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

Wednesday, July 20, 2005

DISCUSSION OF CONCEPTS FOR STANDARDS FOR A MULTI-FUNCTION PAPR

Commencing at 8:30 a.m. at Holiday Inn Select, Pittsburgh South, Pennsylvania.

P R O C E E D I N G S

MR. BOORD: Good morning. I would like to welcome everybody to this second day of the NIOSH NPPTL public meeting to discuss our concept development requirements for CBRN respirators and industrial respirators and CBRN user guidance.

Yesterday, the topics that were addressed were the CBRN closed-circuit self-contained breathing apparatus, and the CBRN respirator user guidance documents.

Today, the focus of the meeting will be on the powered air-purifying respirator, both CBRN and industrial.

And my name is Les Boord.

I'm the acting director for NPPTL. And I certainly extend a welcome to you and encourage you to participate in the meeting today.

The process that we go through with the public meetings and the concept development is a very interactive process, as I'm sure most of you are aware.

It's a two-way communications and

feedback. And I think that over the course of time, those of you who participate in this activity do see the effects and the benefit to this type of dialogue which is created in this meeting.

The continued need for developing CBRN type respirator standards, I think, is obvious and evident by the list of continuing threats of terrorism identified on the slide.

Obviously, we all realize the impact of the incident two weeks ago in London, which heightens the alert and the continued interest in the process that we're undertaking.

So from our perspective, the need continues and will continue into the future.

And the process and the discussions and interactions that we have today are very beneficial towards preparing for the types of threats that are shown on the screen.

Yesterday, we talked a little bit about historical results of the program. And I think most of you are probably familiar with that, the number of CBRN SCBA approvals, approval holders,

and APR approval holders and so on, so I won't go through that.

And with that, I will turn the meeting over to Jon Szalajda, who will run down the planned agenda for today and start the discussions.

Thank you.

MR. SZALAJDA: Good morning.

As Les mentioned, the focus of what we really want to cover addresses the development of the CBRN standards for PAPR as well as for the industrial PAPR.

And at this point, it's important to notice -- or for you to note that, as we move forward, that, you know, we are following an informal process using concept papers to share our ideas and current thoughts regarding what the requirements should be and the test procedures and methodology supporting the development of the concept papers, which will ultimately become requirements.

But at this stage, they're still concepts. You know, until NIOSH implements other

documentation to formalize the information that you are seeing, it is purely for discussion purposes.

Our approach for conducting the meeting is twofold.

And in general, one, the first part I wanted to focus on the presentation of work that we have been conducting over the last several months related to the CBRN PAPR.

We're also going to address this afternoon our initial attempts at developing a concept paper for making a formal modification -- or the process will lead to making a formal modification to 42 CFR, Part 84, to define the requirements for industrial workplace PAPRs.

Part of the presentation as well is going to address some of the research that either we have been doing within NPPTL, or some of our other partners have been conducting for us in support of the PAPR program.

And those include research that's being done within our technology branch as well as other partners.

And this afternoon, you will see presentations by Frank Kho for Art Johnson, who unfortunately wasn't able to make the meeting today, and Mike Allswede from UPMC.

And I think of interest with these two programs, as far as how ongoing research being conducted in this area supports our CBRN and industrial PAPR concepts.

And also, it's also of interest to note that the research, as well, when you look at certain aspects that Frank Palya will be talking about and doing a hazard assessment in trying to identify the hazards that an individual wearing a non-tight-fitting system could see how that hazard assessment is being translated into other requirements that are being used within the industry.

Also of note, you know, in trying to get your feedback, we do have a window available at the end of the day to address comments. We have one presenter who -- or one presenter that was requested to provide some information or at

least -- or their perspective on the industrial PAPR work that we are going to be pursuing.

But if you would like to make a presentation, if you could just please see me at some point during the day and let me know what you want to talk about, and we can incorporate that into the agenda.

A little bit about the meeting logistics. As far as the information that was available in the back of the room, there was an agenda as well as a CD.

The CD contains information relative to what we're going to be discussing today. It contains the concept papers for the PAPRs as well as the guidance documents that were discussed yesterday, and the closed-circuit SCBA.

We also included the standard test procedures -- or we included links or references or the actual documents to 18 of the 25 test procedures that we're considering for the CBRN PAPR.

In instances where we were using existing

STPs, we did not provide those documents. Those have been made available in other forms or can be obtained from NIOSH at your request.

But we did contain the STPs for procedures that we have worked through for the CBRN PAPR program. And those are available for your purview and comment as well.

A couple of other administrative features that -- we had a slide earlier about cell phones. If you can just make sure that your cell phones are on vibrate or in silent mode. We would appreciate that.

We also have in the back of this room, NIOSH -- or the NIOSH division has a monthly newsletter which is issued via email.

And if you would like to receive -- if you currently don't receive that publication and you would like to receive it, there's a card you can fill out and put in the box in the back, and you will be added to the mailing list.

And the significance of the e-news is it provides an overview of what's going on within the

institute, not just what we're doing within NPPTL, but within all the other divisions within NIOSH.

And I think it would be worthwhile for you to spend some time looking at that during the course of your monthly work.

Also, we had some flyers in the back related to a conference that NPPTL is, I don't know if we are co-hosting, but we're involved with or sponsoring at the Virginia Tech in Blacksburg in October related to personal protective equipment and emergency responders.

That is also available -- that information is also available through the website, and there are some fliers regarding that conference in the back of the room. I believe the dates for the conference are October 16 through the 18th.

And finally, during the course of the day and the presentations, you will have an opportunity to make comments on each of the speaker's presentations.

We would ask that you come to the microphone in this aisle and state your name and

affiliation, and then pose your question. The meeting is being transcribed for the public record and will be available through the docket office.

If you did want to obtain a copy of the transcript, you can make your request to the NIOSH docket office, and a copy of the transcript will be provided.

The presentations from yesterday and today will be made available on our website in about two to three weeks.

For the purposes of what we're going to be discussing over the next several hours, we will be collecting and soliciting comments from our stakeholders regarding the current concepts that are defined in our concept paper.

For the CBRN PAPR, the docket number that you should reference on any correspondence, informal correspondence, to NIOSH, is Docket No. 10.

There's a couple of different ways that you can get in touch with us between using the regular mail or email or even by fax.

So just, please, if you are making a comment related to the CBRN PAPR program, reference Docket No. 10.

Usually we provide a little bit of a historical basis regarding our process for the people who are new to the public meeting, and I think I would be negligent if I didn't mention at least a few things regarding the CBRN standards development.

This work has been done in a partnership beginning in 1999. And that partnership has included not only federal agencies in establishing working relationships with OSHA and DOD and the other federal agencies, but also with standards development partners such as NFPA or ANSI or ASTM organizations, as well as involvement with user groups.

You know, we play an active role in working and listening to such trade associations as IFF, IFC, chiefs of police.

We are also working with the Interagency Board for Equipment Standardization and

Interoperability, which is a group chartered to look at personal protective equipment for emergency responders.

Our program -- we have had an active program since 1999.

Obviously, since September 11, the focus of the program has been accelerated with the emphasis on providing protection for emergency responders.

And, really, that was our laboratory's focus from the time we were provisionally established in 2001 for this program, looking at a translation and establishment of existing regulations or requirements or standards into identifying requirements that could be used in protecting an emergency responder at a CBRN terrorist event.

And since that time, we have come a long way. And I think there has been some novel work that has been done by NIOSH to address technical issues that have arisen, and we have talked about them in other forums.

I think one thing that I would like to note when I give this presentation is the relationship that we have established with our RDECOM, with the Department of Army at Aberdeen proving ground.

And in particular, Edgewood Chemical Biological Center, who has been a very active partner in supporting us with the development of the requirements for the standard as well as providing test support to us.

And for the first time, we have talked in the past, or NIOSH has talked in the past regarding using third-party laboratories for certification purposes.

This was the application of that philosophy of using the facilities at ECBC for chemical warfare agent testing and laboratory respirator protection level testing to actually be our third-party test agent for doing that work.

We have also developed and continued to nurture partnerships with the National Institute of Standards and Technology, who is the portfolio

manager for the Department of Homeland Security, in developing a suite of standards to protect emergency responders at CBRN events, not just respirators, but also addressing personal protective equipment, clothing, protection, and decontamination, not to mention other programs.

And this has been a very supportive partner for us in relaying and providing project support, you know, first through funding from the Department of Justice and National Institute of Justice, and now through the Department of Homeland Security, which allows us to do the research and technology explorations that are necessary to bring the standards forward.

What's the impact of CBRN standards?

I think from the user community, it's -- there's one bottom line, the fact that, you know, the CBRN respirator standards provide a baseline that they can go out and procure equipment to protect them in a CBRN event.

And to that end, our standards have been recognized by other organizations and are

considered and used for the use and expense of grant money in buying personal protective equipment, in particular for us, for NIOSH, for respirators.

The Department of Homeland Security recognized the four CBRN respirator standards, the SCBA standard gas mask, and the two escape mask standards amongst the first standards for issuing grants to responder organizations along with work with the NFPA in addressing ensemble standards.

And to that end, the NFPA has taken a look at what we have done in development of the CBRN standards and adopted -- one, they have adopted the use of the NIOSH approved CBRN respirator as part of their personal protective ensembles.

And, second, they have used our methodology in looking at the chemical warfare agent testing and making determinations on how to translate that information into determining how to test garments as part of the NFPA process.

Yesterday, Andy Capon was generous enough

to give us a little update regarding what the British Standards Institute are considering with the implementation of CBRN standard.

And they are actively looking at taking the penetration and permeation approach that we have done for chemical warfare agent testing and applying it to the development of standards within the European realm.

Where we have been and where we are going, you know, it's always nice to reflect on our laurels, and we are proud of what we have accomplished looking back at the past.

That we do feel we have provided significant protection upgrades to the responder community with the adoption of the four standards that I earlier mentioned.

Where we see going ahead, we have active programs related to the development of standards for powered air-purifying respirators and closed-circuit self-contained breathing apparatus.

Starting next year, we are going to be looking at the development of requirements for

combination units, whether they are combination self-contained breathing apparatus, air-purifying respirator, or self-contained breathing apparatus, powered air-purifying respirator.

We have had discussions and continue to work with our colleagues within DOD. They have an active program in the Air Force, who is sponsoring an active program, looking at the combination units.

And I think if you are in the manufacturing community, I think you will note that the Air Force is seriously taking a look at what we're doing, at the CBRN requirements, and applying that to what they see as performance requirements necessary for those devices.

To balance out the remainder of the standards activity, following the completion of the combination units program, we will be looking at identifying standards, CBRN standards, for any of the other classes of respirators that may be in Part 84.

So our approach, as we move forward over

the next few years, is going to be to continue to do standards development in a public process that -- you know, while we intend -- basically, we intend to mirror the process that we followed over the past four years, and relaying information to you via public meetings, encouraging stakeholder meetings either on a small group or one-on-one basis at the preference of the stakeholder.

And to continue to develop our concept papers and make them available to the community for review and comment.

One thing that I wanted to note for the parties involved -- and we will be providing some sort of formal direction, either through a letter or email or combination of both, regarding some of the activities that we're going to be undertaking over the next three or four months.

And we would like to try to apply some of the lessons learned that -- what we have experienced with regard to interpretations and clarifications that we have made regarding the standards themselves or the test procedures that we

have developed in support of the standards.

And I wanted to make sure I note that what we are talking about are clarifications based on our experience, not necessarily changing the requirements of the standard.

But our intent is to do our due diligence internally between the policy and standards group, as well as with our certification branch, to go through our documentation with regard to clarifications or interpretations that we have made regarding the standards and the supporting documents.

And then issue through our website a revised standard -- revised standards and revised test procedures where appropriate for stakeholder review and comment.

And our goal, our objective is to have those posted to our website by the end of October and allow a 30-day review and comment period by the stakeholder community to assess what we have done and either provide and ask for any additional clarifications or provide comment, you know,

regarding the documentation.

And then we would look to post an updated standard by -- updated standards and test procedures by the end of the calendar year.

With regard to the PAPR, you know, it's a -- we like to joke every time we do a standard that this one is -- was a lot more complicated than the last one, and I think that's been true as we have moved along.

And with the PAPR, we have had to address a multitude of technical issues that have arisen regarding the apparatus and how the apparatus is use in the performance of PAPRs.

We have had four public meetings regarding the PAPR so far. At this time, we're going to announce we are going to have one more public meeting, which I will provide a little more detail as I go on through my presentation.

We're targeting on having a meeting here in Pittsburgh probably at this facility on September 29. And we will be moving through the formal Federal Register process to make that

announcement hopefully within the next few weeks.

Also, we have had a very active docket regarding the CBRN PAPR.

We have had 21 formal submissions to the docket for providing suggestions or comment regarding our concept paper, providing technology and rationale that should be considered or that the stakeholders think we should consider as part of our process.

That doesn't mention -- that doesn't completely cover the depth of the comments that we have received.

We have had numerous one-on-one or smaller group stakeholder meetings to discuss the CBRN PAPR as well, as you know, receiving comment informally.

And we always get the question what happens when things go to the docket, and I want to assure you it doesn't go into a black hole, that we go and we seriously consider the suggestions that are provided by the stakeholder relative to the content of the standard or the conceptual standard.

And what I have done, at least with regard to the 303 specific comments that we have received, is to break them down by category without spending a lot of time on any particular one, but to give you an idea of the breadth and depth of the comments that we have received during this process over the past few years.

Now, having said that, when we move through the agenda today, I think you will note that we're not going to cover certain items with regard to the presentation.

The focus of the meeting is going to really address what we have done since the last time we got together in a public forum, which was in December of 2004.

And some of the things that we're not planning on addressing unless there are specific questions from the audience that are related to benchmarking work that was done with the environmental conditioning and durability program, field of view, lens abrasion, the chemical warfare agent testing, and the LRPL.

We have already done our benchmarking program, and those results have been made available in other forums.

Some of the things that I think that are important with the LRPL and with the warfare agent testing related to the PAPR, that one of the things that we wanted to be sensitive to with our STP method development is to address the concern over the respirators off gas and particulate, whether it's from the hose or the blower within the system.

And we're working through the method development to address how that will be covered in the test procedure.

When you look at the warfare agent testing, one thing of note that we have talked about with other programs, when we do the agent testing in the laboratory, that there's a leak test that's done on the respirator up front before the chemical warfare agent is applied. And it measures -- it's the TDA99 YM system, which measures particulates.

And if you have a respirator that,

because of the hose or the blower or the, you know, the method of preservation of the respirator, it has particulate matter, you are going to be sensing particles.

And the option has always been there with that test that if you are confident that the respirator is not actually leaking, that it's just the particulate matter that's being -- you know, within the system that's being sensed, you know, you can proceed with the agent test. You do not have to have it cleared or 100 percent value for moving forward with that test.

With the LRPL, we received an interesting comment yesterday during the closed-circuit meeting relative to the possibility of doing a modified LRPL which would address doing a modified test of the full system on a limited number of subjects, and then doing an evaluation for fit of the facepiece to meet the Los Alamos Panel as a negative pressure technique.

Like, for example, for the PAPR, we would do eight. And if we were to implement something

like this, we would do eight systems, full-up systems at a higher LRPL value, and then we would do facepieces with a filter element on them instead of the blower using the blower assembly at a fit factor or projection factor of 500.

That's something we will take under advisement and consideration as we move forward.

And part of the concern deals with the complexity and the cost associated with the respirators.

And when you start talking about the closed-circuit SCBA systems or some of the PAPR systems, we appreciate that, yeah, these are expensive units, and we also appreciate that the CBRN testing itself is very expensive for the applicant.

So we will take that comment under advisement.

One other aspect on this slide, when you look at the admin category, there's a couple of things there that I would like to address as well.

One is comments that we received after

the last public meeting related to our approach of implementing a standard for protecting emergency responders, that we received a swell of support from the first receiver community saying that we needed to address the needs of the receiver as well.

And to that extent, we took an approach of trying to address those provisions through what we initially called the weapons of mass destruction concept paper, which was for non-tight-fitting types of systems.

And after having received feedback on that item, what we have done with the last version of the concept paper is to roll all of the conceptual test requirements and performance requirements into one standards document.

And with the intent, what we tried to do with the version that's available on the internet and with your CD packet, is that we have identified -- the changes are in red in the concept paper, which identifies the changes that we made.

We have also -- what we also tried to do

with the information is we acknowledge that not all of the tests that we feel are necessary for the emergency responder are necessary for the first receiver community.

And to that extent, when you go through the different performance requirements, I think you will see in the title, they are identified as far as CBRN tight-fitting PAPR or CBRN tight-fitting and non-tight-fitting PAPR.

And the distinction being if you are developing a tight-fitting PAPR for emergency responder use, you follow that with a full range of testing.

If you are developing a product that you anticipate would be a non-tight-fitting used in a non-tight-fitting scenario, you would use only -- you would need to meet only the performance requirements that are identified that way in the concept paper.

We also, with that, we tried to -- one of the concerns that was raised was we tried to link the performance requirements with how the

requirement was going to be evaluated in testing.

And for the first time, we identified the test procedures in the standard itself with how we were going to actually conduct the testing.

And moving forward with our subsequent standards development, we're going to continue to do that.

The other admin topic, which I will provide a little detail in a minute or two, is related to how we are going to implement the CBRN standards. And that is not resolved, at least as of this date.

But with the disposition of the docket comments, I think in general, you know, they fall into four categories.

Some things we can accept the way they are with regard to the content of the comments that they -- there's technical rationale. It corrects something that we may have misstated. And what we were trying to identify as a conceptual requirement.

Some things we reject. There are

comments that we get that we reject.

And primarily, when you look at those areas, they are related to things, you know, technical comments that are made regarding to performance requirements for the respirator.

And in general, we -- the basis for our rejection usually falls within the results of our benchmark testing.

If we see or we have good evidence to believe that a technical performance requirement that we have identified can be achieved through existing technology or with the next evolution of technology, that we will maintain that within the standard.

But just because one particular individual organization may not be able to meet that within their technology, understanding a technology within certain products doesn't necessarily mean it's not a good requirement for the system.

And I think this is bringing the level of technology up, you know, and allowing some

flexibility for manufacturers and applicants to look at evolving technology to apply into the process.

Some of the things that we have been working on and still continue to work on are going to be discussed today with work rates, breathing performance, particulate testing, and benchmark testing with regard to gas and vapor testing and the crisis provision that was established for the standard.

And I think at this point, it's safe to say, you know, for our team, that we still have significant work to do in methods development and validation regarding the high flow particulate testing, the use of breathing machines within our standard test procedures for all we have conceptualized for the PAPR. And you will get some more detail on that during the course of this morning.

Now, with regard to implementation, we have received both internal and external comment that we should implement the CBRN PAPR using formal

rulemaking processes.

And part of the concern related to implementing the standard by policy gets into the history related to the development of 42 CFR, Part 84, and the transition of the PAPR requirements that were identified in 30 CFR, Part 1.

I think that's the right document.

But I don't want to address the history, you know, in this forum, as far as why things were or weren't done. But suffice it to say that the PAPR wasn't as fully defined in Part 84 as other classes of respirators.

And to that extent, part of the concern that has been raised with the adoption of the CBRN standard through policy provisions, as we currently conceptualize the standard, is it will become the de facto industrial standard, that to get products to market, you know, the provisions that manufacturers and applicants will pursue, the development of equipment to meet the CBRN standard, and that will become the basis for what the market uses.

And there's some concerns over the shortcomings of that approach because we have initiated a process for developing the industrial PAPR module, which we will talk about this afternoon.

And the concern is, you know, what the relationship is between the requirements that we have identified for the CBRN PAPR in relation to what the requirements would be in the new industrial module for Part 84, and whether those requirements, those performance requirements would be complimentary, or would they be contradictory.

The process that we followed to date and that -- rather that we are currently on is related to using our provisions within Part 84 to -- and in particular paragraphs 84.60(b) and 84.63, which grant NIOSH the authority to issue approvals not specifically addressed in Part 84 and to develop additional requirements to provide protection for individuals against hazardous atmospheres.

And that's been the basis for how we have introduced the requirements for the SCBA, the gas

mask, and also for the escape respirator.

And even having said that, I think when you look at how we have conceptualized the existing concept paper, I think you can appreciate with the level of effort that is still ongoing, especially with regard to the hazards assessment for the non-tight-fitting system, that we would have to conduct and do some repackaging of the requirements to phase in the performance requirements for the PAPR that in the near term, you know, the requirements for the tight-fitting system as on the road we have currently identified, are relatively well defined.

But it's the packaging and the implementation of the balance of the requirements that would still need to be defined and made available to the stakeholder community.

With regard to rulemaking, I think those involved with the business realize there is a rather lengthy and extensive process. And I think in a business as usual mode, you are looking at 18 to 21 months from the start of the process to

completion.

But having said that, with the PAPR, if rulemaking is the route to go, considering the definition of the standards or the requirement so far for the CBRN program and potential translation of those requirements into the industrial respirator, the review and comment, the review and comment period within the community and receiving comments -- advertising in the Federal Register, receiving comments back, making disposition of the comments, that could probably be done fairly quickly, since we have a good foundation of information and exchange already with regard to the work that we have done.

And it's conceivable that that process could probably be reduced to about a 12-month period, depending on the nature of the comments that we have received and the disposition of the comments.

And we know we have at least a four- or five-month administrative window to staff, the documentation through our parent organization, as

well as through OMB, you know, for approval. And there's really not a lot -- you know, even in a best case scenario, there's probably not a lot that can be done to shorten those review windows.

So where do we stand? Where do we think we're going from today?

Well, obviously not having a standard available for the responder community or others to purchase equipment, you know, we're not providing respirators to protect individuals, which is really the bottom line and why we're here.

So part of what our intent is in focusing over the next several months is to identify a way to continue to move the project forward, either through some sort of repackaging of the requirements that we have identified, or through policy or rulemaking processes to bring the standard forward and to allow responders to start ordering equipment to meet -- to allow one -- allow manufacturers to provide equipment to us for evaluation and certification that they meet the requirements.

And then, two, to allow the responders or user communities to procure equipment for their use and ultimate protection.

One of the technical aspects that we continue to work through and that you are going to hear more of during the course of the morning is related to the verification -- validation and verification of our test procedures.

And I think, as I mentioned, you know, we have some significant work that still needs to be done with regard to the high flow particulate testing as well as the integration of breathing machines into our test procedures.

One of the things that we have learned historically with our standards work is the need for having valid, validated test procedures prior to the release of the standard.

And we will not release the PAPR standard until those STPs have gone through the validation processes.

At least in the near term, as I mentioned, we plan on having a public meeting in

September to discuss the road ahead.

And I think, to let you know, the focus of that meeting is not necessarily going to be to discuss the technical issues associated with the project.

We project that we will have, you know, follow-on meetings to address technical requirements, provide updates regarding the hazard assessment for the non-tight-fitting, as well as addressing the industrial PAPR module probably in the November time frame.

The focus of what we want to talk about at our next public meeting is the way forward for implementing the requirements of the standard, whether it's by policy, by rulemaking, or by a repackaging of the policy and rulemaking provisions.

But with that, our approach for moving ahead and to hopefully provide some clarity with regard to our thoughts regarding the implementation of the standard, is that we expect to post a new concept paper for the CBRN PAPR by August 31.

And we intend on providing some additional information that's maybe a sort of a preamble, if you will, to the document to give the community an update on where we think we are with -- with the implementation process, and then provide clarity to that when we get together at the end of September.

And with that, I will entertain any questions you may have.

Well, I don't know if that's -- if you are all stunned, or if that's a good thing. So what we will do is we will go ahead, and we will move forward with our technical presentations.

And at least at this time, I'm wanted to -- I'm not sure if you are all familiar with our organization and our team as it currently stands within NPPTL.

But I think for the most part that most of you are aware that we have a contractual relationship with EG&G to provide technical and administrative services to the laboratory. And to that end, we have assembled additional staff to

help provide us expertise and manpower to address our standards development processes.

Because when you look at the development of the STPs and the actual methodologies that are employed -- and I will embarrass them by introducing them, but this Rich Vojtko on the end, Jeff Palcic, and Gary Walbert (phonetic). Gary, if you can raise your hand or stand up in the back -- are part of our staff.

And we really see them as an extension of our team in doing the technical work and developing the documentation that has been necessary to support the standards development process. And I think over the next several years, you will see more of Rich and Jeff and Gary.

So with that, I would like to introduce Terry Thornton to give you an overview and lead a discussion of our benchmark testing program.

And I don't know if you recall from the December meeting, but Terry had a bad case of the flu, and at the December meeting, and someone named Jon Szalajda had to give Terry's presentations in

his absence because Terry was indisposed.

So I guess, you know, retribution is nice, and you are going to see a lot of Terry today.

So with that, Terry.

MR. THORNTON: How is everybody doing today?

As Jon said, my name is Terry Thornton. I'm a chemist. I work for NPPTL with Jon Szalajda and the policy standards development team.

You can see by the first slide up here, it's called benchmark testing. We're going to cover quite a few items in here, breathing rates, battery indicators, low flow indicators.

We will probably take a break then for me. You will lose my voice for a while. And we will let Paul Gardner come up from ECBC. He is going to do a little talk. Then we will probably have a break.

This is if -- depending on how the time goes. We will have a break, come back. And I will talk about some service life testing, some

benchmarking that we have done there.

And then we have one presentation by Jeff, who is going to talk about some air flow measurements.

So you will hear my voice for a while, and hopefully it stays good. Hopefully the computer works, too.

All right.

Now, that the computer finally decided to do what I asked it, we will get right into the first presentation that I have.

And this is really around the breathing requirements for the CBRN powered air-purifying respirator. And we're going to give a little bit of benchmark results that we have done as we have looked at this.

Remember, this is ongoing development that we have done.

If you look at our concept paper, the new concept paper, I think -- let me get my notes out here where I can see.

This is Section 4.3 in the new concept

paper. From the old concept paper, I think it moved one section up.

The breathing performance is truly -- and I know that's kind of a scary guy we have in our lab here.

It's an evaluation of the respirator system based on specific breathing rate and time. All right.

The performance that we are really looking for for breathing performance, there's positive pressure inside the facepiece.

Remember, these are tight-fitting facepieces, either tight-fitting around the face, or a hood that's tight-fitting around the neck.

So the breathing zone, these are positive pressure devices. To call them a positive pressure device, we need to see if they could maintain positive pressure during evaluation, during the test.

So that's really what we're looking for. You will hear positive pressure come up quite a bit.

Specific breathing rates and the time is chosen by the applicant. When you do your application, you will apply for either a moderate breathing rate or a high breathing rate. We also kind of refer to them as work rates sometimes.

So you will hear me say both of those, breathing rates and work rates. But moderate and high is what we use.

The times really, at this time, there's actually no minimum in the concept paper. There's no minimum time standard.

