PROCEEDINGS

NIOSH/NPPTL PUBLIC MEETING

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Transcript of Proceedings at the NIOSH/NPPTL Public Meeting held at the Hilton Garden Inn, Pittsburgh/Southpointe, Canonsburg, Pennsylvania, commencing at 9:00 a.m. On Tuesday, May 4, 2004

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P R O C E E D I N G S

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MR. SZALAJDA: I'm now calling the meeting to order at 9:10. Thank you for your attendance and participation this morning. We're looking forward to having a good session and sharing with you some of the ideas and concepts that we're considering for the CBRN powered air-purifying respirator.

I have a couple general announcements with regard to some of the administrative details here within the hotel.

The restrooms are back towards the main entrance where you came in. They're on the left-hand side before you get to the lobby. The hotel asked if anyone needs transportation to the Airport, there is a South Hills Carriage that provides shuttle service to the airport, and I have the phone number for arranging that type of details.

We're going to have a morning break and an afternoon break and there will be condiments in the back of the room. Lunch will be on your own.

The hotel is going to set up a concession stand out here in the lobby on the wall, on this one wall between the two windows, where you'll be able to buy lunch. There's also a Jackson's Restaurant in the hotel as well as a Subway and a Chinese buffet that are out in the parking lot.

Also, please remember to complete your meeting evaluation form and turn it in outside the doors when the meeting is complete today.

And there are also several handouts that are available in the back of the room, including the most recent Rand report on protecting emergency responders.

And so with that, I'd like to start our presentations for today. Our first speaker is going to be the laboratory director, Rich Metzler.

MR. METZLER: Good morning, ladies and gentlemen, partners in working with NIOSH to improve occupational safety and health. Thank you for being here at our public meeting today on powered air-purifying respirator standards.

My remarks will be brief. I just want

to be able to welcome everyone to this meeting.

A brief background, NIOSH has been working with its partners, DHS most recently, the National Institute of Standards Technology, OSHA, SBCCOM, now RDECOM, and many others who have been supporting the process to develop standards for CBRN respiratory protection.

We've been doing this through a public process where we post our concepts for standards on our website and follow that with welcoming comments to the public docket, reviewing those comments, taking them into consideration, and then adjusting the concepts and then following that with a public meeting to give everyone an opportunity to provide your insights as to how to improve these standards.

So far standards for self-contained breathing apparatus have been completed in January 2002. SCBA for traditional equipment, an upgrade program was implemented in March 2003. Air-purifying gas mask standards were implemented in March 2003. And escape sets for both air-purifying and closed circuit were implemented in October 2003.

And as you know, we're in the process of developing PAPR standards. And that will be followed with an integrated self-contained breathing apparatus/PAPR combination and a self-contained breathing apparatus air-purifying respirator, and so on.

A brief update on those who hold approvals looks very good now in the area of CBRN self-contained breathing apparatus. Essentially every major manufacturer of self-contained breathing apparatus now holds at least one approval. And, as you can see here, some hold many approvals.

Scott Health & Safety and MSA also have upgrade approvals for their traditional equipment to bring the equipment in the field up to CBRN status.

The list of the approved equipment can be found at our website through CDC and NIOSH and NPPTL's website and you'll find it easily there.

The approvals have been granted to two manufacturers on full facepiece air-purifying CBRN respirators. And the PAPR concept, as you know, has been in process now for approximately a year, with concept papers posted last September and October

time frame at a public meeting.

This is a truly exciting time. Those of you who work in this business every day, and I'm sure it includes almost all of you or you wouldn't be here, have to realize that the technical challenges, the standards, the new tests that are going to be developed to support this program are going to be felt for at least the next three or four decades. Once these standards are established, it will be a long time before they're changed.

The innovation of these concepts will have a substantial impact on the performance of PAPRs for decades to come. We're very excited about implementing these standards and then seeing the effect of these standards implemented in industrial equipment along the way.

So I encourage you to be proactive in going to the microphone and letting being us know what you think. Follow up with your scientific and detailed comments to the docket. The team that we've assembled goes through those comments, compiles them, evaluates them, and then implements them in new versions of the concept.

As you know, we went to public meeting in October. In my layman's terms, I would say it was almost booed out of the place. You gave us a lot of good comments to change our original concepts and our original thinking. And I think, you know, we have a much better concept today, and I think one that can be further improved.

We intend to take comments from this meeting and those that we receive from the docket following this meeting to further improve the standard.

I want to recognize our partners because it seems like as though up till this part I haven't really expressed my appreciation in great enough detail.

The process was started in 1999 in early partnership with SBCCOM, now RDECOM, and NIST, in doing a number of very important things it's been felt in the country over the past few years.

For one, our early meeting in March of 1999 where Bill Haskell and other folks attended from the Army, I know in a hotel room we started laying out the concepts for the interagency board,

writing the charter for the IAB organization, which has now gone on from DOD and DOJ, and now also a partner with DHS has identified a number of important standards areas for first-responder need to protect them against terrorism.

That was a very important activity which has now blossomed into a major very effective interagency board with joint partnership in many federal organizations and responder organizations.

NIST, through the Department of -- Department of Justice through NIST started the early funding in this program and has continued supporting us now with funds coming through from DHS to NIOSH. It's through these quality partnerships that respiratory protection is going to be improved.

And I'm leaving a number of very important stakeholders off of this list. These are the federal folks and the NFPA standards organization who directly work in developing the standards or functionally support the process. But the International Association of Firefighters, the International Association of Fire Chiefs, the International Safety Equipment Association all have

been primary supporters of the standards and process to make these improvements happen.

Quality partnerships enhance safety and health. At the national laboratory, every project that we develop that is a research effort or a standards development effort starts with identifying who the partners will be in developing the technology or standards and implementing those. And then we work closely with them throughout the entire process. We believe quality partnerships enhance safety and health.

On a personal note, I would say in observing the team's performance in putting together the presentations and the standards, where they are today, I am impressed that this is one of the best public meeting opportunities that we have.

The technical challenges related to PAPRs cover almost every aspect of that technology from how to test batteries under load, for high demand, for moderate demand, so that a range of emergency responders can have the appropriate equipment whether you're a first receiver at a hospital or a responder at a major structural

collapse scene.

Flow rates, how to test filters, how to assure the balance in the manifold system, all of these, as you'll see in the presentations today, are quite technically challenging issues. And I'm extremely impressed at the comments that have been coming into the docket and the manner in which the team has been analyzing, responding, and then building them into the standards.

Your contributions are going to be very important for coming up with the best standard that we can to protect responders. But keep in mind that the standards that we create here will probably set the stage for the next 30 to 40 years.

Thank you very much.

