system of the other performance aspects of the ensemble. And that is where we would look to other standards available in the industry to, you know, supplement what we do as part of the Part 84 evaluation, you know, against the performance criteria that's already set up.

And we would look to other standards, such as ASTM or EN or Department of Energy or other organizations that may have standards to address the dermal protection performance criteria for this type of system and where it would be used.

So looking at least initially, the interest that we have seen from stakeholders are for ensembles, which we think would fall and be evaluated under Subpart J, which is for supplied-air respirators.

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And that is Subpart J as it currently exists today. From the August 20th public meeting, we had discussed the evolution of that standards -- of that portion of the regulation in making the standard a little more robust and a little more

all-encompassing. But at this point, in doing the evaluation, we would be focused solely on the requirements as they currently exist today.

And then, the other thing to keep in mind is that with having said that, you know, we don't want to limit, you know, the thoughts of interested applicants.

At this point that we are solely looking at supplied air. But if, depending on the technology, that were to be considered, we would look at other supplied air as well as air-purifying types of technologies, depending on the configuration of the ensemble.

Next slide, please, John.

And so I think the picture that we wanted to leave with you with going into the discussions that you are going to hear about the addressing the

dermal performance characteristics as well is the respiratory protection characteristics are a strategy, at least as far as how we would address the problem -- or not the problem, but address the opportunity right now if we were to be given an application for evaluation.

And I think when you -- the one thing that we wanted to see, or at least to share is to maintain a consistency with conformance to Part 84 requirements. And I think when you think about this in concert of how we have done other systems. I think you will see there's a continuity there with how we have looked at other problems.

And I think the CBRN PAPR I think is a good example of that, that, you know, this morning, I had mentioned, when the question had arisen, we hadn't talked about CBRN.

And then the standpoint is that the foundation -- the Part 84 foundation is already there, that when you get the certification, the Part 84 requirements, it's certified for that whether it's the Part 84 of today or the Part 84 of 2010.

There will be a consistent thread for the systems.

So regardless of how that evolves, that common certification thread will remain.

And I think in terms of evolving the concept, this is where we would be looking at our using the policy provisions of the standard to be able to identify additional tests that might be required to show the performance characteristics of the ensemble.

And the carbon dioxide testing and inward leakage I think are examples of the additional tests that we would expect at this point in time as part of doing an evaluation for certifying an air-fed ensemble at this point in time.

You know, and other testing, types of tests may be needed depending on the design of the ensemble that's been submitted for evaluation.

And I think in general, when you consider things and consider the requirements of Part 84, you know, for example, if you think about carbon dioxide, you know, one of the things that we would

be looking to see is how you control CO2 buildup in the ensemble as part of the respirator design.

You know, and similarly, we would be looking for the same types of considerations for total inward leakage types of evaluation.

And, again, I think for those that are familiar with the work that we have done in the past, that how we addressed carbon dioxide in the CBRN escape respirators with the air purifying escape respirator I think is a good similarity.

There are some similarities there to how we would approach the looking at the air-fed ensembles, or at least as far as looking -- being able to measure carbon dioxide and the extremes, whether it is a low flow rate, you know, low type of operation versus a high, you know, the other end being like the high demand on the flow in the ensemble.

And, again, you know, in looking forward, what we hope to capture with the air-fed ensemble module is that all-encompassing subpart which will enable us to address these types of devices specifically in the future.

But, you know, knowing the fact that we are going to have other modules in place for supplied-air and for powered air-purifying respirators, the technologies that we know are being applied to these types of the systems, as well as looking at self-contained breathing type of devices,

whether they are open-circuit or closed-circuit, and using the subparts that are either in the process of being developed or will be developed to help us evaluate these systems in the future.

And, again, you know, the other part of the equation being looking at other standards like ASTM, which you are going to be hearing about in the next couple of minutes, or other standard development organizations that may have specific criteria that need to meet a specific performance level.

So with that, like I said, I would like to go ahead and go through the NIOSH presentations to kind of give everyone an overview of how we are -- the perspective on how we are addressing this portion of the -- this perspective development,

whether it's our involvement with ASTM or, you know, our development of a new subpart.

So with that, I will let Shepherd come up from our technology research branch, and she has played an active role, you know, with regard to the development of the ASTM requirements.

And one of the handouts that we had available -- I'm not sure if everyone picked it up. There is the current draft of the standard. If you didn't get a copy of it, you know, on the way in, there are some available at the registration table.

MS. SHEPHERD: Can you hear me okay? I absolutely hate microphones, and they don't make women's suits with pockets so you can put these

things in.

You're ahead of me. Jon mentioned there is a draft standard, and we are not encroaching on any copyright laws. Since it's not an official ASTM standard yet, we can supply the draft. And this is the one we recently submitted in November, and it is available out in the front on the front table. See Judy or Tess for that.

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So what is an air-fed protective ensemble? It's an ensemble with respiratory protective equipment that provides a source of air directly into ensemble without the use of a normal tight-fitting facepiece.

You can see the image on the left that would be what you would consider an air-fed ensemble. And then the one on the right is a normal tight-fitting facepiece.

There is also an air-fed ensemble -- thank you to SPERIAN for letting us borrow it -- in the next room, but unfortunately the mannequin and I had a wrestling match earlier, and he won. It's not in this room. It's in that room.

So for the ASTM, as you heard Jon say, there are actually parallel paths here, and I'll be discussing the ASTM effort. For the ASTM standard, we are looking at two different ensemble designs, one, either using an airline directly to the suit, or the having a powered air-purifying respirator. There is also a provision for having both of those sources of air feeds.

And then both of those designs also can have a means for distributing air inside the ensembles. So that's how it is actually defined within this draft of the standard.

These were developed -- this suits were developed in the 1960s, primarily to protect nuclear workers from respiratory and skin hazards, such as plutonium and tritium.

These replaced airline -- suits that had airline respirators inside of the suits. The new design actually provided much more comfort and mobility and still provided the really, really high protection factors that were needed.

Years ago, NIOSH was requested to provide a standard in testing on these suits, but at that time, NIOSH actually declined. And so the Atomic Energy Commission set up a lab out at Los Alamos in 1973 to test these suits.

So who uses these suits now? There are government and industry uses. A couple of the government uses are the Department of Energy. They have 11 nuclear facilities -- some of them are

listed up there -- that use these suits.

The Department of Defense also uses these suits at their U.S. Army Medical Research Institute of Infectious Diseases. And that is a BSL-4 laboratory there. And the CDC also uses a number of these suits in their BSL-4 laboratories as well.

Some of the industrial uses, you will see with these suits how the nuclear industry protected against radioactive contamination. And it's funny, you think about operation and maintenance, but you don't necessarily think about decommissioning. And a number of these suits are used in decommissioning activities.

The pharmaceutical industry uses these suits for inhalation, dermal contact. It's not only to protect the wearer, but it's also to protect the manufacturing process from contamination from the wearer.

The chemical industry would use these types of ensembles for any kind of toxic chemicals, anything that can provide damage or inhalation or dermal issues to the wearer.

And there's a number of laboratories. In 2001, there were actually five BSL-4 laboratories in the United States that are now, if my data is correct, there are now 15 in the United States since 2001.

So we have tripled the number of BSL-4 labs, and that would be the type of lab that would use this kind of ensemble.

Some of the backgrounds and issues that we have fought for a long, long time with this topic, is it a respirator or is it a protective clothing item? Well, the answer is both, and that really creates some heartburn and some difficulty for a lot of people and especially as you go to write a

standard for this kind of item.

As Jon said before, there is no nationally -- U.S. nationally recognized standard for this type of ensemble. We have had requests from federal agencies such as DOE, CDC, and DOD as well as a number of manufacturers and users for standards for these suits.

So it's not just one group pushing for the

set of standards. It's almost across the board that we are being asked for this.

Currently, another issue is manufacturers can make any claim they wish. There is no third-party certification. There is no real oversight for these suits. And so we have manufacturers -- that is a concern of a lot of manufacturers and users.

As we go to think about how to write a standard for this, one of the problems is these things are used -- as you can tell from the previous slides, they are used in a wide range of applications. So it's not like you just have -- you have to write a standard for an ensemble that goes into one place. You have to think about all of the other uses it could see.

You also need to look at selecting the test methods and, not only selecting the ones that are out there. Some of those may need to be modified, and we may have to create other new test methods that don't exist yet.

Once we have those test methods created,

we have to look at determining what the design and performance pass/fail criteria are -- pass/fail criteria are. So it's not just that you test it to a certain amount, but you have to figure out, you know, where that ensemble has to be.

And then, of course as I mentioned before, the certification manufacturer quality assurance. We have to address that in the standard.

We have reviewed the existing standards out there, and Colleen will go through some other standard that is we looked at, more of a respiratory basis. But these are some of the things that have a real dermal kind of focus.

There is also -- well, the first one doesn't. But Title 42 CFR Part 84, which you are all very familiar with, we looked at that. And it really doesn't contain, as Jon mentioned, specific approval for air-fed ensembles, but we do feel that there may be a possibility -- colleen will talk about that in more detail -- of where we can make it work for now.

There is also a DOE standard, 1167, but

this is really just aimed at nuclear workers. EN1073 also focuses on the nuclear industry, but doesn't contain any certification requirements or quality assurance. NFPA 1991, this one is actually a fairly close standard for what kind of durability issues that these suits would need. But there's no provision for an airline, and these suits are

intended for emergency response only, not for like an industrial going-in-every-day kind of use.

So the objectives. The first one, pretty obvious, fairly simple. To develop standards for these air-fed ensembles will result in appropriate respiratory and dermal prosection for wearers for a variety -- excuse me. I'm trying to fight a sore throat up here -- during a wide variety of uses.

The second one is the harder part, and something that Jon went over earlier.

We have to figure out where to draw the line, where do the NIOSH requirements cover, and where does the third-party outside standard cover? So where do we draw the line between those two?

So this is probably -- thank you. Excuse

me. That's what I get for playing with my nephew over the holiday, my sick nephew.

So this is probably one of the most important slides that you will see today.

We are taking a parallel approach. We are working within the NIOSH standards, but we are also partnering with an outside standards development organization. And I see a lot of the F23 members here today, and some of you may be members of other ASTM communities that I'm not aware of.

But we are working with ASTM. They have a huge background on protective clothing, so we will actually be doing the NIOSH part with the CFR, and then the ASTM part with the dermal. So those are our two paths that we are heading down.

And it works well to have a NIOSH liaison head up this effort because we can work with ASTM and with the CFR efforts to make sure we don't have overlapping requirements.

Some of the other issues. We don't just have to look at performance requirements. We also have to look at things like design, certification,

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classification, labeling, other documentation for the users, which there is really not a whole lot of right now.

We have a couple of different criteria built into the standard right now. We have limited use and multiple use criteria as well as tests for suits that have an airline design or a PAPR or both.

We also had to look at selecting an inward leakage test. The two that we considered were the man-in-simulant test, which uses olive wintergreen, methyl salicylate, or sulfur hexaflouride. Most people know it as SF6.

We also have to work directly with, in the CFR effort to make sure we don't duplicate any requirements. And we also don't have any that are mutually exclusive, which could be -- that would present a major problem for us.

And with these suits being used in so many different applications, we also had to create some kind of provision for permeation performance. Some suits in their use may not need it. Others may need to be protected against a wide range of chemicals.

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So we had to provide that option in the standard as well.

So we started this effort. We created Work Item No. 14247, which is the standard specification for air-fed protective ensembles at the January 2007 ASTM meeting.

Usually -- for those of you that are familiar with the ASTM process, usually you start within a single subcommittee and get the standard vetted out to where it's almost -- where you think it's in fairly good shape, a couple of ballot cycles.

But we wanted really as many people to review this as possible, so we worked within three different committees, the committees on biological, chemical, and radiological hazards. And we got a lot of good feedback from those three committees.