Whether that stays that way or not, we're still discussing that, about the time. But the time is really based on 30-minute increments. So a two-hour operational battery life, two and a half hour operational battery life, something like that.

You can see the breathing rates. You are probably familiar with these. We have used these, and we have had these breathing rates out there for quite bit. But you will notice a little bit of difference in the high if you read the concept paper.

The first one is the moderate breathing rate, and that's pretty established throughout NIOSH and NPPTL.

It's a 40 liter a minute minute volume, 24 respirations per minute. It uses a Silverman cam, the 622 kilogram meter per minute.

That's actually in 42 CFR right now for testing, so we will hold with that and keep that.

We will do the high breathing rate or the high work rate. And you have probably noticed some change in here from the last concept paper.

We're really looking at two breathing rates, and this is incorporate -- a look at crisis provision, crisis mode.

To do the high breathing rate, we're going to take the operational battery life that you give us, whether it be two hours, four hours, whatever it is; we're going to run at 86 liters a minute minute volume for all of that time except the last ten minutes. At the last ten minutes, we're going to move up from 86 to 103 liters a minute.

The 86 liters per minute has a sinusoidal wave form, what we will be using, and is set at 30 respirations per minute. And then for those last ten minutes, we're going to move that 103 liters a minute.

To do that, what we're going to do is we're going to hold the title volume the same, and we're going to increase the respirations per minute.

The big question is, how are we going to do this?

Well, this concept is just going to come about. So at this time, we do not have anything in the laboratory that will actually do this. We are look at a breathing machine that we're going to -- it's on order, should be coming in relatively soon, that will allow us to manipulate the breathing in this way.

So there is some -- still a lot of work to be done on how we're going to do that. I know one of the questions that will come up is how are we going to go from 30 respirations per minute up

to 37 respirations per minute. Will it be an instantaneous raise when we raise that up?

And, really, that question will have to be answered once we get the breathing machine in and see how it controls, and how it operates.

And like I said, it will be using a sinusoidal wave form in that case.

We decided to use the sinusoidal wave form, or we're looking at the sinusoidal wave form really because it's much easier to use and reproduce in the laboratory as far as certification.

It's easier to do that instead some actual breathing rates which may more look like a trapezoidal breathing rate.

And if you overlay those two -- and actual rates have been recorded. The trapezoidal has kind of been used out there for high breathing rates -- they are very, very close to each other.

So the sinusoidal rates are a lot easier for the laboratory to use.

Positive pressure, this is another point

where a lot of questions come up.

The positive pressure is really inside the breathing zone. And if we go back to our very scary looking person here, if I could step away.

You see that -- a facepiece here, and this is the head form that's commonly used in the laboratory, and we will continue to use that.

I think this is a medium.

This slot, right here, between the nose and the mouth opening is actually an opening, and that's where we can put a pressure transducer onto the back of it, and it can record the pressure in the breathing zone at that point, right there.

So a tight-fitting facepiece, that would be at the nose cup. If it's a tight-fitting hood without a nose cup, it would be the pressure zone throughout the complete hood.

So that's where we are looking for the position pressure.

Position pressure is going to be greater or 0.0 inches of water column pressure and less than three and a half inches.

From what I have seen so far in the benchmark studies, three and a half inches is a pretty good amount of pressure inside the facepiece.

So far nothing has really come up at that pressure. So the big point we're really going to work on is the 0.0 and exactly what does that mean and how are we going to say by looking at the indicator that we have negative pressure inside the facepiece.

And that's a question we're going to have to work on.

We're going to look at something -- before I cover that, We will look at some benchmark data, and you can see some results that we have had in the laboratory.

Now, keep in mind that the benchmark data is done for two reasons. The first thing, you want to take some industrial standards out there are some industrial PAPRs and see how they compare to the concept paper as it's written. And remember, the concept paper changes quite often sometimes.

The other reason we do benchmark testing is for the laboratory to start to develop a test to see how the tests are going to be done, how they are going to be performed, how the data is going to be collected, how it's going to be evaluated.

And that's pretty important because sometimes there's new techniques that are being set up, new software, and we really have to run a lot of data to get an understanding of what we're collecting, how we're going to evaluate that.

So far, benchmark data, we started out with some tight-fitting PAPR units. All of them have NIOSH approval, an industrial NIOSH approval, and they are purchased out in the open market.

So we didn't get anything special from anybody. We just purchased these.

The units that we used were both constant flow units and demand responsive units.

And fortunately, Jon Szalajda hasn't quite covered that we're trying to come up with a definition of what that means.

Officially, NPPTL will have some kind of

written definition to describe the difference in detail between a constant flow unit and a pressure demand or demand responsive unit. You will hear me interact with those, both the pressure demand, demand responsive units.

In this case, I will try to tell you an example of what I look at it as far as benchmark testing, the difference between the two.

The constant flow is a PAPR that when you turn it on, it gets a constant amount of energy into the blower, and the blower turns at certain RPMs. And it pretty much stays at those RPMs while the PAPR is on, constantly blowing at that flow.

And I understand when you are breathing in there, in and out, there may be some slight variation of that RPM in there.

But that's what a constant flow PAPR is in this case.

Demand responsive is a PAPR that the motor or the blower raises and lowers the RPMs in connection with how the person is breathing, whether they are taking a deep breath, shallow

breath, inhaling, exhaling. So we have some kind of control over it.

So those are the two differences that we use for the benchmark testings.

All the units had two or three canisters each, and they were all a first responder type of canister.

Now I say, a first responder type of canister, we all know that there's no PAPR out there with a CBRN approval because we haven't written a standard yet.

So when I looked at the canister as a protection, I tried to get what the manufacturer kind of markets as a first responder, for the first responder, in other words, the most protection they can get wrapped up in their canister at that time.

That does not mean that it had protection for all ten of our TRAs.

You're going to see -- when I bring up some benchmark data, you're going to see the good old pass/fail. Some things pass; some things fail.

That's not specifically based on the

concept paper, exactly.

What we were doing in the lab was trying to get a good handle of we think would have passed the concept paper, what we think would have failed the concept paper. It doesn't mean that when we turn it in, it's going to have to exactly perform that in the testing, but we kept that in mind.

And really the failure that we looked at, if we mark it as a failure, normally that means that at the very beginning of the test, there is negative pressure inside that facepiece at some time, or the inhalation or exhalation -- or inhalation point.

There was negative pressure at the very beginning, and it continued that way throughout the test.

All right. Now, for safetywise, all you will see is Model A, B,C and D. And I'm not going to go into detail of what actual PAPR we used out there. Model A, B, C, D, you will see that throughout my presentation. We have used those four PAPRs, and you will see some other benchmark

testing based on that.

The A, B, C, D stay the same throughout all of the testing.

This is a wrap-up of the flow versus the model and how it performed.

Looking in the industry, you can see right now, that the 40 liter a minute, the moderate breathing rate, should be relatively easy for most of the manufactures to pass. In fact, in this case, all four of them did pass 40 liters a minute.

As we step it up to the higher, to 86 liters a minute and 103 liters a minute, you will see we have some failures there. Models A, B, and C actually failed both 86 and 103 liters a minute.

But keep in mind this research data was taken before we come up with the idea of using 86 liters a minute and then the last ten minutes going to 103.

So when we first started this, the high breathing rate was just 103 liters a minute across the board for that given time. So we collected that data first.

When we came up with the 86, we decided to go back into the lab and look at some of those same PAPRs to see if it helped the pass/fail between 40 and 103.

And, as we can see, unfortunately it didn't.

So we can see that the Model D does pass. So we can see that the industry probably has the techniques to be able to incorporate those higher breathing rates. But for what's out there right now, it probably would not pass this.

There is no data collected, like I said, for the 86 liters a minute and then jumping up the last ten minutes to 103. We don't have a breathing machine that will do that. So we're kind of waiting for that breathing machine to come in, and we will do some more benchmark data.

I'm a chemist, so I like numbers up there.

And this kind of a busy slide, but this gives some good indication of what the actual pressures were inside the facepiece.

Remember, there were all types, and they all had nose cups.

This is the 40 liter a minute benchmark test data. And the time over on the end, the total time, hours and minutes, the two that went for eight hours, they probably went a little longer, but we just stopped collecting data after eight hours.

That's pretty much a work day, and we decided not to try to go on to finish that off and see the very end of that data.

B and D actually stopped at that time. The unit stopped working. B, five hours and 20 minutes. D ran a full six hours.

As you can see, at the start, there is some positive pressure, both inhalation and exhalation, which is what the slash is, the high and low inhalation peak, exhalation peak.

And all of those numbers were recorded by taking the graph that's displayed and getting an average value over one minute. And remember, this is 40 liters a minute.

There's quite a few respirations that take place per minute. There's a lot of data that's collected. The transducers collect data pretty fast. I think one per millisecond or one point per millisecond. I'm not positive on that, but I think that's their rate.

So over an eight-hour period, you can see where there is a large amount of data to take place to try to collect.

And so for these numbers, we just averaged over one minute. We grabbed a one-minute window there, took an average of that high and low.

So the first thing you are going to notice is down at the end under A and C, you see some negative numbers. And I just said that it needs to be positive in the facepiece to have a pass.

You see negative numbers that on the slide right before this, we said that those passed. One of the reasons that we kind of gave that a pass and said, Look, they probably will pass that.

Remember, this is a concept paper that

we're working off of.

Because that was an average over a certain amount of time, over that minute. So obviously, there was some negative peaks in there.

How far those -- how low those negative peaks were below zero and how many of them we're still working on as far as how we are going to say that that's a negative number or not a negative number.

We have to look at the transducer and the way that it calculates and the way that it picks up the data and the accuracy of that transducer. But you can see 40 liters a minute, we're doing pretty good.

It looks like everybody passed that, with a pretty good amount of time, eight hours, six hours, five hours, twenty minutes. That's a longer service life than I actually thought we would be getting on those.

If we change to 86 liters a minute, this is when the failures started to appear. And, again, if you look at A, B and C, those did fail.

But as you can see here, those are real negative numbers. We know that.

It starts off at negative 3.5, 1.5, 3.5. So that's a very low number. All right? And they did fail. And that continued throughout the life of the test.

Two hour time, where we stopped A, B, and C, we stopped that because we -- we weren't sure that it didn't fail at the very beginning, so actually we could have stopped running the test, collecting data.

But, again, we're looking at this to see how we're going to collect the data and how it's going to help us in the development of standard test procedures.

So we went ahead and let those run for two hours to see if there's any improvement or decline in those.

D, again, two hours and 20 minutes, and that unit actually stopped at two hours and 20 minutes. It shut down. The electronics made it stop. But you can see, it holds very consistent

throughout the life of that 86 liters a minute.

One more data, we have the breathing performance at 103 liters per minute. This is where not -- a big difference from the 86 liters a minute.

You can see the start, the initial low pressures, actually were a little bit lower. I will go back to the 86.

We have numbers of about negative 3, negative 1, negative 3.5. Compare that to the 103 liters a minute.

Greater negative numbers pretty much across the board there, except down on D, Model D. It actually did run for two hours and two minutes, just a little over two hours before it shut down. The others, like I said, we did stop them at that.

And we can see that, again, it holds very consistent, the high and the low pressures throughout that testing.

And, again, those were averages over one minute.

So that's really the benchmark data that

we have looked at. I think the standard test procedure for that is in the disk that was handed out. I believe it's in there. I'm not sure.

It is in draft form. If it's not on there, it should be made available. We could probably make that available pretty easily.

So in summary, the breathing performance, this has kind of been out there before. We will go through it real quickly.

The units will be certified as a moderate or high breathing performance. The moderate is 40 liters a minute. The high is 86 liters a minute, with that last ten minutes looking at the 103 liters a minute, and positive pressure in the facepiece.

So this is, when you describe the standards, a relatively simple standard to talk about. It may not be that easy to develop a piece of equipment to pass it, but it's pretty easy to read the concept paper.

Remaining issues that we need to clarify. This is one that we have been asked a couple of

times, and we're really looking at that.

Previously in NPPTL, we used this 40 liters a minute breathing machine, and we looked for this positive pressure. So we have a good indication how to do this.

The problem is, we're kind of stepping up the technology. The 40 liters a minute, right now, is done with an SCBA, and they actually have a pen, a pen and ink that graphs this.

So you have this pen to deal with, and that's where the policy has been written about what is zero, what is less than zero. It talks about the pen width and the ability of the transducer to record the data.

We're not using the pen anymore. The strip chart recorder, we have gotten rid of that, mostly because of the large amount of data we collect.

We're using a software, LabView, that collects the data. Probably a lot of people are familiar with LabView.

We have a specific program that's being

written by Data Science Automation. And they have helped us in collecting this large amount of data.

When I say large amount of data, when we first tried this, we were trying to dump it into Excel. And I think we overloaded Excel within five or ten minutes. Excel could no longer handle the 64,000 some-odd points that we generated, and we did that very quickly.

So LabView will help us collect that data, very large amounts of data, and be able to analyze it and look at it.

Now, right now, we can get it to graph out. We can print that, and that's why those were average values because Rich actually did this. He had to sit there with a ruler, ink pen, and kind of look at the numbers, figure out what they were, write them down, and get those averages.

The software manufacturer, or DSA, who is developing the software for us, is going to go into some improvements that will allow us to pick out specific peaks and know the exact value of those peaks with the date and time stamp.

So we can tell how many zeros we have, how many below zeros we have, exactly what they are and where they fall into the accuracy of that indicator.

So that work still needs to be done. And that includes the collection and evaluation of the data.

There is still work to be done there. Once we get that finished, we will probably put that out. I think Jon said we had another public meeting in October/November.

We will probably have a much better understanding of how we're going to collect that data at that time.

My favorite slide. Any questions regarding the breathing performance, how we're going to develop these tests, what we're going to actually test?

Yes. I think if you step up to the mike. Is this mike on?

Okay. And if you could please just introduce yourself for the transcriber.

UNIDENTIFIED MAN: Who provided the software again?

MR. THORNTON: It is -- it's LabView software.

I think it's LabView 7.8 is the current edition that we are using.

UNIDENTIFIED MAN: To gather the data?

MR. THORNTON: Well, the actual software is -- LabView is being written for us by Data Science Automation, who is a company local here in Pittsburgh, and they are a representative for LabView.

UNIDENTIFIED MAN: Good, thank you.

MR. HEINS: Bodo Heins from Draeger Safety.

MR. THORNTON: Yes.

MR. HEINS: Do I understand right that you are not sure if you are -- take the average of the pressure in future for the pull for being at zero or below, or is it allowed to have for milliseconds at negative pressure?

And then, if it takes average, it's

necessary for the manufacturer to have the same quick measurement, which is not easy to get.

MR. THORNTON: Well, it -- I will answer it in two parts.

The first answer -- the first question is are we going to average that over time and how are we going to look at that data?

That's the part we still have remaining issues about, whether the software will allow us to look at the individual peaks to see what they are and actually get values for it, or whether we're going to have to get that average over a certain amount of time, over a minute or 30 seconds.

So we are still working on that.

As far as the data and the software or the actual hardware, the pressure transducers, those are bought right off the market. You should be able to get ahold of those.

The software that's being developed, we will have to see how that's going to be made available from us -- they're actually writing it for us.

I'm not sure how we market that, whether we can put that out there the way it is or whether we will have to have that software and sell it. I'm just not sure how that will be done.

Did I answer your question?

Yes.

MR. DESANTIS: Vick DeSantis, Safety Tech International.

The four units that you used for your initial benchmark, A, B, C, D --

MR. THORNTON: Yes.

MR. DESANTIS: -- all commercially available right now?

MR. THORNTON: Yes, they are.

MR. DESANTIS: Are they all the same type of unit, i.e., constant flow?

MR. THORNTON: There was -- I think I -- hopefully I said that, didn't I?

MR. DESANTIS: I didn't think you did, but unless I missed it.

MR. THORNTON: That's a long time ago.

Yeah, excuse me. They were constant flow

units and demand response -- or breath responsive units.

MR. DESANTIS: Okay, thank you.

MR. LINKO: Bill Linko from Micronel.

Your profile for breathing is sinusoidal.

MR. THORNTON: Yes.

MR. LINKO: But in the actual conditions, I would think a person might hyperventilate. And that is more in a like -- unless it's square wave.

And so I'm curious whether you ever plan to invent that test.

MR. THORNTON: I think some of the actual data that we have looked at is -- it's a square wave or maybe -- I describe it like a trapezoidal type breathing pattern.

The study we looked at is from Kaupfman (phonetic), and I will have to get that specific reference for you, for that paper. It's out there.

He talks about whether a sinusoidal and actual breathing patterns or the trapezoidal breathing patterns for a high breathing rate. And if you look at those and you overlay those, you can

see that they are very similar to each other as far as the peaks, how they go up, what kind of area they take under the curve.

So in looking at that -- and remember we're trying to do certification where we want to keep it the same.

MR. LINKO: Uh-huh.

MR. THORNTON: I think the best way is to keep the sinusoidal wave form, the sinusoidal pattern, because it's so much easier to create in a laboratory.

MR. LINKO: Okay. Thank you.

MR. HEINS: Bodo Heins from Draeger Safety.

MR. THORNTON: Yes.

MR. HEINS: How did you determine the service life of the unit so that you could find out the last ten minutes for the test?

And what's the reason why you picked 103 liter the last ten minutes and not somewhere in the middle?

MR. THORNTON: That's a very good

question.

Actually, the easy answer is for right now, we just wanted to look at the last ten minutes. That's kind of the place we would look at.

Probably the worst case scenario, is somebody working in a high rate in an atmosphere, something takes place where all of a sudden they go up to this much higher rate, and they wanted to escape the area.

So that's kind of just a natural place for it to be put.

But if there's any reason someone can come up with which could give us an indication that we need to put it in the middle or we need to put it at the beginning, please let us know.

Because I don't think we have really thought it through looking at every aspect and why it's at the end, except that would be just kind of a natural place for more of a worst-case scenario.

So any comments you have on that, we appreciate it.

MR. PITTS: Sam Pitts, Marine Corp ChemBio Incident Response Force.

In our filter protocol, we found that both the trapezoidal waveform and the sinusoidal waveform are so similar that the differences are almost negligible.

I just mention that just for a general statement.

I have two questions, though.

On the -- on your use of first responder filters, that's a pretty generic term. And the differences between construction and layering and the fill quantities and types of filling in different canisters can vary, of course, the pressure drop and the performance of the filter.

Will you delineate that some way, the specific filters that you used in this evaluation?

MR. THORNTON: In this evaluation, I don't think we are going to get into actually specifically what we need.

But you are correct, there are some differences.

Now, remember, we bought these as a system. We didn't just go out and get canisters all by themselves.

So it's the canisters that are bought with that system from that manufacturer. They go with it. They are part it. They are NIOSH certified.

Yeah, there is differences.

MR. PITTS: Those differences are vast, and I would certainly want to know about them as an operator.

MR. THORNTON: Well, and I think as this is incorporated into certification, once it becomes part of a standard and the PAPRs are standard, standardized, you will know about what the performance of that canister is because it will have passed, you know, all the other tests to be certified under CBRN. It will have passed all the TRA service life testing, particulate testing, both passed under whatever resistance testing there will be.

But in this case right here, I don't

think it's -- I don't we're going to give out the actual details of this benchmark data.

Because it is benchmark data. We're really trying to see two things for benchmark. Does the industry have sufficient equipment to handle the concept paper, and do we think they can build it.

And then the other reason for the benchmark testing is for our own knowledge so that we can develop the test.

MR. PITTS: So my understanding of what you have just said --

MR. THORNTON: Do you want that data?

MR. PITTS: No. I -- in the case of an incident, say, perhaps we run out of one type of 40-millimeter NATO threat canister. And say another one is available that was not tested with the unit, but we would have -- you would have the data on it.

Could we choose -- I would like the option to be able to choose the different types of canisters.

MR. THORNTON: You know, that's probably a question for higher up than me. I'm not going to be able to give you the answer.

I would say, no, we wouldn't be able to give it out. But I mean, the worst circumstances, you're talking about a specific incident that may be taking place.

MR. SZALAJDA: Let me add something to that, Terry.

One of the things that I guess you must have heard, in the very first public meeting we had on PAPR, we broached the subject of interchangeability of canisters. And I think the feedback that we received at that time was that of a resounding no for PAPR.

So at least from our perspective, we don't endorse -- for PAPR applications, we don't endorse the interchangeability of canisters unless it's within the manufacturer's purview.

MR. PITTS: Just another question.

You chose the loss of positive pressure within the faceplank as the failure criterion.

MR. THORNTON: Correct.

MR. PITTS: That was for your purposes here.

Even if you do go negative pressure, if your seal is good, you still possibly could be filtering and preventing contaminates from entering via the seal or through the filter, but you chose that as an arbitrary failure point.

I'm trying to grasp that.

MR. THORNTON: It is for this specific test.

MR. PITTS: Understood.

MR. THORNTON: For breathing performance.

And, remember, that's why we do it using the specific breathing machine.

So unlike a human, that is not -- that is kind of variable, your breathing goes up and down. With a breathing machine, it's set breathing pattern, and it stays that way through that test.

So the breathing performance is really to see at this flow rate of 86 liters a minute, throughout that test, that there is positive

pressure inside the facepiece.

MR. PITTS: Okay.

MR. THORNTON: Now, on a human, even though it has passed this test, a human may be using it where it does go negative.

You take a much deeper breath, a much faster breath. And so you will see later on in the presentation, we have some indicators for that.

But, yes, for this specific test, positive pressure is what is required for the life of the PAPR at that specific breathing rate and that time.

MR. PITTS: So that I don't misspeak to my CO when I get back --

MR. THORNTON: Uh-huh.

MR. PITTS: -- the testing criterion goes on for the life of the battery at 30-minute increments?

MR. THORNTON: The operational service life of that battery as specified by the manufacturer. If they come in and say it's a four-hour battery, this test would cover that

four-hour period.

MR. PITTS: So you would run this thing out of 40 liters of air per minute for eight hours if that's what the manufacturer said?

MR. THORNTON: If they came in with a four-hour battery, operational battery life, we would go four hours, maybe go a little bit beyond.

MR. PITTS: With the light rate?

MR. THORNTON: Yes. The high rate would be 86, and in the last ten minutes, based specifically on what they give us for their operational battery life, we would kick up to the 103 liter a minute, just by increasing the respirations per minute.

MR. PITTS: So that total time of that test would be based on the manufacturer's -- the words that come from their mouth about their battery life.

MR. THORNTON: Yes.

MR. PITTS: If it's eight hours, that's when you're going to test to the four hours.

MR. THORNTON: That's correct.

MR. PITTS: And the last ten minutes at the high rate? Okay.

MR. THORNTON: Yeah. It's by the manufacturer.

And that's part of their application, you know, having to specify the breathing rate that they are looking for, a moderate or high, and the operational battery life.

MR. PITTS: Thank you, sir.

MR. THORNTON: All right.

Yes. How did I know?

MR. BERNDTSSON: You were waiting for me; right?

I think what you're testing is very good there. Just a comment on what Sam ask here.

I mean, if you can -- as a manufacturer, you can't really allow to put someone else's filter on it because the performance of the PAPR is going to be very much dependent on the pressure drop from the filters.

So you put someone else's filter on with a different pressure drop, the performance and

the -- and how that's going to look is entirely different.

MR. THORNTON: Correct.

MR. BERNDTSSON: The ones with positive pressure here maybe go negative all the way if you put the wrong filters on.

MR. THORNTON: Correct.

MR. BERNDTSSON: So there is some mistake with that.

MR. THORNTON: Some of those reasons are why the interchangeability or interoperability is not in the PAPR concept paper.

I think it was -- Jon was right, it was like a year and a half ago when we proposed that. It didn't go over well.

Is there any other questions on breathing performance? Yes.

MR. HEINS: Bodo Heins, Draeger Safety, again.

I would also like to suggest to measure the positive pressure, not in the breathing zone, but in the mask size.

Because if you have negative pressure in your mouth, it doesn't mean that inside your mask is also a negative pressure, which is important for the tightness and for the fit factor.

Change it into the eye room when you measure the positive pressure.

MR. THORNTON: You know that's a good point. And I'm not sure if I really thought about that. That's kind of something new.

I think the reason we went for this is because this is what we have in the laboratory. It's pretty standard where the pressure is detected there. This kind of goes from the SCBA, so we really haven't thought about that.

Now, if a tight-fitting hood is tested without a nose cup, it would be more indicative of the complete pressure inside that hood.

So we will have to look at that.

And that's a good comment. We really haven't come up with that yet.

Yes.

MR. BERNDTSSON: If you go back to the

value, the problem is that some people -- you have a leakage in here.

MR. THORNTON: Correct.

MR. BERNDTSSON: It will not be picked up up here.

So it really is very important that you stay in there in the mask.

MR. THORNTON: Okay. All right.

Any other questions?

MR. SZALAJDA: Well, I think, rather for the purposes of time, why don't we just move ahead and let Terry do his next presentation, and then we will take a break.

I think one thing I did want to note with Terry's presentation with regard to the testing of the -- when you talk about we have breathing machines on order.

The machine that we ordered is very similar to -- well, I say that, to one that our colleagues at ECBC are currently using in their facility.

But if push came to shove tomorrow, and

if we had to adopt the standard tomorrow, what we're considering and what you may want to think in your perspective is that if we needed to implement a test procedure tomorrow, we probably would use the ABMS, but only use the breathing machine portion of the ABMS to run the evaluation.

But the modification of what the cylinder does that ran from the 30 respirations to 37 respirations.

Just something for you for you to keep in mind between now and the next generation of the concept.

MR. THORNTON: You get my voice for a little bit longer. Hopefully my mouth won't go so dry this time.

The next thing I want to talk about are really kind of two things wrapped into one, and this is -- it sounds like a very easy thing to describe, but it may not be, as I really think about it and look at this.

We're going to talk about the low battery indicator and the low pressure indicator at the

same time.

I'm going to give you a little bit of benchmark results, though the benchmark results are not real extensive amount of results. It's mostly observations that we have had.

But again, we're using the same models here A, B, C, and D.

Let's start off with the low battery indicator. A little bit of controversy, you know, been around, that's exactly what we're looking at, what we're doing.

But this evaluation is of the respirator system to a multiuser when there's at least 15 minutes of battery life sufficient to keep positive pressure in the facepiece.

That's what we are looking for, a 15-minute warning.

This is Section 4.1 in the new concept paper, if you are trying to find it there.

This is a predictive indicator. It will actually come on prior to the situation taking place.

So it lets the people know 15 minutes of battery life is sufficient. To keep positive pressure -- again, as I say, we are going to harp on that positive pressure thing.

The unit we evaluated, this indicator will be evaluated again using the specific breathing rate that the manufacturer has applied for.

That's the same breathing rate for the application of the breathing performance.

Once you put that application in for that PAPR, that breathing rate follows it. If it's a high breathing rate, that breathing rate is going to follow it throughout several tests.

The moderate, it will follow it throughout several tests.

