THE NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH/NATIONAL PERSONAL PROTECTIVE TECHNOLOGY LABORATORY (NIOSH/NPPTL) PUBLIC MEETING

Tuesday, December 13, 2005

CONTINUED DISCUSSIONS of Concepts for Standards for Approval of Respirators for Use against Chemical, Biological, Radiological, and Nuclear Agents (CBRN) and Concepts for Standards for Industrial, Powered Air-Purifying Respirators (PAPR)

Docket Numbers NIOSH-008, NIOSH-010, and NIOSH-039

Commencing at 9:02 a.m. at Sheraton Station Square, Pittsburgh, Pennsylvania.

P R O C E E D I N G S

MR. SZALAJDA: Welcome to Pittsburgh for the NIOSH public meeting to continue discussions of concepts for standards for CBRN respirators as well as Industrial Powered Air-Purifying respirators.

For those of you who don't reside in Pittsburg, welcome. I hope you enjoy the rest of our fall season, not to be confused with winter.

One thing to note up front, that at this point in time, many of the discussions that we have today do not represent NIOSH policy at this time. Any release of policy would be done through other documentation.

For covering our discussions today, we have an ambitious agenda to go over a lot of work that has been done since the last time we got together in the July time frame.

And we have tried to set up the meeting to cover the powered air-purifying topics first. We will be addressing CBRN as well as the industrial concepts.

We would also want to share with you some

of our benchmarking experiences with the test technology and some of the laboratory experiences we have had since July in looking at the testing concepts for the respirators.

This afternoon, we're going to cover closed-circuit self-contained breathing apparatus. In addition, Kathryn Butler from National Institute of Standards and Technology, who is doing a support study on face seal leakage, will give us a presentation on their results of work that they have been conducting for us as part of the process.

There will also be an opportunity for open comments at the end of the day.

During the course of the presentation, we have built in time following each presentation to address your comments and answer any questions you may have regarding the presentation.

As far as some of the logistics, I think probably most of you signed in. There will be an attendance sheet prepared and available for the end of the meeting.

I will also ask that you please put your

cell phones or pagers on mute or vibrate to not interrupt the course of the proceedings today.

The meeting is being transcribed. You can obtain a copy of the transcript from the NIOSH Docket Office.

On the back of your agenda, there are several bits of contact information regarding how to get in touch with the Docket Office.

As far as the question and answers following each presentation, what we would like you to do is to come up to the microphone in the center. Please clearly enunciate your name. We have had problems in the past with everyone so familiar with saying who they are, and they come out quickly, and it won't be transcribed properly.

But also identify your affiliation and then state your comment or question.

As far as the contact information, there are several dockets that are set up to receive formal comments to the standards development process. The first one, for the CBRN PAPR, you need to reference NIOSH Docket No. 10.

For the Industrial PAPR, you need to reference NIOSH Docket No. 8.

And for the closed-circuit SCBA, you need to reference NIOSH 39.

And with that, as far as the remainder of the administrative details, the restrooms are here on the left-hand side. We have 70 minutes built in for lunch today. There's a variety of places around the hotel that you can go for lunch, or eat in the hotel as well, so you're on your own for that.

At this point, I would like to introduce Les Boord, the director of NPPTL, for some comments.

(From another room: Welcome, welcome, welcome. Hello, hello.)

MR. SZALAJDA: I'm not sure if that was for Les or not, but --

MR. BOORD: I wonder if he had a respirator on.

Well, good morning.

And as Jon said, welcome to sunny balmy

Pittsburgh, Pennsylvania.

Hopefully, the cold trough that we have been experiencing has not been too brutal on you, but it has been really cold.

Before we get into the main topic of the day, the CBRN respirator standards, I would like to talk about a few things relative to some NIOSH programs and perhaps give you a little information on the laboratory, the structure of the laboratory, and then talk a little bit about our customer market focus activity.

Most of you are probably familiar by now with the research structuring that NIOSH and the NORA NIOSH program is going through.

For those of you who are familiar with the NIOSH research agenda, the NORA research agenda, that format is being revised to actually reflect an industry sector based.

And I think, if you go to the NIOSH website, you will see quite a bit of information relative to the NORA NIOSH program sectors.

The sectors that NIOSH has identified for

research, for developing of research agenda, are the eight sectors that are listed on the screen. And those are derived from the North American Industry Classification System.

There was some consolidation of the 20 sectors identified there into the eight that we have illustrated here.

And those were based on occupational safety and health similarities between the various 20 sectors and trying to reduce it down to a manageable number.

So as NIOSH and the NORA program are developing their occupational safety and health research agendas for the next decade, they will be focused and oriented along the industry sectors identified here.

Now, in addition to that, there are being identified a cross-sector approach to the research agenda.

And I wanted to show you this because as you scan down the list of cross-sectors that will be research areas that, as the description is,

crosses all of the eight sectors. You can see that personal protective technology is identified as one of the cross-sectors.

So in the institute development of the future research objectives and research programs for the institute and for the nation, in the area of occupational safety and health, personal protective technology is one of the cross-sector programs.

NPPTL is leading the effort to coordinate -- to identify and coordinate what the personal protective technology cross-sector research programs will be.

Then further into the structuring of the research program for NIOSH, we have also identified the coordinated emphasis areas, as illustrated here.

A very important step in the process of developing the research agendas are the events that are being labeled as town hall meetings.

And there are a series of, I think, about ten or 11 town hall meetings scheduled between

December and March of next year that are both industry focused or sector focused, and regional, territory focused.

And those are as identified on the screen now.

And if you go to the NIOSH website, you can see the schedules and the information relative to registering to participate in the NORA NIOSH town hall meetings.

The first one was actually held last week in College Park, Maryland. And there is one scheduled for, actually, next Monday in Chicago to address the construction sector.

So I would encourage you to look at the NIOSH website to gain information relative to the NORA NIOSH research program development, look at the town hall meetings, and try to participate.

I think this is a good forum for those of you involved in occupational safety and health issues to identify the needs and the gaps as potential research projects.

Just to clarify a little further -- and

I'm sure most of you are probably familiar with this, but I wanted to give you some perspective of where we, the National Personal Protective Technology lab, fits within the structure of the Institute.

And you can see that there are 13 other sister laboratories, divisions, and programs within NIOSH, that we work together with to fulfill the research agenda.

And you can see that NPPTL is illustrated there, highlighted with the yellow marker.

And the locations of the NIOSH institute offices, divisions, and laboratories are at the various locations illustrated on the map.

In October of this year, there was a Federal Register notice that appeared that discussed a reorganization, or organizational plan, for the National Personal Protective Technology Laboratory.

So I thought it would be good to illustrate and to talk a little bit about what that reorganization was and is.

I'm sure that many of you have seen that, and I know that a lot of you have seen it because we have received a lot of telephone calls relative to it.

But basically what that reorganization plan came down to is structuring the laboratory to align with the major activities that the laboratory performs as identified through a strategic planning process that we went through about two years ago, in 2004.

And to summarize that, the structure for the laboratory identified in that Federal Register notice and within our strategic plan has the basic operation that's illustrated on the chart here.

We have the Office of the Director, which the Associate Director for Science and the Deputy Director are resident in -- in the OD, as well as technical support activities for the laboratory and all activities that occur in the lab.

Then we have the laboratory structured into three branches, Technology Evaluation Branch, Policy and Standards Branch, and Technology

Research Branch.

The Technology Evaluation Branch is the home for respirator certification and for evaluations of personal protective equipment.

The Policy and Standards Branch, which is the facilitator of the meeting today for our CBRN standards development, is the second branch and activity for the laboratory. And this is really the new structure that was added, or the new component that was added to the organizational structure for the laboratory.

Previously, the policy and standards activity was a component of respirator certification. So under this realignment, restructuring, we have identified that as a branch activity for the laboratory.

And then, third, we have the Technology Research Branch, which remains the same under the previous structure and the current structure.

Then in addition to the three branches, you can see we have identified four program manager activities.

And it's the goal of the laboratory to have the program management functions align with the technical focus for the laboratory, but also with the industry sector focus that the NIOSH research program is identifying.

So with that structure in place, I thought it would be helpful to run down the individuals who are currently in the branch chief positions and in the program manager positions.

So you can see here, the Associate Director for Science is Mary Ann D'Alessandro.

And I think just scanning around the room, I think all of the -- or most of the individuals that we have on the chart here are at the meeting today.

So when you walk up to them, you see their name. You can get an idea for their capacity in the laboratory.

Again, Associate Director for Science is Mary Ann D'Alessandro.

Deputy Director, Ken Williams.

Technology Evaluation Branch Chief is

Heinz Ahlers. And I think a lot of you had some discussions with Heinz yesterday. I don't know if he is here today.

Our Policy and Standards Branch Chief is Jon Szalajda, who is facilitating the meeting today.

Technology Research Branch, Ron Shaffer. And Ron is at the second table back. That's nice. Right, Ron? Now everybody knows exactly where you are.

Then we get into the program managers.

And the four program manager functions we have are the respiratory protection, with also the health care sector focus, and that's Roland Berryann.

And I think most of you know Roland. He is back in the corner of the room.

The Human Performance Program Manager, which also has a mining sector, construction sector focus, is John Kovac. And I believe John is present as well.

The Sensor Technology Manufacturing

Industry Sector Program Manager is George Bockosh. And I don't think I have seen George today.

And then the fourth PM position is the technical focus for ensembles and the sector service for the services -- services sector, and that's Bill Haskell.

So I think that that quick overview will give you a little bit of insight into how the laboratory is structured and the activities managed within the laboratory and the individuals who have some of the key positions within the laboratory.

The last thing I want to mention, touch bases on here, is the CBRN respirator standards and respirator certification program.

The chart that we have on the screen here identifies some of the CBRN respirator approvals that have been issued since we started this program to develop CBRN related respiratory standards.

I think the first of those meetings was -- public meetings was sometime in 2001, and we have progressed over the past three or four years with three to four, I guess, public meetings a year

addressing concepts for developing CBRN respirator standards.

I think it's significant to take a look at that. And I think everybody in the room really has had a part in bringing us to the point where we have CBRN rated respirators that are available to the emergency responders of the country.

So I think that we all deserve a little pat on the back for the accomplishment to achieve these levels of protection.

And I think -- I'm confident that the responder industry is a little more prepared today than they were when the process started. So thank you all for your involvement and participation in helping us bring it to this point.

And with that, what I would like to do is have the Associate Director for Science, Mary Ann D'Alessandro, say a few words about the customer market focus activities that we have at the laboratory.

And I think most of you have probably had some dealings with that activity already.

So I will turn it over to Mary Ann.

MS. D'ALESSANDRO: Thanks, Les.

Good morning. I just wanted to updated you today on the activities the lab is currently conducting to increase our relevance, quality and impact, and our customer relationships and satisfaction.

The first activity is the National Academies involvement in NPPTL activities.

And with regard to that, the first activity we are conducting is the Committee on PPE for the Workforce.

And that is a committee that we have contracted at the National Academies to establish that will meet three times a year and will consist of a form of experts in PPE and academia and experts who will provide us an input to our activities to address emerging PPE needs in the nation.

We have one of those members, Dr. Joseph Schwerha, here today, in the audience, who is participating in this meeting.

And the first meeting of the Committee on PPE was held November 2. And the next one will be in March sometime. The date has not been established yet.

But those meetings are open to the public. So if you go on the National Academies website, you can see when those meetings will be held.

And if you are interested, what we can do is send, on our list serve, send out a message to those who are on our list serve, when the next meeting is held for that activity.

In the second activity we have with the National Academies is the review of Anthropometrics Survey and Respirator Panel Modifications.

Most of you are familiar with Dr. Ze Ching Zwang's (phonetic) work in revising the LANL panel.

And with that regard, what we're doing is we, again, contracted the Academies to conduct a review of his work, to ensure that the work is conducted using the best quality, that to move

forward, not only in our standards, but in ISO's standards as well.

So that committee has held two meetings so far. The third meeting is being held February 9 in Irvine, California. And that meeting is open as well, the first day of that meeting. The second day, February 10, is a closed meeting just with committee members.

And that consists of one member who is also on the Committee of PPE, but an additional expert panel, who is looking at that work from Dr. Z.

And the next activity review that we have with the National Academies is the review of the BLS survey of respirator use in private sector firms.

And what they are doing in that regard is looking at the way that survey was conducted and how we should conduct future surveillance initiatives, whether or not we should conduct a future survey in a similar regard, just addressing respiratory protection, or including other PPE as

well, or if our future surveillance activities should not include surveys, but include some other surveillance initiatives.

So those two activities, we're excited that they will serve as very good inputs into our processes in moving us forward with regard to PPE.

Another activity is our customer surveys. We have customer satisfaction surveys and point of service surveys that we're conducting.

In our customer satisfaction surveys, we have contracted the Office of Personnel Management and Budget. We actually have an interagency agreement with them to conduct -- to look at two of our customer bases, manufacturers and users. And those surveys were implemented about a week ago.

So most of you should have gotten a notice from OPM to go online and to take this survey.

We would encourage you to do that because this is our first systematic approach to obtaining input from our customers, again, to help us move forward in our activities.

So we're excited about what that input will provide as well.

And also our standard point of service surveys after meetings such as this to help us improve the meetings that we're conducting.

And the last activity is the Customer Satisfaction Council that we're currently putting together.

And that will be a council of nine to ten customers, from users, manufacturers, labor, other organizations who will serve on a rotating basis with a minimum of a one-year term.

And the first meeting of that council we envision to take place in the March time frame. And we're hoping that by that time we have the results from our customer satisfaction survey in the summary report from OPM on what the key issues were that were addressed in that survey.

And we hope that the council can help us identify why those concerns came out and how we can address those concerns.

But also, that council will look at any

customer satisfaction issues that are out there.

So we have an internal team that has been looking at who the first nine individuals should be on that committee. But if you are interested in serving on that, Tom Pouchot will be the council coordinator.

And he should be in the audience. He's over there, just raised his hand.

And that committee will meet three times annually for about a half-day meeting. And the first meeting, as I mentioned, will be spring 2006.

So we're looking forward to all of these activities. And especially all of the activities will help us -- serve as inputs to our system.

And for the customer satisfaction surveys, they're using OPM -- nine standard dimensions to help us benchmark against other government agencies.

So many of the questions that are in there were taken from their standard questions. And so we will be able to compare ourselves to other organizations.

And we're hoping that with these outcomes, we will have increased customer loyalty, organizational effectiveness and better value.

So thank you.

Do you have any questions?

So I'll turn it over to Jon.

MR. SZALAJDA: Well, I guess, if you don't know who I am, I'm Jon Szalajda from the Policy and Standards Development Branch at NPPTL.

And every meeting I like to at least, when we get together to talk about CBRN standards, I sort of like to set the tone for why we're here.

And I think if you were present at the July meeting, you saw this slide.

And I debated whether or not to add the incident at the Miami airport that happened last week to this list. While it wasn't truly an act of -- or it could be construed as an act of terrorism.

And I think it goes to show that we still have a lot of issues and a lot of things to address with regard to addressing threats of terrorism and

security issues in our workplaces.

And I think when you go back and you look at the history, even just this brief snapshot over the last five or six years, that I think the one thing that we can anticipate is that there will be other events.

These were major newsworthy events that captured our interest for periods of time, but the incidents of terrorism happen every day throughout the world.

And it's in our interest to provide our responder community with the best possible protection, which is the reason for the development of the CBRN respirator standards.

But for today, there's a couple of goals that we would like to accomplish.

One, is to continue our discussions with regard to requirements for CBRN respirators.

And in particular today, we're going to address the powered air-purifying respirator and also the closed-circuit self-contained breathing apparatus.

We also want to continue our discussions on what we're anticipating to be performance requirements for an industrial based module to modify 42CFR Part 84 for powered air-purifying respirator requirements.

A little bit about our partners -- and I'm sure most of you have seen this slide as well in the past, but it's always worthwhile to mention the fact that, you know, the standards aren't being developed in a vacuum, that the standards development effort involves the input and relationships that we have established with our partners over the past several years.

In particular, you look at the relationship with NIST, who identified seed money from National Institutes of Justice, and now Homeland Security, that support our standards development efforts.

Our partners within the Department of Defense at the Army Research Development Engineering Command, who we use as a third-party test agent for doing our chemical warfare agent

testing and laboratory respirator protection level testing as our test agents, a first for NIOSH.

Also, the inputs that we receive from other standards development organizations, like the National Fire Protection Association, and the relationships that we have established with them, and listening to their feedback with regard to our requirements, as well as hopefully influencing the requirements that are generated for clothing and ensemble technology.

And also, other stakeholders, like the firefighters, The International Association of Firefighters and Fire Chiefs, have been very vocal advocates of NPPTL and the CBRN program.

We also need our manufacturers, represented ISEA, or individually. We receive a lot of input from ISEA, technical and programmatic, to let us know where they think we're on track, or where they think we're off base.

And that's been very beneficial to us as far as being able to identify adequate and specific requirements for the respirator standards.

So what's the impact, the impact of the CBRN standards?

And I think if you're a user, I think the one thing that comes to mind is the fact that if you get grant money from Homeland Security, you should be buying equipment to meet a recognized standard.

And of the possible 5,000 or 6,000 standards that ANSI has recently identified as having applicability to homeland security applications, you know, the Department of Homeland Security has only recognized 14 standards and lent them the grant money.

And three of those are the NIOSH respirator standards for self-contained breathing apparatus, gas mask, and escape respirators.

Also, in the relationship we have with the NFPA, that they have recognized the use of NIOSH approved CBRN respirators as part of their chemical protective ensembles.

And other standards development organizations are looking at what we're doing with

regard to our standards and our test methodology, like the British Standards Institute, and looking at them for applicability to what they're developing for their customers.

We have come a long way in four years, four or five years since the standards work.

We have completed efforts for SCBA gas masks and escape respirators, and we're looking to tie up our technical work here on the PAPRs and the closed-circuit SCBA over the next several months and then rounding out our suite of respirator standards for combination units and evolving technology, as well as supplied air units.

I wanted to spend a little bit of time reinforcing what we do with regard to the standards approach.

And the one thing I would like to say with our methodology is I hope we have been consistent.

I think when you go back, we have tried to set a three-tier foundation in all of our respirator standards development efforts.

I think when you go back and you look at the very first standard for SCBA, it was based on three tiers of requirements.

One, was looking at the NIOSH performance requirements based in 42 CFR, Part 84.

The second tier is looking at existing international or national standards that could be applied to provide certain protections or certain performance requirements for the users to address things related to human factors or environmental conditioning type aspects of the respirator.

And then the final tier is our special CBRN tests, which fall in the categories of the testing with the chemical warfare agents and also the LRPL tests that we do to insure our degree of respirator fit.

That same pattern applies to the gas mask that, while we didn't completely adopt all of the provisions of Part 84 for the gas mask, we adopted a large portion of those requirements, as well as identified specific performance requirements from national and international standards.

We have also gone through, and we have pursued the development of a CBRN and an APR retrofit kit, which we haven't implemented. We have completed all of the development work regarding the requirements for the APR retrofit kit.

And we have held back on the implementation because we haven't seen the need in the workplace yet for this type of capability to be added to our suite of standards.

I think one of the things I would hopefully like to hear back some more from the community is if this is truly something that either manufacturers or users feel would be of a benefit to the requirements, then let us know that, and we will pull that standard forward.

And then the final standard that we have completed has been the escape respirator standards.

And, again, when you look at the two types of escape respirators, the first tier based on requirements from Part 84, either in whole as used for the self-contained escape respirator, or

in part as was used for the air-purifying escape respirator, performance requirements based on our benchmark testing that was done and identification of other standards to address those performance requirements.

And then the requirements for the special chemical, biological, radiological, and nuclear tests.

And Les already discussed the certification programs. So for the 40 charts that I have, I don't think we will need to spend any time on that one.

At least as far as an overview of the standards program, I think we might at least just spend a couple of minutes on where we are right now and where we think we're going in the future as well as talk about some of our internal housekeeping.

One, obviously, the respirator certification program will continue.

As you may have heard at the manufacturers' meeting yesterday, we're continuing

to develop our capabilities in Pittsburgh to conduct certification testing at our facility at NPPTL.

Where that's not practical or possible, we're looking at the establishment and development of relationships with third-party testing.

Again, our relationship with RDECOM is a good example. We're never going to do chemical warfare agent testing in Pittsburgh.

To that end, we have that established relationship with RDECOM to do that testing.

Along with that, though, I think we have learn a valuable lesson from the events of this past year with the explosion that occurred in the laboratory at Edgewood in Building 5100 and having -- or losing that capability for a period of time to do the certification testing.

And to that end, we're in the process of doing some engineering analysis, working with our technical support contractor, EG&G, to look at the possibility of establishing alternate capabilities to do the chemical warfare agent testing.

And I would expect that the next time we get together, next year, we will be able to report to you the results of that project.

Also, we continue -- and it has been a long process, but we continue to march along with our benchmarking for the powered air-purifying respirators and the development of the CBRN respirator standard.

And what you're going to hear a lot about during the course of our discussion this morning, is the repackaging of those requirements and the introduction of the PAPR in a two-step process to bring equipment to bear.

And I will get into the details of that in a few minutes.

Also, that we plan on continuing to develop the CBRN standards using the public process.

We're going to continue to use the concept paper methodology and the posting of that on the internet, continue to encourage to have stakeholder meetings, whether they are done in a

public forum like this, or one-on-one meetings with individual stakeholders regarding to the performance requirements for the standards.

We're also going to continue to use the docket, as far as receiving formal comments for us to reconcile as part of our process.

When we met in July, I had provided discussion about taking a look at our standard test procedures and our standards now that they have been in place for a few years, and trying to incorporate some of the lessons learned from our certification program into the documentation, not from an extent of changing the requirements -- the requirements are what they are in the standard -- but at least as far as providing clarifications based on experience to what we have seen in the execution of the test procedures, as well as clarifications to how the requirements and standards were defined.

And unfortunately, we had planned on trying to have that effort in place by the end of this year. But with the amount of work that needed

to be completed regarding to the PAPR and the closed-circuit SCBA to try to bring those standards to completion, we have had to put that on the back burner for a while.

But we're looking on going ahead and completing that effort during this upcoming quarter, and posting the updates by the end of the third quarter of the fiscal year.

We have had a lot of discussion about the PAPR. I think by far, it has been the most active and interactive standard that we have worked on, I think partly related to the definitions and requirements of the performance characteristics of the system and also the traditional requirements that NIOSH has identified in Part 84.

And we have had a lot of interaction with the stakeholder community. We have had a very active docket input to the requirements that we're considering for the system.

And I guess to mention about the docket -- and I usually try to cover some specifics with regard to the input. But I'm not going to do

that today, but suffice it to say, again, I want to assure you that when you submit something to the docket, it doesn't disappear into a black hole and it's never considered again.