MR. BERRYANN: Good morning everyone. Welcome. Glad to see so many people coming to the meeting. We are looking forward to your input, your comments, your suggestions.

And just to make a comment on Rich's statement about the last public meeting, hopefully there will be fewer boos today.

I'm Roland BerryAnn. I'm the chief of

the respirator branch for those of you who don't know me. Or even for those of you who do know me.

The first thing is the agenda. And everybody should have gotten an agenda in their packet when they came in. And if you didn't, you should go out to the table out in the front and get a packet.

We've got the agenda we hope in a logical developmental fashion where basically we're going to start out with an overview of the development of the concept thus far; and then look at breathing performance and high flow rate studies that we're considering in the development; and looking at various canister requirements; battery requirements; then the human factors requirements on the system; durability testing; the chemical warfare agent; and protection factors tests.

And then we're going to have a presentation to give an update on our I'll say companion chemical warfare agent simulant study.

And then after our presentations, anyone in attendance who wishes to give a presentation. We have one person who has signed up to give a

presentation thus far. If anybody else wishes to, there's a sign-up sheet outside at the table. And then we'll have an open comment period and hopefully get you out of here on time today.

Just some quick rundown on the logistics. For those of you who have been here before at our meetings, it's the same story. For those new, I'll keep it simple. There are sign-in sheets outside. We'd like everybody to sign in for a record of attendance.

The meeting is being recorded by a court reporter. There will be a verbatim written transcript that will be put in place in the docket if anybody wants a transcript of today's proceedings.

We're going to try and follow the agenda as closely as possible. And after each presentation there will be a brief question-and-answer period. And if you do have any comments or questions, please step up to the microphone in the center of the room there and identify yourself with your name and your affiliation.

And again, if anybody wishes to make a

presentation who hasn't signed up, you can sign up at the registration desk, or, you know, if you decide at that point in the program that you wish to, you're allowed to step up to the microphone and give an extemporaneous presentation as well.

Docket information, again, this information for submitting comments to the docket is in the information packet.

And I guess at this point, you know, at the end of the second presentation, I just want to confirm that the -- you know, this is a public meeting to discuss our concepts on the CBRN powered air-purifying respirator standard. And we're going to keep the subject content on that topic area. And hopefully we'll be able to exchange a lot of beneficial ideas today.

Thank you.

MR. SZALAJDA: Okay. I think a lot of the people in the room already know me, but if you don't, I'm Jon Szalajda. I'm with the policy and standards development team at the National Personal Protective Technology Lab.

And historically when we've gone into

public meetings we usually spend a few minutes talking about why we're developing unique standards for CBRN, chemical, biological, radiological, nuclear threats.

I think over time, we've come and we've generally cut back on the amount of information that's provided in each of these sessions because of the familiarity that the manufacturers and other stakeholders are getting with the process.

But I think just as a refresher for everybody, that you know why we had to -- why the approach was taken to developing a unique set of standards to meet a CBRN threat is -- probably a short review is in order.

When we looked at, when we conducted the initial vulnerability assessment and looked at the types of respirators that were available to address the protection needs associated with that threat, we found that neither the existing NIOSH industrial standards nor the military standards completely met the protection needs for dealing with a CBRN event.

And there were a few reasons. Not to go into any detail, but in general, the purpose behind

each of the standards was one main factor. The industrial, the NIOSH industrial standards were geared around development towards a controlled, modified type of event where the chemical or the other material that required protection for was identified and regulated to some extent that the protection for the respirator was easily identified.

The military developed respirator requirements around threats in areas that were identified as what the potential enemy could deploy in a battlefield situation.

Also, user populations for respirators are very different. You're looking at relatively well-trained, well-fit individuals in the Armed Forces that would be using the respirators. There's more diverse population with industrial users as far as height, weight and some of the other demographics associated with the work force.

Also, and I think a key here was the hazards associated with how a terrorist may deploy a CBRN type of weapon that, you know, we could be potentially looking at scenarios, indoor scenarios

where the higher concentrations may be maintained over a longer period of time versus, you know, a military scenario where chemical warfare agents could be deployed in the battlefield, or an industrial situation where the hazards were quantified.

So there were some distinct differences between the industrial and the military standards, which led to development of a special class, the CBRN respirator standards.

And with all of our projects, in articulating what we want to do to the stakeholder community, we've identified a goal. And for the PAPR it was to address CBRN materials identified as inhalation hazards and possibly terrorist hazards for emergency responders.

And I think to some extent that that goal has expanded a little bit. When you consider how PAPRs are used in the work force, that in a lot of hospital or health-care type professions, that PAPRs are used because they are a very comfortable respirator for the user to wear.

And part of our definition of responders

in this instance has included the first receivers, health-care workers, that may receive victims of a terrorist event.

In review, this is the process that we've been following in developing of all our standards. I think those who have been with us from the beginning have seen that we are pretty true to how we address the development of the requirements that you see in the concept papers.

I think one of the things that I wanted to touch on briefly here today because of the importance and the relevance to the PAPR concept is in the bullet E where we said identify test requirements, we also added for the purposes of this discussion at A, research.

And maybe one thing that hasn't always been covered in a lot of detail with the information that we've relayed to the community in these types of settings. There's a significant amount of research that goes on behind the scenes, whether it's done by NIOSH, RDECOM or one of our other partners, in terms of how information is generated and considered in terms of developing the

requirements of the standards.

And I think with the PAPR, and we laugh internally because we always say that the current one that we're working on is the most difficult standard today. But I think in the case of the PAPR, this is really true, that we've learned more with regard to our concepts as we've gone along.

But with the PAPR being such a dynamic system and with the breadth of technologies that could be considered and applied to providing powered air-purifying respirator techniques, that there's a significant amount of research that needs to be done as we move forward in maturing the concept.

And I think that's where today's public meeting is also a little unique with regard to how we'd like to share our thoughts and in turn receive your thoughts on the concept.

You know, in other public meetings when we've come forward, we've had a pretty good idea of what we felt the requirements should be and the standard; and in general, that we worked our research around identifying and confirming the requirements that are identified in the concept

paper and made mid-course corrections based on comments that we've received from the stakeholders whether or not we were meeting their objectives.

With the PAPR, at this point, we're pretty much wide open to any conceptual requirements and any expertise that the stakeholders may have with trying to address how we quantify and identify the requirements associated with this system.

There's a lot of technology gaps that we need to fill over the next several months as we move forward. And what you're going to hear during the course of discussion this morning and this afternoon are some of the approaches that we're taking to fill those gaps.