So this test was based specifically on that breathing rate. Again, we will put it on the head form. We will make it breathe at that rate, and look at the battery at 15 minutes.

A little bit of detail about this battery indicator, the indicator we are looking for is

specifically just a 15-minute warning.

So we're not going to test other indicators that may be on the PAPR. It may give a full charge, a half charge, work its way down or on the charger itself.

I'm not really concerned about those indicators of how that works.

At this time, in this concept paper, as we have right now, the one we're looking at is the 15-minute warning.

The indicator can be -- I think this is a little bit new in there. The indicator can be audible, visual, or vibratory, or any combination of these three.

There's a lot of questions that will come up about that, do you have to have an alarm, do you have -- can you have an audible alarm that tells you to look down to see what the actual indication is?

We really haven't given a lot of thought to that to describe exactly how those alarms have to be used. So it needs to be one of those three

or a combination of those three.

And the only thing that was put in recently is it must be readily detectable by the user.

In other words, the user shouldn't have to stop his PAPR, take it off and look to see what the alarm means to see where it is.

He should be able to see that as he is using the piece of equipment, a heads-up display somewhere where he can see it without having to have somebody else look at it or doing a lot of manipulation for him to use it.

The performance will be evaluated at that breathing performance, two temperatures.

We're going to look at room temperature, which is just 25 degrees C, plus or minus two and a half. That's a pretty common room temperature that we use at NPPTL quite a bit. And then we're going to perform the test again in the lowest specified operational temperature.

And that operational temperature comes from the users manual for this piece of equipment.

So the manufacturer will tell us this is the low operating temperature for it.

Right now, we don't have any specifics in there except whatever the manufacturer has for the lowest operational temperature. And we will try to hold that temperature plus or minus two and a half degrees C.

Jump over to the low pressure indicator. Again, this is very similar to low battery. A couple of differences there. If you are looking at the concept paper, this is Section 4.4.2.

And the low pressure is an evaluation of the respirator system to a multiuser when there's insufficient air flow to maintain positive pressure in a facepiece.

We have kind of discussed air flows. We have looked at flows. We have looked at positive pressure or pressures inside the facepiece.

This test is really to let the user know when there is no longer positive pressure in the facepiece.

It's an alarm. It comes on.

The big difference is, this is not a predictable alarm. We don't expect you to be able to predict when positive pressure is not going to be in the facepiece.

It's there for the user. When the alarm comes on, they will know at that time they have negative pressure inside the facepiece.

Look at this next statement here, it says the indicator will be evaluated while breathing at a moderate or high breathing rate as requested by the applicant.

As I wrote that down and think that's a good way to say it, but as I really think about it, as far as this not being a predictive indicator, meaning some kind of active indicator that you're just waiting for, we will probably test that a little bit different way than that.

And the two ways we can test that -- and we would greatly appreciate any comments you have on this.

One of the two ways is that we can raise the breathing rate on the unit as it's on the

respirator breathing at a high breathing rate.

We could just increase that breathing rate, respirations per minute, until we get negative pressure inside the facepiece.

And at that time, the alarm should come on. If it doesn't come on, and you have negative pressure, that would be a failure.

Another way we could do that is to possibly have it breathing, and we could put some kind of blockage under the filter so -- making it so that the -- not enough air is coming through the filters.

Now, that's one way of doing it.

Which of those is a better way to do it, we're not real sure yet. We have still got some work to do in the laboratory to determine that.

So the big question that comes on is what do you do -- what do you tell the user to do if that indicator comes on?

Well, all it means is he has negative pressure in his facepiece. So he can do two things. First of all, he can just lower his

breathing rate. He can slow down, see if that alarm then goes off.

If it does go off, he can kind of assume that it may be that the only reason that it came on is because he was breathing too fast for that unit, and he needs to slow down.

Obviously, if he slows down his work, his breathing rate, and that alarm still continues to sound, something else is going on. We don't know what. We're not going to test for what. We just know that something else is going on. He probably needs to egress from the area.

The low pressure indicator, again, is pretty simple. The indicator is going to be the same as the battery, audible, visual, vibratory, any combination readily detected by the user we talked about.

Performance, again, will be evaluated both at that room temperature and at the low temperature, the operational specific -- specified operational temperature.

A little benchmark data here. This is

pretty easy. If you look at it, you can understand why it was easy to describe.

First of all, A and C had no indication whatsoever on pressure, flow, or battery.

The reason I broke that into pressure and flow, as you can see, on B and D -- we will talk about the battery first -- both of those had some type of visible indicator that showed that battery life is going down.

B happened to come on approximately 20 minutes before the end of the battery life, before it actually dies and the battery stops working, or the PAPR stops running.

And D, visible and audible indicator. It happened approximately 10 minutes. We have done this several times. We can see that 10 minutes is probably a good indication.

It happens to have two alarms, one that says your -- about 10 minutes, it comes on. Another, a little more sophisticated, comes on when there is about a minute, minute and a half, two minutes left.

So it was kind of a high and I guess an early warning, and then a warning that said, Please leave.

Pressure and flow, B, there were some kind of -- there was some kind of low flow indicator. All right. But we're not really sure how it was related to the pressure. It may have been unrelated to the pressure.

Remember, these things are not specifically built for this concept yet. They are not built for the standard.

And B, again, had some type of visible, audible low pressure indicator that shows something was going on with the unit. And we probably need to do some more benchmark data with that.

As you see, right now, these are all room temperature. They're in the lab. It's pretty easy to control.

We will have to do this testing in cold temperature. We don't know what the manufacturer is going to come up with, zero minus ten, positive ten degrees C, whatever it is.

We will use the cold temperature chambers for that. We will actually be allowed to put everything inside the cold temperature chamber, have it at that temperature, and run this test.

One of the items that we have bought -- we're really trying to figure out how to use this -- is a -- as you can see, some of those tests, when we look at breathing performance, you notice the low. They went out eight hours. Then we stopped. That's because we can't get anybody to work beyond eight hours. Well, these guys will, but I won't.

If things go out ten hours, 12 hours, we may have to run this test continuously to see what it looks like.

Here's one of the things we have set up in the lab. And we can see here, this is a little video of the PAPR unit that we have made go into a low flow.

You see alarms come on. You may not be able to hear it. I don't think there's any speakers, but we are all hoping this works.

I know you can't hear it, but you can actually hear the motor from where I am. You can hear the motor, and there is an alarm going off.

You can see that this changes the indicator from a C, which stands for the charge of the battery, and the F comes up. I think it was a F2.

You will see it drop down to F0.

Yeah, started off at F2, and it's flowing, good flow there. And then it dropped down the F0.

What we did, I think we just manually manipulated this by clogging up the filters with our hand, put something over it to kind of lower the flow.

So as you can see, this is really what we are going to be looking for, the indicators that show what the flow is and what the battery life is.

Let me see if I can make this go away and start. My favorite slide, questions.

Anybody have any questions about the -- okay.

MR. LINKO: Bill Linko from Micronel, again.

The batteries you are allowing to be used are going to be military logistic type batteries or any type of batteries, like the alkaline, lithium-ion, what have you?

MR. THORNTON: I don't think we have anything that specifies a certain type of battery that will not by allowed.

MR. LINKO: I see.

MR. THORNTON: So that would be the manufacturer would come in with whatever technology they needed.

MR. LINKO: We give you a selection of batteries, like four alkaline or two lithium-ion, or lithium-ion four cell pack, you could make the system read off those equally well.

MR. THORNTON: You are kind of getting out my realm and into the certification.

It's really a question for certification with how they would incorporate that into their projects, how it would be tested.

And what I would think is we would need to test each of those batteries. I assuming they are not all going to have the exact same service life.

MR. LINKO: Correct.

MR. THORNTON: Okay. So we would test each set of batteries both at the room temperature and the low temperature to see if they passed.

MR. LINKO: The test that you did run were with bags that came from the manufacturer.

Do you know whether they were lithium-ion or primary batteries or secondary batteries? Because that can affect run time, and also all of the other factors.

MR. THORNTON: Yeah. I'm not -- Rich, do you remember what type we had?

MR. VOJTKO: There were different technologies, the batteries.

Some were nickel-metal hydride, some were still nickel-cadmium, and I believe there were some lithium-ion batteries as well.

MR. LINKO: So they weren't explicitly

military. There were combinations of civilian and military?

MR. VOJTKO: Yes.

MR. LINKO: Okay. Thank you.

MR. BONSOWOLOSM: I'm Cape Bonsowolosm (phonetic) with UK.

MR. THORNTON: Yes.

MR. BONSOWOLOSM: Do you make any distinction in the tight-fitting between a full facepiece, which will still give you protection in the power-off mode, and a tight-fitting hood where you may not get so much protection and high CO2 buildup in a power-off mode?

And were you thinking of any tests, say, on breathing resistance or anything like that that would apply to the tight-fitting gas mask type of device rather than the tight-fitting hood type of device?

MR. THORNTON: Well, in this standard, this specific standard, which is tight-fitting facepiece, it is both the traditional gas mask that you would think of. It's tight fitting around the

face, and a hood that is tight fitting around the neck.

We are going to be touching on them a little, and I know Jon is anxious to answer this question, so you can go ahead and take this one.

MR. SZALAJDA: Yeah. I will take a shot at answering this one.

I think what we considered with the -- the testing and for the purposes of what we're doing for CBRN PAPR, all of our testing is with the blower on the equipment running.

Part of what we're going to address later today is to talk about the concept of failure modes analysis. And I think part of what we're expecting to see to get information back from the applicants are how you are going to address failure modes when the equipment is being used.

And part of that we will consider is if you say as part of your application if the blower fails, that you can still wear it as a negative pressure device, we will go ahead.

But what we're currently thinking is we

will go ahead and test -- take certain tests from the CBRN PAPR process and apply those tests to the PAPR to evaluate it for the things that you are suggesting, CO2 buildup, breathing resistance.

But having said that, we also acknowledge that because of what we find for the APR with a facepiece mounted single canister, there is going to be some variability with resistance, you know, if you are breathing through a hose with a manifold and canister.

Again, we will accommodate that, and we will address that as part of the evaluation.

MR. THORNTON: It's a race to the podium here.

MR. KJELLBERG: Bengt Kjellberg, Safety Equipment America.

Will there be a requirement for fit testing of a tight-fitted hoods of the user, fit testing of the user?

MR. SZALAJDA: Well, the requirement that will have to be met is the LRPL requirement as part of the certification process, regardless if it's a

tight-fitting or non-tight-fitting system.

It will have to meet the LRPL requirement.

MR. THORNTON: Were you talking about as far as a human and how they are --

MR. KJELLBERG: Will that be a requirement that they do annual fit testing and so on --

MR. THORNTON: Right.

MR. KJELLBERG: -- with the tight-fitting hood.

MR. THORNTON: Yeah.

MR. HEINS: Bodo Heins, Draeger Safety, again.

What fit factors is required then if the blower doesn't work? Because it doesn't guarantee that the blower can't shut off while it's in use.

So which fit factor is required when the blower is not running?

MR. SZALAJDA: That's something that we are going to need to work through.

You know, if that's part of the

applicant's instructions that you leave the respirator on and use it as a negative pressure device, my personal reaction would be that we need to meet the APR requirement, which would be 2000.

MR. THORNTON: Yes.

MR. PITTS: Sam Pitts, Marine Corps ChemBio Incident Response Force.

Les Boord, Jon Szalajda, Terry Thornton and Mike Monahan, I think they have all got a restraining order on me already. I don't want to add you to the list.

I have a question basically on the respiratory rates. I know it's a little bit off this subject, but I would like to address that to Jon.

The pump that you all bought, Jon, is identical to the one that you have used at Edgewood for the filter protocol.

And as I understand it -- and I don't know the technical terminology for that particular model -- but is it the one where you get the RPMs up to 5,000 and you let the clutch out, maximum air

flow is 103 liters of air per minute.

Is it that?

MR. SZALAJDA: Okay. Terry actually bought the equipment.

All I did was (rest of statement drowned out by laughter.)

MR. THORNTON: Actually, the one we're getting is from England, somewhere in England.

So I haven't really seen the device. I have seen the pictures of it. I don't believe that it has something like that.

I'm not familiar with the one you are referring to. And I think someone is going to stand up right here and tell us.

I think it has, the one that we bought, that hasn't been delivered yet.

He may be able to help us out.

MR. CARETTI: Dave Caretti, Edgewood ChemBio Center.

Sam, it's not the same pump.

MR. PITTS: That's good.

Because you had me concerned about that

clutch business and everything. I didn't want to mess with that.

MR. CARETTI: It's actually a pump that allows much greater flows than that. It's programmable. It can be programed with different wave shapes.

We have one -- we haven't used it in the type of applications you are talking about, but next time you're in the lab, we will show you.

MR. PITTS: What is the maximum?

MR. CARETTI: Well, the system comes with a pump that can provide a seven-liter stroke, which you would never have.

So it has top end capabilities.

MR. PITTS: Could I characterize -- with this pump that you have just described, could I characterize human cyclic respirations in either sinusoidal or trapezoidal waveforms in the area of 600 liters per minute in peak inhalation air flows?

MR. CARETTI: Yes.

MR. THORNTON: Yes.

MR. CARETTI: That's a peak flow. That's

not a minute volume. A peak flow.

That's an instantaneous, one time, peak value in whatever wave shape you have.

MR. PITTS: What is the maximum air flow with human cyclic respiratory patterns you could duplicate on this device in liters per minute in terms of a minute volume?

MR. CARETTI: I don't know the exact number, but it's up in the 160s, 170s.

Yeah. I don't have the exact numbers.

MR. PITTS: So then, I guess I'm not grasping it.

As I understand it, if we have a pump that's, for instance, pumping 300 liters of air per minute in minute volumes, if you multiply that times three, we would approximate peak inhalation air flows three times that, 600.

Is that a correct statement?

MR. CARETTI: You can go as high as the system allows you in term of actually using it, but the practical application of that is a whole different issue which we can't resolve right here.

We can talk about it offline.

MR. THORNTON: And, too, it's much larger than that. If you have got a seven-liter capacity, and I don't know how fast --

MR. CARETTI: Well, it's the response time in terms of shifting up and down.

If it's that large of a volume, you are limited by how fast you can make that pump operate.

MR. THORNTON: And how quickly it can respond itself.

MR. SZALAJDA: And I think for the purpose of moving on, let's see, I was a little worried about where Goran was sitting since he was next to this microphone.

Let's take another question, and then we will have a 15-minute break.

MR. BERNDTSSON: Goran Berndtsson from SEA.

It's going to be important what you are determining that's a negative peak.

When you are going from the low to the high, if it's a breath responsive system, it's

going to identify a change in the curve, and it will adjust its output accordingly.

But that could mean one negative spike before the higher one is coming. And this is the nature of the driving system.

MR. THORNTON: You're correct.

We are going to have to look at that. And that's kind of one of the reasons I referred that to issues that still are remaining.

Because there is going to be a time where you increase that respiration per minute, whether you do it instantaneously, whether you build it up a little bit, but not everything is going to respond instantly to that.

So we are going to have to really look at that. Not only are we going to have to identify what a negative peak is as far as looking at the 86 liters per minute, whether it's negative or whether it's within the accuracy of the transducer, we're also going to have to look at that ramp-up from 86 to 103.

So it's a good question, and we really

haven't got enough data yet to be able to answer it.

MR. BERNDTSSON: But that's what it will affect, the warning for negative pressure, issues and the warn on the second because of that.

You understand?

MR. THORNTON: Correct.

MR. BERNDTSSON: So it warns on the second spike.

Because that meant that you are out of breath, then it couldn't go up fast enough.

MR. THORNTON: Correct.

And remember those are separate tests that will be run.

MR. BERNDTSSON: The one may affect the others.

MR. THORNTON: It very much could.

MR. BERNDTSSON: Yeah.

MR. THORNTON: And so we will be looking at that when we get that breathing machine in and when we have the ability to collect some actual data.

Yes. Another question.

MR. BARD: Brent Bard from SAMS.

My question is on your battery life, are you determining battery life at the lowest operating temperature?

So if the manufacturer says it's an eight-eight hour battery life --

MR. THORNTON: Uh-huh.

MR. BARD: -- that that has to be eight hours at the lowest operating temp?

MR. THORNTON: I'm not sure if I really thought of that point. I see what you are saying.

Remember, the operational battery life comes from the manufacturers.

So the question is really are we going to allow the manufacturer to come in and say, At room temperature you get eight hours of battery life, but if you have to run it at low temperature, which we say this will run at zero degrees C, for instance, so you only run it for four hours, I'm not sure how you would handle that in certification.

I believe what we would do is at room temperature, we would run it for what they say it would run at. And then at low temperature, we would run it for, again, the time that they have given us for that low temperature.

But I'm not sure on that. I mean, really that's the first time that you brought that up.

MR. BARD: I think it's important that the battery life be rated for its lowest operating temperature.

MR. THORNTON: Yes.

MR. BARD: The reason being because rarely do you actually have a unit operating at room temperature when it's being used.

And, for example, if you walk outside today, it's not going to be your plus 25C, plus or minus.

MR. THORNTON: Correct.

MR. BARD: As well, you are going to have the unit affected by humidity, as well, which is also going to affect the run time on your battery, et cetera, et cetera.

MR. THORNTON: Correct.

MR. BARD: So I just think it's important that you consider that the battery life be at their worst case operating temperatures.

MR. THORNTON: All right.

You know what, that's a good point. That's a good question that you brought up.

So we really have to look at that, how we're going to analyze the battery, what kind of times we're going to allow for it.

MR. BERNDTSSON: Just a comment regarding to that.

Often the environment is so variable, from many, many degrees below zero to the hundred degrees Farenheit.

MR. THORNTON: Uh-huh.

MR. BERNDTSSON: It is very difficult to put criterias for every test.

And I think that the warning when you come to the end of the battery is really the answer to this question.

I mean, if you are in the 15 minute

warning, if the battery is rated for six hours, for example, in all conditions, and it happened to do three and a half in a minus and maybe seven when you come up in the warmer temperature, the 15 minutes is still the operator's warning that the time has changed.

MR. THORNTON: Uh-huh.

UNIDENTIFIED MAN: No. Because that is going to change as well, depending upon your operating temperature.

So your 15 minute is no longer valid at a lower point.

MR. BERNDTSSON: That is true with some result. It should adjust depending on that.

MR. SZALAJDA: I think at this point, it's probably appropriate that we take our break. And if we need to have some additional discussion, we can do it offline.

(A recess was taken.)

MR. SZALAJDA: CBRN Letter, which is Docket No. 10. And the bottom part refers to the industrial PAPR work, which refers to Docket No. 8.

And just as a matter of note, when you come up to ask questions or make comments, if you can make sure that you speak into the microphone so that the information can be accurately transcribed.

And when you introduce yourself, at least, everybody, you know who you are, but if you can slow down so that he can transcribe, you know, your name and make sure we get it accurately.

It will reduce the amount of work that we need to do as well in getting the transcript finalized and making it available through the docket office.

All right. To continue with our benchmark testing results, as I mentioned earlier this morning, we have -- you know, we have continued to work actively with our colleagues at ECBC, which we occasionally refer to as NPPTL East, or the Chesapeake Bay division.

But with regard to some of the work that they are -- they have done in supporting our standards work that Paul Gardener has led an effort to evaluate and conduct particulate efficiency

benchmark testing at the Edgewood site, and he is going to provide a presentation for us regarding the work that was recently complete at Edgewood.

And then we will resume with the completion of the work that we have done at NPPTL.

So With that, Paul.

MR. GARDNER: Okay. Thanks for the introduction.

This testing, again, is benchmark testing for particulate efficiency on canisters. And it wasn't meant to address every canister out there.

I suspect the same models that I believe that were -- that you saw previously in the breath performance or breathing performance test.

When you see A, B, C, D, they are not necessarily the same as what Terry briefed. So I just want to point that out when we get to the slide, when you see Manufacturer A, B, C, D.

Okay. The objective, again, was to assess the particulate efficiency at various cyclic and constant flow conditions. Okay?

Not necessarily the ones -- and not the

ones that are currently in the concept paper.

There are two separate evaluations we did. One was the initial penetration. And the other was DOP aerosol loading to assess the effects of aerosol loading on particulate efficiency.

Again, these were the CBRN type canisters, first responder type, the same -- came from the same PAPRs I believe that Terry evaluated. I don't know that for exact -- that they were the exact same ones, but I think they were.

The initial penetration test, that was conducted on an in-house fabricated test system, basically a chamber which had -- we had a breathing pump and another pump to handle the constant flow. And the canister was inside that exposure chamber and evaluated.

We used -- for aerosol generation, we used the same nebulizer that's used in the automated filter test apparatus TSI Model 8130.

That's done for certification testing now at NIOSH for industrial as particulate standard.

And in this case, we used for this --

since this is the initial penetration test, we're just looking at penetration of the same aerosol size.

We used the PAO, used a poly-alpha Olefin, better know as emery oil, test aerosol. And that produces the same particle size distribution as what's used in -- for DOP in a certificate -- regular certification test, about 2.2 micron count medium diameter particle.

Both the challenge and the penetration measurement was made using the DustTrak, which is another TSI instrument, Model 8520. It's a photometer aerosol detector, and it's very similar to the detectors used in the 8130 test apparatus.

The sensitivity is approximately .001 percent.

I'll get this right yet. Initial penetration tests.

That's the matrix. We have tested three canisters, two cyclic flow conditions, three constant flow conditions, three trials each.

Now, the constant flow conditions were

not tested on each canister, just the canister you see on the left column is saturated with that constant flow condition to -- all the way to the right column.

The two cyclic flow conditions, the parameters are there. 85 liters per minute and the 135 liters per minute.

Again, I didn't mention this, but in all of the results, the actual test flows are going to be proportional to the number of canisters that are in the PAPR system.

And we'll just get right to the results.

As you can see, on the very far right-hand corner, we have the average efficiency results and at the various flow conditions.

Again, the constant was just tested on Canister A at 360. And Canister B was tested at 270 constant. Canister C at 85.

The efficiencies were well below 99. -- I mean, well above 99.97 percent for all of the test conditions.

Now, DOP loading test, again, this was

done to just look at the effect of aerosol loading of DOP on the particulate efficiency of those particular canister.

And we used an automated fit tester to actually do the loading. And when we did that, when they were inside that machine, we were measuring at the flow rate, that minimum specified flow rate for that system.

And for the cyclic and constant, we -- they went from that system to test at the higher cyclic and constant flow conditions, we tested using the in-house fabricated system, using the PAO test aerosol to do that evaluation.

Next.

Three canister models were tested. Again for this test, we didn't test Canister B. We tested A, C and D from those PAPR models. One was a loose-fitting, the top one, that Canister A came from, at least that particular configuration.

And the other two were at the minimum rate were at the 4CFM PAPRs.

We did the loading with the automated

test apparatus, filter tester at the minimum stated system flow rate as proportional to the number of filters used in the system.

And we loaded up to 1100 milligrams total loading. That's more than one milligram for each canister. That's pretty high loading levels.

And we did, again, look at the cyclic and constant flow penetration using those two. The cyclic was at 135, and we looked at constant at 270.

All right. This graph shows a plot of the penetration, average penetration, versus the DOP loading that was done on the certification tester at the, what I would say term is standard constant flow rate, the minimum flow rate for that system, for proportional number of filters.

And you will see, for each filter well below the .03 penetration, which corresponds to 99.97 percent efficiency.

And only two canisters were done for this test. And so this is just a real limited evaluation just to get some benchmark data, nothing

really dramatic there.

It was almost just slightly above the sensitivity of the equipment, until you get way out there at the extreme loading levels where you see a little bit of stuff going on.

Not much, nothing significant.

Okay. I don't think I fully explained that, but when we loaded at 200 milligrams, we took it from the automated filter tester system over to our in-house system to test them at the higher flow rates.

So each increment 200 milligram level, we went back and did a instantaneous initial penetration result at these flow rate conditions, and this is the data we came up with for that.

And again, there's not -- because of the different flows being tested, some of these filters are three -- I believe are two-canister systems. One of them was a three-canister system. One a very slow flow rate.

And we're not comparing the same thing. They are tested at different flow rates, but

they're tested under the system flow rates.

You just can't see the orange is higher than the blue and say, Well, that filter is better, you know.

Anyway, it's all very, very low penetrations to begin with. So there were not significant differences between these filters, which, you know, really shows us these filters have -- these particular filters have tremendous capacity for, at least, for DOP oral aerosols.

And we didn't see a significant effect all the way up to 1,000 milligrams loading per filter.

So in summary, all of the PAPR canisters we tested well exceeded the 99.97 percent efficiency level.

And all of the flow conditions we evaluated where the initial penetration maximum was .08 percent, and that was at 180 liters per minute constant flow condition.

And as far as, again, these filters showed a very high capacity for oral aerosol

loading. And the maximum penetration was measured about .002 percent, and -- well, also as far as -- I mean, excuse me, 9 percent at the cyclic condition and 67.5 liters per minute.

And that was at the 1,000 milligram max rating interval, the highest and the last test we did.

That concludes my presentation.

It's pretty straightforward, but I could have got up here and showed you all of this data which was all up to baseline, but ...

Any questions?

MR. MAN: Bill Linko from Micronel again.

My question is why use canisters?

The canisters can do the filtering job, but from an aerodynamic point of view, they have problems.

The direction of air changes about four times, it takes energy; okay. It's not uniform through the medium.

And so I'm wondering why we stick to canisters rather than an oval or a square box,

which has 25 percent more area, which means I can reduce the flow rates by 25 percent, which means I can get better absorption and filtration and so forth.

So I'm curious why the canister approach seems to be locked in granite.

MR. GARDNER: I will have the manufacturers address that question.

Why -- you're saying why you go to a canister design for particulate testing?

MR. LINKO: Right. I would be willing to submit a filter of the square shape to match one or two or three, and that would give us 25 percent more area.

And we make filters for orthopedic surgeons, and you know, we get much better efficiency out of the filter from the standpoint of power requirements and so forth.

So I'm just curious why we can't shift away from canisters.

MR. GARDNER: Yeah. I don't think anything in the standard precludes a manufacturer

going in with a square canister.

MR. SZALAJDA: There's nothing in the standard to preclude any type of design.

MR. LINKO: Okay. So you would test it if we submitted one?

MR. GARDNER: I'm sure they would test anything you submit.

MR. SZALAJDA: I think just to follow up, though, when you are talking about testing the canisters, we're building on the traditional methodology, how work has been done and how the -- building on the -- continually building on the database that is already there.

But some of the concerns that we have seen, and I think you have alluded to with the design, is that we really do expect to see the filters -- we do expect to see consistent flow through the media, whether it's a combination of a filter or whatever.

I guess at least as far as the part of what was under consideration with this standard in looking at the canister, we're not -- it's not a

specific topic for today.

But unless Terry during his part of his presentation, we do have a requirement for canister uniformity and a standard to address -- to look for uniformity as a result of the production process, which is based on the end standard.