We have submitted a draft for four ballot cycles to date, and we were looking for input from a wide range of people. So we actually put blips in the ASTM standardization news that gave information and asked for input on the standard.

We conducted meetings and conference calls for interested parties, anyone that we could get to participate. And we also conducted a presentation to AIHce in 2008.

The first draft was primarily based on NFPA 1991 because it did have much of the physical durability requirements that we were looking for,

but we did bring in parts from the DOE and EN standards as well.

In your books, these came out a little bit funny, so i apologize for that. But somehow when they printed them, the colors came out a little strange.

But there are several levels of testing in the standard, and I'm not going to go through these in detail. You have them in your packets.

But for the ensembles, we were looking at things like positive pressure, ergonomic impact, air flow, excuse me, liquid inward leakage. And the bottom one you can see is sulfur hexaflouride.

We had a lot of discussions within the ASTM community, and we did decide to move forward

with the SF6 test instead of the MIST test. There was a lot of discussion on that. We are moving forward with the SF6 test.

So that was the ensemble.

That was everything. That was your gloves, your boots, your suit, everything it takes to actually be able to wear this ensemble. Now, for the suit, just the suit part of the ensemble, we are looking at more things like physical requirements.

And you can tell we test materials. We test seams. We test closures. And also in the yellow column, there are criteria for limited use. In the green column, there are criteria for multiple use.

And you can tell all of the criteria for

multiple use are more difficult to. The test is actually performed after five industrial launderings. So that was, yeah, we are trying to build in the durability for those multiple-use suits.

We even test hardware. We actually test everything on there. You can see there are hardware

tests, mounting strength and fold-out strength. Things like the airline connection, that will actually be covered in the NIOSH standards, so we refrained from adding that into the ASTM standard because that is crucial to your breathing air, so we felt like that should fall into the NIOSH standard.

The visor criteria, this is very, very similar to the suit criteria except you don't get -- we don't do abrasion on visor criteria. Hopefully you are not going to be abrading your face like you would it at the bottom of your feet or your arms.

Glove criteria. So you can see in these requirements, they are once again criteria for limited use and multiple use. And we do test on whole gloves, seams, materials, just on the materials. And you can see in there there are liquid leakage tests and a hand function test. So there's actually a dexterity test built in.

So not only do we want you to be safe in the suit, we actually want you to be able to use to suit and use your hands to do the work that you need to do.

The footwear criteria. Footwear criteria for this is actually very difficult because you have the barrier layer, which could be inside or outside of your primary foot protection. So we had to really think as we write these requirements.

So some of the requirements are going to be on whole footwear. Some of them on your upper material, some of them on your sole material. So you really have to -- and there's specific requirements built in as if you have an overboot or if you are actually wearing like a workboot underneath your suit.

Next, please.

Labeling requirements. This is a big deal when it comes to third-party certification. And right now, we have labeling requirements including the certification organization's mark, such as an SEI or a Classified UL mark.

It has to have whether it's an airline or PAPR as the primary respiratory supply.

It has to have a limited use or multiple use statement. And then a lot of information on the

manufacturer's detail -- manufacturer's details.

And this comes back to where if an accident happens or if you have a recall, there is traceability built into the garment.

I can't tell you how many used garments I have looked at -- and probably you guys have, too -- where the information is either gone from the label, or it was never there in the first place.

There is also cleaning and decontamination that is required to be on the label as well as required ensemble elements. Which that means, you know, what gloves you have to wear with the suit, what boots do you have to wear with the suit. So all of that has to be on the label, and that information is there for the user.

Also a requirement in the standard is user information guide. And this would be something that would be on a hang tag attached to the garment that the user would have to remove for the first use of the garment.

It would include any kind of warnings that the manufacturer wants to include, donning and

doffing, that kind of thing. Decontamination information.

Another part that is required in the standard is technical information. And all of this information has to be required -- or has to be supplied from the manufacturer upon request.

It has to include any kind of test data that's required in the standard as well as anything else that you are saying your suit does. You actually have to have test data, and that has to be available to the users upon request.

Next.

The certification program. This is a little bit of a departure for an ASTM standard. Typically, they don't require third-party certification. But since no one else is really

covering this area, we decided that was a thing we were actually going to move forward with.

The big thing here is we require, as a prerequisite to the ASTM standard, NIOSH certification to 42 CFR 84, whatever applicable subpart, depending on your design.

It has mandatory third-party certification and requires ISO 9001 for any manufacturing locations. It not only has initial testing inspection, but it also has quarterly visits and annual retesting is required.

Some of the retesting is reduced from the initial testing, but it is something that -- I don't know if any of you are familiar with the NFPA. It's something that's very common with NFPA, and we decided to use that as our basis here.

There is also a complaint investigation program requirement. So if you get a complaint as a manufacturer, you have to have a complaint investigation program as well as a safety alert and product recall system.

The timeline for this, the fourth ballot cycle will be complete in January 2009. Like I said, we have submitted this draft. It is available to you today. I'm hoping that those of you that are ASTM members, the ballot -- I'm hoping it will be on next week. And then we will be able to deal with the ballots, the negatives and affirmatives that

come out in January, in our meeting in January.

And if we don't get any negatives, which I'm actually really hoping for, we could publish as early as 2009. So this could actually be a standard as early as 2009. So we have been working on it for about two years now.

And submission of products for certification could begin as soon as the ASTM standard is published as long as you are working with NIOSH to get your certification within the CFR.

Next. So this is a good example. You heard Maryann talk earlier about us kind of spreading our wings a little bit and moving into other things other than just respiratory protection.

This is still respiratory protection, but we are also adding in a clothing component as well as, you know, we are broadening the amount of users we are getting to.

So I think this actual effort fits in very, very well with some the National Academies' recommendations.

Through this effort, we will actually have

standards and certifications for manufacturers. So everybody is competing on a level playing field, which I think is a very good thing.

And we will be able to have, for users, these ensembles that have actually been tested and verified through a third-party certification. So that we are providing better protection for the wearers. And overall reduction in all of the

exposures for any kind of area where you would wear these type of suits.

And special acknowledgments. We have an excellent photographer down at the CDC, which is kind of our parents, and his name the Jim Gathany. He provided a lot of the photographs to me today, and I wanted to thank him especially.

And also to Delta protection and SPERIAN. They have kind of worked along with us and provided quite a few images in my presentation today as well as the suit in the next room.

Thank you.

MR. SZALAJDA: We will take questions, I guess, after the next presentation which will be by

Colleen Miller, and she is going to discuss the portions of the effort they are looking at developing the new subpart. And Colleen is the newest member of the policy branch and she has been with us a little less than a year.

MS. MILLER: Okay. Moving right along. Obviously, we are concerned about certifying the air-fed ensembles at NIOSH, and we are specifically addressing the ensemble acting as a respirator.

As Angie just described, ASTM defines an air-fed protective ensemble. The other standards out there, DOE specifically calls it an supplied-air suit.

The European standard actually defines four categories of suits, three of them that they suggest are gas-tight, and one that is non-gas

tight.

The ISO standard goes beyond that and has five types of chemical protective suits, the gas-tight, the non-gas tight. And then they go into liquid-tight, spray-tight, and a protection against airborne solids.

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The last three obviously don't really account for respiratory protection so much as dermal protection.

ANSI goes one step further and has a sixth category. Their first five categories are very similar to ISO, and the sixth category may include aprons or sleeves and other PPT protection that people wear to protect their skin.

NIOSH reviewed all of these standards and the -- we had at that time the draft NASA standard for the certification criteria and their test results for their propellant handler ensembles, which are specific to those workers.

When we began to think about how NIOSH was going to approach the certification of an air-fed ensemble, there were a couple of questions that came up. Should the NIOSH development plan require the air-fed ensemble to be certified according to respirator type used, whether it was a supplied-air respirator or an air-purifying respirator.

Some air-fed ensembles are made using powered air-purifying respirators, which are not

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certified for use in environments immediately

dangerous to life and health. We thought that maybe that should be a concern for us in certifying the ensembles.

In other cases, workers use the ensembles in work environments that have very good engineering controls in place.

But if those engineering controls could potentially fail, then the work environment may be immediately dangerous to life and health.

And perhaps, if the ensemble was certified as a supplied-air respirator, in our upcoming revisions of that module, for example, we would require an escape canister. So these are some of the concerns and things that we discussed in how we are going to approach the certification process.

The current subparts for air-purifying respirators and supplied-air respirators and whether they would be able to meet the future technological advances in the work place and the needs of the workers was a concern for us.

And also, having just gone through the

National Academies' review and their report and actually focusing on the action planning process and how we are responding to it as an organization affected how we wanted to approach this certification.

And we feel that we want to be able to impact more workers and advances in the technology of the air-fed ensembles.

So therefore, next, thank you, the NIOSH

development plan, as you-all are very aware of at this point, would include creating a subpart to 42 CFR Part 84 that would specifically address the air-fed ensembles to give us an ability to certify ensembles that would address a broader range of potential uses of the ensembles as respirators that may not be addressed in the existing subparts.

So in order do that, we began by reviewing, as I said, the European, the ISO, the DOE, the ANSI, and, of course, the NASA standard. And we began to categorize the tests as to those that pertain to respiratory protection and those that pertain to dermal protection. And of course,

we focused for the NIOSH development plan on the respiratory protection, and Angie has already gone through the work that the ASTM committee has done on addressing the dermal protection.

Thank you.

All five of the standards reviewed have these tests in common, the inward leakage test, the CO2 content, and the inhalation air requirement was included in all five standards, although it was a little bit different.

The ANSI and the NASA standards tended to follow 42 CFR very closely. The ISO and the CEN followed a European standard. And the DOE was just more concerned with a, if the airline was shut off, how quickly could you doff the suit and get out of it safely.

There were also noise requirements and

tests that optimized performance of the couplings, the air flow rate, the air supply source, and the external breathing hose.

In addition to that, there were 15 other test requirements that four of the five standards

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tended to include in their draft standards, or their standard. And I have listed those.

We can go on to the next slide, John. Thank you.

The air supply source and the supply tube, the breathing resistance and the breathing tube.

Conditioning either was included as by conditioning by wearing or conditioning by temperature. Both of those things I think are important.

The connections for dismantling and cleaning or the strength of the connections, the continuous flow valve, internal breathing hose specifically its mechanical properties, pressure in the suit.

Resistance to ignition and flame, actually, is the exception, that it wasn't included in our four out of five. It may have only been included in two of the five. But it is so important to those standards that included it that I have included it here.

And then of course vision and warning and

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measuring means. ANSI, ISO, and the European

standard all want a warning device for minimum design flow rate if it is not achieved.

NIOSH, based on its work with the revision of other subparts, we consider these test requirements also important. The air supply harness and the system pressure, especially if it's an SAR or SCBA-type respiratory protection.

The escape test is especially important to the DOE people. Remaining-service-life indicators, which we heard quite bit about earlier today. Test temperature, I'm going to speak about in a moment.

Unmanned CO2 in respired gas is very important to us. We have our human subject review board that is going to want us to be able to say before we put the ensembles on people that we cannot -- that it's safe.

And a weight requirement is also important.

To give you an idea of some of the thoughts we had about test temperature and preconditioning, it seems like a very simple

parameter, but it can be very important to specific users, like DOE and NASA.

And the preconditioning requirement test temperature may be significant together to consider because components in the suit may be made from different materials with widely varying thermal properties.

Polypropylene, polyvinyl chloride and silicone rubber, for example, which are all common

materials in our business all have significantly different temperature requirements.

If the ensemble were made of PVC, but the tubing or the exhaust valves were made of unprotected polypropylene or polyethylene, the temperature conditions at which those materials function well mechanically are very different sometimes.

In addition to meeting some of the requirements that we have just stated, we would also require the ensembles to meet subparts A, B, D, E, and G. I have listed those for you.

Go ahead, John.

And some potential optional requirements that came out of the review of the five standards were service time and temperature. Again, the temperature might not be a consideration if you are only using the suit for a limited period of time.