We go through an iterative process within the group when we look at the transcript of the public meeting, identify comments that were made as a result of stakeholder comments at the microphone, as well as soliciting the input and pulling it back from the docket, categorizing all that input against the different requirements, and then going through those requirements and make a determination as far as what we can accept in total or in part, what we don't think we can accept because of either technical or programmatic reasons, or things that we still need to keep in mind because we're not at a point in our technology evolution of the development of the standard that we can make a decision one way or another on those recommendations.

For the CBRN PAPR, at this point in time, I think it boils down to a couple of program issues

that we're coming through and addressing to bring the standard effort to completion. And, really, it falls into two categories.

The first category is a technical issue. When you look at the high flow aerosol test technology to evaluate the aerosol flow of particulates at high -- and I'm talking above 100 liters per minute of flow in a test scenario -- that the testers that we have and currently we have used over the past several years in certification generally have a maximum output which ranges around 100, give or take a few, liters per minute.

And we saw that there was a need given where technology was going and considerations of physiological effects and the need to address those types of characteristics as part of our development, that we went out and we worked with the two aerosol test technology manufacturers, ATI and TSI, to come up and build flow testers for us that have this capability to generate and maintain aerosol at high flow rates for us to do as part of our particulate evaluations.

We have -- the two pieces of equipment are in hand we have installed in one of our facilities in Pittsburgh. We have been running experimentation with those devices, and they appear to work.

Where we are in the process is that now that we see -- and we have captured the technology, we need to take it to the next step, which is to work it into a repeatable type of test that can be used for certification application.

So we're going to need to go through another iterative process. We're going to buy additional testers, run through a verification validation type phrase to ensure that we are getting verifiable, repeatable laboratory results.

And then have those in a position for use in certification testing by the end of 2006.

The other issue that we have worked to address as part of the CBRN PAPR is the stakeholder needs, both on the equipment supplier side as well as on the equipment users side.

And we hear from our partners at Homeland

Security, as well as our users, we need the PAPR; we need it now; we needed it yesterday; we have got to get the standard completed.

But then there's also another sensitivity that was raised that we have tried to issue or tried to address as part of our standards development work, is to ensure when we look at our tiers of requirements for the respirator that we're maintaining that same platform.

When you look at using Part 84 as our base to maintain that consistency, whether it's an initial step of using Part 84 as it currently exists, or a future step of using Part 84 as it may evolve to over the next several years.

Another program issue that has come up over the past year as well has been the draft OSHA guidance for first receivers.

And part of that was to address the need for powered air-purifying respirators by hospital workers that provided an APF of 1,000. And I think when you look at the traditional methodology of how APFs are assigned, there aren't that many of those

animals to provide for the user community to use in this type of application.

So part of what we wanted to address with the development of the CBRN PAPR as well was to provide a niche for equipment to meet that certain requirement.

So when we looked at all of these competing issues, we tried to provide some of what I would like to call clarity to chaos, I think people have heard me say.

But at least as far as identifying some of the key elements of the implementation process that we need to follow, one was we felt we had to come up with a way to get the technology -- to have the technology available as quickly as possible for manufacturers to make equipment to a standard, and then have that equipment available for the user community to buy and put into use.

A second aspect of the process that we felt was important was to go through and verify that our test procedures that we have developed are accurate and verifiable and in a position that the

manufacturers can use them as part of their equipment development specifications, so that they know what they're going to be subjected to once NIOSH gets it in the certification effort.

And then the third aspect that we were working internally was whether or not to release the standard using our policy provisions, which can be done in a more expeditious manner, or if we would need to go through a longer time frame rulemaking process.

To date, all of the standards that we have released have been done through voluntary approval programs using authorities that NIOSH was afforded in 42 CFR, specifically paragraphs 8460B and 8463C, which allow us to identify additional requirements necessary to establish the quality, effectiveness, and safety of any respirator used as protection against hazardous atmospheres.

And we intend on -- for the first step of the CBRN PAPR, is to release a standard still using those policy provisions.

All right. Now, I think we're in a

position that we have worked through with many of the stakeholder concerns with numerous discussions, and we're in the position now that we are working through our internal due diligence within our agency to get the necessary approvals to approve the standard.

And in looking at how the system works, we figure that probably sometime during the second quarter, between January and March of 2006, that we will have obtained all of the necessary approvals for the CBRN PAPR Step 1.

And the way that the standard -- we're looking the repackaging of the requirements and the things that we have discussed over the last two years, fall into these two categories, with Step 1 being an implementation, as I had mentioned, early next year, using our policy regulatory authorities.

And I'm going to spend the next several charts talking about the technical and performance requirements of Step 1.

But, again, it uses -- when you go back to our three tiers of requirements, it uses 42 CFR,

Part 84 as it currently exists now, as our first tier and foundation for the CBRN standard.

The second step, or Step 2, is going to take a lot of the technological evolutions that have been identified and discussed over the past several years, as well as linking that with the industrial module work that we have initiated, and rolling all that effort together as part of a module that will be released during -- using rulemaking provisions, where the CBRN respirator would be a type of PAPR that would be released under the 42 CFR module.

Again, still using Part 84 as -- Part 84 approval as the basis across the board for the first foundation of the three tiers of requirements.

And as far as the time frames, we expect that probably by the end of 2006, that we will be in a position to begin the formal rule making process, which would take 18 to 21 months to complete.

The requirements for Step 1, the special

tests that we intend to implement along with the requirement to meet the Part 84 requirements for PAPR, are durability conditioning. The durability conditioning would only be done for the tight-fitting PAPR. It will not be done on the loose-fitting PAPR.

We will do a chemical warfare agent test for penetration and permeation against the test representative agents, sulphur, mustard, and sarin, with the only difference in procedure being that for the loose-fitting respirator, we will not apply droplets of HD to the respirator.

One of the things that I neglected to mention up front, with the CD that was available when you registered and you came in, all of the standard test procedures that we have developed that support these special tests, the drafts of those STPs are available in that CD.

And we intend on going through with our due diligence internally and having those available and approved prior to the release of the standard.

But the procedures that you have in that

CD are the basis for moving forward.

And I think in most applications, especially when you look at the gas and vapor testing and the durability conditioning, these are based on the protocols that we have been using in the CBRN and APR testing over the past few years.

The other two requirements that we're adding through the policy provisions are the laboratory respirator protection level, the respirator fit test, and then the gas and vapor testing that's done as part of the certification.

But, again, I think when you look at the special tests that we have identified, again, it comes back to the three tiers.

The durability testing is a test based on national standards, based on the testing that we do with mil standard 810. And the same durability conditioning that we use as part of the gas mask testing, the special test that we use, the warfare agent testing, the LRPL, and the gas and vapor testing.

Just a little refresher -- and I will

thank my friends in Technology Evaluation Branch for helping me with this slide.

But as far as what are the tests that you can anticipate that you need to pass as part of the Part 84?

And I don't think -- for any of the users or for the manufacturers that have approved PAPRs under Part 84, this shouldn't be anything new.

These are the tests that are done for PAPR, whether it be tight-fitting or loose-fitting, as applicable.

A couple of caveats that I wanted to clarify as part of the Part 84 testing that we have had a lot of internal discussion on over the past several weeks.

One is about the PAPR air flow.

And, again, it gets back to the requirements for Part 84.

If you have a tight-fitting system, we use 115 liters per minute divided by the number of canisters on the system.

If it's a loose-fitting system, we use

170 liters per minute divided by the number of canisters for the system.

I also wanted to provide a little bit of the clarification on the requirement for silica dust as far as how we address the Part 84 approval as a system.

One of the things that we had talked about internally was whether or not there was really a need for testing the CBRN canister as part the Part 84 approval.

And as a result of all of our discussions, we felt that there is a need to look at the canister as part of the overall system's performance.

And to that end, what we envision with the canister as part of the Part 84 submittal will be evaluated in two ways.

One is that we will evaluate it to meet the high efficiency particulate testing requirements for Part 84.

The second part is that we will evaluate it as part of the systems evaluation for the silica

dust testing.

But, again, it gets back to reinforcing the concept that we will have looked the CBRN canister as part of the overall systems approval for Part 84.

With the durability test -- and a lot of these slides I stole from my colleagues for application. The durability conditioning is the same that's done with the gas mask. It's going to follow the same protocol that was established for the APR technology, again, specifically looking at life cycle failures, initial life cycle failures of the equipment.

And, again, it also tailors and follows the pattern for that air-purifying respirator, that we're looking for the applicant to identify the minimum packaging configuration that we will test.

And it's going to be -- that part of the application is going to be no different than what we do for the APR.

And the types of tests, it's the hot diurnal, cold constant, and humidity challenge in

our chambers. Also the transportation vibration requirement, and then a drop test of the canister only.

One of the things that we will consider, while the durability STP is not a -- it's a process, that's STP there.

There is no pass/fail characteristic associated with the durability conditioning.

However, what we have seen and will continue to do so with the PAPR, if there are things that are visible to us as a result of the testing, for example, if the battery comes out of conditioning, and it's leaking, that's a problem.

And we will need to have dialogue with the applicant as far as how that problem will be addressed and whether or not there's a need for us to conduct additional testing as a result of that incident.

Similarly, I guess it sort of parallels -- if we condition respirators, and we have seen the distortion of the facepiece or the nose cup or things of that nature, that indicates

to us that, you know, there may be a problem, and we need to continue to have dialogue with the manufacturers, at least as far as to identify and resolve those areas of concern to us.

One other aspect that we wanted to address and I wanted to make sure that I brought to your attention, was following the durability conditioning and the gas and vapor testing that's done, we had a provision in the gas mask standard where we conduct an organic vapor testing, follow particulate challenge of the respirator just to insure that -- especially for electric media types of filters, that the electric media wasn't affected as part of the particulate loading.

And we will do the same tests that we do for the gas mask with regard to that evaluation.

With the agent, the one thing that I wanted to note -- and it's reflected in the test procedure -- is that we're not going to test the battery as part of the agent application.

One of the things that we have learned as a result of all of our benchmark testing is it's

very difficult to dispose of chemically contaminated batteries as that poses a new challenge for our partners.

So what we have done, it parallels what we addressed as part of the SCBA standard when we did not test the bottle, did not test the compressed air bottle with the SCBA, that we provided house air to the system in order for it to be run during the test.

We're going to follow a similar path with the agent testing on the PAPR by running house power to the PAPR. And we will need to work with the applicants, at least as far as being able to provide that adaptor to connect to the laboratory house power and interface it with the respirator.

Again, the testing parallels what we have done with other systems. We will do a qualifying agent test up front to get a degree of confidence that the system will pass, all of the warfare agent testing prior to going through the durability conditioning.

And then following the durability

conditioning we will evaluate the systems against GB and HD.

I notice, I guess, we're running out of chairs. There are some, if you guys are feeling bold, there are some seats available here in the front. Or unless you just need to get up because I'm droning on too long, but that's okay, too.

With the LRPL, again, it's based on technology that has been developed and applied for other systems.

Over the past couple of years, we have had a lot of debate about what the LRPL values should be for the respirators.

For the systems, we're going to evaluate it with the blower on. We're looking for an LRPL value of 10,000, whether it's tight-fitting or loose-fitting.

Then we also wanted to consider for the tight-fitting applications, how to address the potential for were these types of systems would be used.

Again, we figure the tight-fitting would

be used in a responder type activity, either by the fire service, law enforcement, EMTs. And there may be a potential need to have an escape capability, which would lead us to believe that we would need to meet the NIOSH 14(G) requirements for tight-fitting respirators.

And so to that end, we looked back to our gas mask requirement where we identified an LRPL value of 2,000 for the gas mask, thinking that the tight-fitting PAPR should have the same capability as the APR, where the APR may be used.

But I think the one -- I keep saying the one thing, but there are a lot of -- I guess a lot of one things today.

But the significant thing to me with regard to this requirement is I think this is going to provide an avenue to help meet the OSHA guidance for the first receivers by looking at establishing an APF for either the CBRN tight-fitting or loose-fitting of 1,000.

I think this will fit a needed niche within the user community.

We have had some initial dialogue with OSHA regarding this subject. We have put together a synopsis of the LRPL, how we conduct the LRPL versus what OSHA used in qualifying PAPRs that were approved for an APF of 1,000 that they have identified and accepted for that APF.

And I think there's a lot of consistency between the two test methodologies. And over the next couple of months, we're looking at bringing that dialogue that we have initiated with OSHA to more of a formal position where OSHA will recognize that our LRPL test of 10,000 will equate to providing an APF of 1,000 for these respirators.

And the last special test under Step 1 is our gas and vapor and particulate challenge and breakthrough evaluations.

And I don't think there are any surprises here. These are pretty consistent with what we have addressed over the past several months regarding the test technology and the conditions of the test.

We have decided for the CBRN PAPR Step 1,

we're not going to use the capacity provisions that were developed for the APR. We're going to reserve the implementation of the capacity designations for the Step 2 approach.

In order to be more consistent with how we currently test canisters and cartridges with Part 84, we decided to limit the test time to 15 minutes to determine a base performance level for all of the canisters that will be used as part of the CBRN PAPR.

Again, part of that will be up to the manufacturers as part of their user instructions to the users to identify appropriate change out schedules for the application of these type of systems based on their evaluations.

Canisters are all going to be conducted -- testing is all going to be conducted on a single -- using single canisters.

These are the challenges and breakthroughs. Again, I don't think there are any surprises here.

This is for the tight-fitting. This

parallels what was developed for the APR and for what we have gotten equipment certified for for gas mask applications.

For the loose-fitting, we decided to take a step back and take a look at what the concentrations would be in trying to be sensitive to what our stakeholders were telling us with regards to types of protections that they needed in a more quantifiable controlled type of environment.

On the one hand, we felt that we couldn't call it a CBRN canister without testing it against all the TRAs. But we also felt, given how the challenge concentrations were set for the gas masks, it wasn't appropriate to test those canisters at such a high level.

So what we did was we made a determination to base the test challenges on half of the concentration that we test for for the tight-fitting PAPR.

The breakthrough concentrations remain the same.

And as part of the labeling of the

canister, we would be looking to identify, to discreetly identify for those types of applications, that's either for CBRN tight-fitting or CBRN loose-fitting, that there would be a differentiation between the canisters.

The one thing that you should keep in mind as we move forward with this, is that the work that we're currently doing with Optimetrics and our partners at RDE Com, looking at the hazard assessment associated with the loose-fitting PAPR system.

And along with that, there may be room for change with regard to the design of the needed capacities for that type of canister.

But we will look at incorporating the results of that hazard analysis in the Step 2 provision.

For our particulate aerosol testing, we're following the P100 methodologies for testing. The testing will be determined, for tight-fitting, by dividing the number of canisters into 115 liters per minute, for loose-fitting, the number of

canisters into 170 liters per minute.

And one -- I'm sorry. I think I'm on a one-track mind here this morning.

But with the test technology that we're addressing -- and I had mentioned earlier as far as the capability to test at the higher flow rates -- we would not be able to get an application today for something 170 liters per minute with one canister. We would not be able to test that device today.

So at this point, until we have that technology evolved by the end of this year, we would not be able to evaluate the single element application until we have established the test procedure and the test technology for doing the higher flows, which essentially implies that for applications that we see in the near term, we're going to need to have a multiple canister type of configuration.

With regards to cautions and limitations for the respirator, initially, you're going to have two sets of labels, one to show compliance with

Part 84 requirements, and then the other to give you the CBRN rating.

I think a parallel example is to look at how the SCBAs are marked.

You have a NIOSH Part 84 approval. You have the NFPA 1981 approval. And then you get the CBRN label that goes on top of the device.

The same type of application is going to happen here with the CBRN PAPR.

The units are also going to have to include cautions and limitations associated with the type of PAPR, as well as the unique CBRN cautions and limitations.

And if you all want to moan and groan, now is the time to do it.

I understand the next couple of charts are really busy, but I anticipated that someone would ask, if I didn't show it, what are some of those cautions and limitations, Jon?

Well, here they are.

But for any Part 84 approval to date, you see these types of cautions and limitations.

These are things that you can go -- if you go to our website and go to the searchable certification -- list of certified equipment, you can pull up all of the Part 84 cautions and limitations there.

These are general ones for PAPR.

The next slide also provides additional limitations that refer back to the old 30 CFR Part 18, as well as additional requirements for Part 84.

There will be a quiz on this later, so it's -- and the slides will be available on the internet within the next couple of weeks.

You also are going to need to consider the 14G types of cautions and limitations if you're developing a tight-fitting system where it has an escape capability with regard to not being used in IDLH type conditions or having adequate oxygen.

The use of manufacturer approved parts.

You get into the chemical cartridge, the 23C approvals for your loose-fitting, and you have the same similar types of requirements.

And there's more 23C cautions and

limitations.

Then after you're done putting that into the user instructions, we will need to address the CBRN unique cautions and limitations. We already have a set that was identified for the air-purifying respirator.

You're going to see a transition of those requirements into what's defined for the PAPR.

And there's two slides with very small print here that you won't need to memorize.

But at least a couple of things that need to be addressed are the use of the respirators as part of an appropriate personal protective ensemble, whether it's a level A suit, or a less than level A suit.

There are concerns over the use period, the recommended use life of the CBRN respirator, you know, the fact that we are looking at an eight-hour time frame for use after exposure to chemical warfare agents.

But the one thing -- and I'm going to do this all day I can tell.

But the one thing that we will be expecting to see with the loose-fitting types of cautions and limitations are these parameters. And part of it gets back to where we think the respirators are going to be effectively used.

We do not see the loose-fitting technology being used in a potentially high physiological demand type of application.

We don't see where this would be used in fire service or law enforcement or emergency medical technicians.

Again, paralleling the capabilities of the CBRN APR, that if you're wearing a tight-fitting CBRN PAPR or a CBRN APR, those will be used in the same scenarios.

The loose-fitting, we're looking at applications in other areas, the hospital worker, command and control center, things where you may not have that high physiological demand where you can overbreathe the system, but you're still at a level where you're going to need to address respiratory protection.

If you recall when Dr. Roberge gave his presentation in July, which is also available on the internet, he had discussed about, you know, based on his experiences as an emergency room doctor as well as consultation with his colleagues, as far as the need for dermal protection or some sort of shroud associated with the loose-fitting PAPR to protect the head and the upper torso.

And then the fact that, because of the nature of the approval for the loose-fitting PAPR, that they're not appropriate for escape devices.

And by all means, a CBRN PAPR is a bargain.

Compared to what you have seen in other forums, when looking at what we anticipate to be the certification fees, we're planning on doing the durability conditioning for all the PAPRs at our facility in NIOSH.

The agent test, the LRPL, will still be done for the foreseeable future by our partners at RDE Com.

The numbers that we're showing are based

on what was established for the 2005 time frame.

I'm in contact with our counterparts at RDE Com, now, who we're hoping to hold those fees fast for the upcoming year.

And if there are any changes, we will do what we can to mitigate the impact on the manufacturer for what you have to pay as part of the certification process.

And, again, this is our initial look.

Depending on the results of the testing, if we need to conduct additional evaluations, then that testing, that type of testing isn't included as part of the fee structure.

I'm sure this is the most important chart for a lot of you today. So if you need any more time to write down the numbers, I will wait a minute. Okay.

What are the advantages of Step 1?

It still continues to support our traditional approach and methodology for the development of CBRN respirator standards.

We use the relationship and the

requirements established with CBRN using the first tier based on Part 84.

And regardless if it's the Step 1 or Step 2 or any future iteration, the base platform for PAPR meets the existing Part 84 requirement.

The other aspect behind the Step 1, Step 2 approach is that this provides the potential for equipment availability to the user in the near term.

Not providing a recommendation or anything like that to the community, but one of the attractive aspects behind this approach is that Part 84 applications could be developed and provided to NIOSH now, while the -- we're doing our due diligence within the agency to get approval of the process for releasing the Step 1 approach.

That way, with the time on the standard is released in the January through March time frame, if Part 84 status has already been achieved or approval of Part 84 status has already been achieved, we can immediately go into the CBRN testing portion of the requirements.

And that in turn, following our time frame in getting the certification testing done for the CBRN elements, looks to providing approvals and potential equipment release during 2006.

The other aspect, the other advantage behind the implementation of Step 1 is providing a safety and health benefit for hospital workers and other receivers that need -- excuse me, that need respiratory protection, but do not need all of the requirements that were identified for tight-fitting PAPR.

And with the connection with our LRPL test of 10,000, that provides the test basis for linking the respirator fit test to -- with a safety factor of ten to the proposed APF of 1,000.

And, again, we would appreciate your comments on this, either today or to the docket. Sooner is better than later, obviously, at this point in the program.

But at that point, I would like to -- since we're at 10:18, I would like to take any questions that you may have that I or my colleagues

can address, and then we will take a short break.

Please come up to the microphone.

MR. SAVARIN: Mike Savarin, Bullard Company.

A very quick question, actually.

When you ID an area of concern during the durability test or conditioning, since there's no pass or fail criteria, is it mandated that the approval is given, it's just that you're going to discuss the issues that arose with the applicant or manufacturer, whichever is applicable, of course, manufacturer, and then that's really it?

Or is it the nature of the durability testing that it will later affect the past test -- the testing that follows that so it will kind of just come out of it?

Do you know what I mean?

MR. SZALAJDA: Yeah. I will take a shot at that, and then Bill and Frank can bail me out.

But the question is whether or not, if you pass the durability test -- or if you go through the durability test, whether or not that

will impact your approval, with the approval being that, through the reconciliation of issues associated with the results of the durability testing, what has been seen, or what would be required at that point as far as testing; correct?

And I think the short answer is -- well, it's a government answer, but it all depends on the nature of the failure.

I think what we have seen and done historically in the past, that we have seen issues with respirators coming out of the durability cycle.

And at that point, we engage the manufacturer or the applicant with regard to those types of questions and whether or not we feel that the testing could go on or should go on, or if the manufacturer or the applicant needs to go back and reconcile those issues before we can proceed with the rest of the testing.

I mean, for example, I think one of the things that we saw with the -- with some of the applications, when you look at the systems with

canisters, is we saw -- they came in sealed pouches where the pouches lost the vacuum seal, or there was obvious evidence of the canisters leaking carbon.

Those are -- the thought being that you're not going to pass the gas and vapor testing if you have -- with that type of product.

Maybe you need to pull the stand up a little bit.

MR. SAVARIN: You know, as far as that was concerned, it seems obvious to me that if there's an issue that comes out during the testing, during the conditioning, it should really follow that something should -- detrimental maybe should happen in the early stage, I was just wondering if what we have known and granted up to this date is that we're in a better position to inform everyone of what they might expect to see and what may lead closure or suspension or (unintelligible).

MR. SZALAJDA: Uh-huh. That's a good point.

I think that's one of the benefits of

doing the durability testing is because we see that the durability test gives us an indication of initial life cycle failures.

And if there are issues that are identified with the performance of components or the respirator, then it gives the -- and given the -- I think the other aspect of that is given the cost associated with this testing, it gives the manufacturer or the applicant the opportunity to react and make adjustments to their application to reflect design changes to meet the requirements.