And I think we have a slide later in the presentation that talks about dropping one of the tests related to the canister uniformity.

MR. GARDNER: The upshot of all of this is basically the benchmark perspective is giving a snapshot of what the current -- what's out there commercially available, how they can meet the requirement as far as testing to a specific flow rate.

And this date doesn't -- again, I didn't address the specific flow rates in the concept paper, but it does show it has -- the particulate penetration does not appear to be an issue at all of the flow rates being considered.

MR. VIJAYAKUMAR: Vijay from Air Techniques.

I have got three questions. I can ask all at the same time or one at a time.

MR. GARDNER: I can handle three at once.

MR. VIJAYAKUMAR: Is it a typo, or is it a specific reason why you load with DOP but measure with PAO?

MR. GARDNER: I was trying to follow the standard practice right now, which from the 42 CFR 84, and they do a loading test with DOP.

And that's primarily obviously for looking at derivation effects. They were addressing electric filters, I believe, at the time.

MR. VIJAYAKUMAR: So I assume none of the filters you have tested were electric?

MR. GARDNER: No, they weren't, obviously.

MR. VIJAYAKUMAR: Okay. Now second question, when you say gravimetric, you're loading -- you're actually measuring the gravimetric rate increase or estimating it?

I didn't see that.

MR. GARDNER: That's estimated on the flow and the concentration, and that concentration was different for each test.

So we did for each filter, that estimate was based upon the test conditions at the time, the flow and the concentration we measure.

We did a before and after measurement of the aerosol concentration, come up with a challenge concentration mass per cubic meter.

MR. VIJAYAKUMAR: So if it's an estimate, I assume all of them are captured by the filter, sort of?

MR. GARDNER: That's correct.

And with those efficiencies, we can preassume that all of it is being captured and we're actually on the media, very little is getting through.

MR. VIJAYAKUMAR: Last question on the test aerosol.

You stated .2 micron?

MR. GARDNER: .2, uh-huh.

MR. VIJAYAKUMAR: Is that something you

measured, or is it something you will be measuring because it's very close to the worst case condition of the filters.

So a small change is going to give you tremendously different penetrations through the filter.

MR. GARDNER: You are absolutely correct, and that's a good point.

We did -- for purposes of this study, we did stick with the same nebulizer. So we measured that performance, the aerosol size specification of that nebulizer, and we validate that so we know we have that.

MR. VIJAYAKUMAR: But that -- that's --

MR. GARDNER: That is in the 84 right now. That meets the requirements. Okay?

They have --

MR. VIJAYAKUMAR: Did they specify --

MR. GARDNER: They specify, I think, at a .18. I rounded it off to .2. We essentially are right at that requirement.

I didn't put the standard deviation up,

but were on that requirement.

That's it.

MR. THORNTON: Let's see if we can get going here. Have to give me a second to get started.

And this one, there's no more videos that go with it, so we should be able to do this pretty easy.

Well, unfortunately for you, you have got to listen to my voice for another half hour, 45 minutes or so.

This first two that I give are pretty simple compared to the service life testing. And I'm going to assume that right now we're going to have a few questions after we're all done here.

Some of the things I want to talk about on the service life testing, you have probably heard. In fact, if you have been coming to these public meetings, some of it you have heard many, many times.

So I'm not going to try to rehash a lot of the things that have been covered for the PAPR.

And some of this goes back even farther than that.

I'm going to talk a little bit about what the service life -- how the service life is being tested, how the concept paper says it will be tested right now. And remember it's a concept, so things could change based on the information that we get in.

The service life includes gas life testing, particulate testing, and I will touch on that just a little bit, the crisis provision or panic demand, which I know a lot of people have been waiting to here about.

And then we will give some benchmark results that we have done in service life testing as far as gas life.

And then we will have questions at the ends if you need any.

We will start with one of my favorite slides we created, I don't know, a couple of years or several years ago. And if you have been around the business, you see the slide several times shows up.

This is the test representative agents, the ten test representative agents that we came up with to represent the list of 100 and -- I can't remember what the number is now, 139, 136. It's been so long ago since we did that.

You can see the test representative agents, the challenge concentration in PPM. The breakthrough concentration we are looking for in PPM.

And, yes, for the PAPR, we're going to use these same test representative agents, challenge concentration, and breakthrough. Let me make sure I clarify that.

For the tight-fitting PAPR, that's what we're going to use.

You are going to hear another talk later about the non-tight fitting PAPR, may have a little bit different test representative agents.

One thing to remember here, pointing out the 4.7 has a little asterisks, and somebody forgot to put what that means down there.

That's a combination of both cyanogen and

hydrogen cyanide to get 4.7.

The only other different are -- thing that stands out is the NO2. We actually look for 1 PPM NO2 or 25 PPM NO.

For the service life testing, we are going to go back to the manufacturer and apply again for that moderate and high breathing rate, just like we described for breathing performance, low flow battery -- low flow, low battery indicator. It's that same breathing performance during the application, doesn't change.

Capacity 1 through 6, manufacturer will specify, it says filter capacity.

That is the capacity for that system. All right. Don't get that confused with the individual canister. The system will have a Capacity 1 or a Capacity 2, whatever it is that the manufacturer applies for.

And if we think back, the Capacity 1 is actually a 15-minute test time. Capacity 2 is 30 minute test time.

We're not really going to go over that

any more than -- if you have any questions about how that capacity works, please just come see me after this short presentation.

Let me get to my notes here, so I know I keep up.

There were a couple of things in the previous concept paper dated March 30, '05, that did not show up in June 30 or June, whatever it was, June 20, '05.

Some of the things we have been discussing and talking about, and we said that we -- sometimes we had options out there, Option A Option B, decided what we were going to do.

Two of them, right here, that we had come to conclusion on, these really kind of go together.

The first one, from March 30, '05, Section 5.5.2, has actually been dropped. So it's no longer in the June 22. And that's the service life test -- the system service life test.

We talked about how we were going to do the testing, whether we were going to do individual canister testing or we were going to do system

testing, or we were going to do a combination of it.

In the last concept paper, we had the combination in there. We had individual canister testing on some of the test representative agents. And then for a few of them, we test the manifold with the canisters all together. We dropped that.

We're only going to test the individual canisters. All right? They won't be put in there as a manifold using a manifold. They won't be tested in combination. Only the individual canisters.

Now, if a unit comes in, and it has one unit, one canister or one cartridge or one element that's the filtering element, that's what would be used for the testing.

If it has three, we would still do just individual canisters.

Airflow, this has always been something that we have talked about how we are going to do the airflow, what airflow we're actually going to use.

If we go back to the APR, which like Jon said was a tough standard to write, now that we have written it, it's pretty easy. In this case, it was very easy because we had a constant flow of 64 liters a minute, we did 100 liters a minute.

It was pretty easy back then.

We looked at the PAPRs. We see that the PAPR does not show not all PAPRs are made equal, not all of them flow the equal amount of air through that canister or through the cartridge, whatever you want to consider it.

I think canister would be the best terminology for here.

There's also a difference between -- there's a difference in PAPRs. And we can see, we will go back to this concept, the constant flow PAPR, and I describe what I look at that as, and we are going to have a better definition of what that is. There's the constant flow PAPR. There's demand responsive type PAPRs. They operate differently.

They still give protection, but they do

operate differently in how the motor actually works.

So the airflow, the constant flow PAPR, we're going to measure the airflow of that constant flow PAPR, and then we're going to test the canisters using that airflow divided by the number of canisters.

If it's 300 liters a minute, two canisters, divided by two, it would be 150 liters a minute going through each individual canister.

This next one, demand responsive -- and this is where we get a little more complicated on how we're going to do this.

We have actually -- what we have decided to do with this concept paper is take a demand responsive PAPR, and we're going to settle for just establishing flow rates that we're going to use for the service life testing.

That would be service life and -- which would include the particulate testing. So we're going to set those values.

And we set those values based on -- we

decided really what we had to do was take a cyclic flow up and down, somebody breathing, and convert that to a constant flow.

The question is how were we going to do that. How would we go from cyclic flow to constant flow?

And what we decided to do looking at the literature, we decided to use this equation. This is a minute flow, the minute volume flow with the root mean square from the cyclic flow.

So this is our constant flow.

The PIF is peak inhalation flow divided by the square root of two. Hopefully everybody agrees with this.

If we look at moderate, the moderate, you go back to the breathing performance, it's a breathing machine of 40 liters a minute, 40 liters a minute multiplied sinusoidal wave, multiplied times pi, you get 126 liters a minute. Put that as your peak inspiratory flow.

Put 126 in this equation, PIF divided by the square root of 2, and you get the flow of 89

liters per minute. That is for the demand responsive system. All right?

So that's the flow that would be used if it comes in as a moderate flow rate device.

I can see some people itching to get questions already.

If it comes in as a high breathing rate, high work rate requirement, that's what it's being submitted for. We do the same thing. We look at the 86 liters a minute that we're using for the breathing rate, multiply that times pi, you get 270.

Put it in this equation, again, and we come out with a test value of 191 liters per minute.

I would probably expect in the concept as it cames out next time, we may round these numbers up a little bit. That's the numbers that you get from the actual equation when you put it in there.

Probably for laboratory testing purposes, we may round that to -- for 89 liters a minute, we may just go to 90. So it's a very even number to

deal with, or probably -- and maybe round this down to 190.

But we're not really certain on that. We will just kind of keep an eye on those and see how they do, what it can do in the laboratory.

So how would we be doing the service life testing?

We will go back to our old standby of doing three tests at certain conditions. We like to do this because it gives us three points to do.

So, as we have always done in the past, we look at low humidity, and we look at high humidity.

Remember, the CBRN is not a -- is a canister with a one-time use. You open it up and you use it.

So there's no preconditioning that takes place with this. We just run it at the high humidity, at low humidity.

We're always doing everything at 25 degrees C. The capacity is the capacity that's requested, Cap 1 and Cap 2, which is 15 minutes or

30 minutes or on up to Cap 6.

So we got the 25 percent humidity, the 80 percent humidity. And then you see down at the bottom, we decide to come to some conclusions on how we're going to do the crisis provision, which is something we have talked about several times.

The crisis provision was spoken about. And, in the last concept paper, March 30, it had two options that we were looking at in there of how we were going to do that, how we were going to set up the crisis provision.

As we can see, the number was going to be 263 liters per minute divided by the number of canisters. That was the crisis provision.

That 263, again, may be rounded up to a whole number, but that's really the number we are looking at right now. That's what's in the concept paper.

So the crisis provision, we decided to stay with the constant flow test. Again, described in the concept paper, the cyclic flow test that we may be looking at.

A couple of reasons that we came up with to stay with constant flow. The first reason and my favorite is because since I work in the laboratory, it is so much easier to run a test for service life at a constant flow. It's more beneficial in the lab. It's cheaper.

It's not as time consuming, which has big plus for the laboratory.

Commonly, in most of the labs out there, the tests that are run, they are all run at constant flow. So we know how to do that, and we're very good at it.

The second thing is this value of 263 liters a minute.

As soon as we incorporate all of the -- an average maximum inhalation peak flow, and that's something that's probably up for discussion, and people are going to discuss this quite a bit of who comes up with this maximum inhalation peak flow.

And I will discuss this in just a minute, but the value of 263 seems to be able to incorporate all of those maximum peak flows.

So where does the 263 come from?

We have looked at studies that have been given to us and we have found. And what we come up with is an average maximum instantaneous peak flow of somewhere in approximately 370 liters a minute.

Now, that number could be debated, but that's the number we're going to stick with now for this concept paper.

If we can cover 370 liters a minute, we feel relatively confident that this number is covering the majority of people out there that could be using a PAPR, probably up in the 99 -- the 99 plus percentile. Don't quote me on that, but that's what it looks like, 370 is going to cover those people.

So, again, we go back to our favorite equation, there. We just assume a sinusoidal wave. And we have talked about how sinusoidal looks very similar to what an actual breathing pattern could be.

And we can convert that 370, using this equation, peak inhalation flow of 370 divided by a

square root of 2, and we come up with just 63 liters per minute.

So that establishes our crisis provision. We now know there is going to get constant flow, and that's how we are going to test it in the laboratory, as far as our concept paper right now.

Give you some quick examples of kind of how this breaks down. These are just three examples that we pulled out of the air so that we know what we're expecting from the manufacturer or what you are expecting from us to be tested.

The first example, the constant flow PAPR.

If somebody comes in and calls it a moderate breathing rate, we do the airflow measurement, we get 150 liters a minute. That's the maximum airflow that this unit produces.

Jeff is going to come up in a few minutes when I'm done, and he is going to talk about how we have done some studies to look at how we're measuring the airflow.

NIOSH traditionally does it a certain

way. I can't remember the test procedure number.

We have looked at that, and we have looked at additional variations of that and an additional way to create -- or how to measure the airflow.

But what this says right now, for example, let's convert 150 liters a minute.

It has two canisters. It's a Capacity 1, which is the lowest capacity that can come in.

We would test three canisters, open them up one at a time, test that canister three times, 25 degrees, see 25 percent humidity. The flow would be 150 divided by two, 75 liters a minute.

We can do that for 15 minutes for each of the test representative agents at their challenge concentrations, looking for their breakthrough.

We would again do it a 80 percent humidity. So we had that low humidity to high humidity.

And then looking at the crisis provision, three canisters would be tested 50 percent humidity, 25 degrees C, 132 liters a minute, that's

263 divided by two, for five minutes.

Another example we have coming in here, a constant flow, high breathing rate is what the manufacturers applied for.

The flow, 285 liters a minute.

That flow is way above -- or not way above, but it's above the 263 liters per minute. Three canister, Capacity 1.

We test three at the low humidity, 95 liters per minute for 15 minutes. Three canisters be tested at 80 percent humidity, 95 liters per minute, 15 minutes.

And since the airflow was greater than at 263, the testing that we're doing is already incorporated at 263, which is what we base our maximum inhalation peaks.

The normal flow of that PAPR has already covered that, so we would not have to do any crisis provision testing for those canisters.

Of course, we lost our example of demand responsive. Demand responsive, for instance, that came in with a high breathing rate, two canisters,

Cap 1, you see, we go back to those standard numbers that we set for demand responsive.

Three canisters tested, low humidity, 95 liters a minute, 15 minutes, three at high humidity. And then three, 50 percent humidity, the crisis demand, which is 132 liters a minute because there's two canisters, 132 liters a minute for five minutes.

Let me catch up with my notes before I miss something.

Service life benchmark testing.

This kind of goes way back to the benchmark testing that we used for the breathing performance for battery flow indicator.

Again, there are PAPRs that are out there on the market. They have NIOSH approval, or regular industrial NIOSH approval. They are purchased on the market, both constant flow units and demand responsive unit.

And, again, they all had two or three canisters and were first responders type canisters, the canister that was purchased with that unit as

an approved device.

For constant -- let me step back.

For this benchmark testing, some of this was done -- well, really all of it was done back before the previous concept paper when the demand responsive was going to be tested at 300 liters a minute for the high, and so that's kind of the value we used.

Remember our benchmark testing is more than just trying to figure out what the industry has out there.

We had to go into the laboratory and try to develop tests so that we could run at these large flows, 300 liters a minute, maybe even 400 liters a minute.

And in the lab, I feel relatively comfortable we could test up to probably around 450, maybe even possibly 500 liters a minute airflow at that challenged concentration, looking for that breakthrough, and controlling the humidity of that high humidity of 86 percent.

That was really a challenge for us. And

we did some of that testing, and we could see that we could produce that if we had to.

When we did some of the benchmark testing -- and you will see it come up as graphs, what we were trying to do is see the differences between the individual canister testing versus the manifold testing versus some other way we could do the testing besides using the manifold from the manufacturer.

We had a large box that would hold up to four canisters. So we could put two canisters in there, or three canisters in at a time, kind of mimicking a manifold.

What we were looking for is to see if we run, for instance, two canisters at 300 liters a minute, we get a breakthrough time in service life, if we individually tested them at 150 liters a minute, would that service time be equal to the manifold or to the box.

Not all of the data fills in every one of those examples, but we try to do it from across the board to a few of these test representative agents.

Yeah. I think I covered everything.

So we will look at some service life benchmark testing.

And, remember, these are not canisters that are CBRN approved. They are just canisters that were out there for first responders. Doesn't mean that they were actually built to the standards for those chemicals.

But in this one, Model A, I think this is a constant flow device. I can't remember the exact flow that we had measured on this and what we had used for it, but you can see, looking at the medium, it was relatively low, ten -- it was probably actually just about 15, 16 minutes.

Cyanogen chloride is much higher. The SO2, well above the 15 minutes. And even the cyanogen chloride was well above the 15 minutes. That was from Model A.

You can see the -- I don't know if you can read it from back here.

We tried to run these either low temperature or low humidity or high humidity. And

the reason we did that is so that we could, again, look at the method development and make sure we could run these humidities.

The 80 percent was the biggest concern. If you try shoving 300 liters a minute or 400 liters a minute through some small tubing, you will not get 80 percent humidity. It's just not going to work.

You can't crank enough water in there. It won't allow it.

So we had to go from some half-inch tubing up to larger tubing, about one-and-a-quarter-inch, I think, is what the standard test procedure shows it now.

And that would allow enough room to not build up pressure and be able to control the humidity.

So most of these are at the 80 percent for that reason.

I think they normally run at 25, it's a little bit worse case for them to run at 25, but we did run that system at the 86 percent to see if we

could maintain it.

So this is the Model A.

PAPR Model B, again shows the same type of characteristics.

As I was showing, this one is a single canister test. And I try to do this three times on most of the gases.

Manifold 1, Manifold 2, that's just where I used the manifold from the manufacturer that came with that device.

We try to run that test twice. And sometimes we made it, sometimes we didn't.

The box is what I described, the large box that could have up to four canisters in it.

And as you can see, if you look across the tops of these, this one, for instance, the single canister at the reduced flow, is relatively equal to the manifold at the higher flow, the manifold at the higher flow and the box.

Part of this is really what helped us decide that we did not need that manifold service life testing, that we just needed to do the

individual canister testing.

You can see, I skipped Model C.

The reason for that is I ran out of canisters. I have got more on order, but I haven't quite got enough of them in to really do enough testing to be able to describe it.

Model D was a breath response PAPR.

So these flows at that time were set at -- pick at 300 liters per minute. So that's a pretty high flow.

And even at that high flow, you can see that the -- first of all, the readings are very consistent in the single canisters at the half flow compared to the manifold at twice the flow, two canisters.

So the readings are very consistent across there in the service life.

And again, you will see some service lives that are pretty low, somewhere around three and a half, four minutes for a couple of chemicals. I think CK and ammonia.

Again, I'm not sure if these are really

built specifically for CK or ammonia. They may not have been. Plus they are very high flows.

So if you look at these times and you can reduce that 150 or 300 liters down to where the testing would be set at now, they should be sufficient to pass the 15 minute, which is the minimum standard time.

All right. Particulate testing, this is another area where we have had a lot of discussion on what we're going to do.

And we have been putting out, and we have been saying for a couple -- several months now that we are looking at some high flow testers that will produce a higher flow following the standard for 42 CFR, above what the current technology is using, which I think that's limited to somewhere around 90 liters a minute.

We have got these two units on order. One is from TSI, and one is from ATI. One of them has been delivered, and it's actually in NPPTL. There's a laboratory set up there now. It's kind of a temporary laboratory, but it is set up.

The status of it really is we have got the compressed area that's needed. The vacuum is now working. The filtration is working from the hood because we had to get rid of that DOP, away from the people that are doing the testing.

So it has been powered up. It's actually performing to a certain point.

What did I say? There's a little bit of work that needed to be done even though they're brand new, you still have to do some fine tuning to it, and that kind of held us up for a couple of weeks.

So right now, in fact, they just delivered some kind of microchip into it yesterday. And hopefully either tomorrow or the next day we can go in and run some gravimetric test for this specific device.

We will take a filter, or whatever, just like we did for TSI for certification or to prepare for certification. Take some filter paper we have. We put it on there at a certain airflow, and generate the DOP, and we will see how long it takes

to generate 200 milligrams on it.

It's a gravimetric test. That will be the first set of tests that we do.

But once we can kind of characterize that at certain flows it takes so much time to generate 200 milligrams per -- or 200 milligrams on the filter, we can then start some service life particulate testing for canisters.

We will go right back to that same model as A, B, C, and D. Hopefully I have got more canisters for C now, and they will be able to use those.

And this will be the same or was just spoken about by Paul Gardener. It's those same canisters.

So we will see what our new high flow testers can do. And we will kind of look at his results to see if they are very close or the same.

We will have to set up some kind of program to know exactly what we're going to test, how many we're going to test, and how we're going to compare.

The other one what's coming in, the other high flow tester, hopefully it will arrive either this month or next month.

We assume we're going to have to go through the same procedures to get that in there and make sure we have correct air pressure, the vacuum works, and the ventilation actually works.

But once we get that done, we will go back, and we will see what type of testing to it, the gravimetric test, and then we will start the particulate testing.

So that's the status of our particulate testing right now at NPPTL.

All right. Remaining issues for service life testing, there's really three things we need to work on very much, the high flow particulate testing, like I just covered.

We have to get the second one in, and we have to see if these work and if they are working properly, they are reproducible, usable for certification testing.

Formaldehyde study, one of the problems

we ran into when we went into the lab, and we want to just talk about generating the challenge agent and the humidity.

Formaldehyde is not as much fun to work with as some of the other chemicals in the laboratory. And that's being nice to formaldehyde, there. It's pretty tough.

We were really having problems generating 500 PPM formaldehyde at some of the higher flows, higher humidities. It was very difficult in the lab.

We kind of ran out of -- our time to finish those studies and look at that. So we have a contract, I think has not quite been let yet. The money has not been let out yet, but I think that's what we are going to do.

And they are going to be some studies on formaldehyde to give us a understanding of how we can develop formaldehyde at 500 PPM at some higher flows, what kind of agent, or how will it generate that vapor agent. How are we going to heat it.

Formaldehyde normally has to be heated to

get into that vapor phase.

The problem we had in the lab is I had to heat it so much, when I tested it, the canister, it wasn't at 25 degrees C anymore. It was more like 35 degrees C, and that's just too far out of the standard. We couldn't do that.

So we have to figure out how to heat the formaldehyde, get it into vapor, cool it back down to the 25 degrees C that we need to test at, and still have 500 plus per million.

So that is going to help us quite a bit on that.

Sinusoidal benchmark testing on some of the other canisters -- or some of the other gases that we still need to complete, HCN, phosgene, phosphine, those have not been done yet. There's a couple of reasons for that. That's a whole -- it gets a lot of work in there.

Also those three gases are very expensive gases. We really want to make sure we know what we're doing before we start spinning those gases through those canisters.

HCN, for example, is relatively expensive, about $2,000 for a cylinder. And we kick those flows up to that 300 liters a minute, you really want to know what you're doing before you do that because you are going to waste -- you could burn up $2,000, and not get any results if you're not really careful.

So those three gases have to be finished off.

And I think N02 -- I didn't put N02 in here, and you also notice, N02 didn't show up on those graphs. That's because that data is about halfway done. We really didn't have enough to come out and show that data yet, but the N02 will have to be finished off.

If there's no questions.

Okay. At this time, I will attempt to handle all of the questions that come at us.

MR. BERNDTSSON: Goran Berndtsson, SEA.

I would like to understand your logics for your calculation of the peak flow divided by two square roots.

MR. THORNTON: I'm not a mathematician, so I'm not going to play one up here. And I'm not sure if I could describe that equation in the detail that you really need it.

We got that equation from looking at several books, math books, that tell us how to go from a cyclic flow to a constant flow. And using this equation of a root mean square, and I can't do the derivation for it.

MR. BERNDTSSON: But you can provide that.

I mean, we need -- I would really like to understand how you got to that and why you took that decision.

There's no point really to discuss it if it's the right decision or not before I understand how you got there.

MR. THORNTON: Okay.

MR. BERNDTSSON: So I don't -- I think it is too high, but I really need to understand this.

MR. THORNTON: You think it's too high as far as how we go from this peak inhalation flow

to --

MR. BERNDTSSON: Maybe because we know what the real value is.

MR. THORNTON: Okay.

MR. BERNDTSSON: That is what we suggested that you maybe should take that approach as well.

But if it can be calculated, I am sure that we can come to formula or maybe shoot a little bit better in the middle of the bullseye to say, you know.

MR. THORNTON: We would appreciate if you would send in the documents so we can -- to the docket so we can really look at, you know, a proposal that you would have to do that.

And I think I may have that information --

MR. BERNDTSSON: You already have that?

MR. THORNTON: -- that you are talking about, yeah.

MR. BERNDTSSON: But before I can do that, I need some information from you to be able

to understand the logic behind it.

MR. THORNTON: All right. I think we can put something together.

Jon is going to jump in.

MR. SZALAJDA: What we can do is with regard to how we came up with the formula and different references that were used, I think -- probably we can make a collection of the references that were used that derived the values, and we will place that in the docket within, say, two weeks.

MR. BERNDTSSON: Uh-huh, you say two weeks.

MR. SZALAJDA: And if you could request it, that way it's equal footing for, you know, any of the stakeholders, that will go out.

We will send an email or a letter announcing that that particular information is available in the document, and you can request the information.

MR. BERNDTSSON: Okay.

MR. HEINS: Bodo Heins, Draeger Safety.

Same topic. I learned in my studies that

the relationship is constant pi. That's what you have to divide a constant flow to -- the peak flow to come to the constant flow.

It's a mathematic relationship, that sinusoidal breathing rate.

MR. THORNTON: And it has to go from a cyclic flow to --

MR. HEINS: To go to a constant flow.

It a fact of P, pi, or how do you spell it in English.

MR. THORNTON: Okay. Yes.

MS. RICHARDSON: A lot of people up here.

I'm Irene Richardson with the US Army Center for Health Promotion and Preventive Medicine.

And my question is concerning the test breakthrough concentrations on the toxic industrial chemicals.

The same concern was brought up when the APR standard was in development --

MR. THORNTON: Uh-huh.

MS. RICHARDSON: -- realizing it's the

same numbers.

MR. THORNTON: Yes.

MS. RICHARDSON: Nothing was done. So I'm going to bring it up again.

MR. THORNTON: All right.

MS. RICHARDSON: For at least two of the chemicals, your breakthrough concentrations exceed published occupational exposure limits, some of them being ceiling limits, either by NIOSH or by the ACIH.

MR. THORNTON: Correct.

MS. RICHARDSON: And for formaldehyde, again, ceiling limits are being exceeded, such ACIH and NIOSH, as well as the OSHA permissible exposure limit, the time weighted average.

And I'm just wondering why this is.

You don't want to be purposely overexposing people to some of these chemicals.

MR. THORNTON: There is reasons for that, and I know I described this before, and we have explained it. It's not something I really had in my mind ready to go for right now.

But I think I can quickly talk about it a little bit.