Environmental control unit, the NASA people will be speaking to you about that, I'm sure, in just a little bit. Hand-operated valves, self-donning, and contaminated suit removal is very important to the nuclear industry. Again, as I said, flame and electrostatic charge resistance is important to specific workers as well.

And how about UV exposure and sterilization effects on the performance of the suit?

So we have a projected timeline for the continued development of the certification plan.

In May 2009, we will have -- we will post the concept requirements on our website. I'll be very busy apparently until May of 2009. And then in August, we will have another public meeting to discuss that concept. And mid 2010, we would like

to initiate the rulemaking process. And a year later, in mid 2012, we would like to complete the rulemaking process.

We truly welcome your comments about our development plan for air-fed ensembles. We would like information about the suits that are currently produced, how they are used by workers now and how you think they may be used by more workers in the future and what methods are you using to evaluate their performance currently. And any ideas you may have for future evaluations as well.

And I'll remind you to submit your comments by referencing NIOSH Docket 148. And I believe John, if you go to the next slide, there is the complete information.

And I think, Jon, at this point, wanted -- there he is -- to have us take our questions.

MR. SZALAJDA: Yeah. At this point, I appreciate you bearing with us.

We would like to take any questions or comments that you may have on the material that has been presented so far.

MR. BARD: Brent Bard, Supplied Air Monitoring Systems.

The first question that I have, considering that you are going to look at it qualifying as a breathing apparatus, although you have visual acuity for the lens/visor portion of the suit, are you going to require or include anything on impact resistance?

And the reason why I ask is because I think it is something you have to consider and look at. I also think that you need to consider adding, as a NIOSH requirement, your testing of the suit, pre- and post-usage.

I think that you have to clearly define what that criteria would be that you would expect so that a manufacturer can assemble and build a test kit that will meet that requirement.

I also think that it would be worthwhile to consider you had laid out two things, industrial washing and decon. I think you need to clearly identify a cutoff point of when is it no longer industrial washing, and when does it become decon.

And that you would have to have that addressed.

And with reference to the end-of-service-life indicator, when it is used, I think that's great. But I also think you have to include in the standard what would be the maximum storage cycle for the product, whether it is used or not used. Right.

MR. SZALAJDA: Thank you for the comments on that.

I guess just, you know, you mentioned I

guess just the one, on impact resistance. I think that's -- you know, obviously, I think as we had mentioned, there is a short term, and there is like the future.

And I think, you know, again it would probably be part of an evaluation of an application, whether that would be, you know, one of the tests that we would consider as part of the respirator.

MR. SAVARIN: Mike Savarin, SPERIAN.

Yeah, taking the last point, we currently have SARs approved. I don't believe there is an impact resistance requirement for that. So I'm not

quite sure why that we would need to incorporate one here either.

MR. BARD: (Speaking, inaudible to the court reporter.)

MR. SAVARIN: Understood. There is always the possibility of adding an option, agreed.

The temperature conditioning thing as well was something that -- you know, I'm looking at the possibility of integrating any such device under the current regulations and subparts that focus heavily on the supplied-air respirator part. So any comments I make are really in line with that.

I think, first of all, I want to say that selling these kind of products in the industries they are being sold in an unregulated fashion, and us having the ability to create a new subpart in the new standard I think should be applauded.

This has gone on for years, and I don't

know about any illness/fertility statistics that may exist out there. But if there isn't anything, it is certainly just a case waiting to happen.

At the same time as applauding that, I also believe that, you know, waiting six years or eight years or ten years to promulgate a standard on this is almost just as bad because it is just so long.

So if we could find a way to -- fast track isn't an appropriate term used in government circles, but if we could find a way to make good, you know, expedient integration of these products into something like the Subpart J, that would be really good.

I think one of the things that needs to be answered in doing that is that Subpart J doesn't deal with environments that are IDLH. And we would have to decide how the standard would have to address those requirements, if those requirements are something that is a standard and a regular thing that the industries that support these products are going to want to have.

Right now, they are using them. And if they are in an IDLH environment, there is nothing backing them up.

So, you know, I think it would be a really good thing for us to not to get completely bogged down in that because we know we won't have a

standard, is first to try to find mechanisms to either address it or add things to it as extra tests that we could do. Then that would be really positive.

Temperature conditioning environment, we currently don't really have under the SARs either.

Again, it is the environments we use them under are quite benign in that respect. And I don't know about most of the people in this room, but my personal experience of utilizing the Delta protection type suits isn't very high. So I'm not clear on the details of the environments that they would use.

But if we are going to support this kind of standard, we need to understand those things to enable us to make decisions as to which part would you choose.

Finally, there is a lot of work -- which is unusual. There is a lot of work already been done by people in this in standards groups that we

could comfortably extract from and integrate and use as placeholders in any potential standard.

So in the same way that NFPA does, they come up to something, and they will say, must -- as a prerequisite, must meet this element, must meet ASTM, this element, without us necessarily having to specify that.

I was thinking of all of those conditions that relate to the clothing, the burst strength, the tensile strength, a whole list of things that are

currently being considered in all of the joint standards.

You know, NIOSH has been focusing primarily on the respirator element, and we can still do that and have those things added as additional requirements based on the environments they are going to be used under, or the classifications that they might create for those dermal protection and other aspects.

That's all I want to say on that, thanks.

MR. HASKELL: Jon, can I make a comment?

MR. SZALAJDA: Go ahead, Bill.

MR. HASKELL: Well, your point about leverage other standards is an excellent one. And many of the people that are on the F23 committee for ASTM are also working in the other NFPA standards and some of the other committees. So the vast majority of the physical performance requirements we have been able to leverage from those existing standards.

And there's a wealth of information on limited use and multiuse. And so a lot of that has been pulled from it. Maybe it's not exactly what is needed for all of the different environments used here, but it's an excellent starting point.

MS. SHEPHERD: Also mentioned in your handouts, you can see the reference to the standards that were in my presentation.

Many of them reference back to either ISO or ASTM methods because I really don't want to

recreate the wheel. The other thing, it was interesting you talk about IDLH. Because by basing it on NFPA 1911, those type of suits are made for IDLH atmospheres. And so by using that as our basis

for my durability and dermal side, we have kind of taken that into account. Now we are just going to have to figure out the NIOSH side of that as well. That was a good comment.

MR. SZALAJDA: Yes. I'll chime in, too.

I appreciate your comments, Mike, and I think the one point I just wanted to make sure that was clear, you know, and when it is -- I guess to be lost with the discussion on where we are going with the new subpart, is that if there is interest now, we will look and certify, you know, this type of system, you know, using what we currently have.

I think the thought is in trying to go through the process with the -- developing, you know, coming up with a plan for how we are going to develop the requirements and then going through the concept paper is, you know, that information gathering type of stage to, you know, find out what is important and what is not and then be able to make decisions on how to set that performance criteria.

And what I would do is for you and any

other stakeholder that really thinks this is important that we develop this quickly, to please make those types of comments to the docket, you

know, in terms of that helps us.

As Les had mentioned this morning, when you look at these types of efforts, it helps us with our strategic planning and resource allocation, at least as far as being able to bring things to fruition quicker than may have otherwise taken place.

MR. GIANFORCARO: Good morning. My name is George Gianforcaro. I'm with Indutex USA. And I would like to thank you all for taking on this challenge. We have been making these suits and selling them in Europe for over ten years.

And I have been dying for the day that when it comes to the U.S. and the standard has been written, and I applaud you for that. Thank you.

At the very beginning of today, both Jon and Les said that you folks are here to listen and learn. Has your organization or has your group conducted any end user surveys regarding this new

standard?

And if yes, how many and which industries? And I would like to follow up with another question.

MR. SZALAJDA: Well, I will take a shot at that.

At least from the respiratory standpoint, this is the first foray into trying to develop that type of information.

You know, we have not done any formal type of survey, at least with regard to the respiratory standpoint.

MR. HASKELL: I would say we did a lot of fact finding.

We didn't do formal surveys with external stakeholders. We had a lot of different federal partners come to us six, seven years ago saying, Can you start to develop performance criteria for this type of product?

MR. GIANFORCARO: Okay.

MR. HASKELL: So it has mainly been fact finding and data gathering and not actual survey of what external stakeholders and manufacturers needs

or requirements are.

MR. GIANFORCARO: Okay. Thank you. Because I have, and I would like to share that with you.

For the last almost two years, I have been calling on end users. In almost every single meeting, I bring up this topic. And I'm trying to get their feedback on what they want.

And I'm very concerned that what they are looking for and the direction of the standard are going in two different directions.

The way that the standard is going is toward an ensemble, which means that we must include gloves in with the suit. The end user specifically said they do not want the standard to incorporate gloves or to include gloves. The European standard, the standard is a suit standard, not an ensemble standard.

And the standard ends at the cuff. It

does not include the glove.

The reason why the end users don't want this is they might have a work environment, and the

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employees are wearing four or five different pairs of gloves. The direction that this standard is going, we would have to then certify every single suit with each one of those gloves.

And should another glove company come in and convince the buyer to change the gloves, now, as a manufacturer, we would have to take those gloves and now resubmit it for new certifications.

There's an end user I was talking to at one of the breakouts, and in their facility, they have 12 different pairs of gloves for one application where the suit might be used.

So that means as a manufacturer, they would need to submit it 12 different times, each time with a different glove. That's not what the end users are looking for.

Now, my request or recommendation is, if the committee does want to move forward with this because they like an ensemble or they think it is better, more protection, perhaps we can split it into two and have a suit standard like the Europeans where it stops at the cuff, and then have an

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ensemble standard where the glove is incorporated or the glove is included.

And this way we would then -- we would

give the end users exactly what they want, the ones that really require protection and want the glove incorporated, we have the ensemble standard. And the other folks that are saying, Don't tell me which gloves to wear. I just want a suit with positive pressure, defaulting to the European standard, then we can give them a suit certification.

So thank you.

MR. HASKELL: I see this observation, which is a great one, really being aimed more towards the ASTM part of this process. I think NIOSH as far as the respiratory part of this, whether it ends here or includes an attached glove, maybe is not the issue.

So I'm wondering, are you going to bring these forward to the F23 committee in February so we can discuss it within the ASTM?

MR. GIANFORCARO: I have been bringing it forward, and it has been falling on deaf ears at

ASTM, and that's why I'm bringing it here to NIOSH.

MS. SHEPHERD: Actually, let me add some information.

That comment was posed on the negative ballot during the last ballot cycle, and the committee as a whole chose to vote it negative, nonpersuasive.

So the whole entire ASTM committee, F23 committee has dealt with this issue and has had a formal vote, and it is in their records if anybody is interested in looking it up.

MR. GIANFORCARO: Thank you.

MR. SZALAJDA: George, I would encourage you, and anyone that has information from the, you know, from the standpoint on any part of the topics, please submit things to the docket, you know, at least the more information that we can generate and that we have helps us with the development of the requirements.

MR. SAVARIN: I would like to follow up on George's question, not question, on his observations on his feedback from the end user.

As a respirator user, something struck me very unusual that I wasn't thinking about the need to, when you are doing the ensemble, that you would have to approve it with each glove.

I was thinking about actually using the respirator system. If you are using the respirator system and you have a suit on, and you are doing more than one function in that job, you are going to need to switch out gloves. But you may keep the same suit on.

Under the scenario that I just heard, there would be this horrendous situation where actually you would have to change suits.

So this can't be -- this cannot be the way forward. I think it logically has to end at the wrist. I just think we should, as a group, you know, try to enforce that wherever we can, George.

MR. HASKELL: I agree with you. One challenge we may have is the ASTM allows additional

provisions for permeation protection in other chemical environments, so maybe we need to look at case by case and see what the industry needs and see

what is appropriate. Because there is a case to be made in certain high level chemical environments, that you do want some sort of integrated glove protection.

But in other lower cases, what you are saying makes sense. So obviously the situation needs to be discussed.