MR. BERNDTSSON: Goran Berndtsson from SEA.

I have a long list of things, but there's a lot of things you have already answered for me, but there is couple of things here.

First of all, a couple of years ago when we started this process, you had a very nice introduction, and you documented in the beginning where this product actually was supposed to be used, et cetera, et cetera.

And that has all come out, and I would

like to see that come back in because --

UNIDENTIFIED MAN: Could you speak into the mic?

MR. BERNDTSSON: Is that better?

MR. SZALAJDA: It's a little distorted.

Actually, I got your first question, and I will repeat it.

One of the things that we had done in the original developments of the concept paper was to provide a preamble of sorts, up front, which addressed some of the potential applications of the respirator, as far as who the target audience was for the system, where it should be used, that type of applications; correct?

And I think the one standpoint I think when you see this concept paper, basically what you're going to see when the standard is released is if you cut that little bit of discussion up top, you know, Attachment A to the letter of the transmittal is doing to be the following -- the eight and a half pages that follow the little bit of discussion.

But we thought the best way to approach the user conditions or sensitivities, as far as where the system should be used, should be in the cautions and limitations associated with the particular type of respirator, whether it was tight-fitting or loose-fitting.

Along with that, we have a very active program now in developing guidance documents associated with the use of the system, where we're pretty close to having the SCBA document go through external peer review, where we're in a position that we're pushing the APR guidance document along.

And the next step in the iteration this year is develop guidance documents for the escape respirators and for the PAPR.

And I think that that's more of our focus, as far as based on our observations and lessons learned as a result of the whole standards development process as well as things that we think the users should know.

And I think -- and if you go back and you look at guidance documents that we currently have

up on the web, when you address things, you know, regarding, you know, whether or not you should buy a respirator for your own personal use or things that we identified as part of being concerns with the escape respirator, you know, documents, the things that we feel are appropriate that the community needs to know, we will put notice of those types of guidance documents.

MR. BERNDTSSON: Okay. That's fine.

However, three years ago we discussed increasing the flow rates to take care of -- I think it is really important that people who are interested doesn't believe that now this is the result of what was discussed two years ago, three years ago.

It was only halfway there or partly there or whatever it is, intermediate.

MR. SZALAJDA: That's a good point, very good point.

MR. BERNDTSSON: The other thing I have here is that on the MPC, it states that you have durability conditioning that refers to the

tight-fitting respirator, but it doesn't seem to refer to the loose-fitting.

Is that a mistake?

MR. SZALAJDA: No, that's correct. It only applies to the tight-fitting.

Because, again, we're looking at the applications for the loose-fitting, and being in more of a controlled environment in the hospital settings, things that may be command and control.

We're not looking at loose-fittings to be going in the back of a patrol car and being driven around for a year before the respirator is pulled out.

That's the role of the gas mask or the tight-fitting PAPR.

MR. BERNDTSSON: But then you have to write, I think, the conditions of use, that it can't be used in that situation as well.

MR. SZALAJDA: That's right.

And that's part of the cautions and limitations, when you look at the -- which wasn't part of the concept paper as it was posted on the

web, but it is one of the things that we have addressed as far as specific limitations to the loose-fitting respirator.

MR. BERNDTSSON: When it comes to the LRPL, it's going to be tested -- that the tight-fitting respirator is going to be tested with power on and power off.

Is there any kind of limitations of usage going with that, or what did you mean by what's going to happen with that?

MR. SZALAJDA: With the -- the tight-fitting requirement is based on the fact that you can use it as -- with the blower off, you can use it as an escape respirator from IDLH conditions.

And, again, looking at the same capability that was built into the gas mask, that that capacity is built into the APR, that you can use it for escape purposes.

And in looking at the tight-fitting being used in the same scenario as the gas mask, it needs to have that same capability.

MR. BERNDTSSON: As we're doing that with the LRPL with the power on, why do we bother of doing the test of the exhalation valves for leakage?

I mean, we get that in that test anyway.

MR. SZALAJDA: Yeah. I think I kind of lost you on that one.

MR. BERNDTSSON: You have the requirement of you're testing exhalation valve leakage (unintelligible).

That's what you said on the slide.

MR. SZALAJDA: As part of your Part 84 approval.

MR. BERNDTSSON: When you are doing the total inward leakage test, I mean, if you have a problem with the exhalation valve, you see it there. Why are you doing the other tests as well?

MR. SZALAJDA: Well, I guess the one thing that's not -- you know, when you look at the LRPL test as being a fit test, it does a couple of things.

One, it assures that you fit the range of

the population, the LANL panel. And the other is that it's going to provide a degree of protection.

MR. BERNDTSSON: The valves is included in that test. And the system test, everything is included.

MR. SZALAJDA: Again, it gets back to, you know, when you look at the stages that were set up, you have to get Part 84 approval first.

We're using Part 84 as the platform across the base, across all of the applicants for approval.

And then once you have the Part 84 approval, you have the additional tests for -- you know, the four extra tests that I talked about.

And as part of that, they are for specific things.

And, again, the LRPL test isn't looking at inhalation or exhalation resistance. It's looking at fit.

MR. BERNDTSSON: When it comes to the retrofit, you're talking about retrofit for the tight-fitting, but not for the hood. That's what

you mean?

Is that a mistake, or do you intend not to have it retrofitted for the hood?

MR. HOFFMAN: I don't think we envision the retrofit for the hoods at this time. It's not to say that we couldn't.

But our thinking was along the lines that because the PAPRs are a little bit more expensive than the air-purifying, and people would want the retrofit, our thinking was that there was a need for that, but also that it would mostly be the tight-fitting that people would want the retrofit.

MR. SZALAJDA: Yeah. But that's not to say that -- that's something we can consider between now and when the standard is released.

MR. BERNDTSSON: I don't really agree with counting half the concentration of testing the filters for the hoods.

I mean, you have to make a very distinctive difference where these two different products is going to be used to justify the PAPR.

That can also be done.

MR. SZALAJDA: That's a good point as well, but it gets back to part of -- you know, we felt we couldn't say it was a CBRN canister if we didn't test against solid TRAs.

But from what we're seeing, how appropriate those values are is the issue.

And not having the results of the hazards assessment yet, we took -- we just made an observation that we would approach it from half the concentration standpoint.

From the aspect that you're still getting a degree of protection, just that the capacity of the canister is going to be different than that of the tight-fitting. That's something that we will have to be very specific about with regards to the labels and the user instructions as far as the canister capability of one versus the other.

And it could be that in practice you may use the same canister for tight or loose-fitting, and that theoretically could happen.

But depending on your application, it's going to have to be addressed as part of your

user's instructions, you know, how you determine the capacity for that particular application.

MR. BERNDTSSON: Well, do you think that it would help the user community if you are using the different levels of capacity as you have in the APRs, in even this intermediate standard?

You said you're going to introduce in the next level. Why not have it already here? That would certainly help the user community to determine how long they can use the equipment.

MR. SZALAJDA: I think that gets back to -- we were looking at trying to parallel what we did for Part 84 and be consistent with, you know, the Part 84 methodology, you know, that we test as part of the industrial applications, we test for a specified time.

And for this situation, we're going to do the same with the CBRN PAPR requirements, the testing for a minimum time, knowing that the applicants will test systems to the breakthrough, and then be able to provide that information to your user.

MR. BERNDTSSON: That's we hope will be done.

The last question is when do you expect to take applications?

MR. SZALAJDA: In the best case scenario, assuming that March 1 or -- March 1, we release the standard, we would start taking CBRN applications 30 days after the announcement of the standard.

You can apply for Part 84 approval at any time.

MR. DENNY: Frank Denny, Department of Veterans Affairs.

Just to briefly confirm what I think you said, and that is that you don't need a high flow PAPR for First Receivers.

MR. SZALAJDA: That's correct.

MR. SMITH: Simon Smith, 3M Canada.

On the slide of 42 CFR 84 requirements, you listed numbers 33 to 48 or 62 gas and vapor, and you're also doing gas and vapor testing for CBRN.

What are the gas and vapor requirements

on this 42 CFR 84?

MR. SZALAJDA: Well, it's as applicable; okay.

MR. SMITH: What does that mean?

MR. SZALAJDA: This is an iteration.

If you were to contact us as an applicant today, and you said, What do you need to pass Part 84, this is the list that we would give you. Okay?

Specifically for CBRN, when we evaluate the canister, we're going to evaluate it for high efficiency particulate, and we're going to evaluate as part of the systems test for silica dust.

MR. SMITH: So basically gas and vapor, a lot of things fit under that.

MR. SZALAJDA: Right. That's why it's as applicable.

MR. SMITH: That line there.

MR. SZALAJDA: Again, but this is if you were -- for any PAPR, regardless of if it's industrial or CBRN, for any system, if you came to us today and said, What test do I need to address to get Part 84, this is the list.

MR. SMITH: So the only gas and vapor testing is for the CBRN?

MR. SZALAJDA: That's correct.

MR. SMITH: Thank you.

MR. SZALAJDA: You're welcome.

MR. HEINS: Bodo Heins, Draeger Safety.

When I saw your guidance of the piece, I realized that you only have ten gas and vapors which have to be tested now for the PAPR, which is different (phonetic) for the CBRN APR.

Is that what you wanted from? And how can a manufacturer add gases if he wants to have more gases for which his PAPR would protect?

MR. SZALAJDA: Okay, yeah. These ten TRAs plus the particulate go back, and they represent -- they're the same -- they're the same TRAs we test as part of the APR.

One of the things that we're doing -- and we have made more available and are doing as part of our APR guidance -- is to identify what those tests representative agents represent, you know, the families, the different families that each gas

and vapor represents, which we're developing and packaging as part of our guidance document.

And if you're internet savvy, you can go to previous presentations on the website, and you can find what the families are.

But when you see guidance, user guidance coming up in the near term, it's going to show you the breakdown of what the gases represent.

One of the things that we're currently doing as a research project within the organization is addressing doing additional gas and vapor -- now that we have CBRN-approved canisters, we're going and we're taking a sample of those canisters, and we're going to evaluate them against all the TRAs to show how the test representative agent truly represents those particular families.

MS. DEMEDEIROS: Edna DeMedeiros, North Safety Products.

Jon, I just want to reiterate what I heard. And from what I understand, if you have already a PAPR or 42 CFR 84 approval, that once the standard comes out, you can submit your CBRN

respirator for approval.

Is it just that the major components have to remain the same and then you will be able to shroud and do whatever you need to do to in order to meet the other requirements of the standard?

MR. HOFFMAN: I think I will answer that.

MR. SZALAJDA: Okay.

MR. HOFFMAN: You would have to make changes to the respirator to meet the CBRN approval, and you would have to resubmit it and obtain Part 84 approval first.

So we're looking it as like a tier approach. You have the CBRN -- I'm sorry. You have the Part 84 approval, maybe with gases and vapors on there, maybe not, depending on what the intended uses are.

And, as a second step, you would submit that same unit with the CBRN canisters to obtain those -- have the additional testing done to obtain the additional approval.

If to meet the CBRN requirement now, you determine -- you have to replace gaskets or valves

or something like that, then you would have to obtain the Part 84 approval on that.

It's the changes that you're going to make first. It may or may not require testing depending on what changes you need to make.

MS. DEMEDEIROS: Okay.

MR. HOFFMAN: Does that answer your question?

MS. DEMEDEIROS: I think so.

So basically, if I have a system that I would need to make some material changes, you would have to --

MR. HOFFMAN: You would have to resubmit.

MS. DEMEDEIROS: -- submit that, get a 42 CFR 84 approval.

MR. HOFFMAN: Right.

MS. DEMEDEIROS: And then when the standard comes out -- wait for that approval. And like I said, it might not require testing if we're not asking for any additional approval.

MR. HOFFMAN: Right.

MS. DEMEDEIROS: Okay.

And then -- but it would have to include any kind of exception that, going into the CBRN, would allow us to pass CBRN testing?

MR. HOFFMAN: That's right.

MR. COLTON: Craig Colton, 3M.

The question of clarification on some of the terminologies that's used.

In the concept, it mentions, for the gas and vapor, it identifies tight-fitting facepiece and the requirements for the loose-fitting facepiece.

But start with the loose-fitting facepiece term first, I saw in the slides that the terminology was sort of mixed. It just referred to loose-fitting devices and talked a little bit about hoods and helmets, but yet the title refers to loose-fitting facepiece, which is just one of the three types.

I guess the question is does loose-fitting facepiece requirements -- are you talking about -- will that allow all loose-fitting respiratory coverings, or is it restricted to just

loose-fitting facepiece?

And, secondly, is a follow up on the tight-fitting facepiece, does that exclude tight-fitting hoods and helmets?

MR. SZALAJDA: I guess the answer to the first -- the second question, as far as the tight-fitting hoods and helmets, is no.

And if it meets the criteria for Part 84 as tight-fitting, regardless if it looks -- if we have defined it as tight-fitting, that's how we will evaluate.

So if you have a system that seals to the neck, that's a tight-fitting system. In a loose-fitting, again, it's open.

If you meet the Part 84 requirements for loose-fitting systems, if it's a hood, helmet, you know, whatever, it will be evaluated.

MR. COLTON: And then there's a follow-up, if they're allowed.

I'm assuming -- but that may not be a good thing to do -- but in the STP that I haven't looked at that's on the CD, but that would talk

about the sizing of those types of devices for the LRPL?

MR. SZALAJDA: Yes, that's correct.

When you look at the panel, the panel is built around -- if you look at the escape essence, we worked off the LANL panel, which was used for your traditional tight-fitting, it seals to your face, methodology, and also the next circumferences that were addressed as part of the escape respirator.

And depending on what your system would look like, it would fit within that context.

MR. COLTON: Okay. Thank you.

MR. SZALAJDA: You're welcome.

MR. VINCENT: John Vincent, North Safety Products.

Jon, what signifies a pass/fail for battery durability conditioning?

MR. SZALAJDA: Well, there is no pass/fail characteristic on durability.

I used that as an example that, you know, if you go through the durability conditioning, and

we see that something is obviously wrong with the system, then we're going to open discussions with the applicant as far as, you know, what we see and whether or not we think your application is still viable at that point, or what would need to be done to address that issue, that we feel, as a result of the test to identify those initial life cycle failures, there is a problem.

And then we would use the policy provisions to add additional tests to identify tests or give you the opportunity to go back and rework your product.

MR. VINCENT: So the battery -- if the unit does not go on after an O2 type (phonetic) condition, that's not necessarily a failure.

MR. SZALAJDA: Right, that's correct.

And part of what we're looking at with the other testing is, again, where the PAPR -- the user has to make a decision to put the system on.

If the blower is not working because of, you know, the batteries fail or something else is wrong, he shouldn't be putting the system on. He

shouldn't be going into an environment where he needs respiratory protection.

You know, you make a conscious decision about the suitability of your product before you put it on and go in.

And as far as the certification goes, when we go through the agent -- you know, obviously the agent testing we're going to use with house power. The battery is not evaluated there.

For the LRPL, we can either recharge the batteries that were gone through durability, or we can use other batteries that you supply for the LRPL testing.

MR. VINCENT: Thank you.

MR. SZALAJDA: All right. With that, I think I'm only about a half an hour behind schedule, so let's take a ten-minute break, and we will resume at five of 11.

(A recess was taken.)

MR. SZALAJDA: I would like to get started again, please. I should say, if you guys really want to leave by 5 o'clock, let's get

started.

There's just a couple of things I wanted to clarify before we started back up. I guess the hotel asked that for entering and exiting the room, if we use the doors in the back of the room where you registered or these doors over here on the side, that we not use these doors here along the railroad track.

And I guess apparently whatever activity that was going on that was cheering for Les during his presentation earlier is completed. So we shouldn't have that distraction.

There's one thing that was brought to my attention that I just wanted to briefly comment on, as least as far as the air cylinder issue.

There was an announcement in the International Association of Fire Chief's website regarding this meeting.

I think it may have been misportrayed a little bit as far as what the intent of this meeting was.

We're not going to be addressing the SCBA

cylinder interchangeability issue as part of this meeting. We're going to focus it solely on the CBRN respirators and the industrial PAPR.

The technical committee for the NFPA is working on that issue.

There is a report for proposals for NFPA 1981 which is available for public comment -- or it's going to be available for public comment on December 23, with an open comment period through March 3, 2006, and it's going to be available both online and in print from the NFPA.

And I would encourage you, if you do have an interest in that subject, to either talk with Bruce Teele, who is attending the meeting today, or contact the NFPA through their contacts that were identified on the website.

One other thing I wanted to expand on a little bit.

I didn't give -- in retrospect, I wanted to add a couple of things to an answer I gave to Frank Denny earlier about the need for high flow respirators for use by hospital workers.

And, again, I think it gets back to -- I said, you know, well, I think my answer was no. And that's not completely right.

It gets back to, you know, the selection of your respiratory protection is going to be dependent on the application where you're going to be using the system.

You know, in the hospital type scenarios, you may need to have a higher flow capability that could be afforded by a tight-fitting system or a respirator that provides a higher flow if you have people carrying gurneys or things like that.

I was thinking from more of the standpoint of the physician or I think people that may have been doing more of a sedentary type -- the controlled type of application.

So, again, it gets back to the respirator selection needing to be application specific.

And part of the methodology that you would need to do for that setting would be to address the specific needs that you needed respiratory protection for.

So at that point, I'm going to take a break for about five minutes.

Bill Hoffman is going to provide an overview of what we're anticipating to be the PAPR retrofit concepts for CBRN.

MR. HOFFMAN: Good morning.

I'm going to start off by addressing Goran's earlier comment about the hoods and helmets possibly not being able to fit into the retrofit concept.

And I don't think we purposely excluded that. It's just not something we looked into at this time. And we had discussions about it during the break, and we will make the changes necessary so that they could certainly be included.

For the retrofit program, we would have a couple of prerequisites, of course. And as Jon mentioned earlier, one would be the Part 84 approval.

The second would be the CBRN approval.

And then the third thing, which is similar to the SCBA program, which we did for

retrofits, is we would be looking at field deployed units that would be available for us to test.

Hardware requirements, we would be looking for four units that had been in use from approximately one to five years.

This would be similar to the CBRN, which we're proposing. Two that had light use and two that had heavier use.

Testing requirements, we would ask that the units be fitted with a retrofit kit by a factory representative. And we would ask also that field units by retrofitted by factory representatives as well.

The testing will consist of the mustard and the Sarin, the same as it would be done for the original CBRN approval.

And then other tests we would perform as may be deemed necessary, which we always do. If we saw something, whether it was an issue with a field unit where, for example, breathing tubes tend to deteriorate or something like, we may want to evaluate that aspect of it.

Documentation requirements for a retrofit, of course, as usual, would be the standard application form that manufacturers, you know, always submit.

Information describing criteria for determining a retrofit eligible PAPR; what we would want you to look for, what the manufacturer would look for to determine that a unit was suitable to be retrofitted, whether it would be inspection, whether there would be certain gaskets that would be necessary to be changed, and whether batteries should always be replaced if the unit is going to be retrofitted, or whatever is necessary.

Unit instructions addressing a retrofit, which is pretty typical for all of our CBRN applications.

And then the method of recording which units have been retrofitted, so there would be a way of tracking them.

And then the retrofit labeling, which would probably be similar to what we have done with the SCBAs.

Additional details being addressed at this time would be the fees, which we haven't actually worked them out yet, but they would probably be very similar to what the CBRN PAPR fees are, just applying the applicable tests.

Additional QA requirements that would be necessary, for example, how they're going to be inspected in the drawings and documentations, what is contained in the kit to retrofit it, and any performance differences that we may have to address between the industrial and the CBRN requirements if there was determined to be any difference.

And, again, we haven't worked through this. This is a brand new concept for us. The presentation is rather short, but are there any specific questions on this?

Sorry, Jon, you didn't get much of a break.

MR. DESANTIS: In 5.5, you stated you wanted to test some PAPRs that been out in the field from one to five years, light duty, heavy duty.

It's theoretically possible that you're coming up with a new configuration for the CBRN standard, you have got to get your 42 CFR Part 84 approval first.

It's theoretically possible that might go out in the field for a week, and you turn right around and you submit an application to CBRN because you have done all of your pre-submission testing.

It might be impossible to meet 5.5.

MR. HOFFMAN: You're saying because the unit is too new, it's too recently introduced?

MR. DESANTIS: It's carrying out new components for the first time.

MR. HOFFMAN: That's right.

And we have discussed it.

But then the other side of the coin, I guess, is how do we evaluate units that have been in the field to see if they are retrofittable, if that's a correct word.

So I'm not sure what the final solution to that will be at this point.

I can envision you submitting for a Part 84 approval, coming back, submitting for a CBRN approval, the -- you have already had the Part 84 approval on a very similar unit for some time, maybe not for some time, and now you want to retrofit those that have already been sold, but none of those have been sold -- maybe for only six months, is that what you're --

MR. DESANTIS: Let's just say, for instance, if you're marrying it up with an APR approved negative pressure facepiece. It's proven. Even they haven't been out that there that long.

Now you're trying to configure a blower and a hose that's going to meet all of the requirements. They're not out there yet, possibly, and married with that facepiece.

Maybe some manufacturers already have something. Maybe some manufacturers don't.

I just find it real, real hard to meet 5.5 if it's brand new.

MR. HOFFMAN: Okay. If it's brand new, I guess, the point I'm missing is there won't really

be any out there just like that to retrofit.

MR. DESANTIS: So if you can't bring something in that has been out in the field for five years under heavy use, all of this is -- your first approvals for CBRN only go back to 2003.

MR. SZALAJDA: I think I understand where you're going with this, Vic.

I think the initial approach that we took to the retrofit was we looked at there's a lot of products that are already out there that have been marketed and sold as chemical warfare agent protected, you know, those types of things.

There's a lot of pieces of equipment that have Part 84 approval. You know, you may have a degree of confidence that it's going to meet the warfare agent testing, but you need to do something to it to get it to meet the CBRN requirements is the way it's currently envisioned.

Now, we looked at that as being a target audience. And we looked at transitioning the requirements that we identified for the APR, and some of the things, the approaches from the SCBA

with regard to how they had been used to bring those ideas forward into this paper.

I think the type of situation you're defining, it might get into a case-by-case type of basis, depending on your particular product, would be, you know, if you have different components, it -- still, if it falls back to the different stages that, regardless if you're marrying up, you know, a facepiece and adding a blower or other components, you're still going to have to get a Part 84 approval of that system first.

And then once that happens, we can take a look at it from the standpoint of what additional CBRN tests, as far as do we need to do specific tests to address specific things based upon what we know and what has already been tested regarding your piece of equipment, and build it from that way.

So I think for newer pieces of equipment, we probably just have to work the program on a case-by-case basis.

MR. HOFFMAN: And possibly take what's

the oldest in existence rather than -- and maybe that is only six months.