The PEL (phonetic) is really an exposure limit that you don't want to pass up over a given amount of time, eight hours or whatever that is.

But there's also another limit that you need to look at is you should not be in an area where you are getting above IDLH, or where you are exposed to above IDLH.

So whether that their relationship is less than IDLH, from APR, PAPR, working in the area, you should be less than IDLH. And if you are above the PEL, less than IDLH, you need some kind of respiratory protection.

I have been through all the processes in terms of what's unique.

We came up with -- when we did the challenges, and we're looking in the laboratory, if you notice, the challenge concentrations are well above the IDLH.

And the reason for it is we tried to keep that relationship, that ratio of -- idea of three

times IDLH is what we were looking for, to the PEL.

Now, when we get in the laboratory, the problem is that PEL is very difficult to read sometimes.

Detection limits, real time detection limits, you're pushing the envelope there. Some of them you may not be able to read real time.

I'm saying that our detection rate is that you could come up with that, but I need to look at that in 15 minutes. I need to see what that is coming off there. So I needed real time detection limits.

So we held that concentration or that ratio between three times IDLH and the PEL, we held that ratio, and we increased that challenge concentration so that we could get to a level of breakthrough that we could easily detect in real time.

And that's why there are -- if you say there's two, I will just take your word for it. I can't remember how many there was.

MS. RICHARDSON: Yes.

MR. THORNTON: The formaldehydes are similar.

MS. RICHARDSON: Formaldehyde and phosgene.

MR. THORNTON: Yeah, uh-huh.

MR. SZALAJDA: Say that again, please.

MS. RICHARDSON: Cyanogen chloride, formaldehyde, and phosogen, were the three.

MR. THORNTON: But that's the reasoning behind it.

We probably have to explain it a little bit better in some of the paper -- I don't know if we have written a paper on it yet, haven't published yet.

MR. SZALAJDA: And I think the one thing I wanted to add to what Terry stated.

I think the one thing that, I guess, is something that comes up is about what the design of the canister or the design performance requirements for canister.

And our focus was looking on establishing a set capacity that, you know, when put into use,

that the canister was going to have a certain capacity to absorb 139 potential respiratory hazards within the context of how the system can be used when you're in a nonIDHL environment, but yet in an environment where respiratory projection was required.

When you look at for the purpose for the certification testing, the service testing that we are doing is essentially that.

We are doing a service life test to assure that the canisters have the minimum capacity to absorb X amount of challenge.

The translation of that to how the canister is actually used is what we're going to address through the development of our CBRN use guidelines as far as how you translate -- how you translate that capacity into actual application.

And that gets back into the manufacturer's recommendations for use like cyclic and doing monitoring, on site monitoring if the concentrations are available to allow the user or the hygienist supporting the user as far as the

change out schedule for the canister.

So it's not an easy thing. But, you know, I think the one thing that we have to keep in mind is that there's a difference between the service life tests we do for certification versus how the systems will actually be used.

And I think what we will see, even with a Cap 1 unit -- and this is just Jon Szalajda talking. I'm not saying this from a NIOSH quality standpoint.

But I think in actual application, but you could probably see a Capacity 1 canister last for eight hours. And you could look at monitoring, when you get monitoring in place, that is addressing the concentrations that a responder can see.

So it's not an easy answer.

I think the short thing is we're looking at trying to make things easier for the responder or the user community in addressing some of these things in our user guidelines.

And we will keep that -- your comment in

mind as we finalize the development of the guidelines.

MR. THORNTON: Yes.

MR. PFRIEM: Dale Pfriem, ICS Labs.

Terry, you had mentioned that one of the problems you encountered and solutions you found was widening the ID to about an inch and a quarter on the supply line.

MR. THORNTON: Yes.

MR. PFRIEM: What you didn't mention, and what my question is, is what capacity units were you using, 300, 400 units, you know, to reach 261, 300 in each case, and did you find you had to cascade units at all in order to run stable?

MR. THORNTON: I'm not quite sure I follow what you're looking for.

I mean, the increase in the pipe, we have that correct.

We did it on a C60 to run --

MR. PFRIEM: Was 261 stable?

Could you do that with a Miller Nelson 300, or do you have to use two 300s cascaded in

order to be stable at those conditions?

To run it at 300, did you find that the Miller Nelson 400 unit would be stable at 85?

MR. THORNTON: Okay. And I understand your question.

MR. PFRIEM: Or did you have to use two of them?

MR. THORNTON: And you must have been in the lab also because I ran across the same thing.

We have Miller Nelsons that are around, I think, 200 liters a minute, and they kind of progress up to, we have some 500 liters a minute that were specially built for us.

Those Miller Nelsons, even though they may come off of on a single line, they are not all exactly the same. Some of them work a little bit different. They have the ability to go up to higher humidities a little bit better than some of the others.

At the low flows, I think we're talking 150 liters or less --

MR. PFRIEM: I'm not worried about that.

MR. THORNTON: You're not worried about those?

Even with the half-inch tubing, it can pretty much handle that 80 percent humidity.

When you go up to inch and a quarter, that really helps because my problem was at 80 humidity.

In some of the cases, I put together two, maybe 200 liters a minute to get high flows. And we tried different combinations so we could understand what we needed to do at each specific test hood.

But we did cascade some of them where there was maybe like a 400 liter a minute and 150 liter a minute to kind of bend those two together so that the --

MR. PFRIEM: To test to 300?

MR. THORNTON: Yeah.

The key there is to look at where you are getting the humidity and the temperature from.

The way we do that is we have dew point hydrometer, and we pull that in and get the

dewpoint, record the temperature. Edge Tech is, I think, the hydrometer that we use. That gives us our humidity.

And if you're not careful, if you're not drawing your sample from the right place, which is really in the box or very close to the box, you can make it look like you are holding at 80 percent humidity when really you're not.

MR. PFRIEM: I think everybody here knows not to trust what's on the front of the box.

MR. THORNTON: Yeah. So we would cascade some of those.

MR. SZALAJDA: Okay. Why don't we take one more question on this subject.

I would like to get through the remainder of our benchmark testing before we break for lunch.

So if we could take one question, and then I think Terry would like to talk about another topic.

MR. BERNDTSSON: Thank you, Goran Berndtsson.

If I understand you right, over the

discussions here, we have talked about you measuring the maximum capacity on a PAPR and use that number for with some kind of formula.

You have dropped that, if I hear right, what you are saying?

MR. THORNTON: We have dropped it for demand responsive.

MR. BERNDTSSON: Okay.

MR. THORNTON: We are going to -- because one of the reasons for that is the demand responsive looks like it could go at a higher capacity, much higher than really what humans are going to be able to breath.

If we look at that number of 370, that's what the human can breathe in.

And I realize there could be some instances where somebody might go over that, but that's very far and few between who is going to go above that.

So if I measure say a demand responsive unit, and it goes up to 300, 400, 450 liters a minute, a human is probably not going to see those

high flows coming in.

So I think it would be at a disadvantage if I took a demand responsive unit, tested it to 400 liters a minute, said that's it's maximum, and then used that value to do the service life testing, I think that would be very unbeneficial for them because of the excessive amount of air that's going to go through there constant flow to establish a service life test.

MR. BERNDTSSON: I agree with you if the format is not right.

I mean, in reality is that if you are a customer using this kind of equipment, you want to know that it is actually going to work up all the flow rates for the center that it will cover.

And that was our argument with you, that you should -- because then all respirators are different.

Then of course, this is talking, make it all different manufacturers. But it makes it easier for the end user because they can trust the adapter that they are getting.

MR. THORNTON: And I think at this point, they are going to be able to trust that.

MR. BERNDTSSON: And that's what our point was, that for you to find out, you can't calculate it.

Because the principle of all respirators for how to get to that type of number is going to be different.

For some, it's going to be more efficient than others.

MR. THORNTON: Uh-huh.

MR. BERNDTSSON: So if you're using your formula, then are you kind of saying that everyone is the same, so let's use this formula. But if you were in there actually measuring it, it would be related to that design, and you will get the right numbers.

And that is the point.

And I mean, by doing that, you will actually help the user community to get something whose more trustworthy for them because that been tested in accordance.

MR. THORNTON: All right.

MR. BERNDTSSON: That's the point.

MR. THORNTON: I see your point.

And we will go back and discuss this and talk about it, and see how we all come up.

And my understanding, the way I feel is if we can show that we're passing up that peak, peak inhalation flow of this 375 -- 370, maybe even 375, we're going to cover the largest percentage of people out there who are going to use this respirator at the maximum.

That's a very high peak flow.

And so I feel comfortable that we give them that -- that trustworthy feeling of the respirator.

MR. BERNDTSSON: I mean, if you do that, this is benefit to us, if you go down the way you are going.

And the number -- I don't believe the formula is right, but the number comes approximately to the right number for high volume. So from that point of view on our type of

equipment, it's probably not that bad.

But there is other designs going to come in the end of the day, and it's going to work as well for them.

MR. THORNTON: That's true, yes.

But the human is going to stay the same, whether the designer will allow us to go more than that or not, so --

MR. SZALAJDA: I think that's a good point from Terry.

And I think part of what we're striving to do with the concept paper and ultimately the standard is to identify that performance requirement based on the anticipated physiology, and use that as our minimum requirement that needs to be met.

But, anyway, we will move along.

We have one final benchmark presentation.

It's Jeff Palcic with EG&G that is working on the airflow measurements in the apparatus.

MR. THORNTON: All right. I know we had

talked about how we were going to do this measurement.

Actually, Jeff is going to talk to us about how he did that in the laboratory, and how we took a demand responsive type device to get some airflows.

MR. PALCIC: All right. The determination of airflow for CBRN tight-fitting PAPRs.

Okay. Current PAPR flow measurement techniques work fine with constant flow PAPRs.

But demand response PAPRs cannot be evaluated using the same test equipment and the same method.

The purpose of this testing was to determine a CBRN PAPR flow measurement technique that would allow both constant flow and demand response PAPRs to evaluate using the same test method and equipment.

This is a quick overview of the current method used for measuring flow through constant flow PAPRs.

First, the PAPR facepiece is mounted on a head form and leak tested.

The head form with the facepiece mounted is then sealed in a Lexan enclosure with the PAPR bar outside the enclosure.

The PAPR bar is activated, and a vacuum is applied to the enclosure until zero inches of water is achieved.

At that point, with the enclosure at zero, the PAPR -- with the PAPR operating, the flow through the system is recorded.

What you are looking at here, this is a picture of a typical PAPR flow measurement system. And from left to right, you can see the PAPR blower on the outside of the enclosure with a connecting hose to the tight fitting facepiece model on the head form.

The head form is not directly connected to the vacuum system. It's open inside that enclosure. On the top of the enclosure is the pressure transducer monitoring the internal pressure. And on the right side is the vacuum

system with a flow meter, control valve, and vacuum blower.

Our new proposed CBRN PAPR flow measurement method required developing a flow curve for each PAPR tested. The flow curve is developed by mounting the PAPR facepiece on the head form and leak testing the system.

A pressure tap was installed at the manifold outlet of the PAPR, and the pressure tap in the head form is plugged.

The head form breathing tube is then connected to a flow meter and vacuum blower.

And with the PAPR blower off, the flow through the PAPR system is increased incrementally where the corresponding manifold pressure is recorded.

The data points are collected from zero to 500 liters a minute in increments of 50 liters a minute.

And with this, we can create a PAPR flow curve.

This is just a picture of a typical PAPR

flow curves, pressure versus flow.

And this is a picture of the setup that we use to develop the PAPR flow curve.

You can see the PAPR blower at the front with the quarter-inch line coming off of the manifold tap that we installed, going to the pressure transducer. And, again, the tight fitting facepiece model on the head form.

The head form is directly connected to the vacuum system, which consists of a flow meter, control value and vacuum blower.

After the PAPR flow curve have been developed, each PAPR was tested at a low capacity and high capacity breathing maching.

The low capacity machine had a fixed tidal volume of 1.67 liters, and four liters for the high capacity breathing machine.

Again, the PAPR facepiece is mounted on the head form and leak tested. The head form breathing tube is connected to either the low capacity or high capacity breathing machine.

And both the PAPR manifold and PAPR

facepiece pressures are monitored.

The breathing rate is increased until zero inches of water column is achieved in the facepiece during inhalation.

At that point, the maximum manifold pressure is recorded using the PAPR flow curve that we developed.

This is a typical example of a time versus mask pressure graph.

And as you can see, by increasing the breaths per minute, the mouth pressure is forced to zero during inhalation.

At the same time, the maximum manifold pressure is recorded.

And this is a graph of the typical time versus manifold pressure.

You can see the maximum manifold pressure, and it gives us a correlation to the curve in the maximum flow from the PAPR.

This is just a picture of the setup again.

You can see the pressure tap at the

manifold outlet. It's connected to the pressure transducer.

And, again, the tight fitting facepiece mounted on the head form with a breathing machine in the background.

This is a chart of four PAPR units that we tested.

As you can see, the low capacity breathing results are in blue, and the high capacity breathing machine results are in red.

The Model D PAPR was unable to be tested on the low capacity machine due to the higher flow rates required by that PAPR.

In conclusion, based on the data collected during a series of testing, the high capacity breathing machine can be used to measure flow on both constant flow and demand response flow PAPRs.

This will allow the same test method and same test equipment to be utilized in determining CBRN PAPR flows for both types of PAPRs.

And I know Terry has mentioned this a few

times.

The first CBRN PAPR flow measure method has only been tested on a fixed tidal volume breathing machine.

We do have the variable tidal breathing machine on order. And when that arrives, this method will be reverified on that equipment.

Any questions?

Good.

MR. SZALAJDA: All right. Thank you for your attention and participation this morning.

Why don't we reconvene at 1 o'clock, and resume the program there then.

(A recess was taken.)

MR. SZALAJDA: Thank you. I think we will go ahead and get started. There's a couple of things that we're going to do with regard to the agenda.

I think you will appreciate that we're a little bit behind schedule, but I think we will be able to get caught up and conclude the meeting by 3 o'clock, which is our objective for today.

We are going to move things around a little bit in the afternoon to accommodate some schedules.

Frank Palya is going to provide -- be our first speaker, provide an update on what we're doing with regard to a hazard assessment for non-tight fitting PAPRs.

He will be followed by Maryann D'Alesandro, our associate director for science at NPPTL, and then Mike Allswede from the University of Pittsburgh Medical Center.

And then Ray Roberge will follow Mike Allswede, and then Frank Koh, representing Art Johnson, will provide his presentation.

At that point, we will be ready for a break. So we will go ahead and move forward from there.

But with regard to the presentations that you are going to hear, this is going to capture some of the information that we're doing in developing research to support our standard and, not only our standard, but applications on a more

global basis.

And to that end, when we took a look at the comments that we received from the docket, and the need for identifying requirements for a system that could be used by others than emergency responders, we determined that it wasn't necessarily that when you looked at our definition of requirements for a PAPR for emergency responder, which dealt with agent protection, laboratory respirator protection level testing, and then meeting the 11 TRAs, the test representative agents, for canister filtration, that those requirements -- those requirements for filtration may not be appropriate for use in a nonresponder setting.

And part of the project that you're going to get an overview about is what we are doing in conjunction with our partners to identify what may be the appropriate test representative agents, building on our earlier work, but to identify what may be the appropriate test representative agents for non-tight fitting PAPRs that could be used in

other than emergency response application.

And so with that, I will introduce Frank Palya.

MR. PALYA: Thank you, Jon.

Well, welcome to the NIOSH public meeting. As Jon said, I am going to present the goals and the approach of the hazard assessment that we're going to perform for the first receivers and the medical facilities responding to a CBRN terrorist incident.

Again, this is inside the hospital walls and medical facilities walls.

This information, once we estimate the concentrations into hazards, we use this information to develop our non-tight fitting CBRN PAPR standard.

First, some of the issues that need to be considered, what degree of individual protection is required for the first receivers in the emergency departments following a CBRN terrorism incident.

Another is to what extent, what degree of individual protection is required for the first

receivers in the emergency departments following a CBRN incident and during response.

As far as contamination that's coming in on the victims, the contamination, the chemical and biological contamination, will be transported on the victims, off their bodies or off their clothing.

Some basic definitions is the first receivers, and we can see the first receivers of the emergency department staff would be the emergency physicians, the emergency nurses, the patient care associates, clerical staff, security staff.

Second and another definition is the secondary hazard. And that is there's visual contamination from the chemical or biological agents on the clothing or the bodies of the casualties or victims of the CBRN incident that's coming into the emergency departments.

Some background that we must consider is that the chemical and biological agents are orders of magnitude much more toxic than the basic toxic

industrial chemical.

Also, you know, the potential for the first receivers, I mean, what's the likelihood of the first receivers experiencing this contamination inside the emergency departments.

The objectives of the hazard assessment are to identify the chemical and biological hazards inside a typical emergency medical facility in response to a CB attack.

And there, we would estimate the level of respiratory protection required to enable the development of the standards for the NIOSH CBRN non-tight-fitting PAPR appropriate for emergency departments.

This information also, I may add, may be used for development of other PPE clothing standards as well.

The planned effort is to conduct research in the hazard assessment to estimate the CB concentration that can be obtained in the medical facility emergency departments resulting from a potential CB attack.

The medical facility is not the primary point of attack. It's not the ground zero, but the contamination, again, is coming in from the victims.

The description of the hazard assessment, we are going to perform a hazard analysis in modeling on three biological agents, that's anthrax, smallpox, and botulinum. And these agents are on the CDC's Category A list.

Also we are going to do some modeling on two chemical warfare agents that will be distilled sulfur mustard and sarin agent.

And then we're also going to perform some modeling on five toxic industrial chemicals.

This will be determined later once we perform an evaluation. These will be based on toxicity, persistency, and availability of the agents.

The first thing we're going to do is to evaluate 46 of the chemicals from the NIOSH list to determine if they pose a respiratory hazard to the first receivers in the emergency departments.

These 46 chemicals will include 32 acid gases, five nitrogen oxides, four base gases, four hydrides, and one formaldehyde. And these are the same chemicals that are on the NIOSH list.

Again, the evaluation will be based on the toxicity, physical, and chemical characteristics such as vapor pressure.

Then we're going to look at one factor what we're going to do is include the time from where the victim is picked up at ground zero until the time he gets into the emergency department, and that will be -- we're going to use ten minutes for this constant.

Again, the purpose of this is to reduce the number of test representative agents required in the NIOSH CBRN non-tight-fitting PAPR standard for gas life testing by first ensuring that the chemical family is not a respiratory hazard.

I believe Terry touched on it earlier about the test representative agents.

If we could ensure that all of the chemicals within those classes are not hazardous to

the first receivers, we will go ahead there and eliminate some of the TRAs.

We feel there's no use -- if they're not a hazard, there's no use to go ahead and add them to the standard and burdening the manufacturer.

I mean, you burden everybody, the manufacturer, the cost of the unit, the first receivers themselves.

So, again, if we could go ahead there and eliminate some of these TRAs from this hazard analysis, we're going to go ahead there and pursue that.

The venues of the modeling is going to be of a representative hospital. And I guess we want to know is what is a representative hospital?

Well, what we're going to do is determine that from evaluating the terrorist -- five or more typical hospital emergency departments.

And we're going to look at such factors as the configuration, the HVAC systems, the dimensions, and also we're going to take into account the amount of contamination entering the

emergency department will be based on the maximum number of victims entering.

The maximum number of victims entering will be determined based on the calculated average of maximum number of patients in a emergency -- an emergency department can serve per hour, per square foot, from these five or more typical hospitals.

We're going to use the square foot as a denominator because there's a common element among the hospital.

In other words, large hospitals serve a large number of patients, small hospital can serve a smaller number of patients.

The two hospital venues that we're going to go ahead there and -- for modeling is the center console room that generally has around 35 beds maximum.

And then also we're going to look at the individual patient room, and we're going to perform modeling on both the center console and the individual patient room.

The hazard assessment will include an

evaluation of the following four scenarios, and the findings of the evaluations will be included in the final hazard assessment report.

This is to demonstrate that when we go there and conduct this hazard analysis, that we're just not going to go ahead there and -- we will look at all issues, and we look at all factors.

If you have ever done a hazard analysis, I mean, there's infinite possibilities.

But we want to go ahead there and address some of the basic four key scenarios. And we're going to go ahead there and use the worst case condition for the modeling.

First one would be the confirmed events where the patients are EMS transported. The victims would have undergone some partial decontamination. The emergency departments staff will implement CBRN protocols.

In other words, they will be donning their PPE. There will be a lock-down of the facility, some sort of controlled entry.

So that's one of the scenarios that we're

going to discuss.

The next one would be the confirmed event, self-referred.

It would be the same as above protocol, but the victims would not have undergone any warm zone or partial decontamination, but they will be arriving by themselves by public or private transportation or ambulatory.

The third scenario that we're going to describe in the record would be the unannounced event. And that generally would be a biological event where victims arrive days later after becoming ill, and obviously there will not be any decontamination of these incoming victims.

An example would be botulinim, where there's a persistence of 24 hours, where it's persistent for 24 hours. Symptoms occur within 12 to 24 hours after exposure.

The victims can come to be ill and contaminated and still have some particles off of their clothing.

And the fourth one would be the

unannounced event. The victims will arrive at the contaminated with a CWA or a TIC, and will not have undergone any decontamination. And the first receivers will not have implemented protocols.

This is considered to be the worst case scenario. This is what we will be doing during our modeling.

Some research status that NIOSH has ongoing collaboration with U.S. Army Edgewood Chemical and Biological Center to assist us in developing our standards.

Right now, through an existing ECBC contract, there's a task order contract with OptiMetrics that there are contracts under negotiation for their technical support and evaluating the CB threat and this computational modeling of these indoor scenarios.

OptiMetrics has partnered with NIOSH and ECBC in the past, and their information that we got was used to support the development of the previous NIOSH CBRN respirator standards.

Now, the effort, we believe, that this is

quite a task because, I mean, there's a lot of biologicals that we're going to model with the chemical warfare agents.

We got to -- first we're going to go ahead and do the TICs. But right now, I believe that we're going to get enough information, it may not be a finalized report, but it will be enough information that we can go ahead and start formalizing our non-tight-fitting PAPR standard from this information.

And then of course, there will be a final report from OptiMetrics. We're going to have NIOSH personnel and OptiMetrics personnel working together to come up with a report. And eventually it will become a NIOSH numbered published document.

Questions?

Thank you.

MS. D'ALLESANDRO: A lot of you are probably wondering why we're sticking customer market focus right in the middle all of these technical presentations, but we wanted to maximize the potential for reaching the largest audience

here because this is something that's very important to us, and we want to make sure we get enough input and feed from all of you on this initiative.

At the last manufacturers meeting, I introduced a new concept that NPPTL is undertaking, and the initiative is APEX, achieving performance excellence.

We kicked this initiative off about a month ago. And the objective is to help us lead the way in serving the public, the manufacturers, those who we provide audits to, all of our customers, to maximize the potential of keeping all the customers healthy and safe, the workers healthy and safe, and to maximize our potential in meeting the customers needs.

APEX is based on the Baldridge (phonetic) National Quality Program. And although the program isn't magic, it's a tried and true program that we think is the best management tool available to move us forward in meeting our customers need.

The program is a balanced system of

measures that's aimed to align our strategy with all of the activities that we are performing, or actually align our activities with our strategy.

And the initiative will help us assess and improve in the areas of leadership, our strategic planning, our customer satisfaction in our market focus, how do we expand beyond just respiratory protection to all PPE.

How do we improve the employee work life or process management in all of our results.

I am leading the customer market focus team along with the members that you see here. Our internal membership is from the office of the director, the policy and standards group, the certification and evaluation, and our research division.

We have a very dedicated team, and we're very excited about this opportunity. And we want to stress that this isn't additional duties as assigned. This is actually the way we are going to do business.

And this team really wants to ensure that

we're meeting all of your needs and to implement everything that we develop and plan internally and along with our headquarters into the lab activities.

I will briefly go over our near-term initiative and the service dimensions we intend to focus on, and the methodology we are using as our near term initiatives.

In addition to the market focus area, there are two components, customer and market knowledge and customer relationships and satisfaction.

In the past, we have primarily addressed customer and market needs at the public meetings such as this. And about five years ago or more, there was a time when we would just provide you information.

And through the stakeholder input and feedback we obtained from those meetings, we would lead to a more interactive process.

And we are hoping that we're responding to your needs in putting information out on the

web, the information we're gaining from these public meetings, the information we're gaining from web questions and telephone inquiries, we're hoping that all of this is helping us improve our processes in that area.

With regard our focus groups, in the past year, we have conducted focus groups in the construction area and in first responders area. And from those focus group meetings, we have learned information from the customers that has fed into our standards development and into our research activities.

Specifically in the human performance area, the firefighter focus groups that we conducted last year helped with development of the protocol that's now being used to develop the next generation firefighter ensemble in conjunction with TSWG.

We continue to sit on in many standards development activities, standards development committees. And through these standards development committees, we are both nationally and

internationally adding our standards development to these activities in ensuring that we are focusing properly within the market.

And we will continue to do this. The standards development is a main focus of our lab now.

Also, through stakeholder input, we have developed or worked with the National Academy of Sciences to establish a committee on PPE that will look at the emerging needs of the nation with regards to PPE.

This committee will have about a 20- or 30-person membership, and will meet three times annually. From those meetings, they will generate what the emerging needs are with regard to PPE and provide input for us to move forward.

In addition to those three meetings, we are hoping to have one annual public meeting that this committee would hold where we would also receive input at that time.

We are also -- the internal customer market focus team has identified some market

reports from Professors Frost and Sullivan that we are now evaluating and intend to evaluate to also help guide us in expanding the market.

In the area of customer relationship and satisfaction, up to this point, our customer satisfaction has been based primarily on direct customer contact through one-on-one stakeholder meeting, through telephone inquiries where people will call in and eventually they will be sent to the right person.

And we think we are very responsive to those inquiries, but want to have a more systematic approach to our customer satisfaction, and be able to really benchmark some information, and get some baseline data on where we stand and see how we move forward in those areas.

So in that regard, we're going to have an environmental assessment conducted. We haven't determined exactly how this will be performed at this time, but we intend to have most likely some external sources provide us some information and our customer market focus team internally will be

providing information as well.

And what we're hoping with regard to customer surveys is that within the next two months, we're going to have our first annual customer satisfaction survey that we're putting together in conjunction with OPM, the Office of Personnel Management.

And OPM has nine dimensions, which I will get into, that they use to benchmark all other government agencies against one another, and also some private organizations as well.

And we intend to start with those nine dimensions that I will get into.

And with our annual survey, we hope that by identifying these areas in these nine dimensions where we are successful and where we need assistance, that we will be able to move forward and improve our processes.

And with regard to the point of service surveys, a survey like you will receive today at the end of this meeting, like you had yesterday, we're also looking at other point of service

surveys, such as within the respirator certification group, when manufacturers call in and have inquiries, a survey that then would be sent to them automatically regarding the inquiry that they had. And just gathering enough data so we know how we can improve our processes.