You know, however, I think in order to get the best possible product as we move forward, this is where we really need the input of the stakeholders community, both on the user side as well as the manufacturing side, on how we best address those technology needs and identify performance-based requirements that, you know, meet the community's needs for powered air-purifying respirator protection as well as encompass the

benefits of technology that the manufacturers can bring forward.

And if you're familiar with our process in terms of standards development, we are pretty consistent with three tiers of requirements for identifying the requirements for the standards. In general, where possible, we try to use existing standards. And that's a point that you'll continue to hear, that you've heard in the past and you'll continue to hear today.

In part, we look at the requirements in the 42 CFR in the Federal Register for respirators. We also look at using other standards that are either national or international to identify particular tests or particular requirements that may be appropriate to the type of PAPR that -- or the type of respirator that we're working on.

And then also the last here is identify special CBRN unique requirements, new requirements.

As we go through -- I'm not going to spend a lot of time on any one of these charts because you're going to hear more detail about this during the course of the presentation today. But

when you look at the requirements in 42 CFR, there are a lot of general requirements that will translate from the Federal Register into the PAPR standard.

When we look at the various subparts, you'll see things as far as general provisions, quality assurance, how to make an application, things about the application process. Those traditional ways of how NIOSH has done business will continue through the certification of a CBRN PAPR.

Then we look at, and if you go through, and I think my presentation tracks what you would see in the concept paper, as we move through the evolution of the concepts, we look at requirements that we feel are based in whole or in part in existing standards, whether they be national standards like ASTM or ANSI or international standards like the EN requirements.

But in going through, we had initially conceptualized the need for identifying certain requirements that manufacturers will need to meet as part of the certification approval process, things like markings, you know, effective markings and

labelings for the system that are readily understandable that the user can relate to and use as part of his operation of the equipment; things like low-flow and low-pressure indicators as part of the system to warn the user of the potential end of the operational time for the, that particular system.

Also we're looking, with regard to breathing performance, we're looking at a couple different work rates, which I think you've seen in the last few concept papers; a moderate work rate as well as a higher-pressure-demand-type work rate.

And with that we're looking at the incorporation of ensuring that the system operates in a positive mode, that the system doesn't go negative in the operation.

And this is really a dynamic approach for us in looking at the standards and in trying to conceptualize and identify requirements based on work rate. It's a little different with regard to how we've approached the, conceptualizing the requirements in the past.

I think another key thing along with

looking at the breathing performance that will be discussed is that, you know, we tried to identify existing test equipment that can be used with regard to the certification process. And in the presentation you'll hear in a little bit, we'll talk about some of the test technology issues associated with the evaluation of breathing performance.

Some of the other concepts that you've seen in the past with the gas mask program and with the escape standard that's carried forward because of we feel a durability need for the type of equipment that a responder or receiver would use would be things like the field of view; other factors associated with visual haze and luminous transmission; also being able to operate in low temperature and fogging characteristics; things along the lines of being able to communicate while wearing the respirator; and also other requirements for carbon dioxide, hydration, and noise levels that you may see with the systems.

And then the last here of our process addresses special CBRN requirements. One of the things that has been important, and we've used the

term panic demand in the past, you'll also see it called crisis provision, is how do we assure protection in instances where there may be a very high physiological demand by the respirator wearer in ensuring that they can be protected in cases of high physiological demand, high breathing rates in conjunction with the potential for maybe seeing an embedded threat of a higher concentration and providing an additional capacity with the canister to ensure the protection of the user.

We're also carrying forward with two tests that we've established early on in procedure, that a chemical warfare agent penetration and permeation test and the laboratory respiratory protection level testing that are done with our -- by our partners at RDECOM and Edgewood Chemical Biological Center.

Another aspect that was developed as part of the escape standards, and we think there's some merit for carrying it forward with the PAPR given the potential complexities of the system, is a practical performance criteria as part of the concept which would be evaluated during the LRPL to

ensure that the respirator system can be functionally used by a potential user.

As Rich and Roland have stated earlier, the intent behind these public meetings is to bring you our thoughts and our concepts and have an open discussion with regard to our ideas as well as soliciting your ideas and your technical or operational inputs with regard to the system.

You know, and to that extent, you know, we've had public meetings. We've also had individual meetings. And we'll continue to have individual meetings with stakeholders as well as manufacturers to try to get the benefit of evolutions in technology as well as the thought processes for how stakeholders may use the equipment and technology evolutions that the manufacturers may see that can be brought forward.

We will continue the use the concept paper in putting out on the website how our thought process is going for developing the standard. At this point probably the next concept paper you would see following the close of the docket for comments based on this public meeting, which would be after

June 4th of this year.

One of the things I wanted to spend a couple minutes about, as we've received questions in the past that manufacturers and others have provided input to the docket, and from some individuals' perspective it's sort of a black hole that things go in and nothing apparently comes out.

And I want to leave you with the thought that that's certainly not the case. And we really value the comments that we get in through the docket because it gives us insights with regard to maturity of technology as well as other factors to consider with the development of the standards.

This is our second probably of three public meetings that we'll be having regarding the PAPR. And today we've received ten formal submissions to the docket from various stakeholders in the process that we've considered in the development of the requirements.

Also there have been numerous meetings between stakeholders and manufacturers that have also gone into our thought process for the development of the concepts.

And one of the things that I wanted to state that what we've tried to do with the docket is capture the spirit of rule-making without the detail and the restrictions associated with rule-making; that when we have gone through and developed other standards and will continue to do so with the PAPR standard, that when we get comments, we develop an internal technical rationale associated with the selection of the requirements.

And where we receive specific comments regarding the requirements, the conceptual requirements of the standard, we address that as part of our technical rationale.

And basically it's, I think if you're familiar with the rule-making process, it's the preamble. We generate an internal preamble based on which we call a rationale document that addresses the basis for why we selected the various requirements of the concept and eventually become the standard.

And one of the things that we're going to be looking at doing over the next couple of months is to determine how to make our resolution of

docket comments more visible to the community. And traditionally you could go back to the docket office and get information by requesting the docket office for, you know, the submittals to the docket.

But one of the things we're evaluating is how to make this process more visible through the use of our website and the PAPR concept page to allow the stakeholders to go in and see what the different comments have been to the conceptual requirements; and then what we felt about them, whether we accepted them, accepted them in part, or felt that they weren't pertinent to the process at this time.

And with the packet that you received today when you signed in, we've put together a summary by topic of the comments that we received to date on the PAPR. And these are the topics that have been addressed by the stakeholders that we've gone through in looking at the conceptual requirements. And I think you'll appreciate there's been a lot of interest in a variety of potential components and considerations for the PAPR.