I would expect all of those to be in good condition, anyway.

MR. SZALAJDA: I almost feel like, if you're familiar with the movie Independence Day, when -- I think it's Randy Quaid is flying the jet at the alien saucer, and, you know, as he's flying up the, you know, to explode the plane in the missile silo, and he says, I'm back, because you know the inevitable is coming.

And we're talking about the industrial PAPR, and I'm expecting that there's going to be a lot of questions and a lot of discussion on this area.

So I'm back, and we're ready to talk about the industrial PAPR and the implications for the CBRN Step 2 program.

But the thing that I like about this presentation, it gives me a chance to be a little philosophical about where I hope the branch is going in the future with the different modules of

requirements that we're looking at evolving and producing and incorporating into Part 84 as far as changes that we can make in the approaches for identifying performance requirements and ultimately equipment certification and availability for the users in terms of products.

And when we look at the industrial PAPR module, I think there's a huge opportunity here for influencing how we develop standards for the industrial sector and what we do for Part 84 for years to come.

And it's an opportunity to change the paradigm that we have been working under for the past 35 years as far as codes of federal regulations and the definition of requirements and how we address developing and certifying equipment to meet those requirements.

But I think the things that I feel are important, you know, with regard to the industrial concept, and the thing that's become apparent to me the longer I have been with NIOSH, is that in looking at what we develop a one-size-fits-all

approach isn't going to work for this type of technology.

That in identifying requirements, and trying to identify one set of requirements across the board, it's going to be too restrictive for some applications, and it's not going to be protective enough for others.

Another thing that's become apparent to me in this evolution, when you look at how we define the performance requirements for the respirators and building on the tiers of protections and the tiers of performance requirements are that the respirators really need to be flexible in how we test for them in relationship to how they are used.

And examples are -- I think, a good example is what we have done over the past four years with the CBRN program, that we have gone through. We have done a hazards assessment. We have determined what the potential threats were, you know, and identified performance requirements on how to provide the proper degree of protection

for use in those types of scenarios.

And, again, it needs to be, as far as defining these requirements, how do we define a federal regulation to be flexible enough that you can tailor specific requirements for specific applications.

And what we're going to pursue here over the next couple of months is a concept to categorize performance requirements into different areas.

And at least as far as for the discussions today, I'm not going to really debate what we should call these categories.

We can call them A, B, C or X, Y, Z or Type 1, Type 2, Type 3.

You know, those types of details we can work out in this type of forum or through the process over the months to come.

But from a philosophical standpoint, I see these types of categories falling into a few different areas.

And basically they are defined -- or I

defined them for today as base requirements, enhanced user requirements, and advanced specific requirements.

And you can sit there and say, Well, that sounds like a lot of mumbo jumbo, but I think there are some specific ideas I wanted to share with you with regard to each of those categories.

And the first is base requirements.

And I see base, or Type 1 or Type A or whatever we call it, as being performance requirements that all PAPRs should exhibit, regardless of where or how they are used.

And I think some examples are, with the PAPR you need to maintain positive pressure in the breathing zone.

That's the purpose of why you have a powered air-purifying system. You're maintaining a positive pressure in the zone where the individual is breathing.

You know, inhalation, exhalation requirements, how easy, how hard it is for individuals to breathe while you're wearing the

respirator.

And things like a low pressure indicator. How do you know that you are maintaining that positive pressure in the mask, whether it's an audible indicator, a visual. You know, those are details that will be worked out over the next several months with the program.

But I think you would agree with me, or I hope you would agree with me that when you look at these types of requirements, whether you have a PAPR with a half -- a half-mask PAPR that essentially looks like the nose cup with a harness that's attached to a blower, to a hood or a helmet, to a tight-fitting CBRN type respirator, all of these systems will do the same thing.

The level to which they may do it may change, but the basic performance requirements for any type of system would be the same.

And then the second step or the second tier or the second set of requirements relates to what I call enhanced or enhanced user requirements. Again, this could be Type B, or Type 2.

But these would be requirements based on the type of system being evaluated.

For example, if you have a tight-fitting full-facepiece CBRN respirator, we expect you to have a hard lens to resist the penetration and permeation effects of chemical warfare agents.

And we also expect that you would be able to work and do a high level of work in an abrasive type environment for several hours.

So what types of requirements would be appropriate for that?

Well, obviously a guy working at one type environment where we want to have a field of view.

You want to be able to see his surrounding environment to operate in a safe manner.

The lens is going to need to provide a degree of resistance. If he is in an abrasive type environment, you know, there may be particulates or other things or just as a matter of course of doing work, he rubs his -- he has a glove full of grit, and he happens to rub his lens in a reflex action,

that the lens is going to resist the effects of abrasion.

Also, things like low temperature environments.

Some of the things that we have heard as part of our evaluations and benchmarking over the past couple of years is, Let the community decide; let the manufacturer and users decide what their requirements are for operation.

If I, as a manufacturer, say this unit is only good down to zero degrees, then don't test it at minus ten. Don't test it at minus 20. But test it for where the lowest operating temperature is defined.

And then the third area, or Type 1, Type C, or advanced specific requirements, are performance requirements tailored towards a specific workplace use.

And I think we see some living examples of that today with the CBRN respirators being developed for a very specific population to do a very specific purpose.

I think some of you are aware, and we have talked about it at other public meetings, of work that Dr. Art Johnson is doing for us at the University of Maryland, looking at potential requirements for a PAPR used in mining operations.

That type of hazard analysis, as well as determination of functional performance requirements could blend into these types of advanced requirements.

And also health care.

We have talked about in other forums the work that we are doing for the healthcare community in developing a hazard assessment with the Army and Optometrics to address what we think healthcare workers could see in their applications in the hospital setting, and tailor that along with work that we're currently doing with the University of Pittsburgh Medical Center in the Center for Environmental Medicine looking at PPE needs for hospital workers and the healthcare industry.

So, again, I think that the attractive thing to me about this type of concept, or at least

for this stage of requirements, is that we can tailor specific requirements to the different NIOSH workplace sectors that Les had mentioned this morning.

And knowing that, at least initially, we may be addressing very specific sectors where we have done work, where we have done CBRN, where we have done mining, where we have done health care, other -- maybe agriculture or some other sectors, but we can tailor requirements to address those workplace scenarios.

And then in the future, as we become smarter and do our due diligence in identifying hazards analysis and parameters associated with hazards analysis and performance requirements in each of the different sectors, we can tailor and implement those types of modifications into this new procedure over the years to come.

And it may be something that I won't see all the sectors covered before my retirement in another 20 years or so. But with the methodology, I think this would open up the room for advancement

in our standards and be able to address the evolving workplace as well as being able to address evolving technology with respiratory protection.

I wanted to mention, while we don't specifically talk a lot about Step 2 -- and Terry Thornton will address a lot of the parameters that we have -- the technical parameters that we have tried to cover with the Step 2 program in his presentation later today -- but we see a lot of the technical work, when you look at addressing physiological work rates, testing -- high flow aerosol testing for particulates in our gas and vapor testing, or the work that we have done with indicators, whether they're low flow or battery indicators, those types of parameters will transition into the requirements for the industrial standard.

Now, what you have seen in the concept paper -- and please keep in mind that the concept paper is an iterative process.

The concept paper is patterned very much like what you would see in Part 84 today.

And it's my hope that where we are a year from now, when we have a public meeting, getting ready to begin the rulemaking process, is that the concept paper doesn't look like that you see today, that it's going to be broken down into this categorization to give both applicant -- manufacturers and applicants and hardware developers and users the flexibility to address performance requirements and allow the user to select respirators based on protections that they need.

But the Step 2, at least as far as the things that we have worked on and we have briefed you over the past couple of years and that you have seen in the evolution of our concept paper, those specific requirements you're going to see as part of a CBRN respirator that will be identified in the industrial module when it's released.

We're planning on having another meeting in the late spring of next year to discuss the current state of the industrial module.

And hopefully we will have gone through a

couple of iterations of concept papers by then, looking to put out one during next quarter that reflects the categorization idea, and then expand on that prior to us getting together in a public forum.

We're planning on still continuing to use the concept paper and the public meeting process through the beginning of formal rule making.

And at that point then, the structure of how rule making is done will give us a little more focus and a little more formality with regard to the introduction and review process associated with the concept.

And my colleague Mr. Berryann put together a nice presentation that discusses rule making. And I think that would be a good topic for us to present the next time we get together as we further evolve this concept.

But having said that, it's going to be a long process.

There is no short and easy fix that if we have done our technical due diligence and are ready

to go and begin the formal process by the end of 2006, it's a fairly long administrative process to go through the actual release of a module through the rule making processes.

I think the advantage, though, of still continuing to proceed with the concept paper and individual stakeholder dialogue, as well as these forums, is it's going to allow us the opportunity to do a lot of technical clarification and have a lot of technical discussion prior to the beginning of that rule making process.

So when we get to rule making, we're not specifically addressing a lot of technical detail, which tends to bog down the implementation.

And with that, I would like to have Bill Hofmann come up and talk a little bit about what's different in the concept papers that currently exists, and then we will be happy to take your questions.

MR. HOFFMAN: Back in July of '05, we presented the first of the concept papers for the industrial PAPR standard.

And what I would like to do this morning is to go over what those were and what has changed, and what has remained unchanged.

And some of this -- a lot of this is based on the comments that you made at the meeting in July, and the rest of them are based on things that we have learned since that time, or comments that were submitted to the docket that we evaluated and incorporated where we could.

What does remain unchanged is to place all the PAPR requirements in one subpart of Part 84.

And as those of you who are familiar with it know there is no specific PAPR area right now, and requirements are either placed in different sections, or they have been incorporated by policy because a lot of that -- of the design criteria wasn't envisioned when the regulation were written.

We would like to clarify, consolidate and update the requirements.

A lot of times clarification is needed because some of the things in the regulations are

confusing as they're applied to PAPRs.

We do want to incorporate the breath response requirements, which we had before because that is a relatively new development, and it wasn't envisioned when the regulations were written.

We want to keep the existing categories that are the requirements of subparts A to G because they tend to be the general design requirements that apply to all respirators.

And we want to provide provisions for the positive pressure units, which I will talk about here in a minute.

Design considerations, again, is unchanged from July of '05.

Things like accessible switches, the harness design, where it has to be comfortable and held close to the users, the containers, impact resistance.

The low pressure real time indicator, that was originally presented in July of '05, and we're continuing with that concept.

A battery charge indicator, that too was

introduced, and we would continue with that.

And noise limitation we have always incorporated for hoods and helmets to keep the sound level to a reasonable level.

Specific performance consideration, some of this we have revised since July of '05. And now we are considering all PAPRs, as Jon mentioned, to be positive pressure units.

And for the industrial PAPR, we're looking at them as being approved in three flow rating levels, a low level, a moderate level, and a high level. And they would be tested on a breathing machine at the rates, as you can see here.

And as long as they maintain positive pressure throughout that testing, then they would meet those flow ratings, whichever they would be.

A high flow rating could, of course, meet all three. The device could be switchable from one to the other. It could meet only two of them, or depending on what the manufacturer required.

An obvious question is how are we going

to measure that or how will we determine when it goes negative?

And the details of that Terry Thornton is going to touch on when he give his presentation, so, hopefully, most of the questions will be answered.

The filter is unchanged from July of '05, and we're still looking at two filter levels.

We're looking at a PAPR 95, which is sort of a base level filter, and then a PAPR 100, which would be equivalent to the P100 we have now for the one powered units.

One thing that we would do is we would test them at the highest flow rate of the system divided by the number of filters.

And the way we determine the highest flow rate, I will get into that in a minute, but we have changed that slightly, too.

Cartridge and canister testing we have revised that since July '05.

In July of '05, we really only had one level. We have gone back to where it can be

approved for cartridges or canisters, depending on what the manufacturer wants.

We're looking at cartridges to be tested the same as Part 84, except eliminating the one half of the minimum service life test time that are under the little footnote in Table 11, that causes a lot of confusion.

And there's reasons for that because primarily users don't inspect that. They inspect the cartridges for organic vapor, for example, no matter what else it's approved for, to work the same as they would expect for organic vapor.

On canisters, we're looking at changing them, and they would be tested the same as CBRN.

It simplifies it. It updates it. And in my view, it naturally lends itself to the second approval, which would be coming in for a CBRN approval, which we would expect manufacturers to do with a lot of these.

The flow rate is the highest flow rate, again, for testing, divided by the number of canisters or cartridges that would be on the unit.

Other testing we looked at that's revised from July of '05, a CO2 machine test. We're looking at revising that whole test, the test procedure itself, to modernize it and to update it.

We would be testing it at 14.5, which is a sedentary rate, respirations per minute, 10.5 liters a minute.

Breathing gas, human subject test, we would be always looking at performing the test with human subjects where they would walk at approximately three and a half miles an hour.

We're looking at the oxygen depletion and CO2 buildup.

LRPL, we're looking at two values.

The minimum for industrial approval would be now 2000, where what was presented in July of '05 was 10,000, or the manufacturer could request a 10,000 to eliminate the necessity, if they wanted to later submit it for CBRN approval, of having to go through that LRPL test a second time.

This would be as requested by the applicant.

Once you have -- the concept paper that was put on the web, of course, is evolving as we go, and as Jon talked about, the three levels, now the base, the enhanced, and the specific performance level.

But I think a lot of the base concepts in the tests that we're looking at have remained pretty much the same from what I had talked about back in July.

Are there any questions for this?

MR. HEINS: Draeger Safety, Bodo Heins.

I would suggest that you -- that simple PAPR be able to -- for example, you have a very dusty working place.

Why should the customer find such a high efficiency PAPR. It's not necessary for him.

Or if he knows that he only has one or two specific gases, why should he buy an approved industrial PAPR if he only wants a very simple one?

MR. HOFFMAN: Okay. The idea was you could have it approved for whatever gases you wanted, however you want to do it.

We're not saying that -- the CBRN doesn't mean that you have to meet all of the CBRN requirements for a canister, but we're looking at the same test levels that we have for the CBRN.

So if the canister is approved one way, it works for the other.

If you look at the gas mask canister requirements now on the industrial side and you look at the CBRN, the test concentrations and the time are different.

We're looking at them all being what has been presented for the CBRN to make it consistent.

Does that answer your question?

MR. HEINS: Yes.

MR. HOFFMAN: Okay.

MR. SZALAJDA: Let me kind of expand a little bit on what Bill was saying.

I think what we envision with the -- going to the different -- the categorization approach, is that we want to try to provide the flexibility because we recognize one size doesn't fit all.

You know, that when you look at -- and will give you an example. Chip manufacturing, individuals were PAPRs, but they're not wearing them necessarily to protect themselves from the products of the manufacturing process. They're wearing it to protect the manufacturing process from contamination of your products of respiration.

Yeah, that type of requirement, you know, there's no reason for that individual to wear a CBRN canister.

So the standard needs to have the flexibility to provide that type of powered air-purifying respirator capability, but allow the user to work with the manufacturer to select a filtration component that's applicable for that particular workplace environment.

And I think where it becomes contingent on us as far as standards developers and upon the manufacturing community as far as product developers is to work to try to educate the user community as much as possible through guidance documents, through your user documents, through the

training programs to bring up the levels of sophistication of the use so that they can recognize and be able to make those decisions and product selection and not have it necessarily mandated through a one-size-fits-all approach to the development of a standard or performance requirement.

MR. HEINS: So I understood it wrong, that an industrial PAPR does not have to be approved against all the APR -- CBRN APR gases?

MR. SZALAJDA: Yeah. I think that's essentially correct.

I think the thing that we're trying to show is that when you look at Step 1, the foundation of Step 1 is built upon Part 84 as it exists now with the TRAs.

And when you get to Step 2, you're still going to have the same TRAs, and you're still going to go through a series of performance requirements. You're going to have base requirements that address inherent breathing characteristics of the system, other requirements that may look at lens abrasion,

and then you're going to have the CBRN requirements for agent testing and LRPL, and those things at the end.

It's not necessarily all tied together.

And, as Bill was saying, the development of the -- the concentrations that you see in the current concept paper are based on feedback that we have gotten because we still hear from the user community that if you need a canister or if you need gas and vapor protection, they would prefer to have one canister to do everything or do as many things as possible, rather than have to select -- from a cost standpoint of selecting other canisters to meet difference operations.

So we're trying to be sensitive to those types of requirements as we move forward.

And again, with the concept being an iterative process, I think you will see some differences as we move forward.

MR. GREEN: Larry Green with Syntech International (phonetic).

I noticed on your particulate testing,

you were specifying only DOP type testing, and the numbers of markets used to evaluate it, health care and others, they don't have a minimum requirement.

Is there a reason why?

MR. HOFFMAN: Yeah, that's correct.

On the DOPs is much easier to do. It's easier to maintain the equipment.

And if you noticed on the slide, the DOP was an instantaneous test. So the difference is essentially the same as if we were to do salt, except it's not going to load.

The PAPR 100 was the one where we would load it with the DOP.

So if you were to take an N95 now and do an instantaneous test with DOP, the results would be about the same.

So it's initial filter efficiency when tested against DOP.

MR. BERNDTSSON: Goran Berndtsson from SEA.

I think I have some comments here. I understand because it's so early in the development

of the standard (inaudible). There is a couple of things I would like to highlight.

What you are doing now is very similar to what we are doing in ISO. And I think that we should look closer so we that don't end up and get the differences.

(Unintelligible)

The other thing that you should look on is that we are also looking on a higher level of protection on P100. You maybe should consider a higher level of particulate penetration than the P100.

MR. HOFFMAN: Okay. Discussions we had were to possibly consider lower also, looking at a 90 percent efficient filter, but there's not to say we shouldn't look at it both ways.

We do know from the air-purifying, the non-powered one, where we have all those levels, there are very few that stall outside -- you have your N95s and P100s, and there's very few that fall in the other range.

So there didn't either seem to be an

interest on manufacturers or users for them.

But we picked these two because they were the most predominant with the non-powered units.

MR. BERNDTSSON: But I think on the borderline on P100 now you will have people who are doing the total inward leakage test.

They have to be much better across -- we probably should not be making it a possibility late in the day to choose equipment for a higher level of equipment if so needed.

MR. SZALAJDA: That's a good point.

And I also wanted to mention that we have been tracking what the ISO Group has been doing with regard to the respirator standards development, and we're looking to establish that synergy between the work that's being done with the ISO community into the industrial module for Part 84 update.

I thought you were going to get to escape, Bill.

MR. PFRIEM: Point of clarification for me.

MR. SZALAJDA: You are?

MR. PFRIEM: I'm Dale, from ICS --

MR. SZALAJDA: Thank you.

MR. PFRIEM: -- for anybody who couldn't possibly know.

On the 95 percent filter, we have got a 95 percent instantaneous only, no loading, but then also with no dynamic loading, i.e., no silica dust test --

MR. HOFFMAN: That's correct.

MR. PFRIEM: -- of that system at all.

And how do you guys justify that?

MR. HOFFMAN: Because there would be a low pressure monitor in the system.

And if the pressure inside the facepiece drops below ambient, it will alarm the user that he's not getting sufficient air.

So we didn't feel we needed a silica dust test. And also that test has been so --

MR. PFRIEM: No. I'm just saying loading in general.

You're not loading your filter. You're

not loading the system. There's no dynamic loading at all.

MR. HOFFMAN: Right.

But as soon as the air pressure, the air flow drops as detected by the pressure, then it depends on the design of the system.

We feel that the user will know that it's time to get out of that environment.

MR. PFRIEM: You haven't assessed filter denigration under loading conditions, and it happens all the time.

MR. HOFFMAN: Well, we would assume that the 95 filter would be for -- as was pointed out earlier -- for instances where there is not non-oil aerosol, and it's sort of a base filter.

Now, whether we need to get into a 95 tested against DOP in loaded and not, we haven't gotten that far yet.

The initial concerns were, we sort of needed one for healthcare, which would be the 95 or environments similar to that, or we would need sort of what I would term the industrial one, where it's

good against anything.

Most of the people that we have that are users that call, tend to pick one or the other. They said, I don't know how to determine in between, should I just go with the P100 and be safe, and then they know.

And that's usually the one they select.

MR. PFRIEM: I kind of understand, but I disagree because we see lots of filters that you can test instantaneously, and these guys are fantastic, they're great. Then you load them, and they're awful.

So for the record, I would advise that you guys reconsider that.

Also, what's the rational basis for degrading your LRPL down to something on the order of 2,000?

MR. SZALAJDA: I will take a shot at that.

Again, it gets back to, I think with the -- and this is where we appreciate the comments.

You know, in looking at what the LRPL value means, it's an inward leakage. It's respirator fit. It's a number to determine how well -- how much protection the system is affording to leakage, inward leakage of a contaminant.

The leakage that we saw in trying to work to address the OSHA First Receiver Guidance was to link a safety factor on top of that assigned APF that OSHA identified of 1,000 for PAPRs and the healthcare setting.

And through testing at 10,000, we put a -- that's a safety factor of ten on that APF value.

And the selection of 2,000, again, until we get a further clarification as far as a definition of how the systems are used, that could change.

We may have a base requirement that all PAPRs have to meet that as a minimum, but depending on the application, that value changes.

I mean, it's still open to consideration during the process.

MR. PFRIEM: Have you guys done any attempted correlations at APFs as established by Portacount methods, other corno (phonetic) methods, and the LRPL?

MR. HOFFMAN: We're just looking into -- actually, it's in another program area.

But we are looking into Portacount testing as a possible substitute or second test.

MR. PFRIEM: Not as far as a substitute, but just to rationalize your basis for using the 20,000 APF on the LRPL test bed method.

MR. HOFFMAN: Not yet, that I'm aware of.

MR. SZALAJDA: Yeah, not yet.

MR. PFRIEM: You might do that.

MR. SZALAJDA: Okay. Thank you.

MR. SAVARIN: Mike Savarin with Bullard, again.

Ex-ICS by the way.

And I completely agree with what Dale was saying about the degradation of the filters, but that's really not what I want to talk about right now.

I heard something, and I just need some clarification.

If I understand this correctly, there's no loading done on the 95 because the principal is there's a low pressure indicator in the system to nevertheless -- to justify no loading.

But we're going to still have the same load pressure system in the loaded P100 case.

MR. HOFFMAN: Right.

MR. SAVARIN: So we can just remove that as well then. I mean --

MR. HOFFMAN: Well, I guess the concept is different.

The loading on the P100 is to evaluate degradation of the filter rather than to see if it will load down the blower itself.

Our intentions would be if there's a low pressure indicator, that we would actually do measurements to bring the system down to ambient and find out if there's a low pressure alarm, that it does, in fact, alarm when it reaches ambient.

So I'm not looking at loading of the

filter and if the system is loaded down and the air flow stops as being the same, if you will.

We're looking at that differently.

MR. SAVARIN: I'm thinking about how we originally had nine classes of filter.

MR. HOFFMAN: Right.