Now, again, we have the internal customer market focus team, and we wanted to have an external component to that as well who will meet with us quarterly and look at all of the activities that we're performing, the plan that we're putting together, and how this plan is aligning our strategy with the activities and getting customer buy in on what we're doing and the plan that we're planning, and how we're moving forward in these areas.

The nine service dimensions that we will be focusing on initially, will be -- are listed here on the left.

And access is essentially the availability of service and ease with which it can be obtained.

So information such as are you able to get to the right person to get the information you need.

Courtesy, does the staff have the proper attitude of service provided to the customer, really friendly and helpful to you and considerate?

Knowledge, do you have the required skills to perform the service that we are supposed to be performing for you?

Timelines, are we providing information in the timely manner?

Reliability, are you able to perform the promised service dependably, accurately and consistently?

Choice. A good example is looking at this meeting, was it located at a good location; was it convenient. That was something that's on the questionnaire today.

We're hoping that we will get your feedback there, whether we should have meetings here in the future.

Tangibles, the appearance of physical

facilities, personnel, and communication materials. A primary example here is the website. We're working to determine how much to improve our website so you are able to access information better. It's more user friendly.

Recovery are problems and complaints resolved expeditiously.

Quality, what the customer receives from the service provider, or the perception of excellence of the product or service received.

So if we do well in all nine of these areas -- and eventually we will know where we need to improve. If we do well, we will be able to achieve customer satisfaction and be able to improve the way we do business and service you effectively.

And for the first annual survey that we intend to conduct, this will be the first systematic activity that we will implement within this team and this initiative.

And as I mentioned, the survey used the nine standard OPM dimensions discussed on our

previous slide. And these OPM -- again, these allow us to benchmark against other activities and compare ourselves to other federal activities and agencies.

In addition, we will be evaluating ourselves against other standards organizations and private sectors to determine if we're meeting needs effectively.

And the first annual survey will be administered via email. So please be sure that we have your correct email address and any other email addresses within your organization, as well, who you believe should take this survey.

Future surveys may be administered at public meetings, manufacturer meetings or other venues. We will analyze the results with the assistance from OPM. Their experience in assessing organizational performance and organizational strength and areas for improvement.

We will act on these results and plan to develop action plans to improve in the areas that are identified where we need improvement, and will

monitor and evaluate progress as well.

If you have any questions, feel free to email or contact me or any other of the members of the team. I'm sure many of you are familiar with them.

We strategically put together a good team.

As I mentioned, members from all components of our lab and also some here were prior manufacturers as well. And we know those individuals will assist us in servicing the manufacturers better as well.

We are very excited about this initiative, and we do look forward to your input to ensure its success.

Do you have any questions?

While he is coming to the mike, our first meeting with the external group, and if you -- we would like you to provide us names of whom you believe should sit on the external committee.

We are looking at different standards organizations, organizations such as AIHA providing

members to sit on this external committee to look at the plan and moving forward in this area.

And this first meeting, we intend to hold in conjunction with the November public meeting.

UNIDENTIFIED MAN: I have a comment and a question.

I must compliment you. As a public agency set up, funded by the taxpayer to protect the taxpayer from ourselves, you are indeed taking the customer relationship part of it seriously.

The question is are you also going to post any of the comments and the feedback you get and how well you are doing against our own benchmark so the rest of us can see how well or how well it's not working?

MS. D'ALLESANDRO: Oh, most definitely.

We do intend to put that on the website.

Once the information from the first annual survey is returned, we will post that information. And we will also post the plan on how we are moving forward in this areas as well.

Okay. If I have no other questions, then

our next speaker is Dr. Mike Allswede from the University of Pittsburgh Medical Center, which is part of the Center for Emergency Medicine.

Mike will be presenting a plan for a project that evolved out of a significant stakeholder feedback.

In November of 2004, CDC conducted a public meeting in Atlanta. Many of you participated in that meeting.

And out of that meeting, it was a meeting to discuss bioaerosols specifically in healthcare environment. And PPE was a large part of that discussion.

And through those discussions and out of that meeting came a need to have an effective hazard analysis and risk assessment for healthcare workers.

And this is very timely because, with what Frank just presented, the information from his assessment is going to feed into the project that Mike is going to be doing in conjunction with NPPTL.

And it will be -- what he will be developing is an automated tool that will provide healthcare workers the ability to provide information, to enter information regarding their facility and the potential hazards, and it will provide them information regarding the PPE that is required or necessary for the particular area in the hospital where they work.

In conjunction, something else that is very exciting about this initiative is that in conjunction with developing this tool, we are developing a new standard for first receivers, a new ASTM standard for first receivers.

So this is, in my mind, collaboration at its best. We have our research activities, our standards development activities. Now, our evaluation isn't part of this, but we have a lot of good partners, and we're excited about it.

And I'm sure after you hear what Mike has to say about his plan in developing this project, you will be exited about it too.

Thank you. Mike.

MR. ALLSWEDE: Thank you, Maryann.

I think this one is me. Okay.

Well, first let me talk to you a little bit about who I am. I'm an emergency physician that works in emergency departments, so I'm a first receiver.

I'm also trained as a critical care physician, so I take care of people in the intensive care unit. And then also, a toxicologist, which is the care and management of poisoned individuals.

Kind of collateral with that career, I have had a career in the military in which I was a medical military person.

And that combination of civilian skills and military skills ended up with me as an instructor for the domestic preparedness program, which kicked off in '97 or so, was that first 120 cities, America getting ready for bioterrorism kind of thing.

I have been active since then in bioterrorism and these sorts of risks, threat

issues. And my particular area of interest is hospitals and how hospitals should respond.

A couple of points I wanted to bring out before we started the description of the study that I think is important for you all to understand being that the majority of you are not hospital people.

First off, hospitals are funded as if they are commodity. That means that they are funded by piecework the same way that McDonald's receives funds for making Big Macs. So many dollars for a Big Mac, so many dollars for a heart attack or some other thing.

Hospitals are also in something of a problem because they are legislated as a right. So your healthcare you feel you have a right to, regardless of your ability to pay or not pay.

And that combination along with the medical malpractice liability crisis in America, has caused a real financial crisis in America because you can't tell hospitals that they have to care for people regardless of their ability to pay,

and they pay them a Happy Meal price for only a percentage of those patients.

Now, bioterrorism or chemical weapons in which we expect that hospital system, which is sort of gasping on its own, to be able to respond like the fire department.

I don't know if you have a fire station where you live, but if you drive by the fire department, the odds are there's a big truck or maybe three or four trucks sitting there with a bunch of guys on some lawn chairs, or maybe they are in the back cooking some chili or whatever; okay.

They are an example of a system which is scaled; okay, to respond to a crisis, which means that there's excess capacity in their system, which is just sitting there waiting for something to burst into flames, at which point they spring into action.

Hospital systems don't work that way. Hospital systems have very thin margins. About 90, 95 percent of hospital beds are already filled.

About 90 to 95 percent of clinic spaces and appointments are already filled.

There is not very much extra room and there is no way to fund this.

It's my view that the medical system, the private medical system is the primary weakness right now, in America, for our ability to respond.

And specifically, among the weaknesses that hospitals have is the ability to protect our own people.

The people that work in hospitals, doctors and nurses, think of themselves as professionals. And of course, they have professional ethics and things that would bring them and keep them at work even if there were infectious diseases or chemical threats that might be of concern to them.

But the people that work in the cafeteria, the people that sweep up the floors, the people that do the laundry; okay, work for some hourly wage sort of job, at which point they, I don't think, and most psychosocial assessments say

that they aren't going to put their lives at risk to come to work today in order to be able to manage one of these sorts of events.

So we have a very critical need.

And personal productive gear is, in fact, a significant part, not only of the function of a hospital, but of a psychological ability of the hospital's personnel to be able to respond to one of these events, which is why this is so important.

Okay. In order to organize hospital thinking, one of the biggest things that we have to get over is the idea that we're going to have the anthrax plan or the smallpox plan or the flu plan or some thing that we're going to break the glass in case of bioterrorism, get our instruction manual, and get an idea of what we're supposed to do.

My view is that really doesn't happen, and it doesn't really even represent a slice of reality that's useful.

So what we have done is we have created in our hospital system the Pittsburgh Matrix, which

is a matrix of varying plans that says that essentially what you decide to do about bioterrorism depends on two primary problems.

One is, how big is it, okay, relative to your capacity. And the other is, when in the timeline of a disease are you aware and able to respond.

Rather than kind of go off on this esoterically, what I would like to do is kind of show you how this works.

This is an Access database right here, which is our anthrax plan. This is functionally our anthrax plan.

And what we see here in the percentages here, are the expected mortality that we have in our hospital system of different combinations of timeline and scale, which means that at certain combinations of timeline and scale, the disease might be progressed far enough that a person would not be able to be salvaged. Or it might be that a certain level of victims, we run out of things like hospital beds and antibiotics, and, therefore,

people die for want of resources.

So using these mortality statistic numbers, you can actually then start to build up a list of key resources, which is what we have put together in our plan for our hospital decision makers, of which I'm the key architect.

And what you see are key resources that come under pharmacy, personal protective gear for treatment teams, laboratory staff, pharmaceutical staff, all of the various hospitals preparations, how you will triage people, et cetera, et cetera, et cetera.

And every one of these combinations, these 20 different combinations of timeline and scale gets a different treatment because in our view, it's an entirely different set of problems, which a hospital system would be asked to be able to respond to.

We also have collected the key decisions, which are important for decision makers to be able to decide at the onset of one of these events.

In this case, how do we get symptomatic

individuals; how do we establish diagnostic criteria, criteria for management; who do we give a ventilator to, and who do we let die a respiratory death because we decided we can't save them anyway, or spending resources on this person, one life, would perhaps cost two lives in another victim.

So what we have done is be able to create something of a matrix of different ideas about how the hospital should function.

Okay. So with that, I'm going to hopefully go back to my presentation.

And I'm going to offend, I think, all of the engineers in this office or in this group when I say that the standard under which a hospital person should don or doff or wear a personal protective gear is a floating, poorly defined scenario dependent -- agent dependent thing, which means that there is not one marker for a personal protective respiratory status, depending on what the challenge is, and where you may work in the hospital.

What we also have to keep cognizant of is

that hospitals are going to buy personal protective gear largely through their own funding, which means we sell healthcare for heart attacks and then divert part of that money to buy this extra capacity, this fire department function of personal protective gear.

And this gives you an example of the differential in costs of care for different sorts of victims.

This is an office practice victim. This is a general hospital bed, and this is an intensive care unit bed in terms of different costs.

And so from our perspective, it's very important that we incorporate the cost of doing business for a hospital, since we have to have something that's very affordable that's easy for us to be able to stockpile and maintain.

Okay. We also have used this Pittsburgh Matrix idea to apply to other hospital systems to be able to look at where their gaps might be.

And this is something that for the manufacturers in this audience, you might be

interested in as well because it's, in my view -- and I think our study will kind of start to chalk in some of these areas.

It's my view that the personal protective gear strategies that work well in a hazardous material environment on a fireman's body or a HazMat technician's body do not work on a 55-year-old, chain smoking, morbidly obese, diabetic nurse in a hospital.

I don't think you can put 80 pounds of gear on somebody like that and expect them to be able to do their job.

And so what we're going to end up with, I think, is creating some gaps of personal protective gear strategies that just are not exploited well because there are different performance settings, different protection needs in a hospital.

We also have a number of cost estimates a year that we have done.

Summating this whole Pittsburgh Matrix idea is that the threat for which we must plan and for which we must buy and accumulate gear floats

around with world events. Different sorts of people have different sorts of capabilities.

We need to be able to assess the values of mitigation strategies, the cost of that strategy versus lives saved and make wise choices. And we need to be able to develop new technologies.

Okay. So let's talk a little bit about this project, the Pittsburgh Matrix for personal protective gear.

There's a holy trinity that we have established in our little study group.

But first and foremost, personal protective equipment strategies and solutions must provide adequate safety in the workplace, which is not the worst case scenario.

I personally believe that if you look at hospitals and you look at different areas of the hospital, the airflows and potential contaminations of different areas of the hospital rapidly decrease as you go outward from the area of entry.

Not every person in the hospital needs a mask protective strategy. There are people in the

hospital that need to have something that will allow them to work at their workplace, but not necessarily have the gold standard of protection.

Secondly, we believe that the personal protective equipment solutions must be affordable, easy to store, and intuitive to use.

This to me, that last piece is a primary problem with most PPE that I have worked with -- and I have been a paramedic since 1979, been in the military for ten years when -- run around in MOPP suits, you know, for ten straight years in field units and things.

And I can tell you that the biggest problem in training the hospital staff to be able to use personal protective gear is it's just not intuitive.

If you put the gear out and you let ten different people just put it on; okay, you will get ten different configurations of how things are supposed to be.

Lastly because hospital work is not necessarily gross motor work, like fire department

work is, it's a lot of fine motor skills, a lot of sensory assessments.

You need your eyes. You need your ears. You need to be able to hear things and feel things, feel warmth, feel movements, those sorts of things.

Personal protective equipment solutions must also not impair work performance. Because any of these -- if you violate any of these holy trinity, the solution will not work.

It will not work because hospitals won't buy it, because people can't wear it, because it doesn't provide safety in the workplace, and therefore, people will choose not to work; okay.

So those are the holy trinity.

We have got four studies right now put together that were combined with Frank Palya's work that we think will provide a matrix of contacts and data from which we can start to make these recommendations.

First and foremost, we're going to take our hospitals. I'm from UPMC Health Systems, which is 20 different hospitals.

We have hospitals from multistate, big city hospitals in Pittsburgh, to 40-bed hospitals out in the middle of the Styx.

So we're going to take a look at our various hospital configurations as they are and try to answer the question, what moves air around the hospital.

If you think about elevator shafts, that pumps air up and down to various floors. If you can think about the HVAC systems, some configurations are room based, individual HVAC. Some are more central. So you have different systems running in different parts of the hospitals, even down to the types of doors.

If you have ever been in a hospital, you notice that the doors don't work like these doors do here. They have these automatic things so that people can move a cart through with a person on it. And these doors work like big fans throughout the hospital; okay.

So we're going to take a look at our hospital and see if there isn't a way that we can

start scoring risk factors because there probably are configurations of hospital which require a greater degree of protective equipment in every person because air moves about that hospital at a much more rapid transit sort of a way than in other hospitals.

Working with Frank Palya's work, we're going to look at selected pathogens and chemicals in the air.

And unlike Frank's, which is going to be more of a modeling thing, what we're going to do is look at various case report incidents of chemical events, hazardous material, tuberculosis, those sorts of things, and analyze deeply what actually caused the transmission of the infectious disease in a given hospital, relate that back to our hospital type that we have done in the first study, and start to project what other like sort of pathogens would do, and then relate those tests, see if there are any threats.

Lastly -- or the third one is we will assess our PPE strategies related to affordability

and risk.

This is where we start to deviate from the gold standard type thinking and start saying, then what are we going to afford.

The problem with gold standard thinking, by the way, which is currently employed, is that in my hospital, we have about a dozen PAPRs and full body suit ensemble, which is great for the first dozen people that are going to show up and respond to the chemical or weapon event, but the 13th person has nothing; okay.

That's a very brutal strategy to have the gold standard and then nothing; okay.

Well, what we're trying to do is we're trying to create a strategy where our personnel can have a broader range of coverage with acceptable degradations from the gold standard. And where those degradations are are relative to pathogens, strategy scenarios, et cetera.

Lastly and related to this brutalness that I talked about in PPE strategies, it's going to be very important if we're going to expect a

hospital system to be able to ramp up in surge capacity should there be a large volume of people injured in some way.

It's going to be important to be able to have PPE strategies that will ramp up as well, which means that we need to have interoperability between various PPE strategies so that we can beg, borrow, and steal from different area hospitals, county and federal.

You must be able to cobble them together and make them work in a situation where we have a super number -- a supernormal number of victims, and a supernormal number of people that would be caring for those victims.

Okay. So just looking at our first study, the assessment of air movement, we have divided up various hospital features into fixed features, which is the bricks and stuff that you can't change.

This is variable features, which is the sorts the things about a hospital structure that you can change.

For example, you can use elevators, hanging ventilation and air conditioning systems, vacuum tube systems to transport people around and then that air that moves with those systems, or you can choose not to.

There's also a concept of building envelope, in which doors, windows, and outside venting can be shut off, such that the hospital remains relatively isolated from the outside world, or various ventilation zones within the hospital.

We're going to look at our hospital systems and decide are there strategies that seem to work there or not.

The basic view that I have is that there's going to be some combination of hospital configurations and how hospitals run, and some combination of personal protective strategies that will come out to be a economical and cost effective way to look at increasing these sorts of surge capacities.

It's important for us to be able to strategize across a broad range of hazards. We are

not just biological folks. We're not just chemical folks. We're not just radiation folks. We have to really look at things from a global perspective.

Being an ER doctor for the past 20 years, I can tell you unequivocally, you don't get to choose what your day is like in the emergency department.

They, out there, get to choose what your day is like because depending on silly decisions that other people make, you get a different subset of patients for which you must care.

Okay. The affordability and risk, what we intend to do is take a combination of different subject representative threats, pathogens, or chemicals, that sort of a thing.

And the matrix, as you saw here on our Pittsburgh Matrix for hospital planning, is an assessment of costs and benefits associated with potential fail rates.

And then make those PPE recommendations related to risk the same way that we would triage a ventilator.

If you are a person that had a 90 percent chance of surviving a chemical or biological event with a ventilator, and somebody upstairs in the intensive care unit had a 90 percent chance of dying of whatever the disease was, it would be that the proper decision is to let that person with the low chance of survival go, and then make the person that is most capable of surviving, ensure that that occurs.

This is how you decide scarce resources in the medical setting.

And what we will do is attempt to make some of these recommendations as well for personal protective gear.

The personal protective scale issue is going to be an interesting discussion, I think, because no hospital system to which I am aware actually has the ability to scale up large amounts of personal protective gear.

Think of this for a minute.

Most hospitals collect infectious disease patients within an isolation room or colony of

isolation rooms.

The next step up would be to create a wing or group of rooms that would be isolation rooms.

But what would you do if that whole hospital had to be designated the smallpox hospital or, as in the African experience, an ebola hospital.

How does the personal protective gear change, albeit you have a global application of that technology to every person in the institution.

I don't know of a hospital that can do that right now, but I know that we must.

And I know that we must because you might think smallpox is not a threat or other sorts of things might not be a threat, but I can tell you that getting ebola and coming to the United States is just a matter of an airplane ticket; okay.

It happens in Angola, but it could very easily happen right here. And it's communicable, and just as nasty here as it is over there.

With that, I'm going to thank you for

your attention. I will be hanging around to answer any questions.

It, I think, is an interesting look at the topography of personal protective equipment and what should be developed, and what is probably a best combination strategy between facility changes and configurations, pathogen challenges in terms of communicability, and then what personal protective strategy might be needed in various zones of a hospital depending upon what those calculated risk characteristics would be.

Our tool that we envision would have something of an interface where a person who is an environmental health and safety person or a disaster planner could type in his or her hospital characteristics, multi-floor, elevators, amount of air movement and HVACs, come up with a risk rating, and then from that risk rating, come up with a methodology by which you could calculate zones of risk, and then a set of recommendations of personal protective gear for various sets of threats.

That would, at this point, is our

intended target. We think we can do this in about a year, similar to the way that we did our personal -- similar to the way we did our Pittsburgh Matrix project.

And I look forward to reporting back to you all on what we found. Specifically, I'm interested in reporting back to the manufacturers and the various engineers about the sorts of new personal protective gear strategies that are needed for the hospital environment.

With that, thank you very much for your time.

MR. ROBERGE: Good afternoon. My name is Ray Roberge, and I'm a research medical officer at NPPTL.

Today's discussion that I'm going to put forth really has come about as a function of working with the policy and standards development team at NPPTL.

How do I fit into that? I'm not an engineer. I'm not a physicist. I'm not a physical scientist, so I sort of like to think of myself as

their mascot.

And I sort of come to them from the medical community. Because in addition to being a research medical officer, I have been for 25 years, and continue to be, an emergency physician and a medical toxicologist.

So my role, as it were, in helping to develop these standards is really sometimes just the role of looking at certain issues from the perspective of someone who is a first receiver. Because, as with Dr. Allswede, whom I have worked with in the past, too, I'm a first receiver.

So I sort of have this other interest, not just from my position at NPPTL, but from when I see patients in the emergency department.

So with that in mind, I need to go over a couple of definitions first.

If I go downtown in Pittsburgh and ask somebody who a first receiver is, I'm liable to hear Hines Ward of the Pittsburgh Steelers. But actually, we have, you know, a really good definition that comes out from OSHA, a guidance

document earlier this year.

And we're really looking at individuals who are going to respond in the emergency department.

Most of those individuals are going to be, you know, emergency department personnel, but they may call down people from other units and the like.

But really, these individuals who have a role, not only within the confines of the emergency department itself, but sometimes exterior to that also and in other areas, for instance, security.

Those individuals who are going to be involved in decontamination prior to entry into the facility itself, if that decon is being done outside, physicians, nurses, people involved in all difference aspects of supporting these individuals also.

And that could go down to somebody who is a unit secretary, a housekeeper. I mean, these roles are being defined all the time.

So then the second definition, just so

that we are all on board, is what I'm looking at today is an issue that has come up, as Jon Szalajda mentioned earlier today. We get a lot of feedback on -- from first receivers on various issues regarding personal protective equipment.

And so that's sort of the driving force in a lot of these things. And so consequently, one of the issues that's come up is the issue of shrouds.

And so this is something that I want to put forth today because I am -- hopefully, that in presenting this, I'm able to get feedback that will assist us in deciding, you know, what the role of shrouds is, what it should be for first receivers.

And when I discuss this today, it's in the context of bioterrorism, and to get specific, biological agents.

I realize that shrouds have other protective features. But we're looking at it strictly today in this discourse just for biological agents, and specifically those that are Category A, that I have picked.

Summing up, the definition of a shroud is a cover that conceals, protects, or screens. And in the context of this discussion, it's going be the protection factor.

As you can see, and you already know -- I'm preaching to the choir on this -- it comes from a number of different -- there are a number of different fabrics that can be utilized, and the different features.

Interestingly, about two weeks ago, I met with -- while he was at NPPTL, Dr. Gan Sung (phonetic) from the University of California at Berkley, who was working with collaborators at North Carolina State, and they have developed a treatment for fabrics, for instance, hospital bed linen.

And the treatment allows the incorporation of chlorine that's used to clean the bed sheets, as it were, and it traps the chlorine.

Of course, chlorine is a great germicidal agent. It's one of the best. And these researchers are looking at using it in shrouds. So

that's just another future development.

So with that, and again, I know I'm preaching to the choir on a lot of this, but there's hospital rationale for using non-tight-fitting PAPRs.

And the rationale is not only from the ends user, the first receiver, but also hospital administrators who are interested in things like cost, which certainly are important in this day and age.

So, again, these non-tight-fitting PAPRs are attractive to first receivers for all of these reasons. I mean, no fit testing. They're more comfortable. They have a cooling effect. Things of this nature.

You can wear them with glasses. You know, you can have a big, thick, heavy beard on you, what have you.

And also, the last one that I put up there, although this is not a total list in that you can use other masks underneath, although I must mention that this is, as of yet, not NIOSH

approved, but certainly was utilized during the recent SARS epidemic.

So these things make it attractive.

We know, of course, everybody out there knows that non-tight-fitting PAPRs have a down side. Everything that looks good always has a negative side to it.

And certainly things like battery failure leading to loss of protective effect, you know, the protective factor is less than it would be with a tight-fitting piece, these are all issues.

But specifically for me today, I want to look at things that, when I'm in the emergency department, if I have a PAPR that has a shroud on it, what is the up or down side of that.

And the reason that the shroud is important from a biological terrorism agent prospective is if you're using a non-tight-fitting PAPR that's not incorporating a shroud, there's a single area of your body, depending on the protective clothing that you're wearing, that will be exposed.

And that -- specifically, that area is your neck; it could be your ears, back of your head, part of your scalp, what have you.

And so subsequently this is potentially an area of concern and something that I want to bring forward today for your thoughts, your feedback, and also to show you it's a concern that I, as a first receiver, have.

So we know that the down side of PAPRs -- there's any number of down sides, communication problems, and not just communications, speaking, and not just communication in terms of hearing, degradation of that, but try to imagine from the perspective of a victim or a patient who is deaf and who depends on reading your lips to tell them what's going on.

So if you have got some type of apparatus that covers part of that, that's a problem.

And so there are other issues. Similarly is this claustrophobic potential. There's a desiccating effect on the eyes. There's the nose factor from the PAPR motor. There's the inability

to use certain equipment like a stethoscope, what have you.

Those are other issues.

There's also the issue of the way you appear to victims or patients. When you are wearing some of these PAPRs with a shroud, you are about two steps away from Darth Vader.

And if you're a victim or a patient and you see someone coming up to you in one of these things, the first thing you think of as a patient very often is, oh, my God, I must be really sick because look what's coming at me.

And so these are little things that we take into consideration in the confines of the emergency department.

So the issue that I want to stress here, not stress, but put forth is should shrouds be standard equipment on PAPRs that are used by first receivers during response to a bioterrorism event.

And more the focus -- the point that I'm trying to get at is if you are a self-referred patient -- so this is someone who is not EMS

transported. Sometimes we refer to them as the walking worried -- but the issue is, if they come in they -- there has been an announced event. They feel like they have been exposed.

They have not undergone decontamination. It's sort of like what happened, say, for instance, in Tokyo, where a slew of people came in, in a major urban area, and just really overwhelmed the hospitals.

Saint Lukes Hospital received 800 patients -- 800 victims I should say more correctly.

So if that happens, do these individuals pose a threat to the first receivers by virtue of what they carry on their purse or their body, their clothing, what have you.

So in order to be able to answer that question, or to try to answer some part of that question, you sort of have to do biological agent risk assessment, a dermal one. Because really we're looking at agents that are dermally active.

And so you have to look at dermal risk

factors on individuals. So this is the individual, the person's own inherent risk factors.

You have to look at things like how virulent and how infective is the agent. So infectivity, you are sort of looking at what's the minimum number of organisms that are needed to infect the person.

And virulence, you're looking at how sick is it going to make them.

Environmental persistence, we want to know if someone is in an aerosol attack, how long is that agent going to stay active on their person, on their clothing, what have you.

Reaerosolization potential, you know, are we going to blow this off ourselves onto someone else.

And then the last issue is some of the contact factors.

And so I just want to go over those, and this won't take a lot of time. You have got a couple of factors that I think are important.

When we talk about the dermal barrier,

even when we're talking about shrouds, probably the best living shroud in the world is our skin.