And just to give you a couple samples of

how we've addressed them, and I'd welcome your comments later on today after you've a chance to go through the information, what we've tried to do is we've paraphrased the comments just for the purposes of getting it into a presentation and also to capture it succinctly as we paraphrased the comments that we've received from the community.

And in your packet you'll see that if you have italicized comments, this indicates areas where we're still doing active research. And when you look at airflow, obviously I think this is one of the scenarios where we still continue to do active research.

If you see areas like this, with this comment regarding decontamination and maintenance, if you see the regular print, that generally means that we're fairly comfortable with the requirements as they're currently identified. And unless we receive additional information or see other information that would cause us to change our mind, these are not being actively looked at.

And so with that, I'd like to move along with the agenda, unless there are any general

questions regarding the concept paper.

(No response.)

MR. SZALAJDA: Our first presenter is going to be Terry Thornton from the laboratory. He's going to address breathing performance requirements.

MR. THORNTON: Good morning. My name is Terry Thornton. I'm the chemist that worked on the policy and standards development.

I'm going to go through the first presentation here, which is the breathing performance, and Jon just spoke about this a little bit. If you look in the concept paper of 1 April, this is paragraph 5.4 that covers the breathing performance.

As we saw in one of our comments, we talked about different operational technologies. Since we're using this concept in the breathing performance, we're actually looking at two different types of PAPRs: Constant flow or pressure demand.

And in both of those, we're looking at breathing performance, either a moderate breathing performance or high breathing performance.

When the manufacturer comes in for the application, a couple things they're going to specify. One is right now the operational battery life of the PAPR. And that's going to be an important number that we use.

You see we have a question mark there for minimum life of four hours. This is something we're actively looking at right now to determine whether four hours is an appropriate minimum service life. All we're going to have is a minimum service life. The manufacturer will be able to come in with a life longer than that, six, eight, 12 hours.

The other thing is a flow rate or pressure. And you're going to have to tell us what the pressure or the flow rate is that activates the low-flow indicator. The low-flow indicator's going to be covered a little bit later in the presentation. But we'll need to know what that number is, whether it is a rate or whether is it a pressure that activates that.

For breathing performance for a moderate breathing rate, we're going to use the breathing machine that's specified in 42 CFR. And that one's

been in there for quite a while. Most people should be very familiar with that.

That's a breathing machine that operates at 24 respirations a minute and a minute volume of 40 liters per minute. It has a peak volume in there of 115 liters per minute.

For a high breathing rate, we're going to use the breathing machine specified NFPA 1981, the 2002 edition. Right now in the concept paper I think that's all we specify is that NFPA standard.

What we will be doing later in the next concept paper is you'll see more detail on the description of the breathing machine, which will include a lung breathing waveform.

That breathing machine operates at 30 respirations per minute, delivering a minute volume of 103 liters per minute. And it has a peak volume of 300 liters per minute.

So what are the requirements we're going to be looking for? We're going to take the PAPR, put it on a mannequin, hook it up to the breathing machine, and we're going to run it for those operational battery life, whatever that time is that

we're evaluating it for.

And during that time, during that operational battery life, we're going to look for pressures inside the facepiece, probably right at the nose. It will be inside the nose cup area. Greater than zero, less that three and a half inches of water column pressure. Obviously greater than zero. We want positive pressure in there all the time. You don't want pressure too high.

That will be performed for the operational battery life plus 20 minutes. 20 minutes is a safety factor that we put in there for testing evaluation.

That's kind of everything that's covered in your concept paper right now as of 1 April. We think there's some more that we need to do to this. This is a place where we're developing, as Jon had pointed out, we're really developing some more standards for it.

So some additional performance considerations. Obviously we're looking at a load test. We feel like we need to do some type of load testing where we run the PAPR with a load on it.

And load tests, there's a lot of discussion that goes on about how to load-test any kind of filters.

Right now we use in NIOSH a silica dust chamber. Put it in there, it's exposed to silica dust. It loads up the filter and we monitor. What we'd like to do is go ahead and possibly use that silica dust if it's appropriate.

The other place we're looking at is looking into different load values; in other words, a different way to do it besides the silica dust. And we can either have a set load value or we can create a gradual load over time. And that's what silica dust does, you put it in unloaded, expose the silica dust, it gradually builds up over time.

We can also evaluate that possibly by just putting a load on the filter at one time. So the amount of load and the loading rate is still being investigated.

Obviously if we're running at a minimum service life for four hours without a load, with a load test, that service life is going to change some. So we're again looking at what we can use for a minimal operational battery life with a load. So

we're needing information without a load and with a load.

And really again what we're going to set is a minimum. The higher limit could be set by the manufacturer, six, eight, 12 hours.

Equipment that's going to be used for breathing performance, pretty simple in a laboratory. We just need the breathing machine for the moderate and the high performances, pressure transducers and collection of data.

If we look at operational battery life as being six, eight, 12 hours, we're going to have to really investigate how we're going to collect that data over that amount of time. If it's 12 hours plus 20 minutes, hopefully they don't have me in the lab for that long. It's a pretty long time.

So what really information are we looking for and we need help in? First, any kind of studies that we have for an instantaneous load versus a gradual loading, how we could do that.

The second is a total load on the filter. Right now we can look at our silica dust chamber and we can evaluate to some extent on what

the load is that goes on for silica dust over time. We have that capability.

But we're looking for any more information out there that someone has about what the resistance does when the loading goes on the filter.

And third, the rate of loading. If we load these all at one time, we'll just have a set number. But if we do some type of loading over time, we need to see how fast we're going to load that filter, what the rate will be.

So really these are the three areas that we're actively looking into, how to solve the problem to set this breathing performance.

Any questions?

Yes?

MR. NIEMEIER: (Inaudible.)

UNIDENTIFIED: Could you go to the mike?

MR. NIEMEIER: Sure.

We haven't discussed this issue -- Rick Niemeier with NIOSH in Cincinnati.

We haven't discussed this issue in the peer-review group, but curious why you're using

silica as the test material because of its known toxic effects and why something like ferric oxide or magnesium silicate or aluminum silicate wasn't used instead.

MR. THORNTON: You know, I'm really not sure of the answer to that. The silica dust chamber has been around I think in the standard for quite a few years. And it has been used -- it does have some toxic, but it's still used in the laboratory pretty safely.

And that's again why we're asking this information. There could be a different way to load that filter.

MR. NIEMEIER: You know, I realize it's sort of a standard now. But it seems to me that in order to protect manufacturers in the testing facilities, I would go to a much less toxic material, especially with the emphasis now that we're trying to eliminate silica exposure.

MR. SZALAJDA: Yeah, that's a good comment, Rick. And I think one of the things, you know, we are someone -- we do want to be sensitive to the silica dust for the health concerns.