MR. SAVARIN: And you gave people these options.

MR. HOFFMAN: Right.

MR. SAVARIN: What we saw in the marketplace was definite, was a stratification of the marketplace into two levels primarily based on cost, if you ask me.

There's a risk of the same thing happening here because that's what people are going to do.

We're going to have to be very clear about exactly when you should be using this PAPR 95 versus when you're using this PAPR 100 in a situation that's very clear.

And I'm not entirely sure that that's clear right now.

MR. HOFFMAN: Right. As I'm seeing it just based on the discussion here, we may, in fact, move from two to more than two, but we didn't want to go into the full nine for the reasons you pointed out, that people just tend not to use them, and it's confusing.

Possibly two is too few, but nine seems to be too many.

MR. SAVARIN: I'm just wanting to make sure that we can explain in a rational way to the user what it is they need and why they need it.

MR. HOFFMAN: Yeah. And I would think we would be able to do that with either user documents or in the user's instructions that explains the use of the PAPR itself.

MR. SAVARIN: All right.

MR. SZALAJDA: Thank you, Mike.

And I think this is a good opportunity to reflect back, though, on really the need for identifying your experiences, whether you're from the manufacturer side standpoint, or the independent test lab standpoint, or the user

standpoint in as far as there are specific things that you really think we need to address.

And I think this filtration topic is a good idea.

If there's things that you have seen as a result of your experiences, or market trends, or things of that nature that you think are important for us to consider, then either through individual meetings with us or formal comments for the docket, it's a good opportunity to bring those to our attention.

MR. HOFFMAN: Any other questions?

MR. DUFFY: Rich Duffy, I'm with the International Association of Fire Fighters.

I'm just going to have one quick question because I want to show you that I paid attention to your slides with the real small type.

There was one section in there that we have concern with, and that's the statement that these respirators shall not be used in IDLH environments.

Because we're dealing with a WMD agent or

agents, and, of course, which were perhaps or released intentionally to cause just that, I believe almost every environment, with the exception perhaps of the manufacturing process, the release of these agents will be always an IDLH atmosphere.

Because if they're not going to be characterized. And when they are characterized, it will be much, much later.

I'm not proposing that this be the only respirator protection for a WMD event -- and we will obviously supply respirator -- an SCBA will be meeting this -- but for long-term use at a site, these respirators probably would be appropriate.

But they're not -- the site is not going to be characterized.

So that one statement, at least the statement that was lifted from the other APR PAPR standards saying that they shall not be used in the IDLH atmosphere have eliminated all of the work you're doing developing that standard and all of the money that these manufacturers are going to put

into developing these respirators because there isn't going to be any market for them.

Of course the OSHA and the NIOSH decision logic will show that these respirators can't be used because it's an uncharacterized environment that's IDLH.

So I'm not expecting an answer today, but let's revisit that in this process and then perhaps characterize where these can be made.

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

I know that has been an area of discussion over the years as far as the use of air-purifying technology and IDLH environments.

And we have heard comments both ways regarding potential use, as well as what traditional policy has been, but that's a good point to consider.

MR. DUFFY: And just another quick personal note, if I may.

And I don't work for NIOSH, and I don't work for the government. I work for a labor union.

But I noted earlier today an announcement was passed out about the customer satisfaction survey that the NPPTL is doing.

I certainly encourage not only the people in this room, but all of the people that you work with to please fill that out. I think it's important.

And I don't care how you fill it out, so I'm not lobbying for good grades on this whole thing. But I think if we want to see NPPTL grow as we envision it to be, these surveys are important.

It's not about a hotel survey of how comfortable your bed was last night. This survey is pretty important.

So just on a personal note, I would like to just bring that up.

Thank you.

MR. SZALAJDA: Thank you, Rich.

And, actually, that was a good lead into the last comment I was going to make before lunch, that there are two PCs set up in the back of the room just for you to do that, to fill out the

survey.

So if you could take advantage of that either during lunch time or over the break, I would appreciate it.

Since we're right up on noontime, we will start -- we will start at 1:10 with the PAPR benchmarking, and we will resume at that time.

Thank you.

(A luncheon recess was taken.)

MR. SZALAJDA: All right. I have been told we're five minutes late, so we're going to start.

What we would like to do for the balance of the afternoon is to review some the benchmark testing that we have accomplished in our laboratory since the last time we got together in July, at least as far as identifying for you how that may or may not impact the definition of the performance requirement for the PAPR standards to come.

And then we will have a presentation by Kathryn Butler from NIST and then have some remarks on our closed-circuit SCBA.

With that, I would like to let Terry Thornton lead a discuss now on the PAPR benchmarking.

MR. THORNTON: All right. I hope everybody had a good lunch. I will try not to put you to sleep after those large meals that I know everybody has had.

It looks like everybody is in now.

It looks like we're a little bit behind the time on our presentation. I think I was supposed to start at 11:30, so we will try to get through this in enough time that we can get the closed-circuit and the other presentation done.

I'm up here today to talk a little bit about some of the experiences that we have had in the laboratory.

In the past year, two years we have been working on the PAPR, and we have done quite a bit of work to that.

As we have stepped into this area here, where we're doing the Step 1 and then a Step 2, the majority of work that I have been looking at and

doing is really geared towards that industrial, what is the Step 2 standard or the industrial standard?

So today I'm just going to talk about some of the experiences we have had in our lab, kind of in four different areas.

A lot of the work that I have been doing in the laboratory -- this mic is not the greatest here.

Rich Vojtko and Jeff Palcic both are EG&G engineers. They have been working with me quite a bit in the lab.

Harry Walburg, also he -- I don't know how his name got off here -- but he has been doing a lot of the work here also.

We just accidentally left his name off here.

So let's get started.

I have got four areas that I'm going to discuss a little bit about each, probably not spend a whole lot of time on this.

And some of this is information you got

in the last public meeting. I'm going to rehash it a little bit just to catch up everyone.

The first area is the high flow particulate testers. I know everybody is interested in that.

And this is one of the areas that is also geared toward the Step 1, the current application or the current module that we're going to look at, and will also be used in the Step 2.

The service life tests are really geared towards the higher flow, the industrial. The air flow measurements, I think we talked about that quite a bit last public meeting.

And then alarms. We will discuss that at the end.

And if I can make my computer move here.

High flow particulate testers.

I know I talked about this a little last year. And at that time, we had not -- we had ordered two high flow particulate testers, one from ATI, one from TSI.

As of today, we have both of those high

flow testers in. They are located in what's considered a small building, Building 104 on the laboratory.

It's rather small. It was unoccupied, so we could put both of these testers in there. It's the only thing in there right now.

There's two of them. One from ATI, which is really a modified model TDA 100P, and the other is the TSI 3120 is the model of it.

Both of these high flow testers were custom built for flows -- the specs said flows between 100 liters a minute and 500 liters a minute.

Now, I haven't tested that top end yet, but I think it's up there at the 480, 490, maybe 500 liters a minute. Whether it can go beyond that, we're not sure.

The specs really called for following the P100 specifications as it was written in 42CFR Part 84.

Both testers have been powered up and preliminary studies have been started on there.

DOP has been generated for both of them. We have actually got them going. We have got the DOP generated.

We have done some gravimetric tests.

It did take a little bit of extra time to get these things going for some reasons, and we will kind of go through them.

Some of the experiences we have with this was, first of all, power requirements to come in.

Both of them need a much larger vacuum pump to run than the traditional TSI 8130. And so that larger vacuum pump made us look at the electricity requirements in that facility.

Once we got both of them in there, we noticed one thing, when you get two large vacuum pumps going and both pieces of equipment running, you get some pretty high noise levels.

We tested that. It's somewhere between the 85 and 90 decibels, depending on where you're standing in there, which is not unreasonable. But if you have to work in there all day, it's something you need to be concerned about to try to

minimize that noise for the individuals working in there.

Hopefully, when we get a new location, we get a new building, or we get some other facility to put these in, we're going to be able to move those vacuum pumps out and put them out in some kind of separate office, separate building out there, maybe minimize that noise.

Another idea is if we get more than these two testers in, larger supply, instead of using separate vacuum pumps, we will get a larger vacuum pump to take care of both of them or the four of them, whichever we come up with.

So that's another experience that we had in handling that.

The next thing was the DOP.

As you know, you are generating DOP, and it has to generate enough DOP to cover 500 liters per minute. Each time you operate it, there's a lot of waste DOP.

We thought the laboratory was going to be set up, we could just dump this in a fume hood and

get rid of it. As we all know, sometimes it doesn't always work that way.

So we had a little bit of work on air handling units and how to get ride of that DOP, get it out of the building.

So we have kind of come to some terms on that, how we can discharge it properly.

The gravimetric testing, we have done some preliminary gravimetric test, and I'm not going to say that we have done a whole lot of it yet. We need to do more and more.

One of the things we noticed at 100 liters per minute, we do pretty good.

We get up to 150 liters a minute, we still do pretty good. We can get the DOP on the filter -- and this is flat filter paper.

We get up above 150, around the 200 liter a minute range, we start to see the paper just tears.

It just rips out in different places. The penetration goes up, and so we have to stop the tests.

We have got a couple of solutions for that that we have in mind.

And the first is we're just going to use some thicker paper to maintain it so that it can handle that higher flow.

Another alternative is to use multiple sheets on there, so that when we do the gravimetric tests, we will have multiple sheets to withstand that resistance, or that air flow.

The problem with it is, whenever you add multiple sheets, you get thicker paper, you get higher resistance, and we don't want to build up our resistance in the testing all the time.

One other way we may be able to keep the paper tearing is to add a better support medium that holds up the filter paper.

Right now it's kind of a grid network, it's about three-eighths inch holes, and we think maybe if we go to a screen, we can support that filter paper a little bit better, but we want to make sure that we don't drive our resistance up in this.

All right. Specifically, this is the TSI 3120, the high flow tester, it has an external pump.

As you can see, and if you're familiar with the TSI equipment, it's the same frame it was operated for the 8130.

So it takes up the same amount of space, it's on wheels, you can move it back and forth, you can do your maintenance back behind it, it's a pretty good piece of equipment as far as how much room it takes up.

The pump down at the bottom, the -- after I shot that photograph, I noticed you really can't tell what size that is. It's about three -- two and a half, three feet long, sits on the floor.

The hose is long enough that we could maneuver that in some different places to get it out of the way. But it does create some noise when you're running it.

For the TSI equipment here, the gravimetric tests, we have got some preliminary results. If we're flowing at 100 liters a minute,

we can deposit 200 milligrams somewhere around 12 to 14 minutes is how long that takes.

Now, we don't have enough data to confirm that number. I need more data at that flow to see what that number is going to be, how long it's going to take. And also over time, we want to see if that stays consistent.

The only thing we have to compare that to right now is the TSI 8130.

That takes approximately 23 to 30 minutes to deposit 200 milligrams of DOP at an air flow of 85 liters a minute. So we're relatively in the same range.

The ATI tester that was delivered, like I said, this was a modified version of their 100P high flow tester. It still has the external pump.

The only real difference is ATI built a small box that contains the vacuum pump, some extra DOP, some other parts down there. So that can be sealed up a little bit.

But it still takes up about the same amount of space as the TSI equipment.

This one is not on wheels, so we had to leave it out a little bit, so we could do the maintenance from behind.

But in this situation, it doesn't seem to be any kind of problem at all.

This white tubing off the back of it, was how we get rid of the DOP, the excess DOP. We use a vacuum blower on the back of that to pull it out.

For this one, gravimetric tests, 100 liters a minute, 200 milligrams of deposit, somewhere between 27 and 30 minutes. And that's real limited data on that.

I think I have only run six or seven of those DOP tests, or the gravimetric tests on that.

So whether that number stays right there or not, we will have to see as we run some more data on it.

Again, you compare that to the 8130, again, it took 23 to 30 minutes.

And that's one of our pieces of equipment over in certification. And I scanned that over about the last six months. That was the time it

took, as they calculated that almost every day or every couple of days.

And, again, that's at 85 liters a minute.

So these are two pieces of equipment.

We just kind of wanted to show this, so we know we had talked about them, wanted to know what we had, get some pictures so you understand what we were talking about with the high flow testers.

The next big question is what's our next step for validation?

Since we have already run some, run some DOP, we understand that we are generating -- we think we are generating the right amount. The next step is to size the particle. And this is really the standard, right here.

Medium diameter, .185 plus or minus .02 microns. Standard deviation not to exceed 1.6.

That's actually out of 42 CFR.

We're going to get some equipment in to actually prove that that's the size particle that we have. So that's really our next step. If

either one of the pieces of equipment are not generating the right size particle, we're going to go back to the manufacturer to discover why they're not generating it, what we can do to make sure the right particle is being generated.

But that's very important to hit that particle size because that's what's stated in 42 CFR.

The next step will be some verification of consistent gravimetric tests at the various flows.

Now, here is where we need to look at two parts. For Step 1 of the PAPR standard that we're going to come out with here in a couple of months, the air flows of that is 115 liters a minute and 170 liters a minute, 115 for tight-fitting, 170 for loose-fitting.

So those are two numbers that we want to know gravimetric tests, how much DOP is deposited on those two air flows.

And we want to see how long it takes for the 200 milligrams, and whether that's consistent

when we look at the piece of equipment itself.

Not only the one piece of equipment, but it is consistent between the two that we have, two different manufacturers.

Correlation studies between the high flow testers and the TSI 8130.

The 8130 only goes up to around 105 maybe 115 liters a minute. These high flow testers start at about 100 liters a minute.

So we have got a small window there that we think we can do some correlation testing, take some manufactured canisters, test them on the 8130s, and then test them on the high flow testers at the same flow to see if we get consistent penetration results, if we can correlate those two.

The fourth step is sufficient filter elements run at various flows to give consistent penetration results.

One of the key questions there is how many is going to be sufficient filters.

And really, at this time, we haven't done any kind of mathematical study yet to figure out

how many will be running at what flows, but that's pretty far down the step.

The next -- the last thing we will be doing, since we bought two of these, these are the first two really generated, the first two produced, even if we get both of these to agree with each other, we get the right particle size. We get the right consistent gravimetric tests. We still need to make sure that more of these can be manufactured and can go to that same standard.

It's important for that because we know the manufacturers will be looking at buying some high flow testers.

We need to make sure that they will work if they purchase them from either ATI or TSI. They can take them into their office, into their lab, and that they will give some kind of consistent results, consistent with what we bought.

Any questions on the high flow testers?

And I'll take questions after each of these four different areas.

MR. SAVARIN: Mike Savarin, Bullard,

again.

Oh, it's working. Excellent.

Terry, it's very common to use anywhere from one to five sheets of filter media, just during the correlation verification validation of the performance of the machine. So I don't really see that being an issue.

The breathing resistance thing, we're talking about very low loading of DOP, very short time scale, 12, 14 minutes.

I don't really see what the big issue is.

Tell me what the big issue is with the filter media.

MR. THORNTON: We just haven't put the multiple sheets in there yet.

MR. SAVARIN: Okay. So this is just something that hasn't happened yet.

MR. THORNTON: Yeah. That's really where we are.

We put some single sheets in there.

We did have some tear at about 200 liters a minute. So you have brought me very good news if

you think that we can double up those sheets and put three sheets on there.

MR. SAVARIN: Yeah. I think it should be fine.

MR. THORNTON: Then we should be on our way to solving that problem.

MR. SAVARIN: Thank you.

MR. VIJAYAKUMAR: I'm Vijay from TSI.

On this loading test, why are you loading a flat sheet? Is it to test the concentration you're getting in the system, or are you trying to load your PAPR filters itself?

MR. THORNTON: Well, we need to understand what the time is to deposit 200 milligrams.

That's --

MR. VIJAYAKUMAR: Instead of trying to build up sheets and so forth, why don't you adopt the same practice done in other filter testing standards with flows as much as 2,500 CFM, where they take a sample, so that you don't load up 500 liters a minute through one square foot of media,

thereby you don't run into this problem of tears or added back pressures.

Ultimately, if a system has got enough aerosol coming through it -- and both systems, from what I see the picture, are relatively well mixed, a representative sample will not materially affect your estimate of how much loading time you're going to need.

MR. THORNTON: All right. I think what you're saying is instead of just taking a flat sheet and weighing it, running the whole flow through there, measuring -- actually weighing out the 200 milligrams, we could take a slipstream of that --

MR. VIJAYAKUMAR: Right.

MR. THORNTON: -- five, ten, 25 liters --

MR. VIJAYAKUMAR: Even 100 liters.

MR. THORNTON: -- and do a smaller area.

MR. VIJAYAKUMAR: Even 100 liters.

I believe the 8130 or the equivalent from the ATI and the 100 feet will handle 100 liters a minute on a flat sheet.

MR. THORNTON: All right. And maybe that's another answer. We can try that.

Any other questions on the high flow testers?

MR. RUSKEY: Rich Ruskey -- yeah, thanks.

Rich Ruskey, ATI.

My question was you're running -- you're going to do gravimetric tests at 100, 115, and 130.

Why so low?

In terms of the machine is actually rated for 500 liters per minute.

MR. THORNTON: Yeah.

MR. RUSKEY: I would imagine you were going to look for a point somewhere out near the higher end.

MR. THORNTON: I think we're very concerned about the 115 and the 170 just because that's the flow specifically of some PAPRs we will be testing.

When you get into the second step, or the industrial PAPR, there is where we're going to measure the actual flow rate of the PAPR system and

test the filters according to that flow rate.

So we will have to go up some higher flows.

And so we probably will go up and try the maximum to see what the gravimetric tests shows at that area.

MR. RUSKEY: Well, let me just make this comment, then.

If you're going to be testing filters below 120 liters per minute, they can use the 8130 or the ATI 100P, and it's a less expensive machine.

MR. THORNTON: Yes, it is.

We do have that area where tight-fitting or loose-fitting PAPRs, if they come in with one single filter element, we would have to test them at the 115 liters a minute or 170 liters a minute.

So there is a need even right now with the standards that currently set 42CFR to be able to test at those higher flows.

All right. No other questions?

MR. PITTS: Question.

MR. THORNTON: Can I jump ahead before

you get there?

MR. PITTS: What's that, Terry?

MR. THORNTON: I said can I jump ahead before you get there?

MR. PITTS: If you want to.

MR. THORNTON: No. Go ahead.

MR. PITTS: Did I take that you -- the manufacturers come up with various tidal volumes, various plenums between the filters and the various manifolds that they may come up with, you, NIOSH will still not test that particular PAPR with those various possibilities of tidal volumes in play when you're taking a look at filter performance.

Is that a correct statement?

MR. THORNTON: No. I think we will take into account what we measure the PAPR at.

That's our intentions, not in the Step 1, but in the Industrial Step 2 process.

We're going to measure the PAPR, and then test the filters at that flow the PAPR produces.

Is that what you were asking, or are you asking something about how many filters we can test

as a system?

MR. PITTS: I'm concerned that a manufacturer may come up with a bizarre filter manifold that will affect their performance of filtration, and that we will not test that plenum, that tidal volume, as a system, but will test the filter's performance at the manufacturer's rated liters of air per minute, but we won't have that plenum in play when you evaluate the various systems.

Is that a correct statement?

MR. THORNTON: That -- well, we're not -- luckily we're not finished with our standard out there yet.

That's something that we did -- we have looked at before on whether we need to test it as a system or whether we need to test it as individual canisters.

Now, I think the direction we're going now is to test it as individual canisters with the -- as we look at that apparatus, if you can see that there is -- and maybe we need to test this in

some way, but if you can see that it's equal distribution of flow, the air comes in all three or all four, or all two canisters, if that's equal, then I'm not sure if we need to test the manifold with those different canisters on there, as a system.

Now, if we can look at that and say it didn't look equal, it doesn't look like it's essentially coming in all three or all four at the same time, we need to allow some testing to evaluate that.

And if it's not equal, if that would mean that Canister A of a line of three would be receiving much higher flow than Canister C, when we would do some type of testing to show that it is equal, or maybe we will let the manufacturer give us the information that it is equal.

MR. PITTS: That sounds very prudent, Terry, and we are relieved to hear that.

MR. THORNTON: All right. But that will go along with both particulate testing and service life, gas life testing.

So that kind of hits both things there.

And hopefully we can put enough written into the standard that we will not need to test them as a system, but we will have the assurance that it is equally distributive flow throughout the system, throughout the manifold.

MR. PITTS: Terry, could I make one more statement to Jon?

MR. THORNTON: Yes.

MR. PITTS: Respectfully, we think that handling a maybe a 300-pound non-ambulatory casualty on a decon line, it would be indicative of high air consumption for those decon individuals, or AKA first receivers.

MR. SZALAJDA: Yeah. I agree.

That's -- and I don't know if you were -- after the break, I caveated the answer I had given to Frank earlier, that we could see that the other -- it gets back to for the selection of your respirator, you need to look at the application and your hazard assessment for those handling gurneys and things like that.

You're going to need something that addresses the higher physiological demand.

MR. PITTS: Thank you.

MR. THORNTON: No problem. Thank you.

All right. I think that wraps up the questions on the high flow particulate.

I will go in a little bit of the benchmark testing for service life tests.

And these are some tests -- a lot of these are things that you probably saw in the last public meeting if you were there.

The presentations from the last public meeting are still out on the internet. You can get to those pretty easily.

A little experience with high flow service life testing. And when I talk about high flow testing and service life, you're really up there above that 170 mark that we know that NIOSH now can test at.

When you get up into 200, 250, 300 liters per minute of air flow, we don't know exactly how many units or how many PAPRs are going to come in

with that much higher air flow.

So what we're trying to do is prepare for that. We don't know what that upper limit could be, we think it's up there maybe around 300 to 400 liters a minute.

And that's why our high flow testers were at 500 liters a minute. We're trying to cover that range up there.

Some of the experiences we found with high flow testing is traditionally we use a half inch tubing in our service life test.

We develop the challenge agent. It goes in.

When you take a half-inch tubing, and you increase that air flow up to this 200, 250 liters a minute, you increase the pressure quite a bit.

And we, at first, thought we could deal with that, it was okay, because when you start to understand it more, that pressure needs to really be much lower.

So the higher air flows caused increased pressure in the system. We need to cut that down

as low as we can.

I would like to have it right at atmosphere, but it's hard to push a gas through something if you don't have some pressure somewhere.

So we want to keep it as low as we can. And right now it looks like even at 300 liters a minute, I can get somewhere down to .4 inches water column pressure inside my system, maybe even lower.

One of the reasons that pressure is so important is the humidity values.

We're now -- for CBRN, we're testing at 80 percent relative humidity. If you have got a little bit of pressure backing up in that system there, you just can't generate that 80 percent relative humidity. It's very difficult.

One of the reason it needs to be reduced as much as we can, keep it down to atmosphere, that's also how the PAPRs are used. They're used in the atmospheric condition.

One of the areas we came across is just open that pipe size. We went to some

one-and-a-quarter-inch piping. It's a lot bigger. It's a little bit harder to manipulate.