MR. SAVARIN: It is very interesting that ASTM, with the body of knowledge they have on this, chose not to vote -- they chose to vote negative.

Is that right, Angie? Is that what you were saying?

MS. SHEPHERD: We are not requiring the glove be permanently attached. You could have a glove ring system or some other type of attached. But we could change out the gloves, and there is actually a requirement where the gloves have to be -- you can take them on and off in a certain time period.

But the option is they can either be permanently attached, or they can be removable. So it's not necessary that you have to redo all of the

testing. It is just that, you know, we feel like it is important to provide full body protection in any kind of atmosphere that you could be in.

And for that, you need a glove.

MR. SAVARIN: And what's ASTM's position precisely on that?

Do they say it's one way or the other, or do they make it so that you can do all of those in the one standard?

MS. SHEPHERD: No. You can have it permanently, like maybe a welded, or you can have one that's detachable.

And you could use 12 different gloves or 20 different gloves.

MR. SAVARIN: Thank you.

MS. SHEPHERD: And there is also a provision where you can actually test a glove independently from a suit, and the glove can carry its own label, so you could interchange them.

MR. SAVARIN: Right.

MR. HASKELL: Yes. But every time a different glove is used, the entire ensemble has to

be tested and certified.

So if one person is wearing nitrile glove, and the other -- he or she decides to take it off and wear a different glove, they are not in compliance with the certified ensemble unless that secondary glove was also submitted for testing, went through the MIST or SF6 test or something, and tested as a separate unit.

MS. SHEPHERD: That is correct.

MR. SZALAJDA: We will take one more internal question, and then we will see if we have anything on the LiveMeeting.

MR. BARD: This is directed more as a comment.

One of the things that you need to consider is, if you use an interchangeable glove with a cuff ring system, you now have to address the changing of the gloves, because that's going to be part of your seal.

How do you test that prior to going to use? In other words, it would have to be assembled, tested, and then put on prior to going to work.

MR. SZALAJDA: John, do we have anything from LiveMeeting? No.

All right. With that, I would like to -- hold on a second.

I guess the last presentation we have in this topic is from our colleagues at NASA. And this past summer, I had the opportunity to go to the NASA Occupational Safety and Health annual meeting that they had in Baltimore, and I happened to meet Mike Cardinale, and we struck up a conversation following my presentation on PPT, at least with regard to some of the perspectives that NASA has had in approaches towards personal protective technology.

And we felt it was appropriate, at least at this time, to get their perspective on how they have addressed the development of the particular requirements for their propellant handlers ensemble. And so with that, I was going to let Mike introduce the NASA staff that's here, and then Dennis Dudzinski is going to give a presentation on their

experiences.

MR. CARDINALE: Once, again. Thanks for

letting us be here and participate in this.

My name is Mike Cardinale. I'm the industrial hygiene officer for NASA Kennedy Space Center, and my role in this is initiating our own certification criteria for propellant handlers ensemble, which we have been using for quite some time for the space operations program.

I brought with me some of our coworkers to be available to answer some of the questions that you might have.

We have Chrissy Du Quesne. She is an engineer over at NASA life support engineering office. She has prepared the criteria test report, and she can answer questions about the test methods that we have used.

Don Doerr, biomedical engineering branch chief. He did all of our human factors testing in his laboratory. And Kenneth Ahmie. Kenneth is with EG&G, life support engineering. He is responsible for sustaining engineering for our propellant handlers ensemble. He is also part of our improvement team lead.

And finally, Dennis Dudzinski. Dennis is the manager of our EG&G life support operations. His operation provides support for all of these hazard procedures that occur at the Kennedy Space

Center involving use of rocket propellants. They do deeper level maintenance of all of our ensembles and repair the ensembles.

And Dennis, he is going to go ahead and do his presentation now. So thanks.

MR. DUDZINSKI: Hear me okay?

I'm going to just -- my presentation is going to be kind of at a high level. NASA has used this type of equipment for over 40 years at the space center.

As a result of that, there is volumes and volumes of data and information that we have as directly users of the equipment as well as designers and participation and continuous improvement of the program.

The SCAPE, Self-Contained Atmospheric Protector Ensemble, that is used at the space center, SCAPE is a generic term used for all the

protective equipment or protective clothing that is used or protective suits for propellant handling. Actual SCAPE predates shuttle operations. And, in fact, the Air Force was the first user using a rocket fuel handlers coverall in the late 1950s.

When NASA started supporting propellant operations in the early '60s, they developed their own standard, which was done in 1964. And it ended up being a -- they ended up using the modified rocket fuel handlers coverall as a result of that spec.

The next year, the Navy explosive ordnance

disposal team up at Maryland developed their own specification as well, and that was based on the NASA standard.

Go back, please.

The equipment has evolved throughout that 40-year time span dependant on the different launch programs. Each program seems to bring its own requirements for protective commodity, the type of access that users have, and other specific requirements that have been met throughout the 40

years with each ensemble.

The current SCAPE that we are using right now, the propellant handlers ensemble, it has been in use for over 20 years. And all the SCAPE that we have had are used in IDLH environments.

The classification of SCAPE, NASA has determined in categories. The Category 1 is a self-contained suit that uses an environmental control unit which gives total mobility to the user.

The ECU is also a cryogenic-supplied unit that works for two hours time span.

Category 4 is an airline-supplied suit, the same suit, but using an airline adapter. And it also uses a portable air supply for ingress and egress from the operational unit.

The Category 2 and 3 were used as modifications throughout the program, and they are no longer in use at the space center.

Features of the SCAPE, or the PHE, it's got detachable various size boots and gloves. We

have either a bubble visor to accommodate people with glasses, and that seems to have been more of

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the standard right now, as well as a flat visor, a polycarbonate visor.

It also has an internal air distribution system that distributes air in specific quantities, and I'll go through that a little bit later throughout the suit.

On the left-hand side, you see the early 1960s version of SCAPE. On the right-hand side is the current propellant handlers ensemble, and this is a Category 1 mode. You notice on the left, you have got a protrusion in the backpack pouch, and that's to accommodate the environment control unit. It is worn with the suit.

Next slide, please.

On the Propellant Handlers Ensemble, you can notice the same protrusion, a little bit larger. The suits are made on average a little bit larger than the initial suits primarily because the user population has changed in size themselves.

Next slide, please.

The Environmental Control Unit again uses locally manufactured liquid air that we make at the

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space center in a 20 to 30 percent oxygen content. Again, the unit is authorized for use for two hours.

It will run much longer than that, and everything that we use at the space center has a type of redundancy built in. So there -- are on top

of the operational criteria and performance specification we have for the unit, there is an additional safety factor built into almost every facet of the operation.

Next slide, please.

The Category 4 is an airline-fed suit. On the left-hand side, again, you will see the 1960s version of the SCAPE that was used at the space center. It uses an vortex cooling unit.

That has also been in use right now for the propellant handlers ensemble, which is on the right-hand side.

You note that the propellant handlers ensemble also has the capability of snapping the backpack closed to provide a lower profile for areas where we need access in some small areas to provide protection and also prevent damage to the suit

material.

Next slide, please.

And again, this is a Category 4 with the egress bottle that we use, or ingress and egress bottle, going to and from the operation.

Next slide.

In the early 19 -- or late 1960s, early 1970s, there were a couple of factors where NASA needed to update their 1964 specification.

What drove that was that NIOSH was changing the allowable exposure limits for the propellants that were used out at the space center.

Another factor in that is that the Air

Force rocket fuel handlers coverall was involved in an incident, and it wasn't just personal injury. There were fatalities as well.

And because of the similarity between the NASA suit and the Air Force RFHCO suit, NASA and Air Force partnered in an effort to develop a new specification for a new suit.

The things that they found most important were single point failure mode. And what I mean by

that is because you have got a totally encapsulated suit without wearing a full-face respirator, any puncture in the suit is considered potential single point failure.

Again, glove and boot disconnects and seals. The two first items there were the ones that were directly involved in the Titan incident. Single Point Failure Mode, the operator ripped his suit in the presence of severe oxidizer, and the glove and boot disconnects and seals were also involved because there was liquid impingement past what seals and attachments there were to the gloves.

Further down, the visor -- go back, please.

Visor improvements, and the rest are pretty much improvements that were to be made as long as they were doing -- developing a specification. They wanted to make improvements all the way around and come up with a totally new suit.

So the visor was under consideration to prevent better properties in the presences of

hypervalves, vent valves, suit fabric. The gloves

themselves, torso closure assembly. Communication, and emergency air supply. And I will go through each one of those individually.

The way they developed the execution for the program to develop the spec was they first did a survey of all users' protective suits and propellants operations, and those propellants were the ones that were used by NASA at the time.

They then developed a test program to evaluate propellant resistance and other characteristics, physical properties of the suit, materials and components for an improved suit, as well as the physiological testing and maintainability analysis afterwards.

Then there was a specification prepared to define and describe an improved ensemble.

Next slide.

Single Point Failure Mode was one of the first things that NASA considered. What they wanted to do was prevent or minimize the circulation of toxic vapors in the head area or breathing zone in the event of a puncture or tear in the suit

material.

Some of the things they looked at were manual mode change to head air only. They evaluated using a neck ring with air to the head first, and that was just a mechanical connection.

They also looked at automatic mode change to head air only, as well as an internal face mask.

What they ended up was a manual mode change to head air only, and the -- that went through qualification testing, but it was removed because it wasn't determined really feasible for the operational scenario.

So what they settled on was an air distribution system that directed 60 percent of the incoming air to the head area at all times.

Glove and boot disconnects and seals, primary they were trying to prevent liquid impingement, which was a contributing factor in the fatality in the Titan silo.

They also wanted visual and mechanical indicators to ensure to reliable connections. And that is our answer to part of the testing and

design. Because we can duplicate the connection every time, we don't do pre-use inspections of the suit. They are all post-use and then staged. But, again, that's by design because of the repeatable connection and a proven connection.

What we ended up with was aluminum quick disconnects with O-Ring seals and visual indicators of locking.

Gloves, they tried to improve on the gloves that were used on the initial SCAPE. And the glove thickness, because it was 50 mils thick, limited dexterity. And the material became sticky when exposed to high levels of oxidizer, which they

used all the time.

What they found out was the oxidizer actually degraded the crushed butyl rough coating on the outside of the glove, but it did not actually penetrate the glove proper itself. And what they ended up again is they reviewed different glove configurations and different glove materials, but they ended up with the same glove that they had before as far as material goes.

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The suit fabric, NASA worked with one of -- the fabric manufacturers to develop a more robust fabric that than they had before. Their goals were to improve flammability resistance, also to help improve maintenance.

And what they ended up with was a thicker fabric that incorporated a wear indicator to assist in the maintenance process.

They validated the protection through permeation testing and other physical properties testing. And it also ended up having reasonable flame resistance.

Flammability is always a big deal. The suits are not meant to be used in a fire, but we do our best to try and protect against enabling an operator who might be in a fire to egress to a safe area.

Next slide.

The visor improvements were, the goals were to minimize and prevent scratches on the visors. And because the operators have to work in

close proximity to a lot of flight hardware,

facility systems, and things like that, sometimes they need to get close to see what they are trying to get at. And also the facilities were not built with protective clothing in mind. So access, as you would expect, would be kind of a problem.

So this was also an attempt to try and design around those kind of problems and trying to get in advance to at least have some kind of prevention so that the equipment could be reused.

Also, for improved chemical resistance, to prevent -- an N2O4, a tap or hit a PVC visor would fog up in the presence of water when you are trying to decontaminate. So they were trying to improve the characteristics of that so that operators would always have good visibility throughout.

What they ended up with was a polycarbonate material with a chemical resistant hard coating, which was also a scratch resistant hard coating.

Vent valves have always been a problem, I think, for any protective equipment.

The goal is to prevent vapor migration

under steady state venting and negative pressure scenarios. Every suit that we have looked at, you can have a momentary migration depending on what levels, if you squat down quickly stand up again real quick.