Through eons and generations and thousands of years, it has become a great protective barrier that only allows penetration of just some of the smallest molecules.

It keeps us from getting dehydrated. It keeps us from getting infected. It keeps us from having some chemical agents into our bodies. So it's pretty effective.

Anybody see War of the Worlds? Show of hands, anybody; okay.

So they got off because -- maybe because their skin barrier wasn't that great. They started to get infected, the aliens, and that's what saved them.

So we have great protective barrier, as long as it stays intact. So it's like anything else, as long as it stays intact.

Well, I'm going to go over some issues that, you know, sometimes we don't really think of.

For example, I'm a male physician. Say a

male nurse, security personnel, male security personnel, assigned to respond to an incident.

Well, like anybody else, I shave in the morning.

Well, the surgical literature has shown for years and years and years -- we have known for years, that prepping somebody's skin before surgery markedly increases their risk of a post-operative infection.

Why? You're disrupting the skin.

And so there are a lot of ways to disrupt the skin. There are any of million infectious disorders and skin disorders that can do this.

You get herpes that ulcerates. It exposes underlying areas. Ectopic dermatitis. Eczema. These are all associated with increased risks of skin infections.

The problem is that you can have skin that looks completely normal, but the barrier has been disrupted because it's disrupted microscopically, not macroscopically, and not visually like we can see here.

So that the point of this is that you really can't tell if you are a person at risk for transmission of skin disease because you might have microscopically disrupted skin, in addition to all of these other things that I have mentioned.

And, again, infective doses, is obviously important. How much of the agent you are going to get, how virulent it is.

I mention age because newborn infants, their skin is basically developed in terms of the layers of the skin, but there are other factors that put them more at risk.

It may be a little bit thinner skin. It may be also that their PH and hydration status of the skin is different, and that helps it -- you know, that has to do with infectious capability.

I mention also the immune status.

I should mention the older individuals, very often they can develop what's call papyrus skin, like papyrus paper, real thin with age.

Or if they're on various medications like steroids and the like, puts them at risk for

microscopic and macroscopic trauma. So these individuals would be at risk.

Immune status I mentioned not so much to be able to tell if someone is at higher risk for infection. I mentioned it because there are certain immune disorders that are related with skin disorders.

There's a much higher incidence of seborrheic dermatitis and this and that in HIV positive individuals.

And certainly in the first receiver and healthcare arenas, there are people who have any of the number of immune disorders with HIV.

And it's interesting. It has just been reported that the National Health Organization from Great Britain was hiring nurses because they were low on numbers of nurses and physicians.

And they just hired 2,300 nurses last year from many third world countries, other countries including say Sinsihara (phonetic) and Africa.

They just found out that of the 2,300

they hired, 700 are HIV positive.

And so I make the point just to say that they're in our community, our first receiver community, just like anywhere else.

You have individuals who work with lupus. They're on, you know, steroids or what have you.

So, anyway, enough said, and certainly it's a significant consideration.

I might also mention in shaving, there are already two reports in American literature on people coming down with anthrax related to shaving, nicking their face and then coming in hand contact with it.

So that's certainly an issue.

So I have picked three representative agents to try to make my point on this. Try to make the point people who have concerns about just in the first receiver community.

I picked three agents, three biologic agents from the Category A list of the CDC. And of course, that Category A list is the Category A because these are the agents that tend to impact or

impact -- I should say the most morbidity, mortality, and also the ability to spread public panic because they are so virulent.

And so some features about these three agents, anthrax, tularemia, and bubonic plague is that they are all skin active. They can all cause cutaneous diseases, and I won't get into the skin causes. But, importantly, they can all cause systemic disease.

So if you're a first receiver, and you happen to get this, you may not end up just with a skin disorder than can be treated with antibiotics. You may end up with a disorder, systemic, that has an exceedingly high morbidity and mortality.

The other issue with these is infection virulence.

You see from what I have up there, it doesn't take many organisms to cause these disorders.

I must make a point that with anthrax, this has never really been proven in a human. This is based on animal data that infected with the

organisms.

Suffice it to say that, you know, they're active, dermal and transdermal, and they can cause some really, really bad illness.

So then we look at the other factor of environmental persistence. And so for anthrax, I'm not going to spend a lot of time.

Really anthrax is in the state of suspended animation. Times are tough. They go into suspended animation because the temperature is bad, the humidity is bad, whatever.

It's interesting -- it's really probably inaccurate to say that they can last for just days, weeks, months, years.

There are -- in the Dominican Republic, there are mines down there of amber. And amber, of course, as everyone knows can be made into jewelery, and that's how it sells.

But if you are really lucky, and you get a piece of amber, and there's a fly or insect from thousands of years ago, like a fly in there, makes it sometimes a little bit more valuable.

They have found flies in amber that had anthrax spores that were still viable after thousands of years.

So, you know, I'm not going to spend any more time on it. It's bad bug. It sticks around.

Tularemia is kind of interesting. Tularemia is really a disorder that we see more in many other climates, even though it is named for a California county, Tular County, where it was discovered. But it's a problem in Scandinavia, in Sweden, Denmark and in various areas of the world.

It's a really hearty organism that can live, stick around for a while. It's been shown to be able to stay on environmental surfaces, like stainless steel after an aerosol disbursal for a couple of weeks or better.

But in general, the thing that we look at after a bioaerosol attack is the decay rate.

And so, as you all know, the decay rate is really related to factors like temperature, other environmental conditions, like pollutants, humidity, ultraviolet light.

So the decay rate that's been developed in testing is really three to three and a half hours. And with plague, even though the world health organization has estimated that the decay rate is very rapid -- it's about an hour for plague -- that really depends on the time of day.

It has been shown that if it were a nighttime attack, it would be three hours.

Why do I mention this?

Because what I said before. If you are exposed to this, it's on your person, your clothing, whatever, most individuals in an overt attack, they are going to flock to an emergency department. Okay?

You know, you can bet -- there are three sure things they say in life, death, taxes, and a visit to the emergency department.

Each year without these attacks, one-third of the population, 108 million people, go to the emergency department.

So you know that if it is flooded -- so they still have these organisms on their bodies, on

their person, making it a threat.

The reaerosolization potential, I'm really not going to spend a lot of time on this either.

However, the Ricin (phonetic) College, after the Senate anthrax scare, they presented a really big paper on this, did the sampling within the Senate office buildings during the remediation efforts, and they have shown clearly this is a problem. The potential is there for reaerosolization.

Tularemia, it's kind of interesting. Tularemia, we have real life examples of reaerosolization potential. And those are literally hundreds of individuals in Scandinavia who have developed Tularemia from working on farms, pitching hay.

The hay is -- I don't know if any of you have ever worked on a farm. I have. And, you know, you pitch hay so you can dry it. You roll it over so you can dry it because it stays loose, and the organism is still in there.

And literally hundreds of Scandinavian farmers have come down with because of this.

In the United States, the most recent development like this was on Martha's Vineyard where the risk factor for developing tularemia among the individuals who had it, basically, you know, were people who worked outdoors, weed-wacking, cutting grass, mowing lawns, caretakers on property.

So we know from real life experience that that's an issue.

Plague, we don't have, you know, really a lot of data on, other than some anecdotal reports. And to say that, you know, clearly it's a very low possibility, but certainly there. So it's sort of the same issue.

And still, recommendations are that you should consider this potentially reaerosolizable.

This is the last issue, the dermal contact transmission.

And I mention this, there are reports there of individuals, you know, just getting --

1 although when you read in the literature, it says
2 that anthrax is not, you know, is not transmissible
3 through person-to-person, they are speaking
4 respiratory wise.
5 And so in terms of contact transmission,
6 skinwise, there are a few reports out there. A lot
7 of them are from third-world countries. And so you
8 can't really, really tell, you know, how much
9 voracity there is to them because it's difficult.
10 Somebody says that two kids are in bed.
11 One kid has got the disorder. The other kid gets
12 it. He might have been bitten by a fly and gotten
13 it. So it's very tough.
14 But there are some reports in the United
15 States and other countries that point that there
16 clearly is a capability here.
17 One of the more recent cases, there's a
18 child who developed anthrax, got very ill, whose
19 mother works at NBC. And she brought the child in.
20 Somebody there picked the child up to play with it.
21 They had anthrax essentially in their hands.
22 Within 24 hours, the kid had developed a

cutaneous disorder and when on to get a systemic disease.

So clearly, there's an issue there.

And the reason that I mention it is because it can be spread by fomites, by non-live material.

And so there are a number of these in the literature. A suitcase, if somebody in France went to Morocco, got a suitcase. The suitcase was made from goat skin, may develop anthrax.

I know that most of you are looking at number one, the shared community toilet article, which certain brings a lot of possibilities to the imagination. But actually what that was was a loofa brush that was used in a communal shower in a third-world country.

Suffice it to say, this could come in on your clothing, your loofa brush, whatever, and be transmitted.

Tularemia, never been reported person-to-person transmission. Individuals have gotten it, and the issue here is individuals who

have had it from labs and from handing animals -- and many of these individuals have no apparent cuts, scratches. They weren't bitten by the animals they were handling.

And so the possibility, again, there was microscopic injury to the skin that's not seen by the eye.

And for plague, again, same type of issue. You can miss a microscopic opening, and then you end up with this problem.

So the bottom line on all of this for me is that as a first receiver, I'm concerned that if I come in contact with individuals with this, and I have a certain area of my body that's not protected, then for any of the reasons that I have mentioned, my skin barrier may not be able to protect me, and I can go on to develop, not only skin disease, but systemic disease that's very serious and very significant.

And so in summary, we know that some bioterrorism agents are dermally active across the skin, and these can lead to systemic disease.

There are individual risk factors and other factors that we have to consider.

Without a shroud for a first receiver -- and, again, that first receiver could be somebody decontaminating someone outside the hospital doors before that person gets entry into the hospital, security personnel, what have you.

Without a shroud, there's a certain part of their body that may be exposed, depending on what type of personal protective clothing they are wearing, and shrouds would offer protection against this.

And with that, I'm going to use Terry's famous last slide, questions and comments.

MR. SZALAJDA: Thank you very much, Ray.

I think at this point, since I think we may have a little PowerPoint overload, why don't we take our ten-minute break now.

I think we have about 30 to 45 minutes left of presentation material, so why don't we start again in ten minutes.

(A recess was taken.)

MR. SZALAJDA: We have a couple of items left on our agenda, plus a presentation by Craig Colton before we accept -- open up for general comments, and conclude the meeting.

We invited Art Johnson to make a presentation today just to synopsize some of the work that the University of Maryland is going to be moving forward and doing for us regarding the -- regarding some studies on loose-fitting PAPRs.

I think most of you are aware that Dr. Johnson and his staff have done -- conducted several efforts for us over the past years related to the multifunction PAPR that has been addressed for the mining community.

And the requirements associated with that Dr. Johnson has presented at other forums and we're not going to be covering today.

But what we're doing is using the knowledge base that was established at the University of Maryland, and taking some of our homeland security funding that we received for this fiscal year and applying it to have the university

conduct some additional studies for us related to loose-fitting PAPRs.

And the university is gracious enough to send Frank Koh up to represent Dr. Johnson today.

And Frank Koh is going to spend a few minutes talking about what we have contracted with the University of Maryland to accomplish for us.

Following Frank's presentation, we will have a short presentation on what we're doing on the industrial PAPR, and we will move towards the conclusion of the presentations.

MR. KOH: Thank you, Jon, for the gracious introduction.

Okay. So the title of this PowerPoint is specifically to visualize the order of breathed air on a multifunction PAPR.

So this is an ongoing project right now. We actually started this about a month ago.

To identify the leak flow path during the inhalation cycle, we have to make sure that the inhalation flow is greater than the loose-fitting PAPR blower flow rate.

We're hoping to go ahead and test this with both a human as well as a breathing machine.

And an additional future measurement I'm going to do is, is that we're going to somehow measure the tidal volume of the contaminated air while wearing the loose-fitting PAPR.

So some of the modification that we had to do to actually visualize the airflow path ways. One, is that we took the existing portable breathing chamber that we tested for previous studies.

By the way, please ignore the fog inlet. That was just incorrect labeling.

And this portable breathing chamber has an inlet hose for the blower. So this would be connected straight into the loose-fitting PAPR inlet.

And then another tube would connect straight to the fog generating machine, and so the fog would be interjected into the chamber.

Initially, we have to remove the transparent plastic so that the loose-fitting PAPR

visor sits right next to the portable breathing chamber.

And to kind of limit the fog from escaping the chamber itself, we filled the gap between the visor and the portable breathing chamber with plastic.

So to identify the leak points of the loose-fitting PAPR, we had the vacuum flow rate at steady state flow rate on the PAPR, blower flow rate.

So I'm going to go ahead and hopefully show you guys some .avi pictures of this.

When the PAPR is at maximum and the flow pathway -- well, let me rephrase that.

When the PAPR is at maximum and the vacuum flow rate is higher than the maximum PAPR flow rate, then there's a lot of turbulence and mixing.

But I -- you can still identify the leaking points. And let me go ahead and show you a picture of that.

So this is an .avi picture of that, where

the vacuum flow rate is higher than the portable breathing chamber's -- well, let me rephrase that.

The loose-fitting PAPR's flow rate.

And you can see that the scarf and the chin wipe between is exactly between, you can see that the fog is passing over the cheek and going right into the mouth.

To better visualize this overbreathing pathway, let me go to the next slide.

We will go ahead and slow down that process, the loose-fitting PAPR's flow rates. And let me go ahead and jump on that slide.

Here we slow down the loose-fitting PAPR's flow rate so that you can better visualize the airflow pathway.

You can see that, again, it's leaking between the space between the shroud and the cheek going in. Some of those are actually bouncing against the shield flowing it around and coming back into the mouth.

Okay. Let's close that.

Back to the presentation.

I originally had it so that this synchs together, but somehow it didn't load properly, so please forgive me as I go back and forth.

So that's the steady state's commissions that we just did.

So now, how would it look if there was an actual breathing simulation attached to that.

The .avi is not going to run on this, so I'm just going to go ahead and open up the -- so as you can see the crude breathing machine breathes there, is going to be an introduction of fog.

The fog is leaking through the side, going into the mouth. And then during the exhalation cycle, that fog is exhaled back, hitting the visor.

I could go ahead and delete that, and I can -- this is actually a plot that we did with respect to time.

So if you have time and seconds here, this is actual volume of breath taken during the cycle of the breaths of the breathing machine.

And this curve is actually the net flow

rate. So we subtracted out the loose-fitting PAPR blower supply, so that this is fully the net flow.

Let me see. The ranges of this flow is, I think, 200 liters per minute. I can't see it from this screen.

Next screen.

With respect to future studies, let's see, we also wanted to see and visualize possible CO2 buildup within the visor.

This is important, especially since exhaled air may actually be contained within the visor, and some of the exhaled air may also follow the same pathway as the inhaled overbreathed air.

So that is -- that exhaled air may pass through the scarf, go to the back, go back into the inlet of the loose-fitting PAPR. And in essence, you will be inhaling back the CO2. So you want to kind of make sure that that doesn't happen.

So we also improvised some of the -- some experiments to measure that exact tidal volume of the contaminated air.

So let me just go to the next slide.

So here is the actual volume of contaminated air -- let me just rephrase this.

All right. So how are we going to measure the actual volume of the contaminated air?

Well, this is just a quick pictorial diagram. I just made this today. Forgive me for the rough boxes.

You have essentially a head form and the loose-fitting PAPR and the portable breathing chamber, as you saw in the previous sides.

These are pictures, essentially one-way gates. So the airflow, then, will go in one direction.

So during the inhalation cycle, you would inhale the contaminated air. And then during the exhalation cycle, that exhaled air, which contains the contaminates, will be pushed into the back.

And then essentially you would have the volume of the contaminated air. And then you can go ahead and do this -- replace this breathing machine with humans, et cetera.

You could even have them even running on

a treadmill.

This would be sort of a medium rather than -- well, if you put a human subject right into a loose-fitting PAPR, you're introducing other variables, like facial configurations or increasing -- you're decreasing volumes, big (phonetic) volumes, things like that. Because if you put me on one of those, I have a bigger face than most people, so I'm not going to have too much big volume in there.

So you just introduce that kind of variable.

You could probably just have that individual breathe a hose and have the head form just sit there and then measure that contaminated air.

So how are you going to identify the CO2 pockets within the loose-fitting PAPR?

Well, we thought of an interesting way to do this. And, again, we resorted back to the breathing machine and the one-way valve.

So in this case, you can see that during

the inhalation cycle, the bag will be filled with fog. The fog would be inhaled into the breathing machine. And during the exhalation cycle, that fog would be pushed into the head form.

So in essence, it is flowing, and you will be able to see the fog being pushed out through the mouth, and then you can identify pockets of CO2.

On a side note, if, using that same technique, if you see actually -- probably, we're hoping -- I'm going to cross my finger -- we're hoping that you can actually see that exhaled air traveling back into the inlet of the loose-fitting PAPR.

And if that happens, that should be something that should be of concern.

All right. With that, I would like to thank you, again, for allowing me to present, and leave myself to the mercy of the audience.

Thank you.

MR. SZALAJDA: Well, I think Terry must have worn everyone out this morning, so we will

thank Terry for that.

But the last scheduled presentation that NPPTL had put together was related to our current concepts for the industrial module and upgrading Part 84 to meet the -- or to incorporate the new technologies and new procedures into 42 CFR, Part 84. And I'm going to talk about a couple of slides, and then let Bill Hoffman finish the presentation.

Again, I think that one thing to notice is that there are separate dockets set up for the industrial PAPR versus the CBRN PAPR. The industrial PAPR, we're collecting comments under 008.

Where we think -- from an administrative standpoint, I think where we're headed with the industrial is that we're trying to leverage as much of the technical work, the research that has been done in support of the CBRN PAPR, and translate that into the performance requirements associated with the PAPR.

And understanding concerns within the

community regarding the readiness features of the CBRN PAPR and whether or not those are -- are appropriate for any industrial applications, we're not going to debate in this forum.

But I think we can say, though, that we have noted that comment with regard to the concerns within the industry and are looking at taking the performance -- the basic performance-based requirements identified for the CBRN PAPR, and where possible, translating them into the industrial requirements.

And I think when you look at items such as -- good examples of that are items such as the battery indicators, the low flow indicators, and the work that we're doing in addressing the breathing rates.

I think most of you that have been involved with the ISO committee, I think, have recognized that ISO is moving along in sort of the same paths with looking at the different work rates.

And there is a combination there when you

look at what we have identified for moderate work and high rate. There is some correlation between what has been identified in the ISO standards for those types of requirements.

Along with that, though, knowing -- I guess understanding and acknowledging that to implement the industrial module, we are going to have to follow the rulemaking procedures up to the point where we actually introduce into the Federal Register and begin a formal process to implement the requirements.

We're going to continue to use the concept paper as a means of information exchange with the community with regard to what we see the performance requirements, the base performance requirements being for the industrial PAPR.

And based on feedback that we have received so far, plus what we get following this public meeting, we expect to have a revised concept paper up on the web within 45 to 60 days, leading towards having another public meeting, which we're targeting for November 8 or November 9, here in

Pittsburgh, at a site to be determined, to continue discussions on that concept.

In addition to the discussing the PAPR, the industrial PAPR requirements at that meeting, we will also address the continuation of our discussions with the closed-circuit apparatus at that session.

The formal rulemaking process, what we envision taking place is sometime after the holidays, of announcing the intention to make a formal change for the formal rulemaking process in the Federal Register notes, looking at the January time frame for releasing that document.

And, again, following the traditional methodology, you can expect up to two years before the module would be in place.

So with that, I will introduce Bill Hoffman.

Bill has primarily worked in the certification area for NIOSH for many years on policy and standard.

We're fortunate enough to have him on

loan for a while to help us with the development of the PAPR industrial module.

So Bill.

MR. HOFFMAN: Okay. So the first thing I want to point out is this is the first overview concept paper, so we do encourage your comments on what we have presented.

And what I'm going to present this afternoon is what's already out there on the web. But also present a few new ideas at the end of it.

The first concept we want to undertake is to place all the PAPR requirements in one subpart of 42 CFR 84.

Right now, they are scattered throughout or, a lot of things that we look for aren't actually stated in the regulations as they presently stand.

Our proposal is to keep the existing general categories, which are Subparts A to G, supersede Subpart KK, which really is the only part that specifically addresses the PAPRs. Clarify, update, and consolidate the requirements that are

in there, and also state publicly the things that we do more or less by policy now.

Incorporate requirements for breath response and constant flow PAPRs.

Of course, when the regulations were written, breath response wasn't even envisioned at the time. And provide provisions for the positive pressure units.

Some of the major areas under consideration, we do want to have indicators for low flow or low pressure and battery. That's easy. A lot of the units presently have it, and we think it's a good idea.

We're looking at three sets of categories right now. We have already talked about the moderate and the high, and we also have a low in the industrial one.

And I do need to say that the -- we have tried very hard and very deliberately to keep the CBRN requirements and the industrial PAPR requirements the same where we can.

We think in the long run, that would be a

benefit for certification, so it doesn't require a lot of changes, a lot of retesting and things like that.

At this point in time, we are looking at two filter types, a PAPR 95 and a PAPR 100. And I will get into the details of that in a few minutes.

Single level canister/cartridge testing, which I will explain.

We're looking at some conditioning and rough handling, maybe not to the degree of CBRN, but to some degree because we have had comments expressed that units that are used in the field aren't durable or things occur to them just in storage prior to use.

General use things, visual factors, human factors, ease of use, things like that.

And we're looking at rated duration of batteries, maybe even one-hour increments. You know, now, in the PAPRs, it's pretty much you're limited to at least a four-hour battery, and that's dictated by the silica dust test that we now do.

Some specific considerations -- and a lot

of these are the same as what is presently in the regulations -- accessible switches, flexible breathing hoses, a harness design we look at for the holding the unit to the body, as well as the head harness.

Marking the containers.

But we don't have anything on durability of containers. And, actually, that's something that's present already in the regulation, but we really haven't enforced for quite some time.

Low pressure indicators, we want them to be a real time indicator. And this -- or low flow, if that's the case, and a battery charge indicator, especially low battery.

And of course, noise requirements, which would be pretty much the same as we have now.

We're looking at this time at two pressure flow requirements. One would be a variable rate or a positive pressure type respirator, and a continuous flow.

The flow requirements for the positive pressure are the same that we went over this -- or

that Terry covered this morning, with the addition of a low flow unit that would flow at a much lower flow rate for people working in more or less sedentary conditions.

People working in situations like hospitals or people that are working on assembly line things where they're more or less in a sedentary position, but they need some type of respiratory protection.

Continuous flow requirements, the moderate is pretty much the same as we have now, 115 liters a minute for a tight fit, and 170 for a loose fit.

Now, we're looking at a higher flow rating and again, a low flow, constant flow rating.

Specific performance requirements for the filters. At this time, we're considering two different filter levels.

One would be a PAPR 95, which would be along the lines of an N 95, where we're just looking at initial filter efficiency we test against DOP.

We're not using the DOP for degradation because it's in the initial efficiency. But to DOP is something that we can generate at high volumes, where salt or some other means would be very difficult.

The PAPR 100 would be the one I would equate to what's the P100 today, where the filter is loaded to see if it will degradate. And we look at those two as being the ones most people want.

If you are familiar with the nonpowered filters now, the predominate market is N95s and P100s, and there's very few in between.

Again, similar to the CBRN standard, we would test these at the highest flow rate of the system, divided by the number of filters that are used on the system.

Gas and vapor testing, again, we're looking at testing in the same manner as would be tested for the CBRN.

One difference would be, of course, gas and vapor has to be specific for the gas.

One thing that we are considering is when

we're testing the TRAs, the test representative agent, if it's tested against one of those, it's approved for all of those that are covered in that area.

So it could be for all of the acid gases, which is something similar to what we do for organic vapor presently.

When we test it with carbon tetrachloride today, we're in essence approving it for organic vapors as a family.

The concentrations and the flows would be the same as we had talked about this morning in a CBRN, which means that we would divide it by the number of units.

What we're trying to do is look at a way through certification that we don't have to retest cartridges or canisters.

Test them at the highest flow rate of the system on which it's designed to be used. And then when it comes in with other systems, hopefully we don't have to retest it, recertify, and it moves the process along much quicker.

Specific performance considerations for the inlet covering. We are looking at CO2 machine tests and human breathing gas tests, both.

The CO2 machine test is the same as its done now in the supplied air side. And in human subject breathing gas tests would be in addition so that we can measure O2, and measure it as it would actually be used on a person.

The LRPL we have here at 10,000 or greater. Of course, as I believe Terry mentioned this morning, we are considering that. We're looking into that value.

Other considerations we have, eyepiece impact resistance, or if it's not impact resistant, the manufacturer would simply state that it's not.

Most people that use it and they have a lens, they do expect it to be impact resistant.

Low temperature fog resistant. That's a requirement that we have had concerns about where people say that the facepieces do fog up.

End of service life indicator, we're looking at similar requirements to what we have

now.

Failure mode effects analysis, that would be something new on the industrial PAPR, although there are a couple of alternatives that we have discussed since this, that I will get into near the end.

The internal hydration device, as an option, we would allow that, and we would test it for leakage similar as we do now.

Intrinsic safety, something we're changing -- what we're considering changing there is presently, we only recognize as being intrinsically safe is if it's evaluated by AMSHA (phonetic).

And we're considering saying if it's evaluated by any recognized lab, then intrinsic safety makes sense.

Some new considerations that we're looking at, and this occurred since the May 30 concept paper was put up on the web.

Possibly we would consider all PAPRs as being positive pressure.

We have tested, I guess, literally tested some hoods, and we believe that they can -- even they can maintain position pressure under the test that we're using.

If we did it that way, it wouldn't matter what the type of flow device was, whether it was a breath response, pressure demand, whatever you choose to call it, or constant flow, as long as it maintained above ambient during the test condition, and that's what we would be looking for.

We have also been asked to evaluate criteria for a silent mode operation, which means we would have to go back to test requirements with the blower off. And that, of course, would probably only apply to tight-fitting.

People have asked for that for industries. For example, if you have mechanics looking for a leak in a line and they need to turn the unit off to try to hear a leak, or there's a motor noise on you, and they don't want the noise of the PAPR blower interfering with that.

We have also talked about that could

serve as a failure mode effects analysis.

Since the FMEA is to try to design in so that the blower won't fail, if a unit is designed to operate with the blower not operating, then you wouldn't need to do that twice.

And also something that wasn't added in the concept paper was a field of view requirement, and simply because we hadn't put it in there at that point.

And that's a real quick summary.

I know we are running behind schedule. And, again, we wanted to emphasize that this will go through the rulemaking. So the process here is going to be -- tend to be quite a bit longer.

But at this point, since this is the first paper, we do encourage any written comments or questions that you may have.

And in fact, can I answer any at this point?

Must be tired, end of the day.

Thank you.