Right now we're using just regular old piping from Home Depot.

Now, we understand that we may not be able to use that for the actual testing due to the fact that chemicals may react with it. We will have to look at the material of that.

But for right now, we're just trying to get that sized for what we can get away with and still keep a reduced pressure.

One of the ways to not have high flows is by doing the single canister testing in the laboratory.

By taking the air flow of the unit and dividing it by the number of canisters and testing those canisters individually.

The last thing we have looked at, a couple of times when we want some very high flows, high humidity, we went to some dual Miller Nelsons, where we just stacked them on top of each other and we would split that flow in half using two Miller

Nelsons to produce the flow and the higher humidity that we needed to get in there.

When you have a single large flow going through the Miller Nelson to get a high humidity, you have to put a lot of heat into the system to get the water into the air flow.

When you develop a lot of heat, that heat continues on down to the tester. And we all know that our temperature is 25 degrees C that we need to test at.

So that's one of our problems that we have had, we have kind of worked out by using some dual Miller Nelson controllers for establishing that flow and that humidity.

I will cover pretty quickly here some of the benchmark testing.

A lot of this testing has already been reported, and you can see what we have used.

Most of this was done for a tight-fitting PAPR units, already had NIOSH approval. We bought it right off the market. They were both constant flow and demand responsive units. And they all had

two or three canisters that were purchased as a first responder type canister.

For constant flow, at the time we started this, we were going to look at the flow ebb of the PAPR, and we had measured, I have got four different units that I use, I measured the flow, the maximum air flow of those according to the NIOSH standard at the time.

And that was the air flow that we used.

For the demand responsive unit, we were setting it at 300 liters a minute at that time.

Sometimes we tested them as singling canisters. We also tested them as using the manifold or the blower housing for the actual PAPR unit.

And then other times we have a box set up that can handle up to four different canisters, and we would use that.

You will see some comparison in there.

Single canisters, the air flow is divided. Two test chambers, two or more canisters used in addition to the manifold.

This doesn't want to move very fast for me up here.

This was for Model A, and we looked at a couple of different gases for it.

And you can see the three on the left, marked 1S, and that may be difficult to see in the back, but the three over here, this set of data, this set of data, this set of data were all done as individual canisters at that fair flow, divided by the maximum.

In the middle, if I don't blind my workers over there, these are some manifold -- we actually used the manifold of the piece of equipment.

And then the last one was where we just used the box that housed the two or three canisters.

What you can see especially, this is, I think, ammonia. They're pretty even, pretty consistent across the service life.

Model B, again, the gases may not be the same from one model to the next. But, again, we

get very consistent readings across as far as service lifetimes.

And Model D, I guess Model C didn't get too much testing done to it.

But, again, we can see that we have pretty consistent service lifetimes whether we test it as a single unit, single canister unit, or as the multiples either in the manifold or using the box.

What this really gives us a very good indication that we should be able to test all ten of the TRAs at higher flows, and that what's out there right now on the market should be able to pass the test.

One problem we did run too was phosphene.

And if you have done testing with phosphene, the bed depth is a concern here.

Some preliminary data I did a couple of weeks ago, I had a two canister system. I set it up for phosphene, 300 PPM at 300 liters a minute. So there was a box, two canisters were in there, 300 liters a minute coming through, and I got

almost instantaneous breakthrough.

In other words, as soon as I let the phosphene start to flow through, I looked down at the detector, I would get breakthrough from that.

I set that up a couple of times to make sure I didn't have a leakage, and that continued to give that instant breakthrough.

I could take those same two canisters, lower that flow down to about 120 liters a minute, still maintain 300 PPM, the same canisters now, start this test, and the breakthrough would fall less than .3 PPM.

And that's the breakthrough for the phosphene.

So that shows that the phosphene, you don't have to be concerned with the bed depth. And this is something you will have to keep in mind so that it can pass that test.

But I think that they can be made to pass the test.

Phosgene turned out just the opposite. The phosgene I was generating came from a cylinder

of 2 percent phosgene. And I just couldn't find a breakthrough time.

I ran several tests, both multiple and single canisters. At the 30-minute mark, I just stopped the test. I was using up a lot of phosgene, about to hit the end of the cylinder. And I consistently got more than 30 minutes out of that.

So phosgene could not be a problem.

Any questions on any service life benchmark testing we ran across?

MR. SAWICKI: Jack Sawicki from Global Secure.

Can you go back to the phosphene data for just a second? I have a question on that.

MR. THORNTON: Yes.

MR. SAWICKI: At 120 liters per minute, what was the time?

MR. THORNTON: I didn't run it to breakthrough.

MR. SAWICKI: Didn't run it. Okay.

MR. THORNTON: I think I left it on there

ten minutes or so.

And I could see during that time I was less than .3.

I think my detector was recording about .1PPM, so it was less than the breakthrough.

MR. SAWICKI: So you didn't run it out to failure?

MR. THORNTON: I didn't run it out, no.

I think at that moment, phosphene is also one of those gases that's kind of hard to get ahold of in large quantity.

So you're running a cylinder of either one or 2 percent.

MS. DEMEDEIROS: Terry.

MR. THORNTON: Yes.

MS. DEMEDEIROS: Edna DeMedeiros, North Safety Products.

MR. THORNTON: Go ahead.

MS. DEMEDEIROS: Okay. I'm just wondering, are you planning on doing all of the canisters at once once you get your high flow under control, or are you still planning on testing on

the single canisters?

MR. THORNTON: We're going to evaluate them at single canisters.

MS. DEMEDEIROS: Okay.

MR. THORNTON: Yes. That's the intention right now.

I think that's what's actually written in that industrial concept paper.

MS. DEMEDEIROS: Okay. Thank you.

MR. THORNTON: All right. If there's no other questions on that, if there's nobody in the back sneaking up, I saw somebody moving back there, we will go to some air flow measurements.

In this air flow measurement area, we're going to talk about three different things.

The air flow measurement procedure.

The last public meeting, we had put something out on a draft STP on how we would measure some air flows. And I think on the disk that went out this time, there's again another updated draft of that.

That's still in draft form.

That's not replacing the current NIOSH procedure for measuring the air flow.

Talk about the breathing machines.

We have gotten a new breathing machine in. We have got a little bit of comparison data on there.

With that, we did a little bit of looking at some different PAPR models, the same manufacturer, a manufacturer with one model. There was just three of them that we had bought to see how reproducible that data is.

I got a new computer up here.

All right. This is just a quick review of what we talked about at the last public meeting in July.

There our objective was, as you see, to drive an air flow measurement, that we could do both constant and demand responsive at the same time, same equipment.

That methods, we used -- try to do something, get another picture going here so we can see it.

This method that you see described up here, this is really a picture layout of it.

We had -- the PAPRs here, this is the pressure trap, which is between the blower, right after the blower and the hose. That's where we're measuring the pressure.

You can see the facepiece is on here with the head form. And this is the blower assembly, it's actually a vacuum blower. This gives us our air flow.

So we were taking the pressure measurement versus the air flow.

We set this up, and we increased the air flow or the vacuum flow through the PAPR and just recorded the corresponding manifold pressure.

We collected several data points to create a graph. It was a pressure versus the flow graph. It had a good polynomial fit to it.

We have changed a couple of things here.

I just want to describe what we think we're going to do a little bit different. This is through some peoples comments, manufacturer

comments, work that we have done in the laboratory.

This schematic up at the top here really takes the place of that picture, but this is the way we're doing it now, or we think we're going to be able to do it.

We have moved the pressure tap.

We were recording the pressure right here, coming out of the blower into the hose. We have now moved those so that we tap between the canister and the blower.

And we also put a tap at how many other canisters there are, either two or three. That way we can average that out around there.

We have taken the facepiece and the head form completely out of it. We thought that was an error, where we may get some error to come through, so now it goes directly on the vacuum blower.

We still start at zero. We got zero pressure.

We increased the air flow through there, 50, 100, 150, and collect the data point that goes along with that.

And then we can store that on a -- we can put that on a graph to give us a correlation between the pressure and the air flow.

This is really describing this bottom schematic, and you can see, we have left the pressure taps in the same place. That's where we're measuring the pressure.

Put the facepiece on the head form and hooked it up to a breathing machine. The breathing machine will breath at the different breathing rates that we can set it at.

We're also measuring inside the facepiece, which is an important point.

We want to measure inside the facepiece to see that it stays positive pressure, and that's one of the ways we know that it's positive pressure in the facepiece, hence we have a positive pressure PAPR.

So we know it's positive, and we can get the pressure here, correlate that to the air flow.

And this is just a typical linear fit that we have.

You can see air flow versus the pressure and inches of water.

This is actually one PAPR unit, two different days. The red dots are one day, broke everything down, a couple of days later we set it up again, tried it on here, we got almost the same data.

We really had questions of whether it was a linear fittings, polynomial fit.

You can see this is linear, and we got .9987, .9985, that's a pretty good correlation.

If you go to a polynomial, second order polynomial, you get a little bit better fit, and that takes place -- in all the times that we recorded data, we get a better fit with the polynomial.

We have done a little bit of work with the breathing machines, from the pictures up here.

This is the breathing machine that's typically used in a laboratory.

This one specifically we set up fur 103 liters a minute. And this is the breathing machine

that he had purchased, brought in, this is from Warwick Technology.

And it gives us a much better ability to change both the tidal volume and the respirations per minute.

And the reason we like this breathing machine a little bit better, it does -- it is controlled by the computer, so we can collect that data. We know exactly what's going on.

We tell it how to make that wave form.

Where this one is fixed, it uses a Silverman cam.

One of the drawbacks is this is just a sine wave, where this is a Silverman cam.

The bad part of the fixed volume is that this tidal volume cannot be changed.

So once we purchased it, it comes in. We can't change that tidal volume. You could change the respirations, not tidal volume.

And you can see, this is kind of a busy graph here, but the variable is what we can do now, where we can specifically hit the liters that we

need to generate the 103, which is in the standard.

If you compare that to the fixed, one of our problems was with this unit here, 103 liters a minute, but it's 4.1 liter tidal volume.

Well, that's a very large tidal volume, and I think larger than most would resemble a human.

And then change it from the 86 to 103, we could not change these, but they were also in the wrong area.

The 3.43 is a much closer resemblance to an actual human. So we can now run the 103, the 86, and the 40 liters a minute all from one breathing machine.

This data shows at the manufacturers -- a different manufacturer at the bottom, A, B, C and D, and we're just comparing the maximum and the minimums that we got from the breathing machines.

This is the air flow from the PAPR at the maximum, minimum.

And you can see it's pretty consistent, that the variable probably does a little bit better

job in getting an actual air flow.

So you could see they're not equal, they are different, but that's because of the tidal volume we can hit.

You can change this.

This is the same data with D, manufacturer D, and it will do the 86 liters a minute, and it will also do the 103 liter a minute.

That particular piece of -- that particular PAPR will stay positive inside the facepiece at those air flows of 86 and 103 liters a minute.

The last thing on this was just reproducibility of different PAPR models.

There was a concern that if we bought from manufacturer A, we bought three different -- or three PAPRs of the same model, would it be reproducible? Could we measure the air flow consistently for those.

We measured a few of the air flows at 40 liters a minute and then at 86 liters and 103 liters a minute.

This right -- what we're going to show is just really a snapshot. We could run these for a very long time.

This is only a couple of minutes.

And we could superimpose each different PAPR unit to see does it correlate from one to another.

Unit A, and this is I think at a 40 liters a minute. We were actually running another PAPR at another time, we get pretty close data.

The third one, relatively close, not as close as I thought it would be when I first come up with this to look at it.

As we go to PAPR model B, we can see these fall a little bit closer.

In fact, from the back you may not even be able to see the difference, except if you look at the very bottom, this is the trace for Unit A, on top of that is the Unit B and Unit C.

Another manufacturer, again, we have the three traces, very, very similar to the same -- this is PAPR Unit D.

This is the one that will take both the 40 liters a minute, the 86 and the 103. And if we want to know if these are reproducible, you really have to watch the bottom of the screen here because the data virtually lays right on top of each other.

So it is reproducible within a model from a manufacturer.

Any questions on this, the air flow measurements?

Good, I'm wearing you down. I have only got one more place to go to.

We will talk about the alarms just slightly, no longer here.

Low pressure alarm.

In the studies here, that we looked at trying to determine how we would set a procedure to test the low pressure alarm.

Somebody asked me a question a little bit ago, it looked like at one time we had had flow and pressure in the system, in the concept paper.

And all of a sudden we have taken the word "flow" out of there. And the reason for that

is we just think that it's easier, it's easier for NIOSH to measure the pressure inside the facepiece and not the flow.

We had a lot of trouble trying to figure out how we would measure the flow inside the facepiece.

Now, that's not to say that your alarm, if you want to measure the flow to make sure that you still have flow inside your PAPR, that's up to you.

You can do it any way you want, measure pressure, measure the flow.

We, for the testing, are going to measure that the alarm comes on when there is low pressure inside the facepiece.

So this is the way we're going to test it. We think we can do this for both tight-fitting and loose-fitting PAPRs, though we need to do a little bit more work on that.

Hopefully, we can keep this very simple test. Remember, all we want to do is know that the alarm comes on when the pressure inside the

facepiece goes down.

So the simpler the test, the better it is for us.

We're going to do it both room temperature and cold temperature, and we have done some of this testing at both of these temperatures.

Come on laptop.

So we keep it very simple. This is a device we use to do this.

If you can see, this is a PAPR unit over here. All we have is the hose instead of the canister. We have taken the canisters off. We put hoses on there. We can clamp the hoses down.

So we are restricting the air flow that goes into the facepiece.

We clamp the hose down.

Once it comes negative inside the facepiece, the alarm should go off.

And this is one of the tests that we did.

I'm not sure if we did this at room temperature or low temperature, but we can see this is the facepiece pressure. And you can see, it's

breathing up and down. This is done on a breathing machine.

We start to lower it and lower it, clamp it off, and finally we get these three peaks below zero. And when we get three peaks at a certain depth below zero, what is no longer negative in the face -- or positive in the facepiece.

And the alarm did go off in that area.

In fact, I think it went off on the third peak. So the third breath that it was below negative, the alarm activated.

Low battery.

We also want to try -- we're just doing some studies to see how we can develop a procedure to test the low battery alarm.

The battery alarm is to give an alert to the user when there's sufficient battery time for a sufficient amount of time. Right now I think we have 15 minutes established in there.

We probably need to look at that a little bit better to see what kind of time we need, and at what conditions we need it at, is it room

temperature or is it low temperature, and what kind of breathing rates.

All of those, there's very dynamic -- the battery alarm is a very dynamic alarm. All three of these will affect that time.

And so we will have to come up with some way to develop what that time will be, what will be sufficient to alert the user to leave the area.

We have done some testing right now.

The way we plan to evaluate the alarm, it can have an audible or visual or vibratory alarm to it.

We're going to measure inside the facepiece, and that's our measurement.

We will not be taking measurements of voltage across the batteries or across the piece of equipment.

We're going to try to stay away from that.

We're going to have the piece of equipment running at a certain breathing rate, and we will look at the facepiece pressure.

We have done some testing in the laboratory.

We only had to models that actually had an alarm, and so we were pretty limited on what we could do.

Some of the things we did, we evaluated at the minimum recommended operating temperature. We just looked it up in the users manual to see if the temperature was zero or minus ten.

If it wasn't written in there, we just -- for now, we just kind of came up with a number that was relative to the others.

The batteries were not cold soaked. We would cold soak the unit, put the battery in off the charger, take it in there.

That may not be the best way to do it. We're just going to evaluate that a little bit more.

One of the units, you could not separate the battery from the blower. So that unit was cold soaked to do this testing.

What we found out really, right now, we

just have insufficient data to draw any kind of conclusions on how we're going to do this testing, and what we're going to have in the concept paper.

So we're always open to more comments on the low battery alarms.

We did run some at a lower temperature, which is something previously we had not done. And again, we got some inconsistent battery lives on those cold temperatures.

So we need to evaluate -- the first thing we need to do is make sure we know how we're testing them. Then we can evaluate batteries to see if they can pass that, to actually benchmark what's out there.

I'm not sure what you will be able to see from these pictures, but if you have been in our building where we do environmental conditioning, we have four large chambers.

This is set up to do the cold temperature testing, one of the chambers. This vacuum pump, or breathing machine is actually on these brackets here. This the outside the chamber.

So the breathing machine is outside.

All the computers and controls that go along with it to monitor the facepiece pressure outside.

The pictures at the bottom are some pictures of how we're going to do it inside the chamber.

The pressure transducers are inside the chamber. And we have a camera at the bot here. You can see a camera and a microphone, so we can record everything.

The tubing just goes through into this cold chamber, and here is the facepiece we can put it on.

Any questions about any alarms and how we can develop some tests?

MR. DENNY: Frank Denny, from Department of Veterans Affairs.

Actually, it's the presentation before that.

It occurred to me that you were talking about phosphene breaking through almost

instantaneous.

There are certain materials that are on your test list that have an instantaneous or very rapid breakthrough regardless of their concentration?

MR. THORNTON: I think the question is are there some that need a certain amount of resonance time.

Phosphene is one of them.

I'm not sure of the other chemicals that need that resonance time.

I can't think of any right offhand.

MR. DENNY: Well, I just want to clarify what I'm saying, is that there is -- there are -- as you increase the flow rate over the filter, will there be some materials that will not be able to be captured because of that flow rate?

MR. THORNTON: It depends on the material that's inside the canister and the bed depth, how much time you can leave that material in that canister in reacting with the carbon.

So if you -- I think --

MR. DENNY: Will that be evaluated as part of your certification process?

MR. THORNTON: No. It will not be except that it's part of the testing.

We would expose it to the phosphene or all the other chemicals at that concentration and at that flow, they have to pass the 15 minutes.

MR. SAWICKI: Back to your battery life.

There were some interpretation questions before, on -- Jack Sawicki from Global Secure.

Interpretation questions before, where your warning had to be when exactly you had 15 minutes of time left, or when you had a minimum of 15 minutes of time left.

On some applications you might, as a manufacturer, say we would prefer to give a longer time, particularly if you went then to a cold temperature.

The idea of saying okay, you have to have a 15 minute limit of time both at a high temperature and a cold temperature, provides some challenges that I think might be a little too much

to get in this process.

MR. THORNTON: Uh-huh.

MR. SAWICKI: I recommend you maybe establish a 15-minute minimum at your alarm point, and then relate that to temperature independently to allow us some design freedom there.

MR. THORNTON: Yeah. I may have misspoken on that.

I think in our concept paper, right now, that what's out there for the industrial, it is set that way.

The 15 minutes, I believe, is room temperature. And it's specific breathing rates.

And then at lower temperature, a colder temperature, I don't think we designate that time.

I think we either leave it up to the applicant, or we just understand that it is at a lower time.

MR. BERNDTSSON: Goran Berndtsson from SEA.

When it comes to the batteries, it's very, very difficult because as you're changing the

temperature, the characteristics of the battery are going to be changed.

And the question is what do we really want here? Because the other thing is that say, for example, you do some 15 minutes at the 20 degrees Celsius or what that means in -- 64 degrees Fahrenheit, and then the person gets an alarm, two things can happen.

He can slow down and go out, or he can start working harder and go out.

Both of these, if it is a breath responsive respirators, going to affect the time that you come to the end of that alarm, or the end of that service time.

So what you're going to have to do is to work out some kind -- what does the user community really want.

Because if you're not careful, you can end up to get an alarm when there's 45 minutes left, and that's probably not what we want.

You understand?

MR. THORNTON: Yes.

MR. BERNDTSSON: So I think that the communication with the user community is very important to get the permits for how this alarm is going to go.

MR. THORNTON: Yeah. And I think that's what I put out kind of in the first slide, that we are looking for information on that because what is a sufficient time, and at what characteristics, what time of temperature, how, much demand are we putting on there.

So it is very important, and it does change.

We don't want to have somebody go in and have an alarm that lasts for 45 minutes or an hour. If it comes on prematurely, that would make it rather difficult to use that piece of equipment.

But we also don't want to wait until it's got two minutes left to go on, and then you can't escape.

So we are looking for some of that information.

MR. BERNDTSSON: There is one thing you

can do, and that is to make multiple types of alarm, who will give you different alarms of different times.

So in other words, you started with the one alarm, and it is, say, 15 minutes. And when it comes down to half that time, goes all the time, for example, which will give them some kind -- the user some kind of understanding for how close we're getting to the end of life.

MR. THORNTON: That's true.

I mean, we could mandate something like that.

We could also leave it at just a minimum time and hope that the manufacturers come through to put that more technology on there, more than what's actually demanded from us.

MR. HEINS: Bodo Heins from Draeger Safety.

Did you take into consideration that your pressure sensors are also sensitive for cold temperature and probably not calibrated for the temperature?

MR. THORNTON: Actually, we have taken it into consideration. It's something we're keeping an eye on.

The transducers that we're using right now are not -- they are calibrated at the lower temperature, but they're really not rated for that lower temperature.

I think we either have some things on order, or we're looking at some items to make sure that our transducer is able to be used in the temperature we're going to be using it at.

And the calibration will be done at that lower temperature.

Yes.

MR. PITTS: Terry, Sam Pitts, Marine Corps Chem BioIncident Response Force.

In regards to the alarms --

MR. THORNTON: Yes.

MR. PITTS: At what point -- what percentage of loss of like total advertised function have you thought about having the alarms go off at?

Like if I have got a battery life that the manufacturer says last eight hours, and I can blow 300 liters of air per minutes for eight hours, at what percentage of loss of that total function would we have the alarm at?

Have you though about that?

MR. THORNTON: For me, I think it would be better to set it at a certain time, so that somebody didn't have to calculate what that percentage is or what that time amount is for their battery.

All they would know is the alarm is going off, I now have this 15 or 20 minute window to escape.

If you put it on percentage, they would have to know what their regulated battery life is supposed to be and then kind of do some mental calculations on that.

So that may be a little bit more difficult for the manufacturer to hit as spec on that, some kind of test for that.

MR. PITTS: As you step off across the

forward edge of the battle area, and you're going down range, the clock is ticking, and your battery life and your performance is decreasing, and your air flow is decreasing your amount of time.

I was just curious as to what your thought patterns on that were.

MR. THORNTON: Well, I think that's what we're going for as a strict time.

Now, your airflow may not go down depending on the type of unit you have.

So I think there's a lot of things to consider. If you go with a percentage, that the user would then have to know that going in, and that may be more information than they need to be carrying around in their mind at that time.

I would like to see just the knowledge that when the alarm goes off, we have some type of time limit, 15, 20 minutes.

But, I mean, it's a good point, and we could take that into consideration.

MR. PITTS: A filter question?

MR. THORNTON: Yes.

MR. PITTS: Could theoretically a manufacturer submit to you for testing a unit where one manufacturer would have a filter that, say, has 500 grams of fill and another one has 100 grams of fill, and they would be evaluated on the performance and breakthrough based on vastly different filters.