It may not be open all the time, but there

is just a momentary flutter, if you will, before it actually closes. We deal with that operationally, as do a lot of other organizations.

The testing was performed in the NASA lab to try and understand the flow characteristics of the vent valves, and they use helium to try and do that because of the small molecular size.

The design preference was they implemented a diaphram tight exhaust valve, basically the same thing you would have as an exhalation valve in a respirator, to direct air flow and provide impingement protection.

And in addition to that, they had a relief valve cover, and they tested it in at optimum lengths that would also help to divert the flow in the event that you had some kind of migration.

The torso closure assembly, the previous design worked against the positive pressure in the suit. And what I mean by that is that the zipper lips themselves were formed on the outside. So that if you had -- when we had positive pressure in the suit, it would tend to put stresses on the zipper lips and would try to force them open.

What NASA selected at the time was a ziplock style that, with positive pressure, it would end up actually trying to make them lock tighter together.

Communications. Because the suits were used at various locations, Air Force and NASA, and each had a different communication system, they

wanted to go ahead and try and incorporate a universal system that could be adaptable to other facilities. So what they ended up with was a headset that you connect with a cable inside the suit and a bulkhead connector on the outside that you could adapt to whatever kind of cord you wanted to.

Emergency air supply was attempted at

first with the initial suit. It ended up being something that also wasn't feasible. It was a bottle worn on the back with a SCUBA-type mouthpiece on Velcro mounted in front of the hood.

Users didn't like it. It got in the way. It added weight to the suit. And it was removed based on lessons learned from operators actually trying to use it.

And what we opted was with the bottle that you saw originally, was an ingress and egress bottle that they actually carry in and out of the areas.

The suits have been through a lot of testing, and this is where you can find volumes and volumes of the information. Don Doer, Ken Ahmie, have been greatly involved in all kinds of testing from day one on the suit.

Most recently, the suit was sent up to Aberdeen Proving Grounds, and we did protection factor testing.

The suits in the Category 1 and Category 4 modes exceeded 50,000 protection factor as far as test results go, but were assigned a 20,000

protection factor.

That factor includes what we did also is because we wanted to double check the penetration of vapors inside the suit under maybe operational conditions as we initiated penetrations in the suit, punctured holes in the suit with known leakage rates to test and see if that had any affect as well, and they still passed with a 20,000 protection factor.

So we kind of had a chance to play, and we like doing that because there are so many different things that operators will do to be creative to get their job done.

And that's been the challenge all along, to try and make sure that the people are protected. And NASA does a really, really good job because of the redundancy they built into the system and because we what everything to death -- what-if everything to death, to try and figure out ways where people might try and compromise the safety of the suit, and then take action to try and design that out.

The physiological testing that was done

incorporates a lot of things to check for dermal stresses, CO2 testing, testing oxygen levels under different workloads, suit pressurization, as well as interior suit temperatures.

Some of the additional testing that was done was done by Lawrence Livermore labs back in

1988. And they also found high protection factors with this suit.

And later on, some of the people from Kennedy went to DOE because DOE was looking for suits also to compare their three suits with. And they evaluated the NASA suit, and maybe -- I don't think they end up incorporating anything from that, but they were impressed with the fact -- the air distribution systems and some other things. But for various reasons, they couldn't implement them.

In addition to those manned and unmanned carbon dioxide testing, the ECU testing and vertical and nonvertical attitudes, the ECU was built with a swivel pickup in it so that within the first half of its level, it could be used in a horizontal position or near horizontal.

Air flow decreases. Operators are taught that they need to pay attention to that. And if it decreases too much, they just stand back up. Air flow restores, and then they can go about their business.

Other testing that was done, we did liquid impingement testing from all attitudes. Again, that reverts back to the incident in the Titan silo. We wanted to make sure that in the event that we had a high pressure leak -- and what we did for that was throughout the space center, all of the operations units reported on what their credible leak would be for all of the hypervalve systems. And we used the top end of that as the measure of what type of

impingement testing we give.

The ensemble was also -- went through exposure testing in addition to component level testing for permeation and those kind of things, the physical properties.

We also did a prolonged ensemble testing. And one of them was to instrument the inside of the suit and then douse it with chemical with the

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positive pressure that we see during normal operations to see what, if any, effect that had on this suit. And the suit passed with no penetration whatsoever.

We went a little bit further beyond that, too, as well as the flammability testing of the different components. We actually took a suit, doused it with chemical, and then lit it on fire. And we are very pleased to see that the suit sustained very little damage. As a matter of fact, the only damage it sustained was where the thermocouples entered into suit where we could take our instrumentation.

So, again, you know, there are certain things -- maybe we have gone a little bit extreme on how we try to do our testing, but it has given NASA and the users a level of comfort and confidence in the equipment because we have gone above and beyond.

Once we have done all of the testing and the design work is done, we need to, and do, go back and validate that it still performs the way it is supposed to.

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And we do probably more maintenance on the suit than maybe anyone else in the industry that I have seen.

What we do is we go through -- first of all, the suit is deconned on site. Once it comes to the shop, it goes through a soap and water shower with biodegradable detergent. And all of this maintenance is done every time the suit is worn, directly after it is worn.

We also have what we call light inspection where we look for small pinholes that you can't pick out with your naked eye as far as visual inspection goes. We also check for any material degradation, and that includes the boots and gloves as well.

We also do an ensemble leak test to make sure that there's no leaks in the suit and that all of the components are secured properly.

The airline that is attached to the suit, we do an airline flow test as well to make sure that the airline is still clean and that it performs the way it is supposed to.

We do a leak test, reverse flow test on

all of the relief valves as well to make sure that there is a proper seal.

We also do a flow test to make sure that -- and the suit, because it's at a positive pressure, you have to make sure you don't get too much pressure in the suit.

So it is designed to have a certain amount

of -- less than two inches of water pressure inside the suit. So we check to make sure that the -- with the flow that we get during airline or ECU operations, that the suit still is not overpressurized and is still below two inches of water.

But on the other hand, too, we also check and make sure that the relief valves don't leak if you have a pressure from the outside -- a greater than ambient.

After that is all done, we make our repairs, and we go through a quality inspection and verification. And they use the same criteria that we use when we do our inspection and repairs. And then all of the boots and gloves are tested

individually.

In addition to the maintenance, we also have a comprehensive -- and I didn't put this in the slide -- but there is a comprehensive training program as well that very much mirrors what NIOSH requires for respirator tech where we have got a stringent physical.

We have operators actually wearing, donning. They have to demonstrate that they can take themselves out of the suit in the event of an emergency and all of the other normal things, that the fact that have -- because of their stature, they either can or can't wear an environmental control unit because it might change their center of gravity. And it's all centered around safe

performance of the suit during the jobs.

And any questions?

MR. SAVARIN: Mike Savarin, SPERIAN.

Thank you, Dennis, for that presentation, answering many questions that we have been asking this afternoon. If we had waited five to ten minutes, we would have got what we needed to know.

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I think the environment that your people work in is an extreme environment, and so, therefore, you know, these mitigations are all in line with that, and actually it is really comforting to know, we can certainly learn some stuff from the approaches taken. That's for sure. For me, I have one question, and it relates to the protection factors.

In the earlier presentation, I believe that Colleen or Angie, someone mentioned that they are going to use sulfur hexaflouride, SF6, for the protective factor testing, and obviously RDECOM uses mineral oil aerosol.

Do you have an understanding what the correlation might be between those two?

MR. DUDZINSKI: No. The protective factor testing that was done up at Aberdeen was done with corn oil.

MR. SAVARIN: Right. I'm familiar with that.

I just wanted to know if we could correlate that to anything that was done on the

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proposal for sulfur hexaflouride?

MR. SZALAJDA: Mike, I'll see if I can clarify that a little bit.

I'm not aware of any correlation work between the -- at least from the perspective for the respiratory protection standpoint, we are using corn oil just from the standpoint of the database and understanding what you are seeing in the breathing zone.

My thoughts in looking at the other testing with methodology was that is geared more towards the resistance of the suit, or the ensemble, at least with regard to resisting penetration or permeation. With corn oil, we are just solely concerned about what your individual is seeing in the breathing zone.

MR. SAVARIN: I mean, there is a distinct demarcation between the test paradigm used in Europe and the testing here, and that's where the sulfur hexaflouride came from in the first place. And they are both trying to give an understanding of the level of protection that the suit provides.

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I'm thinking if we are going forward with this, would we have any problems not adopting the sulfur hexaflouride and just carrying on with our knowledge base that exists with corn oil?

MR. SZALAJDA: Yeah. I think the other issue with sulfur hexaflouride is I think nationally, it's not -- you know, for the United

States, it's not considered an acceptable, you know, product to be used.

So from that standpoint -- internationally we know it is being used in Europe, but domestically, I don't see how we would able to adopt that under the current guidelines.

MR. SAVARIN: Thank you.

MR. SZALAJDA: Any other questions for Dennis?

Well, I think I would like to give him a round of applause.

At this point, I think what we would like to do before me move into the next session is take about a ten-minute break.

Verizon says it is 3:26. Maybe we can

reconvene at 3:36 Verizon time, and we will move into the next topic.

If Barney Lambert is present, if you could stop up and see me in the next couple of minutes, I would appreciate it.

(A recess was taken.)

MR. SZALAJDA: The final topic that we are going to address is an initiative to look at the requirement for an end-of-service-life indicator for the self-contained apparatus.

And we have two presentations on that topic, which will be provided. One will be delivered by Roland Berry Ann, who is the deputy director of NPPTL and has been involved with this topic for several years.

And also we are going to have a presentation by Dave Bernzweig, who had raised the topic originally, and will be able to provide us some of the historical perspective on why the stakeholders feel that there is a need for making a change to the federal regulation.

We had also received a request to provide

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some additional information. I don't know if that individual is here today or not. I haven't been able to track him down, but the input that he had submitted, we will consider as part of the -- and make it part of the docket submittal and make it available through the docket.

So with that, I'll introduce Roland Berry Ann.

MR. BERRY ANN: Thanks, Jon.

I'm going into work. I'll try and speak faster. For those of you who know me know that that's not possible. Now, everybody is laughing at that.

Okay. The background on this requirement, or request for change in requirement, looking at the current requirements, Section 84.83, paragraph (f) requires that warning device or remaining service indicator be provided that gives an alarm or an indication within a range of 20 to 25 percent of the rated service time of the device or the apparatus remaining, as in warning for -- under the NFPA, it's called an end-of-service-life indicator for

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withdrawal, exit from the scene.

There is no provision stated in the regulation as to when that would initiate. But our traditional enforcement policy has been that it cannot initiate before the 25 percent level, and it has to initiate by the 20 percent level.

There is also no specification on the duration. So it can remain on for the entire time that there's air remaining in the cylinder, or it can just be for a short duration and then cut off before it runs out of air.

Okay. But the significant thing, it's based upon 20 to 25 percent range of the remaining service time.

Okay, John.

The current status in this rulemaking activity is that we receive the petition for rulemaking from, as Jon said, Dave Bernzweig, who is here today and is going to give some background as to what his intent and thoughts were.

But he has requested through his petition that we eliminate the range concept and just have a

minimum platform of 20 percent for the alarm to sound and allow the setting to initiate at any predetermined adequate level by the user. Okay.

And the user in this case we would expect to be the program manager of the respiratory protection program of the jurisdiction that's using the device.

Okay. There was an article which Dave put

in the fire engineering journal on June 2004 talking about the time to exit. I won't go into that because I'm sure he is going to cover his desires and thoughts in that area.

We have received more than 30 docket submissions. Most of those were form-letter type submissions, which there's not a problem with that except we don't get much detailed information from those. It's just a basic statement that says, I support the concept, and we have not received anything in opposition to the change. The IAFF has endorsed the change.

But all of the information we have received has been from the firefighter community,

and those specific uses.

John.