I think another issue longer term that we've heard with regard to the certification program has been the difficulty of manufacturers being able to replicate this test.

So we're very open in soliciting input from the community with ideas for alternate ways to do this and not use that protocol.

MR. THORNTON: Also alternate ideas. Not even just another chemical that could be used, but some other approaches.

We're open to any consideration of different approaches of just restricting that flow going into the canister. So you wouldn't have to physically load it with a chemical or some kind of dust material, but we can simulate that maybe by restricting the flow into it.

So we're open to about any suggestion that would come up.

Yes?

MR. PARKER: Jay Parker with the Bullard Company. I have a question about the breathing machine.

Why couldn't we use the Bio Systems

Posicheck machine? Because it could do both flow rates. Maybe there's some problem with the pattern, the breathing curve. But I was just wondering why, because that machine is another option I would think.

MR. THORNTON: I guess it is and isn't an option. If you look at the NFPA requirement, the Posicheck has been built for that requirement. So the Posicheck would fit the requirement of the NFPA.

And you're correct, it does perform also 40 liter a minute. And we're trying to evaluate that to see whether the Posicheck would be the appropriate piece of equipment for both of those breathing rates or whether the machine that we have mentioned in 42 CFR, we also have that same instrument at the 103 liter a minute. So we are evaluating both of those.

MR. PARKER: Thank you.

MR. BERNDTSSON: Goran Berndtsson from The SEA Group.

What is the -- do you have any thought around the four-hour hour battery life? Have you -- is that just a figure or is it based on an actual

(inaubible) or an assumed time spent a first responder could be exposed?

MR. THORNTON: You know, again, I'm not sure where that number came from. The four hours is from the silica dust that is performed right now in the industrial standard. It's put in silica dust for four hours and then the airflow is checked again after that to see that it meets the minimum standard, the minimum flow rate.

So the four hours that we've come up with is based on that test. And that's why we, again, we're open to allowing the manufacturer to go beyond that. And if we can get information that would show that we need to lower that minimum, we could possibly do that and come down below four.

MR. BERNDTSSON: I think it would make sense to put the minimum up, the figure where it is likely that first responder is going to have to be staying in.

Secondly, as we are going to be looking on active warning systems, it's not as critical to have a minimum battery type because the operator will be warned when it is time when he's running out

of battery by the warning systems.

And of course any of those tests is not relevant to the reuse as the work rate is going to be different to how you're testing it. So it's kind of not necessary I think to have strict minimum requirement, but what is necessary is to have the warning systems in to warn the operator.

MR. THORNTON: Yes, and the warning systems will be in both low battery life and low flow or pressure indicators.

MR. SZALAJDA: And I just had one other comment I wanted to add to your first question, Goran, was, you know, with regard to setting a minimum value.

This is really one of the areas that over the next few months we plan on pursuing with our stakeholders, whether or not that when we deal with the fire service and the medical community, whether or not it is appropriate to have a four-hour minimum life or if they have -- whatever ideas they may have for minimum battery life.

MR. CARETTI: Dave Caretti, Edgewood Chem Bio Center.

Terry, one thing on one of your slides that you need to be careful of. As you said, the flow rate had a peak volume of 300 liters. And it's really not a volume, it's just a rate. You're not moving 300 liters of air at that moment, okay. So just be careful with that for clarification.

MR. THORNTON: All right. There may be a typo on there. Thank you.

MR. NAYLOR: Jim Naylor from Avon Rubber.

It may be a little premature to bring this up given the presentations that are coming. I applaud the efforts to introduce a standard for positive-pressure PAPR. I think it's overdue and I think it's not just the CBRN community that will benefit from that.

One thing that does concern me slightly from the thrust of the presentations is there seems to be a link between that and work rate. And I'm not convinced that enough work has been done to demonstrate that a positive-pressure PAPR system is necessarily beneficial to somebody who's working a high work rate.

Surely the benefit of such a system as we see in SCBA is the higher protection that is afforded to the user. The loading of a respirator depends not just on the inhalation resistance but also the exhalation resistance, the weight of it, and heat-loading issues, et cetera, as well.

So I'm a little bit concerned that I'm hearing that. And I don't see in this standard any different levels of protection afforded by a positive-pressure system.

MR. THORNTON: I don't think we put any levels of protection on there. We'll have to take that in consideration.

MR. SZALAJDA: I think what you'll hear though over the next couple of presentations are going to address some of those issues that you've just raised.

And I think with, you know, one of the things, and really the way we decided to focus the approach for the discussion today, in the past we've usually talked about some of our research, our research projects at the end of the presentation.

But we felt we wanted to introduce the

two concepts for the constant demand and the pressure demand at different flow rates up front, and lead that into some work that we have ongoing, some of it conducted by a contractor to NIOSH as well as our partners at RDECOM that are addressing high flow rates as well as pressure drop and resistances through the canister.

So I think given the nature of some of these questions, it's appropriate that we're going to do those at this time.

So our next presenter is Dave Caretti, an old colleague of mine from the days with the -- days at SBCCOM. Dave is a research physiologist in the Edgewood Chemical Biological Center.

MR. CARETTI: Thanks, Jon. The comment old is probably not right. I think you're older than me. Former colleague.

What I want to discuss briefly is at the October meeting we introduced to everyone the research effort we were trying to do for NIOSH to take a look at ventilation rates that are really occurring in the workplace.

We had proposed to do some literature

search and some studies related to that to try to get to the question about what are the work rates that these types of systems may be utilized under in the workplace.

Some background information. The objectives of the research effort were again to try to define ventilation based on real world work rates, try to examine both nonrespirator conditions, so what may be occurring just naturally at a workplace without someone wearing a respirator, and those instances where respirator wear would be a requirement.

And the overall goal is to really try to establish or to confirm, if you would, airflow rates currently utilized in the 42 CFR and into the CBRN standards as they're developed.

The approach agreed upon was to, first, to do a literature review, try to be comprehensive in our search, review as many articles as possible, and see what we already know; and also to identify what we don't know; also try to gather and compile data on more recent respirator studies that have gone to that extreme to look at more high work rate

types of things, which is kind of not new, but there's been more of an effort placed on that independently and some of it related through different government groups lately and some independent researchers.

And the third approach would be, the third part of the approach, was when we do identify data gaps, if the information is really important to what we're trying to get towards, we may have to implement some human-use testing.

So I'll focus in first on the literature review. I'm just going to give you a background on where we stand with this part of the project.

The literature review was completed around December-January time frame. We reviewed some of the concepts. We focused in on parameters of ventilation pertinent to respirator certification, like peak flow rates, minute volumes and such.