MR. HEINS: Bodo Heins from Draeger

Safety.

Up to today, I understood that this industrial standard would be to be seen also on the CBRN, but obviously it's not.

So why do you require the same ten TRAs for the industrial, or is it allowed only to get approval single of these gases?

MR. HOFFMAN: Either way.

If -- what we were thinking of is if you meet the requirement for one of the ten test representative agents, it would cover all of those in those groups.

So in essence, it's conceivable that if you met all the ten TRAs, you would have approval for the whole 139 gases and vapors.

We have also allowed for other ones not listed there or adding new ones, things like ozone, we have had request for in the past, or anything like that.

So that we would be able to go -- try to keep it open and keep it more universal.

MR. BERNDTSSON: Just a question.

If we have pass the CBRN, do you have to go through another approval for this because all these requirements are actually lower than the CBRN?

MR. HOFFMAN: We still have to resolve that issue, but we have talked about that.

If you had one that met the TRAs, it's industrial, and it also now has met the CBRN, could it not -- would it not meet both?

And there are some differences that we have to work out. That is something that we are aware of.

And in our initial discussion, we didn't see any reason why it couldn't be, why it couldn't meet both requirements.

MR. BERNDTSSON: The next question then is that -- and this applies to both CBRN and industrial.

Will you eventually allow full body protection to be part of the approval as tested, not only as accessories?

MR. HOFFMAN: That's not something we

have looked into this time.

You are talking about a complete suit.

And that's not something we have considered yet.

But people have asked that question in the past, and I'm thinking it's something we probably would need to look into.

MR. BERNDTSSON: In the guidance document you have already produced the draft of encourage the use of complete dermal protection, complete body protection.

So, I mean, if it's identified and encouraged that you have to use it together, it makes sense that it is actually tested and certified together as --

MR. HOFFMAN: Part of the respirator.

Yeah. I agree with that in concept.

It's not something -- we haven't gone that far to look into that yet.

MR. SZALAJDA: That's something historically, you know, when you look at our mandate, our mandate is -- you know, our

legislative mandate is to test respirators, you know.

But, you know, having said that, you know, what goes forward in the future and, I guess, will still be determined.

But, you know, again, it's -- and I think we have discussed this a little bit, that when you look at the respirator usage and the selection of appropriate, you know, clothing ensemble, you know, ensembles there, there are existing standards, whether they are, you know, NFPA or other standards that identify, you know, the balance of the ensemble.

And I think it's a good point that you made, you know, the interface, ensuring that the interface between the respirator and the ensemble is important.

MR. BERNDTSSON: Also, and you need one to get the other to function. So they are a system.

And I may be talking about system approaches.

There is another issue, as well, which I would like to get on record and you can consider, is that we're talking also in the guidance document that all pieces of equipment that have been exposed to a nerve or blood agent need to be disposed of after six or eight hours.

Of course, if there is a second impermeable skin on the outside, that might not apply.

Like if it's used inside a suit, then, of course, it would be the suit who is -- and maybe that should be recognized in the guidance document and taken into consideration.

Because it would make, for example, in the rebreather, very expensive equipment. If that was used inside a suit, you don't have to throw away the rebreather, maybe just a facepiece or something like that.

MR. SZALAJDA: All right. Enough said. And that's good point as well.

I think when you look at the nature of what we have developed for the disposal criteria,

it's based on our test time or our actual exposure time in the laboratory.

But, yeah, having said that, when moving forward and for my perspective in my previous life working at Edgewood, you know, the M-40 respirator, for example, is used every day, very often in training at the chemical training facility at Fort Leonard Wood and also in use at the training center at Fort McClellan, or whatever they may be called now.

They don't dispose -- they're working with -- the responders or the servicemen go through the training where live agents are used, but they don't necessarily dispose of the respirator after every use because of the provisions that have been taken.

Part of what we will do as we move forward with the guidance document is look at those parameters.

But given -- you know, given the nature and the expeditious timing of trying to get the standards out, which the cautions and limitations

were safe sided based on the knowledge within the community, as well as limitations of decon and detection equipment.

MR. HEINS: Bodo Heins, last question.

What is it about the intrinsic safety for the other two standards?

The intrinsic safety is only mentioned in the industrial standard.

What is it about the CBRN standard and the WMD standard?

Is it also required, or would it be implemented or --

MR. SZALAJDA: Well, I guess, from one standpoint, there is no WMD standard anymore. There's only a CBRN PAPR standard.

I don't think that completely came out on the website when the information was posted. There was supposed to be an asterisk on the PAPR program to say that WMD was being discontinued.

But to answer -- I guess to answer your base question on it, intrinsic safety, that has been something that has been identified, I guess,

in other public comments that we're still addressing or still haven't come to a final disposition yet, you know, with regard to this equipment.

And we will consider it before the standard is implemented.

MR. COURSEY: Bert Coursey, with the Department of Homeland Security.

And DHS appreciates the work that NIOSH and your partners at ECBC have done to develop the CBRN PAPR standard.

But the issue is -- we understand there are multiple requirements in the standard and that these requirements will continue to evolve over time. And the manufacturers will step up to the plate and develop better equipment.

But we're concerned that we have to have a standard sometime in the near future to meet the requirements that we have to give guidance to state and locals for purchases with FY '05 and '06 funds.

MR. SZALAJDA: And we appreciate your concerns, Bert.

And I think as we move forward, I think over the next couple of months, hopefully in continuing our dialogue with the stakeholders, we will be able to provide some clarity with regard to the plan forward, you know, whether we, you know, implement the CBRN -- or repackage the requirements for the CBRN, and that will allow us to have an earlier implementation as compared to a later implementation.

MR. COURSEY: Thank you.

MR. SMITH: Simon Smith, 3M Canada.

Just for clarification in what you presented, you were merging the conventional cartridge and canister standards into one level?

Because you had cartridge canisters and other types --

MR. HOFFMAN: Yes. That's the initial intent.

MR. SMITH: Yeah.

MR. HOFFMAN: That's correct.

MR. SMITH: Well, for the tight-fitting, will that be permitted for use outside IDLH in the

industry?

MR. HOFFMAN: True. I guess --

MR. SMITH: Yeah.

MR. HOFFMAN: I mean, I haven't thought about that, but I would think, yes, as long as it meets the test requirements.

MR. SMITH: And would it be introduced in different capacities, as in the CBRN standards, or would it be just one capacity?

MR. HOFFMAN: That we haven't really resolved yet, how we want to do that.

There are several issues that -- do workers expect that -- when they put on a new set of industrial cartridges or canisters on a unit, do they expect it to last an eight-hour work day, or is there going to be a changeout schedule, or how it's going to work.

So we haven't looked at it from the other end.

MR. SMITH: There's another question in correlation with existing equipment, as well.

That has to be dealt with in a very

detailed manner.

MR. HOFFMAN: Right.

Because on the CBRN, there's a Cap 1, Cap 2, Cap 3, as far as the industrial side, but we haven't really got to that level on the detail.

As of this concept, this was the first one, May 30, of our ideas at this point, and we will have to resolve that.

In fact, we will be looking for some input on that and how best to do it.

A couple of ways we could think of is canisters could be offered at different levels, depending on if you are going to use -- if this is intended to be used for certain periods of time, or if there's an end-of-service-life indicator, or it's one way -- which to me is more restrictive -- but there's only one industrial type that you use, and it's going to last you a full day.

We have indications that people use them for -- depending on the business that you are in with the industry, you might use it for a short time each day, or you might use it all day long.

So there are still a lot of unresolved issues.

MR. SMITH: Thanks so much.

MR. SZALAJDA: And I think that's a good -- just to follow up on those points, I think that's a -- one thing that we want to be sensitive to with how the requirements for the industrial PAPR defines because we realize one size doesn't fit all.

And, you know, with the vast number of potential users, it doesn't make sense to develop overstringent requirements for, say, pick somebody that's working in chip manufacturing that's wearing a PAPR because they are trying not to contaminate the product that they are making.

And you're looking for having a system that's comfortable that they can sit and wear for long times, and maybe just has particulate efficiency for what they're breathing versus, you know, industrial applications where you may be using PAPR in the chemical industry or, you know, on a construction site or things of that nature.

So what we're going to try to do is achieve a balance in the requirements to allow that variability for the selection so that market can determine and respond to the needs of the individual in identifying the equipment they need to provide the right protection.

MR. DESANTIS: Vic DeSantis, Safety Tech.

I would like to ask NIOSH that they put on their website an index of all STPs, possibly by category, however you wish to break it down.

Also to let us know when an SPT is formally signed off, even if like doing an email or something.

And also when an STP is modified or revised for any reason.

MR. HOFFMAN: Actually, we are working on that.

And that's one of the topics for tomorrow's meeting, at the manufacturer's meeting.

MR. DESANTIS: All right. Thanks.

MR. SZALAJDA: Thank you, Vic.

MR. DENNY: Frank Denny, Department of

Veterans Affairs.

Just so everybody -- you know, trying to keep up with all this stuff, one of the things that I found useful is they have a program called ChangeDetect.

And what it is basically is it's a website where you can specify areas, other websites that you want watched.

And if there's any change, then you're sent an automatic email showing that that website has been modified.

And they even have -- for a small fee, they will even go through, and they will show, if there's a document, what has been changed and yellow out what has been changed in that document.

If you want to know how to get on that kind of a system, I have it on the VA web page. One of the things I have done is recommend to our people that they do that.

If you just go for -- if there's a change, it's free.

So that might be helpful.

But our main page is VA Safety, www.va.gov\vasafety, and at the bottom you can click onto this detect type of system, which will allow you to monitor websites automatically.

You won't have to worry about looking at them.

MR. SZALAJDA: Thank you, Frank.

All right. Thank you.

We have one additional presentation for today's venue.

However, before we have that presentation, I would like you all to stay seated. We have a survey regarding the content of the meeting today that we would like to pass out and get your feedback on.

If you could -- Betty and Marlene will be passing that out.

If you could stay seated, fill out the survey, pass it to the center aisles, and we will collect them.

Then we will conclude the -- we will have our presentation by Craig Colton and conclude the

program.

(The survey was passed out and collected.)

MR. SZALAJDA: Not to rush everybody, but maybe another minute to complete the survey. Okay.

Again, if you are finished, if you could pass the surveys towards the center aisles, and the ladies will collect them, and we will conclude the last few items on the program.

But, first, I would like to thank everybody for hanging with us.

I know we have run a little bit over with regard to our program, but, you know, we felt it was important to at least provide you the opportunity to comment on some of the recent changes with regard to the concept paper and our benchmark testing, as well as seeing some of the range of research that's currently being conducted in support of our respirator standards development.

We have one presentation, requested presentation, in response to the notice that we had issued in the Federal Register.

Mr. Craig Colton from 3M will provide

some general comments on the industrial PAPR concept.

MR. COLTON: Thanks, Jon.

And 3M appreciates the opportunity to make these general comments here about our standard or the concepts early in its development.

And this won't be a point-by-point discussion of the issues, but overall relating to the direction of the standard.

So in that way, we -- they will be actually identified by three areas that I would like to comment on.

And the first one is that we believe that after we looked at the concept and the comparison document between them, that the industrial PAPR seems to be a lot like, very much like -- at least in our opinion -- like the CBRN PAPR.

We don't disagree with the ability to use the technical work that was done for the CBRN standard and apply that to the industrial PAPR, but it -- outside of a few tests, every PAPR seems to be recommended for the -- or used for industrial

applications, would have many of the CBRN requirements.

And in doing this, we believe that this will result in an overdesign of some of the PAPRs for industrial applications.

So we would like to see them move away from that and put some other criteria, if you will, for respirators.

As we also looked at the concept, the proposed standards seemed to be very design specific.

In fact, if you look at the comparison document, it talks about tight-fitting. They actually would end up being gas mask approvals. Whereas the loose-fitting would be the cartridge approvals. And there's no option to have cartridges with full facepieces as we read that concept.

We heard here, just prior to this, that they were looking into that area, so maybe we will see a change.

As such, we would encourage that there be

performance requirements that would allow for many of the options, many of the requirements that NIOSH has specified to be options, that would then be available to the market.

So there may be some PAPRs that have all the requirements that are specified in the industrial concept as it appears today, but there may be other PAPRs that wouldn't need so many of those features, if you will. Then the market or the users can decide which ones are appropriate for them.

The other thing is just a little bit about the revision.

It seems like that there is some significant differences between the industrial PAPR, the existing industrial PAPR standards, if you will, that are scattered throughout 42 CFR 84, that was mentioned versus the concept that was published.

And if there's a reason that all of the industrial PAPRs need to look like CBRN PAPRs, minus the few tests, then we would encourage NIOSH

to make that rationale available so we could understand where they are coming from and why that is.

Then, the last issue I have deals with the cartridges and the canisters and differences there.

Simon sort of mentioned that a little bit.

But in looking at all the requirements based on those CBRN test concentrations, it could end up requiring some overdesigned, very large canisters or cartridges for industrial markets.

And in fact, our experience is that the trend really in the market is that users are -- where there's gas and vapor exposures, the concentrations are actually going lower and that people actually, since they have less or lower concentrations that they are being exposed to, there could be an argument made that the cartridges should be going smaller rather than larger.

In fact, as a spray painter, which was like over 30 years ago, when I worked, the

exposures were to the particulate pigment and not to -- or the overexposures, I should say -- and not to the solvents.

And especially in this day and age where now the manufacturer -- or the user has to develop change schedules and that, having large canisters with extra capacity may actually discourage them from changing them when they should, especially if it's a material that would migrate on the cartridge.

And a smaller cartridge would actually maybe promote better use of cartridges in the workplace.

So to wrap it up, what we would encourage NIOSH to do is to, as they revise the concept to, again, make it more performatory, and allow for different devices of PAPRs for different needs.

And you might have different levels of PAPRs, some with basic features, others with somewhat more advanced features.

And based -- and we would also like to see more -- using the input from industrial users

as the -- establishing the needs for the industrial PAPR.

Thank you.

And I'm not going to ask for questions or comments.

MR. SZALAJDA: Thank you for your comments, Craig.

Well, this is part of the day that I think everyone has been waiting for, when we conclude the program.

I would like to open the floor for a few minutes for any general comments regarding the material that was presented today, for the record, and then we will -- I will have a few concluding remarks, and we will adjourn.

MR. BERNDTSSON: Goran Berndtsson, SEA.

Overall, I think you have done a terrific job. The presentation today is heading in the right direction.

And if you can finish it as soon as possible, we will have a good set of standards. And I think that is true for the CBRN and the

industrial part of it.

Just one thing I would like you to consider, and that is in the terminology as we are talking about two different things. We are talking about volumes and flow.

And what we have done on the ISO is that we have determined that every time we talk about flow rate, we go over to liters per second, so not confusing it with volumes.

And maybe you could at this stage consider that in the document just to make it harmonize with the rest of the world.

MR. SZALAJDA: Okay. Good comment, thank you.

MR. BOBETICH: Ken Bobetich from MSA.

There's obviously a lot of people here who are interested in standards development and the future of standards.

Reference has been made over the last several days about ISO and the need -- and the way the world is going and joining the European standards with the ANSI standards and the NIOSH

standards.

There's a very skeleton crew of people working on the U.S. TAG, the Technical Advisory Committee, to work to help to present the U.S. position, the North American position, as a part of that standards development.

NIOSH is very involved in this.

They are very committed to this, which to me, as a manufacturer means, at some point in time, the standards that are written for the globe are going to have very close application here.

To that end, I would encourage those of you who can find the time and the energy and are willing to participate in the standards development program to contact NIOSH and let them know of your interest, or the ISEA, and step up because there's a lot of work to be done on a number of fronts.

All of these global standards are being harmonized right now. And of you're not going to participate in that activity, you're going to have standards that ultimately don't meet your needs or are less than what you expect to compete with.

Thanks.

MR. SZALAJDA: Thanks, Ken.

MR. FRANK: There's only a few, but I can't remember them all.

Bill Frank (phonetic) from ICS Labs.

I want to go back to the CBRN standard, if I could, and the LRPL test.

And my question is why on the LRPLs, for the loose-fitting hoods, has NIOSH determined to disclude hands on knees, head side to side, facial grimace and steps, and what was the rationale?

MR. SZALAJDA: I don't believe that's part of the -- what we have discontinued.

MR. FRANK: It is.

MR. PALYA: The first responders exercises.

MR. SZALAJDA: Oh, the first responder.

Okay, Frank, maybe you can come up and help me on that.

I don't know the detail on that.

MR. PALYA: What, was there eight exercises?

MR. FRANK: I don't know.

But, you know, the general exercises that we have had traditionally for the tight or loose-fitting hood in the draft proposal, the grimace has been eliminated, the hands on knees, head side to side has been eliminated, and then the steps at a normal pace, even though it's kind of a joke, has also been eliminated.

And I was wondering as to the rationale for that.

MR. PALYA: Yeah. Other than just for the loose-fitting hood --

MR. FRANK: Well --

MR. PALYA: -- I mean, first receivers -- I mean, they are first receivers and not the first responders.

I just don't -- I don't recall that we even talked about -- we will have to get back to you.

MR. FRANK: I would call for consistency in which you guys apply to me, anyways, it doesn't make sense.

If you look at a loose-fitting hood, many of them on the market today have nose cups internal, which are going to really be affected by head turning. They are also going to be affected by the positioning of the head.

I saw that, and it didn't make sense to me. Even the grimace makes sense, just because of the way these hoods are being composed today.

MR. SZALAJDA: Okay. That's a good comment, and we will look into that.

I think off the top of my head, I think we can say that probably the initial that was looking at, you know, from our original concept of the CBRN tight-fitting PAPR, looking at it from the emergency responder application.

And there may have been something lost in the translation when we set the criteria up for the loose-fitting, but we will look into that.

MR. FRANK: Okay. And the next, same thing on a loose-fitting hood design, we have discluded the assessments for transmittance, abrasion, haze, and also low temperature fogging on

these PAPRS.

Again, I question what was the rationale for any one or these being discluded.

You don't have to answer any of these. You can email me an answer if you don't have one. But it's a cause of concern for me when I read it.

We talked briefly about the measurement of airflow, and there was a presentation made on the measurement of airflow.

As there has been a historic flip-flop in inconsistency by the agency in measurement of airflow in PAPR devices, going to point, is a respiratory inlet mounted or unmounted?

As you write the standard, please be sure to be specific and then to apply it specifically. And that's just kind of a side note.

And then also, please be specific on the head form and the IDs, as some of us will be making our own head forms per design, and those will, of course, have an affect.

Next question.

For the FOV requirement, we have the same

FOV requirement for a loose-fitting hood as we do for a tight-fitting respiratory inlet.

We have got a drastic difference in vertex distance between these two types of generic designs, which of course, is going to have substantial effect on FOV.

Has NIOSH done a raw research study on loose-fitting hoods that are currently on the market to make sure they are going to be compliant with that requirement?

I mean, I haven't done it, but it was an immediate question in my mind, just given the vertex difference.

And maybe Dave, if you are still here, do you know something that I don't?

MR. SZALAJDA: Yeah. On that, you're ahead on me.

I guess on that one, we haven't done the benchmark testing on field of view for loose-fitting yet.

MR. FRANK: Okay. Jon, I think you have saved -- I had two more, and I think I just died.

MR. SZALAJDA: Well, here, I will buy you some time and answer the one on the abrasion and fogging.

When we looked at the requirements for where we considered that the loose-fitting system could be, you know, again, you're talking about inside the hospital.

Our concept is that these are used inside the hospital doors. They are not used for responder --

MR. FRANK: That will buy you the fogging, but it won't buy you transmittance and it won't buy you haze.

MR. PALYA: Well, now, that's not true.

We don't think it's going to be that harsh of an environment.

MR. FRANK: Right.

MR. PALYA: There will be storage --

MR. FRANK: I'm talking initial haze. I'm talking units that have been subject to an abrasion. I'm talking as received.

You should have an as-received

transmittance requirement, about 80 percent, 85 percent minimum, okay, just for visibility.

And some kind of minimal haze -- and you need this more so in a loose-fitting device because you are talking about using acrylics and sheet polymers rather than lens quality polymers that are going to have substantially more haze in them than on a tight-fitting.

So you need to have haze.

MR. PALYA: Right. I think we were talking -- yeah, again, we were going to keep those, you know, keep the luminous transmittance and haze values, and then go ahead there and drop the abrasion resistance.

MR. FRANK: Abrasion resistance.

MR. PALYA: That was the intent there.

MR. FRANK: And then one more.

MR. PALYA: Okay.

MR. FRANK: My initial review, there's no noise level measurement for a loose-fitter where there is for a tight-fitter, but then we have the same communications criteria for a loose-fitter and

a tight-fitter. And that kind of just didn't make sense to me either.

And then plus we have the language, when we're applying it to a tight-fitter, that should the tight-fitter cover the auditory inlet, that the measurement should be taken, you know, inside the respiratory inlet, which is the same as a loose-fitting hood.

And many times you have more noise levels.

And you have to look at it, not only from a communications aspect -- and you do have a communications criteria -- but you also have just a pure lot of noise and reverberation aspect.

MR. PALYA: The non-tight-fitting standard is going to be heavily on human factors.

You have communications -- a lot of this stuff is going to be put in, you know, as far as the noise levels and everything, the field of views.

At this point, you know, we're waiting for the tight-fitting PAPR to go ahead there, and

we will resolve a lot of these issues with that.

And the last one is hazard assessment, then we're going to go ahead there and pool all of these other human factors, and we are going to nail these things down.

Again, we're going to look at the hazard assessment. That's our biggest focus right now.

Getting back to what Ray was saying and what his input was from the medical community, I think we're going to go ahead there and look at having -- that they will be able to see the lips of the healthcare worker, you know, so the patients could see that.

So there may not be a nose cup; okay.

So, again, we're looking at a lot of these things here.

MR. FRANK: Now, you wouldn't look to be design restrictive, would you?

MR. PALYA: Well, I mean, the thing of it is, is it's performance.

Okay. Let's put it this way. How are you going to read the lips of this guy with the

nose cup on?

MR. FRANK: Right.

MR. PALYA: So I mean, we could go ahead -- but, again, we have got to look at the performance based on that.

So we're going to go ahead and try to meet the needs of our first receivers.

MR. SZALAJDA: I think that, with the concept paper as currently defined, please keep in mind for the non-tight-fitting provisions, it's still -- this is still a real evolution in progress.

You know, we're playing catch up because of the focus being on -- really over the last two years has been on the needs of the emergency responder in addressing those tight-fitting --

(Talking simultaneously)

MR. FRANK: -- my initial remarks.

MR. SZALAJDA: And those are good comments that we will consider.

And if you have other things, we look forward to hearing them, of course.

MR. FRANK: Thank you.

MR. SZALAJDA: All right. I think at this point, let me throw a couple more slides at you, and then you can go from here.

But I think you gained some appreciation that with the CBRN PAPR we still have some work to do to complete, our determination of our technical requirements.

And as Terry had discussed this morning, the critical path continues to remain the high flow test equipment for doing the particulate testing.

I think when we have talked about the need for the breathing machines, I think in the short term, while that's a need, that's something that's going to be a little easier for us to overcome with regard to the apparatus.

There are some workarounds that we could consider in the interim to use the breathing machine portion of the ABMS if we needed to conduct testing in the near term.

But, again, the critical path remains having the high flow particulate testers

operational, doing our diligence, and making sure that the results are repeatable, we can validate our procedures, and make that test procedure available.

But also, having said that, at this point, I think you can also appreciate that with the high flow particulate testing at this time, we're sort of in a situation where we were with the SCBA a few years ago, that, at least for the interim, until some Round Robin type testing could be conducted to validate the systems commercially, that manufacturers could go out and buy these systems and use them for their own internal research, as well as pretest evaluation, and our machines will be the only game in town.

And we would need to address that as part of any implementation of the standard, including the high flow particulate testing.

One thing that I didn't address today that is still an evolving concept is the failure mode effects analysis.

And in the concept paper, we address that

as part of the quality control plan.

And just as a sideline, this an evolving concept that I think as we move on over the next few months is going to be a little more focussed with regard to what our needs are, our expectations are in getting that information as part of our quality control plan.

You have heard a couple of different ideas today on how that would be addressed.

But I think, suffice it to say, that where we ultimately end up, I believe with this concept is that we, not -- we as in NIOSH, as part of your certification package, I don't expect that we will ultimately see a formal FMEA as part of that process.

But I think, however, we will be looking, in terms of your application and seeing evidence to the fact that you have done an FMEA by how your cautions and limitations and your user instructions have been developed to address, you know, our concern that the system is functioning the way it should once the user gets it in his hands, assuming

that they followed all the proper preventative maintenance checks and services.

The road ahead. I think short term, you know, you have got a lot of good information today. We continue to develop information. Our plan is to host a concept paper, the next revision of the concept paper by August 31.

And, again, my intention with that concept paper is also to include some sort of a preamble to at least give the community an idea of how we feel the standard will be implemented, whether it's through policy, or whether it's through rulemaking, or if it's a repackaging or combination of those types of features to bring the standard to a point where the community can accept it, use it, and the certification program can begin.

The public meeting will occur here on September 29. We will work through the formal process of having that advertised in the Federal Register notice.

We're looking at having a window between

11 a.m. and 5 p.m. to have that meeting in this facility. More detail will be provided as we get closer to the meeting.

But I think suffice it to say that it's going to be more of an administrative detailed meeting rather than a presentation and inclusion of technical content, much like you have heard today.

And, again, for your comments to the CBRN PAPR, the docket number is 10.

For the industrial PAPR, we appreciate the comments that we heard from the community and some of the concerns that have been raised regarding the content of the industrial standard.

We're going to take those into consideration, as well as any other comments received through the docket or through other formal or informal sources up to the point where we begin rulemaking.

Again, we expect that to happen sometime after the holidays. And then once we begin the rulemaking process, we will be following the formal procedures that have been identified for

rulemaking.

And the docket number for collecting information on the industrial PAPR is 008.

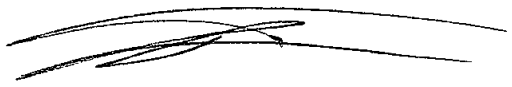
And with that, thank you for your participation today. Thanks for bearing with us. I guess we spared you a long day yesterday, if you were here with the shortness of the meeting.

You know, we didn't intend to make it up today by having this go a little longer, but we appreciate you bearing with us, and thank you for your participation.

(Whereupon, the proceedings in the above-captioned matter were concluded at 3:50 p.m.)

CERTIFICATE OF REPORTER

I, Joseph A. Inabnet, do hereby certify that the transcript of the foregoing proceedings was taken by me in Stenotype and thereafter reduced to typewriting under my supervision; that said transcript is a true record of the proceedings; that I am neither counsel for, related to, nor employed by any of the parties to the action in which these proceedings were taken; and further, that I am not a relative or employee of any attorney or counsel employed by the parties thereto, nor financially or otherwise interested in the outcome of the action.



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