Would that be possible?

MR. THORNTON: I don't think we do testing based strictly on how large the canister is.

The manufacturer submits for a specific certification, either 14G or 23C. I don't think in the PAPR standard we limit or say how much carbon it has to be. And I don't think we changed or testing based on the size of a canister.

MR. PITTS: Okay. So one manufacturer could submit a very large deep bed filter, and one could submit a very shallow based one.

MR. THORNTON: And they still would -- to be certified, they would have to pass the minimum standard.

MR. PITTS: Okay.

MR. THORNTON: Now, if they built a device that surpasses that minimum standard, we would still just set a minimum standard and test it to that.

MR. PITTS: Thank you.

MR. PFRIEM: Dale Pfriem, ICS Labs.

I was going to not come up, but then Bodo posed the question, and I don't think you came to the core of it, or at least not the question I was going to say.

You guys are only experimenting with cold soaking batteries now, but the issue is not just your transducers and their temperature coefficient effects, it's the transducers in the PAPR, and those are definitely -- they have temperature coefficients to them, and it doesn't seem like you're -- you're only taking half of the picture, and you need to take the system into perspective.

So when you had the dialogue with Bodo about the transducers, he wasn't talking about your transducers, but a total system.

MR. THORNTON: What could be inside the actual PAPR itself.

You're right. I was talking about the transducers that we use to take our measurements.

And that is very important.

MR. PFRIEM: Yeah. And that's not what we're talking about.

MR. THORNTON: When you get into the cold soaking of these units, how long they will be cold soaked, will they be cold soaked without the battery or with the battery. I don't think we have come to a real good conclusion on that yet on what we need to do.

We are going to go with the manufacturers' lower operating limits. So they will be able to set that.

And so if you're building a piece of equipment, you may take that into consideration based on your transducers.

But we do need to come to a conclusion whether they need to be cold soaked for four hours.

MR. PFRIEM: But when you guys evaluate

it, or we evaluate it, it has to be a system approach. It can't just be looking at half of the current perspective.

MR. THORNTON: If you want the batteries and the PAPR --

MR. PFRIEM: You would have to.

I mean --

MR. THORNTON: -- all put in there together.

MR. PFRIEM: -- how could you not look -- how could you only -- you know what I mean.

MR. SZALAJDA: Yeah. Let me help, Terry, here a little bit with that.

I think that's the beauty of the categorization system because we will be able to tailor specific requirements to the specific applications.

If you are going to have a cold -- depending on where the system is used, if you're going to have a cold temperature operation, then those enhanced or those advanced requirements can be applied and directed to look at the system

performance at cold or hot temperature.

And I think that's -- you know, when you're looking at the snapshot of what we have done for here, we're still building upon what was considered as part of the CBRN application at that time.

MR. PFRIEM: I understand.

I just wanted to --

MR. THORNTON: I would say that's a good point.

MR. PFRIEM: What I heard, I just wanted to throw out that word.

You can't look at half of the -- because in some aspects, depending on your circuit dynamics and what transducers you're using, those could have a higher, you know, suseptibility to temperature drift than the denigration of your battery.

MR. THORNTON: Right. It's a point well taken.

Thank you.

MR. BERNDTSSON: On the same issue -- Goran Berndtsson, SEA.

On the same issue, that's why it's important that you follow the manufacturer's operation temperatures, I think, because that is where it's doing to -- if the manufacturer is going to know what the maximum and minimum temperatures for those transducers are.

The other important thing is that you follow the instruction in case it doesn't work because it should be in the instruction what to do if you don't get the right performance of the respirator because it is too cold, and then you're putting it on.

MR. THORNTON: Yes.

MR. BERNDTSSON: And you will do that, I assume?

MR. THORNTON: I think there is something written in the standard or in the concept paper about the functionality. I think. I'm not positive on that.

But you're right, that's a good point. We do need to have that just written somewhere.

MR. BERNDTSSON: The system could be

assigned in such a way that it identified that you have a drift in the transducers, and it will not function properly, but get you to do some kind of seals adjustment to get it back into operation conditions before you can start using.

As long as that is identified, then it is not a problem for the user.

MR. THORNTON: That's a good point.

Thank you.

MR. VIJAYAKUMAR: Vijay from TSI.

A little bit of good news, at least as far as the batteries are concerned, I believe there's a lot of data on extreme temperature operation, draining at different rates, recharging.

I don't remember the association. There is an international association of batteries. They have published a lot of data on the RLAs, that is lead acid battery, the techniques, the methodologies may still apply for what we're trying to do.

If you want to set a standard test that's based on other data.

MR. THORNTON: All right. Thank you.

MR. VIJAYAKUMAR: If I have the link, I will send it to you.

MR. THORNTON: Thank you, very much.

All right. If there is no other questions. Okay.

MR. SZALAJDA: I think what we would like to do, since we're pretty close to being back on schedule, I would like to take ten minutes right now, so we can get Kathryn's presentation set up on the computer.

So we will reconvene at maybe 20 of -- 20 of 3.

Thank you.

(A recess was taken.)

MR. SZALAJDA: At this point, what we would like to do is to start the transition out of discussing PAPRs and provide a presentation conducted by Kathryn Butler from NIST, who is one of the principal investigators for a project called Modeling Dissipation of Oxygen from an Outward Leak of a Closed-Circuit Breathing Device, a project

that we have discussed and are collaborating with NIST on, sponsored through the funding that we received through Homeland Security addressing research needs associated with the different classes of respirators that we're working on.

With that, I would like to -- and I had the opportunity to look at this presentation last night.

I think you will enjoy it, and it will give some good food for thought with regard to design of these types of respirators.

So with that, Kathryn.

MS. BUTLER: Thank you very much.

I would like to start by acknowledging my collaborators, Rodney Bryant, down here in the third row, has been looking at this with me at NIST.

And John Kovac, while this was at his behest that we started looking at this problem in the first place.

The closed-circuit self-contained breathing apparatus, the main purpose for them is

to give the first responder extra time in a dangerous environment.

Compressed air tanks contain at maximum, a one-hour supply. If you're under stress, that can become much less than that.

And there are many occasions in which longer durations may be necessary, including if there's an environment that is contaminated over a wide area.

If you are fighting a fire in a tunnel, mines, ships, high-rise buildings, and the CC SCBA enables you to have up to a four-hour use basically because the tank that you're carrying on your back contains pure oxygen.

You're rebreathing the air. You have got the CO2 in your breath being reabsorbed, and you're recirculating your exhaled gas, and constantly feeding in oxygen.

So NPPTL is developing a standard to address the use and CBRN environments.

And there is a concern expressed from firefighters in that if you have this pure oxygen

tank on your back, if there is a leak in a high heat, radiant heat environment, is there a danger special to the closed-circuit system in the fire environment.

So the approach that we're using here is to look at this using computational fluid dynamics.

This gives you an advantage of being able to test a variety of situations with -- very easily.

Once you have set up the initial problem, you can look at various breathing patterns, various geometries of the leak, change the external environment that you're breathing into, and visualization is quite easy.

The model itself will supply the results in terms of what are the behaviors of various kinds of chemicals.

In this case, the oxygen and the full gas, and what kind of velocities are we looking at.

The first step, of course, is to define the complex geometry of a person that's wearing a respirator mask. We address that in a couple of

different ways.

The first thing is that NIOSH has this very nice scanner. And one of the things that I have in my database is my own head, which I can use now to put a mask on, virtually.

But for this study, I used a head form that NIOSH has in their experimental apparatus.

They scanned it in with a 3D scanner that gives you a set of point cloud that contains a set of X, Y and Z points defining the geometry.

I used some software to smooth the whole thing to find where the surface was. And then you can see that there is this kind of rough edge around there.

Well, in the apparatus, that's where you have some clay. And if you're putting on a mask, you need to smear the clay around it.

So in this case, I took off the clay and ended up with a nice head form that I could work with.

Separately, because we didn't have any nice CAD cam files, I took a mechanical drawing

that John Kovac got for me, and I don't know, a month's work, managed to put that mechanical drawing into the form where my CFD code could look at it.

And here you see it in a couple of different views.

And the next thing I have to do is to put the whole thing together. And here is the final setup that I have.

This particular mask doesn't have a nose cone, but, because we're going to be interested in the leak outside of the mask, that isn't necessary for this problem.

You can see a little red line here.

This is a region that I have defined as a leak. So I'm saying that for this particular problem that I will be talking to you about today, I have got a leak around the temple of the person wearing the mask.

So here's the problem geometry that I'm solving for. It's exterior to the head and mask because I'm interested in the flow of oxygen out

into the fuel containing environment.

One of the things that will save me a bit of time doing the study is that I can cut the problem in half, and assume that I have got a line of symmetry through the center of the head, and then, of course, I have defined my leak region.

When you're setting up a problem of this type, what you need to do is to have mesh that's refined around the area so that you're defining things in every region.

And here the critical area is the area around the leaks.

So I wanted to make sure that the velocities that I say I'm defining as coming out of that leak are actually there.

So you can see that it's very well defined around that leak region, and not so carefully defined elsewhere.

And I have also defined the mesh, so that in the area where the oxygen is actually coming out, it's more refined.

The number of elements that I ended up

with is on the order of a half million nodes, which well, basically with every exhalation or inhalation it's an overnight job.

So these are not trivial jobs, but they are doable.

The next thing that I have to do for my problem is to set up boundary conditions.

I have got a plane of symmetry, so basically all the gradients there, the changes in every variable are zero. Around the mask, around the face there is no flow except in my region of leak, where I'm defining a velocity.

And then I have got these outflow boundaries, and I'm simply assuming that there's atmospheric pressure going out through those regions.

Here you see my geometry.

I'm kind of showing off the capability of making animations for this. And this particular end point is what you will be seeing later on because in a lot of cases what I'm interested in is the top down view of what's going on in a plane

that's kind of parallel to the ground.

Now, this slide simply demonstrates that I have got a leak in that region.

You can see that the velocities there have very strong. And as you go to the point up or down from that leak, the velocities go to zero.

The next thing that I need to define is what kind of a breathing pattern do I want to look at.

And for the first set of problems I have done, I'm assuming 15 breaths per minute, half a liter tidal volume, a regular normal breath.

I'm also assuming that 20 percent of the breath is lost through the leak during exhalation only.

I'm assuming that during inhalation, the leak is not open. And that certainly may be arguable, but that's the assumption that I'm making to look at these tests.

With the leak the size that I have assigned here, what that gives me is the velocity, a boundary condition that's one meter per second

during exhalation only.

And you can see the profile that I'm giving it down here.

So that I'm doing now is four cycles, an exhalation and inhalation, then another exhalation and inhalation.

The first set of conditions that I started with was to simply assume that I have got 100 percent oxygen coming out. We were kind of looking for worse case conditions, and this turned out not to be it.

But under a worse case, a firefighter might be standing still, not moving through the space. You would have 100 percent oxygen coming out. And in this case, I'm assuming that the environment is 100 percent propane.

So I'm hoping that you in the back can see this.

I have got, now going through, two cycles. So I have got oxygen coming out and going into the space, kind of moving away. This is on a plane that you can see up here, which is right

about in the center of the leak region.

And you can see that during the exhalation, this is coming out, kind of moving away in a balloon cloud of oxygen. And as it moves out, it's also defusing into the gases around it.

So as it moves away, it kind of becomes much more amorphous with time.

So now what can we say about this, as far as is a firefighter going to be in trouble.

And as a first order estimate of what problems might be run into, I thought of using the concept of the lower flammability limit and the upper flammability limit. Below the LFL, you're in too fuel lean of a region for anything to burn. Above the UFL, it's too fuel rich of a region to burn.

And so those limits kind of define a space, a volume that would be a flammable mixture, and you might have some kind of a problem with it.

Well, in this case, where you have got 100 percent propane coming out, if you came up and looked really close, there are two contours right

next to the head, less than a millimeter away from the head, and those are the regions that define the flammable mixture.

So in this case, where I have 100 percent propane environment, really there really is very little space for any kind of a spark to ignite the gases because the environments is simply so fuel rich just about everywhere, including pretty close to the head.

So I showed this at a conference in October, and afterwards somebody came up and said okay, here is what I would give you for a worse case scenario.

Why don't you take an outer environment in which you have got 10 percent propane, which is just above the upper flammable limit of 9.5 percent, and then spew 100 percent oxygen into that region and look at what happens with that.

So this is the next thing that you see.

And this purple region that you see there, that's the contour that indicates the 9.5 percent propane upper flammable limit.

So inside of that bubble, and you can see as it defuses, you can see the bubble kind of get smaller and smaller, but that, inside of there, is a flammable mixture, if you will.

The thing that I wanted to point out for this, is that if you have a tank of compressed air on your back, and you have the same kind of leak with 21 percent oxygen coming out, you're going to have the same kind of the problem.

This is a very dangerous situation, period. And a firefighter probably doesn't want to find himself there.

Okay. Next thing, an even worse situation. You have got 5 percent propane gas, which is actually inside of a flammable mixture. And so this was the next problem that I decided to do.

Again, 100 percent oxygen going out into this environment.

And in this case, you have got a flammable mixture that you're wandering through here, a very dangerous situation.

And it's hard to see, but there is a green contour there, that is the lower flammable limit.

So in this case, you're actually putting into the environment a fuel lean mixture that, I don't know, I guess it makes you a little bit safer in a region next to your head.

I don't really think so, but this is just kind of looking at this particular problem.

And the problem that I did not do was a problem in which you're moving through a fuel lean environment to begin with, in which case spewing out oxygen, of course, is not going to cause any problems for you whatsoever.

So the conclusions that I came to with this study are that you have got oxygen coming out through a leak in the respirator, that is propelled away from the head region through the vection, through the velocity that it's coming out with dissipates into the environment through diffusion.

You have got a risk of a flammable mixture near the head that you can observe in a 10

percent propane environment, very close to the upper flammability limit.

But this is indeed an extreme environment, and a very difficult place to find yourself to begin with.

In a flammable environment, an oxygen leak may give you a small fuel lean region near the head.

And in a fuel lean environment, you're decreasing the fuel concentration even further, probably not significantly.

But I would like to end by acknowledging our funding sources, of course, NPPTL and OLES, Department of Homeland Security, and a number of people at NIOSH and at NIST that have helped us both to conceive of this project and to think through the problems involved.

Thank you very much.

I will be happy to answer your questions.

MR. RUSKEY: Rich Ruskey, ATI.

First, compliments on your presentation. That was very good. I would like to hire you to do

some PowerPoint presentations for me sometime.

I did have a question, though.

Your boundary conditions for this test using the CFD software, is the air, the ambient air surrounding the head form still? Zero velocity?

MS. BUTLER: We decided that that was also a worse case.

If you're going to have blowing away the stuff that's coming out through the head, of course, it's going to make it less of a problem.

So, yes, it is still.

MR. RUSKEY: That was what my question was going to be.

Given normal conditions, and you had maybe turbulent mixing, that would sort of mitigate this risk.

So the worse case is where? Still air?

MS. BUTLER: Right, exactly.

MR. RUSKEY: Okay, thanks.

MR. BERNDTSSON: Goran Berndtsson from SEA.

I have to agree with the previous

speaker. It's a very good presentation.

MS. BUTLER: Thank you.

MR. BERNDTSSON: Just one question, and that is why do we choose to assume that 100 percent oxygen is going to leak out of the mask?

MS. BUTLER: Well, we thought about that as a worse case condition, as well, but actually I also did a couple of problems with 60 percent and with 21 percent, found that that balloon -- no, I was looking at things that -- 10 percent propane environment, and that balloon defining the UFL contour is pretty close.

It's perhaps an inch or two different.

MR. BERNDTSSON: But I mean, in the mask you would not -- correct me if I'm wrong here.

But you wouldn't have more than 21, 22 percent oxygen in the mask after the mixing chamber.

So it would only be on the high pressure side you would have a high concentration of oxygen. And then you would have a constant flow if it leaks out there.

MS. BUTLER: We looked at some -- at a report that Nick Kyriazi came out with -- and correct me if I'm wrong, Nick -- but I believe the measured results that he had were between 20 percent and 95 percent.

There were some very high ones in the 60 percent range.

MR. HEINS: Bodo Heins from Draeger Safety.

Yes, it's right. After some minutes, middle or end of the service time of the units, inhalation is nearly 100 percent, 95 to 100 percent, so that's not the risk.

We run it differently in Europe to find out if it's dangerous or not. We did it in practice.

We made a test on a dummy head. So a unit operating, and we fitted less tube underneath the sealing line of the mask. And then the heat and flame tests were started, and nothing happened.

So our unit is approved in Europe and complete unit also for firefighting, even if it's

100 percent oxygen and the breathing circuit.

MS. BUTLER: Excellent. Do you have a report on this that I could get a hold of?

Excellent. I would like to talk to you about that.

I don't see anybody else, so I will hand it over.

MR. SZALAJDA: Thank you Kathy.

We're just going to need about 30 seconds to switch over to the other projector, and then we will have our SCBA presentation.

MR. KOVAC: My name is John Kovac, and we're going to continue our discussion on developing standards for closed-circuit breathing apparatus that have been CBRN hardened.

Closed-circuit self-contained breathing apparatus have been deployed in the hands of first responders since the turn of the last century.

Especially in my rescue and recovery operations, if we look at the photo on the upper left, it's from about 1910 for the creation of the Bureau of Mines, that's somewhat later.

Technology of course, has improved and it's still being put to good use by mine rescue teams to mitigate the aftermath of a major mine fire or explosion, try to recover the mine -- rescue trapped miners, and even in some cases fight fires underground.

Today at least in small numbers, fire services have procured these devices and deployed them.

But we need to remember that there's a NIOSH limitation of use, that the apparatus, while approved, they cannot be used where there is direct exposure to open flame or high radiant heat, nor do they satisfy any particular NFPA standard.

And especially, as we will come to see, the positive pressure requirement at high work rates. Nor are they hardened against chemical, biological, radiological, or nuclear contamination.

So our goal is very practical, very pragmatic.

We would like to develop standards for full facepiece closed-circuit self-contained

breathing apparatus that address CBRN materials.

And it's intended use would be for long duration missions involving entry into atmospheres where contaminant concentrations are IDLH, and they may not contain adequate O2 levels.

As a matter of philosophy, we tend to try to develop effective standards, and we work for a three-fold process.

First of all, the standards themselves focus on performance or functionality. They begin with the hazards analysis. They address human capabilities and limitations. And they take into account quality assurance issues at the point of manufacture.

We would also like to see devices, apparatus which are reliable. An apparatus which have to some extent been tested in practical use.

We do this through a public process. And it's public because it's transparent. Our best information is made available to the user community, to the stakeholders.

We identify who they are. We form

partnerships. We interact, and we try to make things better.

Ultimately, standards are grounded on good experimental science, which is reproducibility and repeatability of results, hence we conduct benchmarking to assure that the tests we propose can be achieved, that they're practical.

Where there are gaps in the technology, we conduct research. And ultimately, we submit our best work for peer review so that it can be vetted.

Our accept standard is three-tiered.

At the base 42 CFR, Part 84 dominates.

It establishes the duration of the apparatus. It also imposes a limitation on use.

We would like that to make the apparatus appropriately fire hardened for use at a high radiant heat and flame environment.

You might ask why, if there's a general limitation.

First of all, we might be able to relax that limitation. Much remains to be done in that area.

But, secondly, in the aftermath of a WMD event, the threat environment is fluid. It's contingent. It's emergent.

To suggest that a closed-circuit breathing device that's intended for deep penetration, long duration missions, might not be accidentally contingently exposed to a fire environment would be imprudent on our part.

We would also like to see that the device funtion of higher work rates, which are pretty typical of open circuit devices.

And lastly, we would like to harden the apparatus against permeation and penetration by CBRN materials.

The concept that we're invoking calls for adapting the NFPA open circuit standard, in as much as practical, carrying it over to closed-circuit performance.

Some of the things that we're going to be suggesting are points of contest, points of controversy and debate.

That debate is also welcomed.

There is going to be disagreement. We believe that we can technically work through that disagreement.

It is also our intention to force that technology to grow, to stress it, to strengthen it, make it better.

One of the keystones of our proposed requirements is the use with automated breathing and metabolic simulator for performance testing.

Simulators, computer controlled breathing machine whereby we could program it to execute different sequences of oxygen uptake rates, CO2 injection rates, and the like, so that we're able to look at very, very high ventilation rates, very high performance levels.

We're able to do this in a way that the tests are repeatable, reproducible so that we can compare results and look at performance in a level sense.

We talk about the special requirements for firefighter protection.

We would talk about fabric, flame and

heat resistance, thread and heat flame resistance performance in general of the ensemble.

For CBRN use, we're going to look at operational performance. We're going to have to look at the environmental conditioning in terms of accelerated corrosion, the shock and vibration resistence, particulate resistance, functionality of the facepiece, communications performance, ultimately permeation and penetration of chemical agent and LRPL, to look at respiratory protection level.

And that's about all.

We will discuss these matters further in the following presentation.

We will take any questions, and take it from there.

MR. PALYA: We're sorry for the delay.

Thank you for attending the NIOSH public meeting.

My name is Frank Palya.

The purpose of my presentation is to discussion the special requirements and updates of

the concept standard for the closed-circuit self-contained breathing apparatus.

Some of the special requirements consist of the special requirements for the CBRN use, and the high radiant heat and open flame requirements.

In addition to the base 42 CFR, Part 84 requirements that John mentioned here earlier, their apparatus must meet both the special requirements for the CBRN use, and the high radiant heat and open flame resistance requirements to gain NIOSH CBRN certification.

These are the special requirements for CBRN use, lists here, the operational performance, the environmental temperature operational performance, vibration endurance, accelerated corrosion resistance, particulate resistance, facepiece lens haze, luminous transmittance, and abrasion resistance, communication performance, and chemical agent permeation and penetration resistance to sulfur, mustard (HD), and Sarin (GB) agent, and the LRPL test.

The operational performance must meet

the -- must still meet the requirements in Table 1.

Thank you, just in time, Jon.

So, again, they were -- they still need to meet this performance.

This performance requirement was extracted from the draft 1984, NFPA draft 1984 standard.

And this is the NFPA standard that -- it's not official, but it was a draft, and we're trying to have these performance requirements in addition to the 42 CFR requirements.

We also added a test of functionality at the end of service life alarms to the requirement, and any monitoring systems.

So in addition to this performance requirement, we will test the functionality of the end of service life alarms and any monitoring systems.

There is also confusion to this requirement is that it was supposed to go ahead there and operate for the entire duration, for the 42 CFR, meeting a certain protocol.

I will show you this protocol right here.

As you can see, there's hour 1, hour 2, hour 3, hour 4, and at the different workload rates.

And the workload rates are such, workload A is 100 liters per minute, workload B is 40 liters per minute.

So there was some confusion that they would have to meet for the whole rated period at these workloads rate, meet the operation performance of -- for -- in this table right here.