Okay. The proposed changes to accommodate this request for rulemaking would be to remain at the 20 percent service time for, if you will, for the alarm to be given and allow settings at higher settings for the alarm to come on. And like I said, it would be the respiratory protection program manager's determination as to what would be appropriate based upon their actions and their mode of operation within the fire department.

Okay. We would continue to evaluate the operation of the alarm or the indicator to make sure that it operated at the appropriate setting. Okay. So basically verification of operation.

Okay, John, the next.

Okay. So what we are looking for is input from stakeholders. And this is an attempt to try and get some additional input. And we have listed out here the issues that we have raised that we would like to get some input on and some thoughts and considerations.

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Basically, when you are going from a range to a single setting, do you have -- you know, how do we determine where that setting may be in the field to make sure that the setting will be accurate and repeatable from time to time to ensure that the user is going to get the proper notification, whether it's at 40 percent, 50 percent, or 20 percent level.

Are there other ways to achieve the additional time to exit that Dave is proposing?

Is there a way, since everything we have gotten has been from the firefighter community, is there a rationale and a method that we would -- that we should look into to differentiate the firefighter apparatus from the traditional industrial apparatus?

Now, one avenue that we can take, which makes this important, is since we have gotten no objections to the proposal, we have the capability to go to what is called the direct final rule, which would be the publication or the change to the regulation.

And I think it's 30 days that's allowed for anybody who has an objection to pose an

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objection. And if we don't get any objections, then it automatically becomes a final rule. So, again, that's called the direct final rule.

So we are going through this effort to try and make sure that we have covered everybody's opportunity to speak their minds for this issue.

And the information -- if you will turn to the next slide, John, there is the information for submittal to the docket.

And that's all I have. Any questions? Comments? Suggestions?

MR. BARD: Brent Bard, supplied-air Monitoring Systems.

My initial thought on it is, seeing that it is being brought forward by the IAFF, what I would recommend would be that you look at the implementation involving NFPA compliance SCBAs and leave the industrial units completely alone.

But I think the danger of doing it for the NFPA and leaving it up to an individual respiratory protection manager is now you are going to have a scale that's going to be all over the place.

And I think that's going to cause greater confusion. I think it is going to cause greater issues upon servicing, who is servicing their pack and what information they have as to what the desired limit is that they want.

I would suggest that I would go back to the IAFF and ask them to come up with a standardized level of change -- I believe the one that had been

mentioned was 30 percent -- and get them to come to a consensus on their own and come back to you with that.

But I think it is important to keep the NFPA community satisfied, but keep it separate from the other end users who don't have the same stringent requirements that they do.

Thank you.

MR. BERRY ANN: Could I ask for a clarification?

Are you suggesting moving this -- the setting to the NFPA standard, or getting input from the NFPA as an official body?

MR. BARD: Getting the input from the NFPA

to you after the IAFF goes to the NFPA.

And because I'm pretty sure the NFPA would ask them to give a unified, What do you want that alarm set point to be?

I don't think that they would accept one that could be set by an individual department respiratory protection manager.

Thank you.

MR. HODSON: David Hodson, Draeger Safety.

One of the things I think that just caused confusion with regard to using percentage of the volume that's already left in the cylinder is it's different for every size of cylinder.

You have got a 1,200 liter, 1,800 liter, 2,400 liter cylinder. Therefore, the time that you have is different in each case.

I think perhaps a different approach would be to identify what is the required amount of air to accommodate all of the users, firefighters or whatever the users are, and to ensure that they have sufficient air to get out in 95 percent, 99 percent of all of their escape cases. And then work from

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that where the setting should be.

As an example, you would perhaps set it at say 500 liters remaining in the cylinder, 400 liters, whatever is an appropriate amount remaining the cylinder.

I think that would then potentially say to all the end users, it doesn't matter what size cylinder they have. They know how much air remains in the cylinder. And, depending on their work rate, they know how much time they have to get out.

One little aside to all of that, and of course the training of the firefighters is always one of the difficult areas. And the question really is what is the firefighter supposed to do before he gets to his end-of-service-time indicator.

And there is some controversy over that, and I think there always will be. 4b04 in the Alex (phonetic) indicates that you should be out of IDLH atmospheres before the end-of-service-time indicator goes off.

I don't think there's many firefighters or perhaps industrial users that actually pay attention

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to that. Therefore, I think it is better to

actually look at how much air do you need to cover most escape cases and give the guy that amount of air.

Thank you.

MR. BLANK: George Blank with Draeger Safety. I think if you have to be very careful if you allow the program manager to determine the amount of escape time that a person needs.

SCBAs these days have mechanical alarms that are driven by air, and they have electronic alarms that can be set differently and they can be very confusing.

I think a very productive point, just another sidebar here, is to some manufacturers, allow their electronic alarms to go down to zero air and other manufacturers have their breathing rates go down to a time of warning.

I think that would be better to create a standard wearer as all manufacturers will be required to have their electronic breathing rates go down to the alarm rather than down to empty.

Just a comment.

MR. BERRY ANN: Could I ask a clarification on your concern about the program manager having the authority to determine the proper --

MR. BLANK: Well, that was in the -- that was what your --

MR. BERRY ANN: Right.

MR. BLANK: But I mean to make sure that

if they adjust them, if they are allowed to adjust them in field, you are talking about a couple of different alarms which are really set at the manufacturer. So now somebody would take that and set it out in the field.

Provided the correct software, it is very easy to -- it could be very easy to set the electronic alarm, but be very difficult to set the mechanical alarm at the correct pressure. And any kind of discrepancy could be very confusing to the user.

That was my point.

MR. BERRY ANN: And did you have an

alternative to the user making a determination?

MR. BLANK: I would rather not have the user make that determination. I would rather have the manufacturer set it, and really set it what it is right now, 20 and 25 percent of the cylinder capacity.

Or come up with something like Mr. Hausman came up with a specific pressure -- or a specific escape time for all cylinders.

MR. BERRY ANN: Okay. Thank you. Appreciate the clarification.

MR. WELLS: Jesse Wells, NOVA Chemicals.

But for purposes of my comments and questions, let me just say that I spent 26 years in a professional fire department. So just so the background is understood.

Couple of things I have heard up here

really strike a true tone. Most firefighters don't watch the amount of time they have been in the building.

On a hazardous material response or in a technical rest due response, we time how long people have been in. We don't typically do that in a tire service.

Big red truck pulls up. People run in the building. We do a personal accountability report every 20 minutes, but we don't mark the on-air time typically.

If there's departments out there that going that far, I applaud them, but I haven't seen it.

So if the fire service is asking for an earlier warning, then I think maybe there is a better methodology than having people just set their alarm whatever the way they want. And here's my concern.

If you going to allow people -- each individual manager to set his alarm, there needs to be some very strict training requirements and controls on that so that we don't have mistakes being made that cost people their lives in there because somebody didn't do something right in resetting an alarm.

MR. BERRY ANN: Thank you.

MR. SZALAJDA: And with that, the next

presenter is Dave Bernzweig, who is with the Columbus fire department and originally raised the issue that has precipitated this discussion.

MR. BERNZWEIG: How about that? Okay.

I guess I probably should have gone first, actually, Roland.

Let me just state for the record, I am in no way advocating -- this is very loud -- that the program manager should have the ability to adjust this. It should not be field adjustable.

What we would like in the fire service is that we can specify -- like we can specify turnout gear. We can specify fire trucks. We can specify our hose. We want to be able to specify where our end-of-service-time indicator would alarm.

It would not be field adjustable. It would be whatever local economy dictates in the absence of a consensus standard. And from there, we would basically be able to avoid all of the problems that just got raised.

Because it would be a serious problem if

we just opened up the door and said, Field adjust it or program manager adjust it. Who has got what on and when does it go off? Everybody has got something different. So get that out of the way.

A little background about me. My name is Dave Bernzweig. I'm a Columbus firefighter. I'm also a principal member of the NFPA Respiratory Protective Equipment Technical Committee. I also serve on a federal USAR team in Ohio, Ohio Task

Force 1.

And how we got started on this was actually back in 2003, in Columbus, Ohio, we were getting ready to go out for bid for a new SCBA. And based on some research that we had done and some recent line-of-duty deaths, our own experiences going back a fewer years farther back, but some deaths around the country as well as some statistics, reports that had been put out by the U.S. Fire Administration, NFPA, we realized that really we probably weren't carrying enough air on our backs for an emergency if we got into trouble.

And so we decided we would like to go from

a 30-minute rated cylinder to a 45-minute rated cylinder, a 1,200 liter to an 1,800 liter cylinder, with the intent that we could increase the work period.

As on the slide up here, the objective was to have an appropriate work volume, an appropriate exit volume, appropriate reserve air, and the EOSTI set in the appropriate place.

And as you see, I have used the word appropriate a lot, and I have kind of put it in a parentheses because I'm not trying to tell you where it needs to be. We don't think that -- you know, that's not what we are looking to change within the regulation. We believe it is better left up to consensus standards or even local economy do determine what are those appropriate numbers and where they need to be.

But there is significant research out there which does say that, you know, there are reasonable work periods, and there are unreasonable work periods. We also know as far as reserve air, how long after you get into trouble, how long it takes for us to get you, the reflex time to get out to a firefighter.

We know these from empirical studies, and we know them from experiences on the fire ground.

Next slide, please.

Okay. Just a quick review. This is 8483 Subpart F there or Part F. And as I have gone around speaking about this the last five years, I have always asked people what is the flaw in the law.

And, really, there is two things here, one of which I was kind of ignorant to. The other is that the 20 to 25 percent is a range. And really was it intended to be a range, and what is the purpose of having an upper limit and a lower limit?

Most standards specify a lower limit, and that's their minimum standards. But here we have a minimum and a maximum. And the effect of it is that it prevents us from being able to add a margin of safety if we want to for when that EOSTI goes off.

Next slide, please.

So why the upper limit? I'm going to take these in reverse order because it's probably a little more appropriate there.

As I did some of this research and talked to people who had been around a lot longer than I have, the explanation was that, actually, the percentage, the range was really probably intended more as a testing tolerance. And that -- the language -- not necessarily the language, but the regulation or the requirement, the 20 to 25 percent, dates back to the Regulation 1995 and actually goes back to when this was a regulation or a standard under the Bureau of Mines before 1960, so that's how it was.

So the rationale back then was that it was a testing tolerance, a range of success for when the EOSTI sounded.

The rationale back then and what's really been relayed to me is that there are several things that really didn't make it much of an issue because 25 percent was really -- was probably the best thing they were going to do that was appropriate. One was SCBA technology.

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When firefighters first started wearing these, there were 1,800 PSI cylinders. They were much heavier, carried less volume. Our protective clothing, we didn't have the level of protection that we have today. We couldn't go in as deep. Smaller structures than today. We weren't going as deep for that.

Strategies and tactics, firefighters were able to -- were putting fires out from either the outside a lot of times, but also just not going as

deep into structures. And the fuel packages changed, where we have fuels which burn much hotter, more quickly.

So all of these things kind of really didn't force the issue of firefighters becoming lost, trapped, and disoriented, which is what killed a lot of firefighters inside of structures.

Next slide, please.

So what has changed? Well, if we look at some of the statistics over the years and some recent studies by the NFPA, we find that in the years from '77 to 2002 and really up until today, we

have had more than a 50 percent decline in the number of structure fires in the U.S.

At the same time, though, if we look at the traumatic firefighter deaths inside of structures -- these are noncardiac deaths that occur inside structures -- we have actually had an increase, almost a twofold increase in the number of firefighters who get killed.

And this was at the -- not just the number, because the number hasn't gone down as the structure fires have declined, but the rate of firefighters, 1.8 per hundred thousand firefighters -- or hundred thousand fires in the late '70s to the late '90s, at 3 per hundred thousand structure fires.

So as you can see, it is actually more fire -- despite the decline in structure fires, more firefighters are getting killed inside of

structures.

63 percent, the cause of death is listed as smoke inhalation.