We took a good look at all the articles that we reviewed on the methods that were utilized to measure ventilation. There are many different ways to measure ventilation of someone during active

breathing.

We scrutinized the different methods that were utilized so that we could feel comfortable with the data or at least identify what some of the problems may be with certain data in some of the articles we reviewed.

We reviewed literature related to maximum ventilation rates for individuals performing maximal capacity testing, not much unlike a cardiac stress test that some people may have undergone before in their lifetime.

We looked at speech rates, flow rates related to speech, to try to get a better feel for some of the literature that's being purported about how speech flow rates are very important to consider.

And then we looked for ventilation rates for occupational activities, and then went further and tried to get more information about some of the earlier work done with respirators and how breathing resistances impact ventilation.

In total, we reviewed 155 papers. Some of these were quick reads because we've read them

many times in the past. Some of them required a little more in-depth analysis.

And out of those 155, you can see there's very few papers that have anything to do with breathing in the workplace. Most of the work is done in laboratory settings. A lot of simulated workplace activity.

But the bottom line is most ventilation is -- or ventilation studies are kind of a side information related to other things like energy consumption or energy expenditure rates. And a lot of times researchers measured ventilation but they didn't report it.

So we had very limited empirical data to try to meet all of our objectives. So we tried to think about ways we could at least get a good feel for what flow rates may be related to certain occupations and activities. And we went back and, using some information, there's a relationship between the amount of air required for a certain level of oxygen consumed.

Now, oxygen is the substrate utilized mainly for performance, particularly for

aerobic-type activities which are generally low to moderate intensity work loads that are carried on for a long period of time.

Using the information that we understand between the relationship between minute ventilation and oxygen consumption, we adopted an approach of a couple exponential functions that actually defined this relationship using an empirical relationship with a formula where we could at least estimate and have a good estimate, we felt, of what ventilation rates may be required for specific activities where oxygen consumption or energy expenditure data is reported.

In doing so in the paper we did go through great lengths to define some of the assumptions and limitations of using these types of predictive equations if you will. So they're not absolutes. But we felt that the information provided was better than having nothing at all.

And because it is supported in the literature and this relationship is fairly well researched over the years, we feel -- we felt pretty comfortable in going forward with at least

estimating some ventilation rates if they were not reported.

We looked into peak inspiratory flow rates. This refers back to what I said to Terry. It's, you know, the highest flow rate occurring at any time in an inhalation cycle or an exhalation cycle, however it's defined.

There's not a lot of literature on peak flow rates for normal individuals. It's more of a, something that's reviewed for people that have some kind of respiratory disease or some kind of respiratory problems.

But there is some good literature, old literature and a few new articles related to peak flow rates just of normals doing different types of activities or at least under certain work-load conditions.

We were able to take some of that data and combine it with data that we've collected in-house in our laboratory with some data that we've also been privy to through partners that we have with University of Maryland at College Park and tried to come up with a way of estimating peak flow

rates based on measured values and relationships to minute ventilation.

Again, in doing so, it's not absolute, hundred-percent correct, but knowing the assumptions and the limitations associated, we believe we're getting good estimations of what some peak flow rates may be. And if we look at the data from the estimations with the data reported, there's pretty good correlation there.

We went further then after we reported this information and looked again at the respirator wear and ventilation rates.

And if you can't hear me over CVS, I'll try to speak a little louder here.

(Laughter.)

MR. CARETTI: Our focus in looking at the respirator and breathing resistance literature was, you know, this has been reviewed in the past. Other researchers have reviewed this information, reported this information.

It's difficult to know that if you have a resistance of X, you're automatically going to have a change of ventilation of Y, because

resistances are never the same in anybody's one paper to the next paper. Very difficult to define.

So we took the approach of trying to say, well, what were the differences from the nonmasked conditions if a researcher also did report that information. And we tried to at least identify trends in what happens when you wear a respirator based on some broad categories of respirator types.

The purpose here was to say, well, if you have a peak flow rate of X without a respirator, is it safe to say that you even get that high with a respirator when you're breathing against a resistance, as more try to interject that information into the paper.

The status of the paper is the last bullet on the slide. Initial paper draft was finished in March, provided to contacts at NIOSH for their review.

This is just a summary chart of some of the ventilation data we found for minute volumes. Along the X axis would be minute ventilation, minute volume, pulmonary ventilation. Pick your term, they all mean the same thing.

And it's just a frequency distribution, which is just a count of flow rates reported in the literature, flow rates estimated based on our relationship of minute volume to oxygen consumption. And if you look closely at the information, it's fitted with a gassing distribution to show where the average flow rate would be.

Looking at the data in terms of seeing the actual number, for the occupational activities of the energy expenditure literature that was reviewed, ventilation rates reported, ventilation rates estimated, mean minute volumes for the distribution was roughly 39 liters a minute out of 565 data points. Median, 95th percentile.

And highest peak, now this is a peak minute volume, an actual volume of air moved in a minute, was an estimated value of 162 liters per minute. That is for the occupational activity literature that was reviewed.

Estimates of peak flow, based on these values, from the relationships that are in the paper for the mean VE is minute volume, which is the 38.5, peak values range anywhere between 72 and 183 liters

per minute.

The reason for defining a range is because human beings do not all react the same to everything. So we thought it was better to define a range of these values where we felt comfortable that in all likelihood, if you really were to measure a peak flow rate under that particular minute volume, you'd be fairly hard-pressed to find too many values that fall outside of these ranges.

And probably -- of course we're more concerned about the highest values there, but we like to report the entire range.

Based on the 95th percentile minute volume, the range was 182 to 295. And if we took that peak 162 value, we could not try to estimate peak flow rates because it violated assumptions that were made in the paper for estimating our peak flows.

I would not venture a guess of what the peak flow rate would be for 162-liter-per-minute minute volume, but if it was a pure sine curve, you could multiply by pi and get a rough estimate of that information. But humans do not breathe in a

pure sine wave pattern.

Based on some of the human performance literature, really where we went to look for maximum values, what are some of the highest values reported for some of these ventilation rates, a couple papers gave us good indications where they actually looked at norms, quote-unquote, norms for different age ranges based on gender.

And the 114 plus or minus 23 liters per minute was a value where it was reported in two separate papers which were pretty close to one another. So there was some validation in terms of saying probably for normal individuals, nonathletes, whatever the differences may be in others, and norms were defined in the paper and in our literature review, would be roughly 114, 120 liters per minute if you wanted to round it off to more -- a better number to deal with.

For females, slightly lower. It's known that basically because of body size, females do not generate as high minute ventilation values on average. Does not mean that some females cannot generate greater ventilations than males.