But this test is just a test of functionality of it. It's not the test of duration.

NIOSH will write the standard test procedures for the NIOSH ABMS, and it is under development right now.

For the environmental temperature operational performance requirement, the breathing wet-bulb temperature in Table 1 was waived, this requirement right here, parameter right here.

The reason it was waived was that in the

high temperatures, it would be nearly impossible for a unit to go ahead and have the breathing gas less than or equal to 50 while it's being tested at 71 degrees C.

And that's the temperatures right here.

During the hot temperature at 71C, and then the hot temperature shock at 71, see. So, again, it would be very difficult to do that.

Another change to the requirement was that the manufacturer gets to set the operational limits of the cold temperature test. So that's established by the manufacturer right here.

Also, in this, there's a requirement -- well, there's a change more to the test method, is that we're going to replace the absorbent and the cooling mechanism in accordance with the manufacturer's instructions, between the hot and cold temperature shock test, right here.

And the rationale behind that is that absorbent degrades at these low temperatures.

Now the challenge may be is to do this all within three minutes because between the

temperature -- they have a hot temperature, cold temperature, you have -- there's a three-minute time frame, and we're looking at replacing the expendables, the absorbent and the cooling mechanism within three minutes, which I would imagine would be a challenge.

We're going to perform some benchmark testing to see how it goes.

As far as the vibration endurance requirement, the only change to this test was that we're going to test, during the vibration portion of the vibration test is we're going to test with an empty bottle.

The weight difference between an empty bottle and a full bottle is really insignificant.

It's less than 1.75 pounds.

So, we really feel that it won't have any bearing on the outcome of the test.

These are the CBRN requirements with no changes. There's no changes to the requirement, no changes to the test, nothing.

NIOSH will develop the STPs for these

particular requirements, and that will be based on the NFPA 1981, 2002 edition.

And the rationale is that by NIOSH having their own STPs, it doesn't bind NIOSH to a particular method or to a particular edition.

And if necessary, NIOSH can always go ahead and change their STPs to reflect the changes of NFPA 1981, if we merit -- if we feel it's worth while to do so.

MR. HEINS: Excuse me. Bodo Heins, Draeger Safety.

It would be of a great effect if you only would change your STPs and the manufacturer is not aware of it.

And it could mean that the unit which passed before could not any longer pass it if you are only changing this in a test procedure.

MR. PALYA: Right.

So you're saying that just changing the NIOSH STPs or keeping them still, as opposed to just calling out a particular standard at a particular edition.

Correct. Because we really don't have control over that edition of a reference to test procedure.

For the chemical agent permeation resistance requirement, these are the following changes.

Again, we're going to test the functionality of the end of service life indicator and any monitoring systems.

The minimum service life for this test, both for the HD and the GB, they're pretty similar, except the HD is a liquid.

But for the minimum service life is equal to the applicant's identified duration, that's established through 42 CFR plus one hour.

And the change is that we were not going to monitor the oxygen nor the carbon dioxide concentrations in the breathing gas in the last hour after all of the absorbent has expired.

The reason is that we're trying to test the main thing, and -- of this test, and that is that the test, the permeation and penetration

resistance of the HD and GP.

Also, there is a change to this, is that the decay rate of the vapor challenge will follow the same profile as the decay rate of the NIOSH CBRN standard for the open circuit.

The closed-circuit is just that, it's closed-circuit.

So in the mixing chamber or the challenge chamber, it's not getting -- the agent is not getting flushed out or filtered out as with an air-purifying respirator or with an open circuit.

So we feel that's unfair.

So we're looking at to learn the decay profile, and then have the same decay profiles to the open-circuit to keep them equivalent.

Yes, Bodo.

MR. HEINS: Excuse me.

The service lifetime is plus one hour.

How will you do that if after waiting four hours, the unit is at the end. Oxygen has run out and all of the CO2 and scrubbers at the end.

Will you refill the scrubber and fit a

new seal in there, or how should it work?

MR. PALYA: Well, again, we're not going to monitor the O2 and the CO2 that last hour.

So it's not going to be critical for it to be --

MR. HEINS: Without oxygen in the cylinders, the unit will not work.

MR. PALYA: Okay.

Again, we're just looking at the -- we're going to have to run some benchmark testing on this.

We haven't got down to that yet, for the benchmark testing. And we just came up with this to go ahead and test the permeation.

MR. SZALAJDA: Excuse me. I think at this time, instead of asking the questions during Frank's presentation, if we can just wait until he is done with his presentation, then we would be happy to take your questions.

Thank you.

MR. HEINS: I will hold it.

MR. PALYA: Okay, please do.

Okay. We only have two more slides here, so.

For the high radiant heat and open flame resistance requirements, there was basically no changes to the fabric, no changes in the requirement or the test method for the fabric, flame resistance, fabric heat resistance, or thread heat resistance.

Again, NIOSH will develop their own STPs based on the test methods from the NFPA 1981, 2002 edition.

And the last one we're going to discuss here is the heat and flame resistance during operational performance.

The current approach that we're going to have is that we're going to use the breathing machine instead of the ABM mask.

Therefore, the apparatus will only have to meet the minimum and maximum breathing gas pressure requirements in Table 1.

The rationale is it's very difficult to integrate the ABM mask with the AFPA open flame and

test apparatus because of the trachea tube length, and the logistics of the ABM mask, with all the tanks and -- the nitrogen tanks and air tanks.

In addition, the test period is very short for this requirement. It's 15 minutes in the test oven and actually 10 seconds for the open flame.

So therefore, really nothing is going to be gained by using the ABMS.

Also, there's a safety issue with exposing a full O2 bottle to the high heat and open flame tester.

But again, NIOSH plans to perform additional testings to validate this approach.

And at this time, I will be glad to take your questions.

MR. SZALAJDA: I just want to contribute one thing regarding the chemical warfare agent testing.

One of the things that we're continuing to address with RDECOM is the establishment or the capability to do -- or to evaluate systems that use

rebreathing technology, and integrate the ABMS into the operations.

And I think you can probably appreciate as a result of the laboratory accident or explosion earlier this year, we're still in the process of working through establishing a walk-in hood for the ABMS to integrate with the Smartman, and allow us to evaluate systems that use the rebreathing technology.

We still need to do our benchmarking in that area.

And I think part of what we were looking to pursue with the additional time is the pattern along with what we did with the other systems that we evaluate during the duration, to make sure that we aren't getting penetration and permeation effects.

I think once we get a better grip through benchmarking as far as what the technology limitations are, we may have to make some clarifications to actual duration of the test time.

MR. PALYA: No questions?

MR. FLYNN: Bill Flynn from Biomarine.

As someone said earlier, I'm back.

I just want to bring up an issue that I have brought up a number of times about breathing resistance and the comparison of a closed-circuit system with the standards for open-circuit and the fact that we seem to be paying a penalty for the fact that our limits are much lower than what is for open-circuit systems.

And that affects us more greatly, obviously, with the new standards with the higher breathing rates.

So we still want to have that to be considered.

MR. PALYA: Well, I think -- let me just back up, and maybe this will help, Bill.

This is what you're referring to; right?

MR. FLYNN: Well, what I'm referring to is the fact that you have a high limit there for the CBRN standard, the draft standard for now, but to meet the 42 CFR, our limit is two inches.

And whereas with the open-circuit system,

you have a limit that allows for the static pressure in the face mask, which give you a higher upper limit.

And I assume at this point when the changes were made to the standard, there was no consideration for that static pressure. It doesn't really exist in the closed-circuit system the way it does in the open-circuit system.

So we still feel as though we're paying a penalty there compared to an open-circuit system.

And you do have your earlier slide that says we're trying to mimic what we're doing with the open-circuit systems.

So that's just a statement, not a question.

MR. PALYA: Right. Noted.

MR. FLYNN: Just if I can have a point of clarification, that the draft standard then will have no reference whatsoever to NFPA.

It will just be STPs?

MR. PALYA: Right.

MR. FLYNN: So we won't see any NFPA

references at all?

MR. PALYA: Only maybe the test equipment, okay, but we're going to have our STPs written independently.

But taking most of it based off of the technology.

MR. FLYNN: The question I always ask, any update on the estimated costs.

You had a good estimate on the cost earlier on the PAPRs. I wish our cost would be like that.

Can we get that cost?

MR. PALYA: No. Not at this time.

And I will tell you why because we're still going through the benchmark testings.

MR. FLYNN: Okay.

MR. PALYA: And we need to go through each one of these and go ahead and fully understand these, write the STPs, so we can go through each step and document the little snafus that always pop up, and take that into consideration.

We don't want to go ahead and give you

some false cost and then we will -- just bear with us until we start marking through these benchmark testings.

MR. FLYNN: And the last question is about benchmark testing.

Do you have a latest time line on that, or when you're expected to be done?

I remember in the past, the biggest problem was the walk-in hood at the test facility. Where are we on that walk-in hood?

MR. PALYA: Well, we just contacted them, and they were going back and forth, some internal issues on funding and everything, and it's back on again.

That's going to probably -- I'm thinking within the next three months for the walk-in hood.

But there's a lot of the other tests on benchmarks that we need to do as far as the -- we need to do the vibration test. We're almost ready -- that's almost ready to be completed.

We're going to do the environmental testing, and then some of the communications, a

lens abrasion test. Now, that's pretty well standard tests that have been conducted.

So we should have some idea of that, but we would still like to go ahead and do some benchmark testing on that, and even develop our own STPs for that.

MR. SELL: Sit down Bodo. I'm first. I'm first.

Bob Sell, Draeger Safety.

One thing on, I think, the next Table B that you have your work rate, workload starting out at A, which is the high rate.

I would suggest that you maybe flip those around and maybe look at a 40 liters per minute work rate, on the assumption that, you know, emergency personnel would probably be staging and prepping before they go jump into a higher work rate.

A suggestion there.

On the slide where you discussed the heat and flame test. You said you weren't going to use a -- without a full O2 bottle?

MR. PALYA: I think that was the vibration test.

Well, hold on.

MR. SELL: That one too, with a full.

Okay. I'm sorry. I didn't read right.

And then, again, on the chemical agent, you're going to go back to using the automated breathing simulator with the walk-in chamber.

MR. PALYA: Yes. We're going to go ahead and evaluate that because we don't know what kind of chemical reaction that will be with the absorbent or if something that gets contaminated.

We want to keep that as realistic as possible. And we think that's a very important feature in the test.

MR. SELL: Okay. Go ahead, Bodo.

MR. HEINS: Bodo Heins, draeger Safety.

Again, I want to come back also to the 51 millimeter for the breathing resistance.

At the beginning of your standard, you are listing one of the paragraphs as 42 CFR.

My suggestion, again, is only delete the

two paragraphs where the breathing resistance is mentioned, which is 1991.

If you cannot do so, then hesitate to make changes to the 42 CFR. You can be sure that changing the 42 CFR, which means two years, maybe less, than new units being developed by a manufacturer, which cannot fulfill both at this time.

MR. PALYA: Noted, thank you.

Okay, thank you.

MR. SZALAJDA: While we transition -- I'm sorry, go ahead Mike.

MR. KREUGER: Mike Kreuger at EG&G Technologies.

You had mentioned the end of service time alarm indicator, and then you also mentioned other monitoring devices.

Give me an example of what, what are you talking about?

MR. PALYA: A heads up display, HUD.

MR. KREUGER: Okay. Pass devices, I mean is that any of those things.

MR. PALYA: Pass devices, yeah, and anything, monitoring systems.

Yes, sir.

MR. KREUGER: Okay, one other thing.

You're going to use a metabolic simulator to evaluate the performance of this.

Has anybody thought about how a user in the field would maintain and test this equipment to ensure that it's work properly?

MR. PALYA: Go ahead.

MR. KOVAC: Mike, they're commonly deployed for mine rescue teams, and they're and prepared on an as-needed basis.

So that technology, the practice, the experience, and the trading is there.

MR. KREUGER: No. I mean, but how would you test this?

Like with SCBA, with open circuit, you test it manually. How do you test this if you don't have access to a metabolic simulator?

MR. KOVAC: The metabolic simulator doesn't have anything to do with the preparation of

the devices.

MR. KREUGER: Okay.

MR. KOVAC: Okay.

MR. KREUGER: All right.

MR. BARG: Brent Barg (phonetic) at Samms.

I just want to add one comment.

I think what's really important given the way that the absorbing material works in closed-circuit, that you should probably determine based upon your operating temperature that you're testing at, to consider an activation prerun, prebreathing time, prior to starting your test procedure because otherwise you run the risk, especially at cold temperature, as to whether or not you're going to have an adequate O2 level inside that circuit.

MR. PALYA: Yeah. I think that's what Bob's concern was because at that higher work rate, it doesn't give it time to react, so at least at the lower work rate, I think, that's on the same principle as what you're saying.

MR. BARG: Well, not really.

What I'm saying is that I think that you have to establish a prebreathing cycle prior to initiating the test period.

Because if you don't do it, you're going to run the risk of having a lower rate.

MR. PALYA: Okay. All right, thank you.

MR. SZALAJDA: While we still have a captive audience, the ladies from EG&G Management are in the process of passing out a survey that we would like you to complete.

And upon completing that, I have a couple of closing slides, and then we will open the floor for open comments.

So at this point, I guess, as you get the survey, if you can complete them, pass them down to the center isle, and then we will collect them from there. Maybe take about two or three minutes to do that.

If you could finish and pass them to the center isle, and we will collect them from there.

And I would also like to encourage you,

if you didn't get an opportunity to complete the NPPTL customer satisfaction survey, the laptops running the program are in the back corner of the room.

Also, you can contact Mary Ann D'Alessandro about information. It can be accessed through the internet.

And we can provide that information for you, as well, if you would be interested in filling out the survey from that standpoint.

Now, we had a former director of NPPTL, and it would take a lot of you to guess who that is, but sort of at this point there's a mild feeling of euphoria amongst the people who are doing the presentation that would make you want to burst into song.

And he was good at doing do-wap, but I don't share his auditory tones for carrying off a song, so I'm going to hold back at this time.

But I did want to leave you with a couple of thoughts, at least as far as where we see the program going forward from this point and get your

feedback with regard to the implementation strategy that we have laid out today for the systems.

But with the CBRN PAPR, the approach is to use our regulatory authorities and implement Step 1 by policy.

And in the current environment that we currently are conducting our business in, we think that this is going to be the last opportunity to introduce a standard using policy provisions, at least with regard to the CBRN requirements.

But assuming that we have done our due diligence and obtained our agencies approval in going ahead and releasing the standard using the policy authorities, we expect that the standard will be completed and letters to manufacturers and stakeholders will be sent out sometime during the second quarter of 2006, which is the January through March time frame.

Again, as I mentioned this morning, if you are a PAPR -- potential PAPR applicant, now is probably a good time to get your Part 84 application in order, and get it submitted so that

when the standard is approved, we can move in a timely manner on getting the CBRN related testing accomplished.

Along with that, the other key piece, the technical issue that remains to be addressed is the development of the capability for doing the aerosol testing.

I think Terry provided a very good update on that this afternoon.

But once that capability has been established, then we would be able to look at testing single filters at these higher flows.

PAPR Step 2, again, part of what we discussed today being a function or being a portion of the industrial respirator module that we're going to be working on, in particular being a specific type of requirement in that standard.

A lot of technology has been explored over the last couple of years.

There's still more work to be done, but we envision on completing that work during 2006, leading us to starting the rulemaking process by

the end of this year.

What about the rest of the respirators that we're working on? During the closed-circuit presentation, we didn't discuss implementation.

And what we envision doing in trying to complete during the course of this year is to combine the remaining classes for respirators, the closed-circuit SCBA, the combination units, and also supplied air systems into one CBRN module, which we intended to develop and release by the end of 2006.

And this way, we will tailor, still using the concept development and public process, the concept paper, development and posting on the web to share our ideas with you with regard to what those performance requirements may be.

But combining them all together in one condensed module that will be released and implemented through the use of rule making procedures.

And to reiterate, as far as we appreciate your comments to the dialogue and the feedback that

we get at these sessions is very valuable to us.

Obviously, with the CBRN PAPR time, and I have heard from other people, time is of the essence.

So if you have specific questions or concerns regarding the requirements of the CBRN PAPR, I would really encourage you to submit those within the next 30 days to the docket.

If they are things that formally you want us to consider as part of the concept before we finalize it as the standard, again, the docket number is ten for the CBRN PAPR.

The industrial PAPR Docket No. 8, and the closed-circuit SCBA, 39.

And with that, I will take any questions that you may have about the implementation of the standards, and then following that, we will open the meeting for comments from the floor.

MR. BERNDTSSON: On your first -- Goran Berndtsson.

On your first slide here, you had finalized or the policy, Second Quarter, then you

say January to March.

What is it, second quarter or January to March?

MR. SZALAJDA: March is the third month of the second quarter.

MR. BERNDTSSON: No. That is the last month of the first quarter.

MR. SZALAJDA: The federal fiscal year.

MR. BERNDTSSON: Oh, I see.

MR. SZALAJDA: So it's January, February, March.

MR. BERNDTSSON: Apologize.

MR. SZALAJDA: Those are the types of questions I appreciate having the opportunity to answer.

Any other comments?

Okay. With that, I would like to open up the floor for any general comments regarding our CBRN standards development work, or the work concerning the industrial PAPR.

MR. SMITH: Simon Smith, commenting on the standard, just taking advantage of the venue to

do two things.

One is to advise people of the forthcoming conference of the International Society for Respiratory Protection, ISRP.

I have a brochure here.

This is going to be in Toronto, Canada for the last week of August, next year. And it is for respiratory protection for healthcare workers, emergency responders, and for emerging hazards.

And I hope everyone here is a member already, but if you're not, the membership is $45 per year, and the conference is open to everyone.

Again, that's Toronto, Canada the last week of August, next year.

I have some brochures if anybody would like them.

The other thing I would like to comment on -- and I'm afraid it is not relating directly to today's discussion -- but is some of the work that has been done in Canada on CBRN issues.

And I just thought it might be worthwhile having an update on that, as it does have some

bearing on questions that have been asked today.

What has been doing is something called the chem bio and radiological nuclear research and technology initiative.

It's a Canadian government initiative for addressing response to potential CBRN events.

Is it all right if I turn around?

MR. SZALAJDA: Yes, sir.

MR. SMITH: And it's to address three main areas, those being grouping laboratories, acquiring equipment and research from fundamental through to technology taken into the field.

I have been on a team that is entitled PPE for First Responders. It's project No. 29.

There is a website I can give you. Unfortunately, it's probably quicker just to do a search on CRCI and go from there.

But the website for the overall program, and there are links into individual subprograms is www.crci.drdc-rddc.gc.ca/en.

Sorry about that, it's because it's in both languages, and the slash at the end is for

English. You can have it in French, if you wish.

Continue being involved with is being led by the Royal Military College of Canada, and some of you may be familiar with Dr. Huber Dixon there, who has done a lot in the way of testing PPE ensembles.

It's a team of both and government and industry partners, and involves participation from first responders groups as well.

And the objectives have been twofold.

One, to produce guidance documents for use by first responders. And the second, to look at equipment performance and address needs there.

With this program, we're coming to the last year of four years.

And in fact, there are two programs spinning off this, that are going to continue.

So I'm just going to go ahead to on what's coming out.

We do not have the guidance document fully issued yet, but it is being circulated for approval among the first responders.

And this will endeavor to address guidance for first responders needs.

What is being done is that the role of the first responders have been identified in detail, along with the work rates that are anticipated for those job.

We have done some exposure on them, and from this, on the PPE side, looked at respiratory protection, skin protection and the overall issue of ensemble protection.

This has involved the use of a test chamber, which is at the Royal Military College.

We have looked at providing data to support filter level development because it is being undertaken by one of the parties, and also, fit testing.

The outcomes that are perhaps different from some of the discussions from NIOSH, we have based this very much on the emergency response training guidelines.

And produced some broad guidelines of necessity addressing the issues for the zones in

those guidelines, the isolation protective action and support zones.

For the approach to the scene, we have to face the fact that the air-purifying respirator is effectively going to be the primary resource available.

It's nice if everybody has SCBAs, but they may not have them as needed for an emergency, and we have to face the fact that air-purifying respirator use under other IDLH conditions is inevitable.

So the next stage of this program will address writing standards for the use of APRs under such circumstances, and address the performance requirements that are necessary.

At the present time, we can identify that equipment similar to the NIOSH APR standard, the CBRN APR standard is going to provide the best short term protection. But we want to look at modifying that.

Once the scene is established, we have determined there should be a break at around the

200 kilogram level of material. Above that, SCBA is going to be mandatory in the support zone and protective action zone.

But below that, again, air-purifying respirators are likely to be permissible.

We have looked at fit testing also. And some detail has gone into this. In fact, it's been carried on into a program for the Canadian forces.

And some evaluation has been done of current fit testing protocols and modified protocol developed using very high challenge levels of particulate.

And also some special equipment involving active telemetry of fit. And that's for inside and outside counts, using sedirometers (phonetic) on the mask and video so that you can gain a real time measurement of the fit as you view the action that the worker, or in many cases soldier is undertaking. This is being developed by the British forces and adapted for use in Canada.

But for the fit testing, we're looking again that target protective factors are likely to

be greater than 10,000.

For further consideration of APR use, we're looking also at the test chemicals, recognizing we needs to have an all hazards approach.

We have done an assessment based simply on chemical toxicity and volatility, respecting the fact that terrorists may not rely only on availability of material.

This has come up with a list of about 25 top compounds. Some are the test representative agents the NIOSH has been using on those lists, and some are not.

So, again, the next stage of this program we will actually look at modifying filter performance, if necessary, to address these chemicals, evaluating filters, and potentially proposing a revised standard for them.

So that's what's on the cards.

There is stuff coming out probably in the next three to six months on the guidance side.

And we anticipate that the further

programs will continue into the next two to three years. Thank you.

MR. SZALAJDA: Thank you, Simon.

And I guess if anybody has any specific questions to Simon, if you could just meet with him following the meeting, I would appreciate that.

MR. SMITH: Thanks. Oh, and I forgot to mention, for the conference, the website there is www.isrp.con.au.

And I have some of these brochures if people would like them. Thanks.

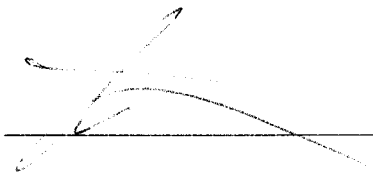
MR. SZALAJDA: Any other comments at this time?

Okay. Well, with that, I would like to wish all of you, even though it may be politically incorrect, a Merry Christmas, Happy Hanukkah, Happy Kwanza, whatever your beliefs may or may not be, and best of luck in the new year. And we look forward to working with you in the year to come. Thank you.

(Whereupon, the proceedings in the above-captioned matter were concluded at 4:02 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.



Joseph A. Inabnet

Court Reporter