I'm not showing any of this to try to make

you believe that everybody is dying from smoke inhalation there, is running out of air and dying. There are other contributing factors that lead up to it.

But many of the firefighters who are dying are becoming caught, lost, or disoriented. And they do run out of air before they die. There is other precipitating events, but they run out of air. And they end of having a high carboxyhemoglobin levels.

Some other things we look at is the rate of firefighter death by occupancy. And as you see, we are quite a bit more likely to die in nonresidential structures. Some of the reasons for this are probably related to the size of the structure.

You know, before I go on to that, there's some work that has been done. Really, since I have started this, there was a U.S. firefighter disorientation study trying to identify what is causing firefighters to die, and it's noticing a sequence of events that occur.

But the gist of all of this is that

firefighters are getting too keep in the structures; they are running out of air; and they are dying.

And that we do have a problem with how our reserve air is met, and maybe even how we are using the air that we have.

Next slide.

In order to maybe better understand why we are dying inside of structure fires, I want to take you through how we use our air, how we interpret it, and how we pay attention to what is in our cylinder.

Next slide.

Historically, air allocation was made up of -- you have a cylinder on your back; you have a work volume; and you have basically an exit volume in there. And if you hit the button one more time, we put our alarm right in there.

After you are done working, that was the interpretation. When your bell goes off, that's when it is time to leave.

I have been with the fire service for about 20 years, and that is how it was made back then. That is how most fire departments still teach

it today.

Although there have been some changes in that because there has been a reaction from the fire service -- and the fire service does realize -- I'm not the first person to come up with this and say, Hey, we are killing guys inside because they run out of air.

The fire service, in order to address the inadequate volume that remains when our bells go off says, Hey, leave before your bell goes off. And we

call it air management, and I will talk more about it a little bit later.

The other part of it was -- and the theory behind it, if you could go back, actually. If you go back, the other part of it, the theory behind it was that, Well, 25 percent to go in. You get to work for 50 percent. You have 25 percent to go out. That was the 25/50/25 rule, which probably goes back a generation.

But today's reality, as I mentioned, we don't allocate enough air.

Next.

Just a chart here that gives you some idea of what it looks like inside the cylinder and how that's broken up with a 25 percent alarm.

I have done it through the various rated service life and volumes. And the top was a 30-minute rated cylinder, which is the most prevalent cylinder in the industry.

The one underneath it, which is shaded a little bit is also a 30-minute. That is kind of an anomaly. That's the 3,000 PSI. It is a 1,700 liter cylinder.

It is out there in the fire service, but it's a 30-minute rated cylinder, and it has virtually the same volume as a 45-minute rated cylinder. So it's -- whenever we are talking about SCBAs, I want to make sure that we are comparing apples and oranges, know what we are talking about.

But in any event, I broke it down. I

based it on 100-liter-a-minute work rates. In a couple of slides, I will talk more about why that is important because it is what is probably a more realistic work rate for the fire service.

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But in any event, if you look at the exit time, as you can see, the 30-minute rated cylinder, which most people are wearing, when your bell goes off, you have about three minutes.

Something else that was found in the disorientation study -- and really all of the work when you look at firefighters who become lost, trapped, and disoriented -- is that the vast majority of the time, when firefighters become lost, trapped, and disoriented, they do it at the end of a work cycle.

When we walk into a building, when we go into a building that's on fire, we are disoriented. We just don't call it that. We are just going to work. We are going in the door. We are doing what we have to do.

The bell goes off. Now it's time to go out. So either we realize, Well, maybe I don't know where I am, or, on the way out, a lot of times we become separated.

Hose line or tag line separation is usually one of the things that occurs inside a fire.

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If we are on our way out, we become separated from our hose or tag line, or we didn't bring one in, and the smoke hasn't cleared. Now we

call it disorientation, and that's when we start to get into trouble.

At that point, my bell is going off. I have maybe three minutes of air. That's at a hundred liters a minute.

When that stress goes in, one of the things that's really going to kick up that respiratory rate is stress, probably more than so than even work, and I'm probably going to have a lot less time than that.

As you can see, though, as you go down there, even at 45 minutes, you are not gaining much.

So as you increase your volume on your back, you are increasing your work period, but you are not increasing your exit period a whole lot. And I think what it points out the most is if you look at 60-minute rated cylinder, or the 2,400 liter cylinder, you really have about six and a half minutes -- or actually six and a quarter minutes of

exit time for all of that air that you are bringing in.

That really points to me a real deficiency as far as where that set point is.

Next slide, please.

Okay. Just as an example -- and I'll go through some of this. But, again, looking at the predominant cylinder in the industry, the 30-minute cylinder and the 25 percent alarm.

The first is rated time. And this has been a point that has been hard to drive home to the

fire service, but it's -- we are doing better with it. And that's telling people that, Hey, we call it a 30-minute cylinder, but it's not really 30 minutes.

Again, we talked about it in the other slide, the 1,200 liters at 30 minutes. 1,200 liters of air gives you about three minutes of exit. It gives you very little margin of error for what-if scenarios.

And we don't do this anywhere else in the fire service. We don't pack for one scenario. If I

pull up to a structure fire in a house, I have one hose. I will probably take a smaller hand line, inch, and inch and three-quarter line.

I pull up to a commercial structure, and I take in a bigger hand line. My tool selection changes. Everything changes. But the bottle that's in the back of my seat, that's one that I get to choose whether I go to a high-rise, a residential, a commercial building. It doesn't matter.

And so really, there is a flaw in how much air we are packing for that one scenario.

Next slide.

Okay. What is the appropriate range of service time? NIOSH uses 40 liters a minute, and that's where they come up with that 30 minutes, is 1,200 liters based on 40 liters a minute. It roughly comes out to about 32 minutes, and they call it a 30-minute cylinder.

A hundred liters per minute, you are

really more likely to get a little more than 12 minutes of air out of it. How does this play out for the real world?

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Next slide, please.

There aren't many line-of-duty deaths where you get everything you need, when you know when people have their last transmission, where you get all of the timestamps that you need, but there's a handful of them. There is probably a few more out there that I haven't found yet.

But here are three that have been well documented by the NIOSH Research and Training Branch. And what we have is about basically 12 to 13 minutes in most of these cases.

They are fire departments. They have an early on-scene time, but they have timestamps with everything. And we are looking at 12 to 13 minutes from on scene to last transmissions.

Now, this is life experience. There is actually empirical data. The Trial Fire Services just completed a pretty extensive research study in 2007 -- it is published. It is out there on the web -- looking at firefighter work rates doing firefighter tasks, high-rise fires, subway fires. And they actually got work rates well in excess of a

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hundred liters a minute.

So the empirical data and the life experience does point to that a hundred liters a

minute is probably a more realistic work rate.

Next slide, please.

What if everything doesn't go right with their margin of error? As I mentioned, we know when firefighters get into trouble, it's toward the end of their work cycle.

We don't have time, whether it's a 1,200 liter cylinder, 18 or 24, if we are waiting to leave when our bell is going off, then we are -- the best we are going to do is six and a half minutes or six and a quarter minutes with a 60-minute cylinder, which very few firefighters are using for structural operations.

We don't have time for self-rescue. We don't have time for receiving assistance from others because, as I mentioned, the reflex time. It is about eight to nine minutes.

Some studies that were done in Phoenix and Seattle after a fatality in Seattle in 2000. And

they did some -- again, some pretty empirical data. They used universities to help them do some evaluations on how long it took to get to firefighters.

It was eight to nine minutes. And that was about 200 feet into a building. So we don't really have enough of a margin of error for this.

What is our backup plan? Well, historically, our backup plan is rapid intervention, which is very reactionary. I would rather see us have a backup plan which says that you have more air

set aside for if you get into trouble.

Next slide.

Okay. How have the consensus standards dealt with it? Well, NFPA 1981 basically is -- we are kind of boxed in on that because we have to -- we have to meet a NIOSH standard. And there is really no way around that.

I think the comment was brought up that the -- if the NIOSH changed, the consensus standard should change. We can't change unless NIOSH is going to allow us, so that's kind of why we are here

today.

Some people point to the heads-up display that was added in 2002, that this is a possible solution because it does -- it is an end-of-service-time indicator that will alert you earlier.

The problem with the heads-up display is I guess really twofold. One is that it is a personal alarm, and firefighters shouldn't be operating on a personal level. We operate in crews.

And as a supervisor, I need know when people in my crew are getting low on air. So it puts the responsibility on the end user instead of making it something that really the crew knows, the supervisor knows, and even other crews in the area know that, Hey, somebody is at the end of their work cycle.

The other part about it, the other deficiency with it is that there is, at least with

some of the older generations of -- there is some deficiency or some -- basically it is called attention blindness, which is when you are doing

heavy work and focusing on other things, you just don't notice it so much. Sometimes it's hard to see.

So it's a start, but it's not really the solution. What we do need is we do need an audible alarm and something which alerts everybody at the tactical level.

And the universal air connection was another thing that has been repeatedly pointed out. Well, that was a solution if we run out of air. That is, again, a very reactionary solution, that's to give a transfer of air to a firefighter who is down.

NFPA 1500, which is the health and safety, and 1404, which is the training for respiratory protection, basically point to two things. They say situational awareness and air management.

Next slide.

They say that those are the solutions that are the keys to prevention of inadequate air supply. And I will talk about those here in the next slide a little bit and really the limitations of them and

some the problems with having good situational awareness.

The heads-up display, as I mentioned earlier, may not be the -- really isn't the solution

the fire service needs. It is a great solution, and it gives personal awareness of your air level, but it doesn't give the group awareness.

Another comment that we have heard a lot of was that an earlier EOSTI will only result in being ignored by the user. Really, if that's the attitude of it, well, shame on that person. That's not why -- we don't not make a standard, not make the change because we think it's going to be ignored.

If there's an individual who is going to ignore the EOSTI, my guess is they are probably not going to have very good air management skills either, to leave before it goes off.

And then the other thing is people say the EOSTI shouldn't be used for an exit alarm. You should leave before that. And that's really the premise or the key behind some of the thinking

behind air management.

There are people who, along with that, believe that the SCBA is not a backup system. And we spent the last two years on the NFPA technical committee looking at -- looking at maybe some potential backup systems in the forms of APRs.

And really, in our last meeting, we decided it really was the wrong way to go. That an APR wasn't the solution. That supplied air is the solution or what is needed for the firefighter who gets into trouble. And we are tying to be able to create a solution which might push us in that

direction.

Next slide.

So what's the problem with air management? Well, air management basically came about because we recognized three things. We said your working environment varies. Your air consumption varies. And exit time.

So basically it says that, Hey, the 25 percent in the end-of-service life in here probably isn't right, probably isn't adequate, so let's not

pay attention to it. Let that be the reserve air, and let's leave before it.

And I think it's a -- conceptually, it's a good concept, and it may work in some places. But the problem is that it takes a positive control factor, a mechanical alarm, which is not very error prone, and it puts it in -- it replaces it with a human solution, which is error prone.

And why I say it's error prone, I guess it's because it relies heavily on good situational awareness and also the lack of human error, which incidentally are cited as the two number one issues or two of the top issues with firefighter injuries and fatalities in a recent report that was done looking at firefighter injuries.

As well, if you read the NIOSH fatality investigations, it is continually cited as poor situational awareness, poor air management are factors contributing to line-of-duty deaths.

But situational awareness is defined as

the degree of accuracy by which one's perception of his current environment mirrors reality.

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Next slide.

It's affected by your view of the situation, incoming information, expectations, and biases. And it's reduced by the things over there on the right, unsufficient communication, fatigue, stress, task overload or unload, degraded operating conditions.

Everything right there on the right, that's my work environment.

So everything that the firefighters are doing degrades our situational awareness, and it's no wonder that we have problems maintaining good situational awareness. But to put on top of that the responsibility to try to be able to gauge when is the right time to leave, really, it results in firefighters fatalities, as we see.