And extremes in the literature reported anywhere in the range of 180 to 200 liters per minute. These are extremes. They may be single values. Most of that data was related to well-trained, highly competitive athletes.

If we looked at the human performance literature again looking for peak values for peak flow rates, literature suggests the maximums of approximately 300 liters per minute.

Data that we have in-house where we've tested some of this information, we have one peak value of 485 liters per minute, one-time value, one-time measurement, during hard work.

Speech values that we looked at in terms of the data in the literature, yes, you can get, generate high peak flows rates during speech under rest conditions. But in the data that we looked at, we did not see peak flow rates during speech that were substantially different than what were found under hard work or exercise conditions.

So some of the conclusions or some of the recommendations, or whatever the best term is here in the review that we conducted, is that we

didn't find -- we found that occupational minute volumes rarely approached minute volumes for maximum values reported for, you know, strenuous, to-exhaustion-type activities.

We felt that the review of the occupational data for ventilation, both again reported and estimated, that the 73-liter-per-minute was a sufficient representation of the upper limit of minute volumes anticipated in the workplace. And 114 was a reasonable estimate for maximum minute volumes.

For peak inspiratory flows, again, we found that our high-end predictions based on minute volume corresponded very well with values reported in the literature. And plugging in the 114 into our estimates of peak flows suggests that an upper limit of 430 liters per minute would be pretty good value for focusing in on peak flow rates occurring in workplace conditions.

It's important again to understand that higher minute volumes and peak flows will occur. You will find them on occasion. They can happen. But based on the literature, the indications are

that these are not the norm.

For respirator wear information in general, minute volumes and peak flows were lower during intense work, not so much under low work rate conditions.

For APR and SCBA types, and referring back to the gentleman from Avon, probably the SCBAs, the changes really have a lot to do with the weight of the SCBA. And for supplied-air or PAPR systems, they seem to have less of an impact on minute volumes and peak flow rates for at least those conditions where they've been reported.

What the implications may be, and now I will not speak on behalf of NIOSH, but this is generally what we felt with the ventilation rates and review of the literature.

If you really wanted a better representation of occupational ventilation rates to account for more flow rates that may be occurring in the workplace, a minute volume value of 73 liters per minute covers that 95th percentile. If we wanted to try to adjust a greater range of human ventilation and account for peak flow rates, then

114 value is a good value to focus in on.

But there are many factors involved. You cannot just adopt these types of flow rates carte blanche without considering is it a cyclic flow rate type of test or a constant flow rate test to evaluate different things related to the filter performance.

And the second part of all this of course is, you know, what are the contaminant exposure levels. If you continue to use three times IDLH to test something, does it make sense to quadruple the flow rates for testing? Just general considerations that we felt needed to be emphasized.

The second part of the review, and I won't go into great details here, but we're in the process of collecting more data from other researchers to try again, relook at some of the ventilation data due to respirator conditions to help us identify data gaps for further research.

We've gotten data from three sources. We're anticipating from one other. So we're currently building that database. And we will

initiate a, it's not really a meta-analysis but a new analysis of all the data based on work rates. We'll try to base it on resistances, respirator types, whatever common parameters we can find between the different databases. Not an easy challenge.

Just some sample data. We do have some breath-by-breath data. We are doing some calculations from one of the data sources, required some programming to analyze. This is a waveform of somebody spontaneously breathing during a test. We've seen that before.

As far as recommendations for further work based on our literature review, as we do feel that we need to really establish the relationship between ventilation and oxygen usage based on a population of respirator users. A lot of the respiratory performance literature doesn't even use respirator users.

So a lot of times the subject population is not the norm that you're going to see in the workplace. Many times it's young, apparently healthy, active individuals because, let's face it,

they need money for college. That's why they participate.

But the issue about measuring workplace ventilation rates is not an easy issue to tackle because not too many industrial settings where somebody's required to wear a respirator for protection is somebody going to allow you to stick a flowmeter on that respirator by somebody maybe working with some hazardous substance for the potential of, well, is it going to interfere with the protection of that respirator?

There's some work there that we're trying to discuss with NIOSH, and we'll see what we can do with that. And recommendations based on the compiled data will be determined once we get that data set analyzed.

A brief overview of project milestones. The goal again here is to try to complete the analysis of the data from our data compilation effort in early summer and provide some final updates to the flow rate datas that I've already presented here to you.

With that, any questions?

MR. DUNCAN: Paul Duncan, Scott Health & Safety.

When you were evaluating the, some of the peak inhalation flows, did you find any data on how long those respiration rates can be sustained?

MR. CARETTI: We did not take an absolute look at, for instance, if somebody was breathing at a rate that produced peak flow rates of 430 liters per minute, how long could they exercise under those conditions.

Part of that information is available, but not in total, so we didn't feel comfortable with reporting that just yet. We're hoping from the data compilation to get a better feel for that.

But we are probably talking about short-duration activities with those high flow rates. Exact time frame, I don't know. Five, ten minutes of activity. It's very difficult to sustain those high work loads, especially for, for instance, somebody wearing a 17-, 18-kilogram SCBA.

MR. SAWICKI: Jack Sawicki, GlobalSecure.

Any of the data that's coming in, is any

of it going to be from the Marines?

MR. CARETTI: Let's say that that's the data set we're waiting on.

And that's in reference back to, I guess it was the fall of 2002 maybe, Dr. John Kaufman presented some ventilation rates for some heavy activities that were collected with Marine volunteers.

MR. BERNDTSSON: Goran Berndtsson from The SEA Group.

I just want to say you've done a good job here I think. I really appreciate seeing this data coming out and the way you put it together.

To answer some of the questions which Paul raised, I think it is that the duration time of people can work that hard is probably connected with motivation.

If you took the first responders in the World Trade Center, they were really motivated to find their mates. They were working over and beyond what we normally would be expecting at those kind of work rates.

If you take someone in the opposite

side, they'd probably find that ah, this is too hard. I don't want to work this hard, and give it up pretty soon.

MR. CARETTI: And there is quite a bit of good to come from that comment. Motivation is probably a factor with anybody wearing any respirator under any condition.

But the literature under these peak values, at least for the minute volume, the high minute volume rates, some of the simulated workplace factors or tests were done under escape scenarios; mine escape, escape from an oil-drilling platform off the coast.

And, you know, those conditions, they used workers that do that type of stuff. Even though they knew it was -- they were supposed to escape as fast as possible and as safe as possible, they still knew it was a research project.

MR. COBES: Hi. John Cobes, AJE Testing and Research.

Just had a quick question. Looks like all your average values you determined from a galcion (phonetic) distribution. Did you try to do

anything with say a log normal distribution since didn't really seem to fit a normal distribution to what the difference would be?