The reality of air management. Again, it relies on a high degree of situational awareness. It's subject to failure due to human error, unknown factors. Unknown factors might be things like building construction, modifications, or alterations to a building, catastrophic events that may occur,

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structural failures or collapse.

It doesn't take those into account.

A human solution for mechanical deficiency, which is really an alarm which goes off

too late for us. And, again, it replaces a positive control system, the EOSTI, with an error-prone human solution.

Next slide.

So how do we add more reserve air? The current regulation basically gives us a couple of options. We can either increase the time in the hazard zone by going with the larger cylinder, but it probably doesn't give us an adequate exit time even at that.

Human monitoring prior to alarm, which would be air management concept. Okay?

In either case, if we add more air to the back of our cylinder -- or onto our backs in the cylinder, we risk getting additional work stress and other work period issues.

What we are requesting, basically to propose changes that we remove the ceiling from

EOSTI and allow us to determine an earlier set point.

Next.

Some of concerns that get raised when we talk about adding more air, too much weight and bulk. That's one you hear a lot of. Although it needs to be noted that the size and weight of our cylinders has gone down considerably in the last 25 years.

And, actually, they are due to have some other big changes. There is new cylinder technology which is being worked on which will reduce the size,

the weight, the profile significantly more.

Also, too much air. Again, a concerned firefighter will ignore the alarm, go in too deep. It is very important to stress that in no way am I suggesting that we need to add more air for work period, that we actually want the air to be set aside just for the escape purposes.

Next slide.

Some of the work period issues if we were to use more air, some of the things that we would be

concerned about if we added more air back and it was intended for work, is that the -- certainly more work stress, cardiac stress. Thermal stress on the body, which also will cause greater cardiac stress. How deep we are going into structures, and fire progression, what is happening with -- if we stay in longer.

Structural failure. And within all of that, really, there is a fire ground rule of thumb which is touted in many books and has really been a tradition of the fire service that has been passed on, and that's that, Hey, when the bell is going off, that's the incident commander's time to really assess and see, Hey, how are we doing? Making progress. If we are not, maybe we need to think about changing our strategy.

And so we don't really want to expand that window because what happens if we do? What happens as far as the structure? What happens as far as the depth of entry and things like that? So our work

period is probably appropriate.

And some work stress studies that been

done within the last three or four years also indicate that really about 900 to a thousand liters of air by volume is probably an appropriate work period for a firefighter, regardless of whether it is a large individual who is physically -- or large individual who may not be physically fit, or a small individual who is physically fit, or either way around, the volume is the volume. And if we start working beyond that volume, we start seeing the cardiac markers saying that we have worked too long.

So what are the benefits of adding more air and keeping an earlier EOSTI, basically keeping the work period the same? We have a larger exit window. We have a larger window for self-rescue or rapid intervention, reflex time, to get to us.

The work stress, depth-of-entry concerns, all of those concerns are able to be kept in check, and we are able to meet our local needs for what we want to -- what we want to achieve in keeping our people safe basically.

Just a few points to clarify.

What we are trying to do here? We want

the authority of having jurisdiction to be able to specify an EOSTI greater than 25 percent.

And that was another point. I know that in the handout, we have mentioned 20 percent as a rule. I don't know that -- most of the fire service

and most SCBAs that I'm familiar with, the EOSTI goes off at 25 percent and remains alarming through the end. But 20 percent is probably pushing it, if we lowered it from there.

But, again, it's not the program manager. It would be that we would be able to specify it, and the manufacturer would have to meet that.

It allows the fire service to address -- go back a second -- allows the fire service to address its escape time needs without increasing the work period and allows us to a determine the appropriate set point.

In the absence of a consensus standard, which says that -- what is the appropriate set point, because that point was brought up, that maybe the NFPA or I think we mentioned the IFF needs to determine what is the appropriate set point.

In the absence of that, the local authority should have the ability to do it. I think it becomes problematic if we try to say that this is what it should be. That's how we got into kind of the mess we are in right now, is that there is too many variables that are out there if we try to stick with a percentage.

I like Dave's suggestion that we use -- we determine what is a reasonable exit period. What is a reasonable escape time as well as a reserve air, and that sort of solution may well be a good direction to go in the future.

Next slide.

Here is things that we are not trying to do, that any change really shouldn't do.

It shouldn't require you to change from your current EOSTI set point. We do not want to give individual firefighters, the department, the ability to adjust the EOSTI set point in the field. And we don't want to define -- I'm not trying to define the EOSTI beyond the minimum level.

This is just a quote taken out of the US

Firefighter disorientation study in 2001 -- or actually, it was a 2004 study.

Because of disorientation, firefighters frequently exceed their air supply in efforts to evacuate these extremely dangerous structures.

The picture there actually is the Wooster cold storage building. Six firefighters died in that fire there after becoming lost.

So that's all I have.

MR. SZALAJDA: Any questions for Dave at this time?

MR. WELLS: Jesse Wells, NOVA Chemicals.

So, yeah, you should have gone first.

So given that we are not changing them in the field, my previous comments would have been I'm sure recorded as, you know, a don't do that, you know, a disagreement with their suggestion.

So at this point, with this information, I don't disagree with allowing them to order an SCBA with a higher set point.

What I don't want to let pass by is I

think Dave has presented a good enough information

that somebody, whether it's NIOSH, OSHA, somebody, needs to take a realistic look at what should that minimum set point be, whether it's an amount of time or percentage of the bottle.

Perhaps it is time for us to take a real critical look at that and decide what actually is the right alarm point.

MR. SZALAJDA: Thank you. That's a good comment.

And I think one of the things that kind of struck us, at least with regard to listening to the dialogue is I think one of the things that you may see with the evolution of our standards is going more away from time to capacity.

I think if you look at the closed-circuit technologies, where the standards are mature or maturing, that we have gotten away from the two hours, you know, 45 minutes, and gearing it more towards the capacity of the system.

And sitting here and listening to the discussion, it seems to me that -- I think what Dave's comment was earlier, you know, regarding

determining that volume, the volume that's necessary. And that may be, you know, capturing that information in terms of capacity may help identify the proper level.

MR. BERNZWEIG: Let me just add one

more -- when you talked about earlier the industrial versus fire service and whether a need to identify it or pull it out separately, and I really don't have much of an opinion on that.

If there's a different need in the industrial sector to break it up, and maybe it is as easy as the rulemaking, recognizing that for fire service SCBA instead of minimum set point.

But I'm really not looking to do anything other than just allow people to set it earlier if that's what they want to specify, if they can justify it and do it that way.

MR. BERRY ANN: And I would like to address the authority jurisdiction. What you said is consistent with what I intended to say. So if I misspoke, I apologize.

But the intent was it would be the local

jurisdiction to determine what setting they thought would be appropriate, not necessarily to be doing the settings, but that they would -- and the issue is still, How do you determine what that upper limit or what the, you know, that the settings at some unknown value potentially is repeatable and accurate.

MR. BERNZWEIG: Right.

MR. BERRY ANN: Even if it is done by the manufacturer.

MR. WELLS: Thank you.

MR. SZALAJDA: Thank you. Are there any other comments on this topic before we move into the

final presentation?

I think the battery is going on the remote microphone. It is probably time to quit.

Just a couple of things. One on the administrative notes, the survey. If you have the survey, if you still have it with you, if you could fill it out and just pass it towards the center aisles. Or, if you want, there is a box on the way out. You can put the survey in the box. And, you

know, we will collect them from that point.

Also, with the name tags, if you are not inclined to want to take it home for any reason, if you could put it in the recycle bin and we can reuse it for the next public meeting, we would appreciate that.

Just a very few brief comments. And I think just keep in mind keep and keep an eye out with the Federal Register notice here in the next several weeks with regard to the near term standards development efforts for the closed-circuit escape respirator and QA modules.

Items that we discussed today and that we are actively looking for comment, please go to the document for comment page on the NIOSH website. And there are links, specific links there to some of the material that was discussed today for the PAPR, for the air-fed ensembles and also for the EOSTI.

Near term, we will have information up regarding the personal protective technology action planning effort.

For the standards development activities,

we are looking at a mid April -- I think it is either the 15th or 16th due date for submittal of comments. And that I would ask that you try to submit your comments by -- within that time frame, so we can take the steps with regard to either finalizing the proposed rule or developing our next iterations of concepts for developing the standard.

And I think, John, if we could jump -- the next few slides relate to the docket comment, or how to provide information to the document. If we could go to the save-the-date slide.

For those of you who are still here, somehow -- I don't know how it happened -- but I made an error when I put together the slide.

I think it was probably because the stakeholder meeting last year was on March 6, and I must have had in my mind. The stakeholder meeting upcoming in this venue is going to be on March 3, and I'm sure there will be additional information forthcoming over the next several weeks with regard to the content of that presentation.

But if you can change your handouts to

reflect the March 3 date, I would appreciate it.

And with that, are there any other general questions or comments with regard to the content of today's meeting?

MR. WELLS: Jesse Wells, NOVA Chemicals.

We have moved on -- we were ready to move

on with the discussion about air-fed suits, so just a couple of things.

I don't know if manufacturers intend to bring these forward, the way that chemical protective garments are now where they are tested against a battery of chemicals and you are either rated well against this chemical or not.

But if so, then the idea of having gloves that come off and you change the gloves -- and I was part of this discussion earlier, this side discussion earlier.

If you are going to have an air-fed suit that you are going to use against chemicals, then if you breach your glove, you breach any part of the suit, now you have depreciated your breathing apparatus. So that suit to me is the same thing as

a Level A ensemble for a hazmat response. And my belief is that the gloves should be built in, that it should be an ensemble instead of a suit.

My other question is at -- the one that we saw over here, next door. Some of the discussion was about having like work boots inside the suit.

So my concern with that would be work boots inside of a suit against a hard surface, and now you are grinding that suit material underneath while you walk.

Some kind of boot cover or maybe a built in boot or some kind of hard sole so you don't have to wear a work boot under it might be more appropriate.

That's it.

MS. SHEPHERD: Can you hear me?

This a really good comment about the boots wearing through the base. And so we have actually gone back and built in some very stringent abrasion and slip resistance requirements, especially if you are wearing your suit over your boots. And you actually have to test -- if you are using a boot and

then an overboot, you actually have to test it in that formation.

So that's a good comment.

The question earlier -- if you don't mind me going back one second. The question earlier about have we vetted, have we surveyed any users, I actually should have mentioned, for those of you that are not familiar with it, ASTM F23 is made up of users, a number of the manufacturers in this room, academic institutions, government institution, other special interests.

So we have vetted it through, you know, a wide number of users. We also did, as I mentioned, the presentation at AIHCE. So we have gotten a lot of user input in on the standard. So we haven't -- we are not doing this blindly. We have a gotten a lot of input.

MR. SZALAJDA: Thank you, Angie.

I guess one other thing. I just wanted to thank everybody for being patient with us as far as trying to use the LiveMeeting capabilities. And I think overall, it is going to provide -- you know,

the more we do it, the better we are going to get at, you know, being able to address the use of the technology. And I think by the time we come around to our next stakeholder meeting in March and subsequent meetings in 2009, we will get more proficient at it.

But thank you for bearing with us today on the use of this new technology for us.

So with that, any more questions?

All right. Well, thank you very much for your attendance, and we will look forward to seeing you at the next event.

(Whereupon, the proceedings in the above matter were concluded at 4:47 p.m.)

CERTIFICATE OF REPORTER

I, Joseph A. Inabnet, do hereby certify that the transcript of the foregoing proceedings was taken by me in Stenotype and thereafter reduced to typewriting under my supervision; that said

transcript is a true record of the proceedings; that I am neither counsel for, related to, nor employed by any of the parties to the action in which these proceedings were taken; and further, that I am not a relative or employee of any attorney or counsel employed by the parties thereto, nor financially or otherwise interested in the outcome of the action.

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Joseph A. Inabnet
Court Reporter