MR. CARETTI: The data that was presented in that graph was just a descriptive statistical look at the frequency distribution of the values. We did not do any analysis to see if what one flow rate, how it differed from another based on work intensities.

The review of the literature was more to see what's out there. Now, in the data compilation we will apply whatever statistics are appropriate to analyze that based on respirator types or work loads or resistance conditions, whatever parameters we determine.

And in that case, if the data is nonparametric, we will proceed with nonparametric analysis.

Okay. Thank you for your time.

MR. MONAHAN: Good morning. I'm Mike Monahan. I'm a member of the policy and standards development team. We're going to review a summary of work that was contracted by NIOSH to AJE Testing

and Research.

We're looking at a study to determine the effect of differing canister resistances on service life in PAPR applications. Our objective was to conduct a study to determine the effect of differing canister resistances on service life of a PAPR by artificially altering the pressure drop through a pair of simulated test canisters.

The pairs of test canisters were prepared with differing pressure drops by adding appropriate restrictor plates to the influent side of the canister according to the following table below. These were -- we chose to use 85 liters per minute as just a benchmark for a flow to target our pressure drop percentages.

We decided to use two challenge gases. One is physically absorbed cyclohexane and a chemi-absorbed sulfur dioxide. We used the APR, or what is proposed in the new PAPR concept papers, and at the flows of 115 liters a minute and 300 liters per minute.

The canisters we used were simulated canisters. They're five inches in diameter and with

the capability of adjusting the bed depth. Fill, the carbon we used was a 12-by-30 URC respirator carbon produced by Calgon Carbon.

And for the two different flow rates, we decided to use different fill volumes to get a better idea what the service lives would be. We used 300 cc's for the low and 600 for the high.

These canisters were filled using a sifter-flow method. And the effluent, we determined the effluent flow, airflow, and the break point for each of the individual canisters used each test.

System breakthrough times were determined by combining the data of each of the individual flows and breakthrough concentrations.

Here's a diagram of the canister that was used. Basically you have a, a, oh, a standard sort of canister configuration. You have a top plate, a fill pad, a carbon bed, another fill pad and a bottom screen.

Here we used a retainer ring which supported the flow restrictor material. And we varied this according to what the amount of resistance we needed by using a combination of

screens and filter pads.

The apparatus itself is a basic standard service-like-type apparatus. You have your conditioned airflow, challenge introduction into a mixing chamber, and then into a test cell where each canister was monitored for breakthrough.

At the beginning of each test, in the first minute in the test, mass flow controllers were inserted into the effluent stream and the flow rate was determined. And each of the -- then they were removed and the airstream was allowed to pass through the detectors.

This is the calc -- it is an extreme sample of the calculations. This was actually the 30 percent difference in flow or in resistance. These are the resistances, 13.1 for the low resistant cartridge. And the higher resistant cartridge was 17.2 millimeters of water.

The flows that were determined for the low flow or the -- yeah, the low flow, the low resistance cartridge, was 63.4 liters a minute. And the high resistance cartridge was 51.6 liters. And this just shows you the mass flow equation that we

used to determine the system breakthrough.

We took -- you take the concentration at any particular moment and multiply it by the flow plus the flow of the second cartridge and the concentration divided by the total flow.

This is sort of a graphic illustration of one single test. As you can see, when -- the cartridge with the lowest resistance is breaking much quicker than the cartridge with the high resistance. And because of -- and you can see the flow difference.

So at the system breakthrough of, I don't know, somewhere around 39 minutes roughly, where you would get cyclohexane at 10 ppm, the, actually the one cartridge is actually around 18 ppm, whereas the other cartridge isn't contributing any concentration at all or any contaminant to the total flow.

These are the compilation of data of two -- each point represents two sets of data, the average of two sets of data. As you can see, that the lower flow produced higher service lives than the low flow. They're very comparable as far as

their slopes go.

And for sulfur dioxide, we saw the same type of trends in which the lower resistance cartridges had higher service lives and the effect of -- go on to the conclusions here.

The difference in resistance occurred between cartridges will cause the following: It changes the flow patterns, airflow patterns between the cartridges. It leads to lower service lives. And the decreased service life is more pronounced with the higher flows.

There was no significant differences in service life reduction due to the contaminants chosen, the sulfur dioxide or the cyclohexane.

However, one issue that needs to be considered is that there's another class of reactions which we didn't really consider in the first study was that the ones that aren't chemical or physically adsorbed that are more or less catalytic, have a catalytic effect, such as with the test representative compounds that we use of phospsine or cyanogen chloride.

And we're going to look further at this

and study this a little bit further before we introduce the standard.

There was an additional issue that come up right at the pressure drop that we saw and I think I'm going to bring up. We were doing some preliminary benchmark testing and we started looking at the actual manifold on a multicartridge PAPR. And what we started to see was the same type of information that we were getting with the cartridges.

The flows through each of the ports of the manifold were different. This would probably end up, what we think will show the same type of effects that we saw with the cartridges. In other words, you're going to get exaggerated flow through one port than you would the other ports.

For additional studies, we're looking to look at the catalytic effect of adsorbed chemicals, phospsine and cyanogen chloride. We're also going to look at bed depth. And we feel that we can probably accomplish this work within the next three months.

And if anybody would want to suggest any

additional studies that they feel might be necessary, we'd appreciate your input.

Implications for the standard. I've been working with the iso group for test methods. And one of the things they're looking at is with PAPRs, or multi-cartridge respirators, is testing single cartridges rather than one or the whole unit.

And if we were to address something like this in our standard, which is maybe a good idea, we'd have to address the canister uniformity in some of our quality control documents that would have to be supplied from the manufacturer. You would have to have, allow this canister uniformity, you'd have to base it on some sort of an average value supplied by the manufacturer.

And this would reduce testing costs. The testing costs at these extreme flow rates are going to be maybe three to five times what you would see in a regular PAPR-type of test.

Also, because of the manifold effects, we're suggesting that we may have to look at a systems-type test that would allow for the different

types of designs that would be brought forward.

That's it. Any questions?

MR. LINKO: Bill Linko from Micronel U.S.

We've been running some tests on filters for orthopedic surgeons and we're finding out -- the goal was to achieve 99.97 percent efficiency down at the .3 micron at 15 cfm.

When we measured the velocity per unit area, we found great variations in velocity of certain material. And we assume, although it's not proven, that's going to affect the efficiency at some point in time.

My question here is in testing these filters, have you did any work in measuring unit velocities? You've run at 15 cf -- I'm sorry, 15 square inches of area. Did you test velocity per square inch?

MR. MONAHAN: No, we didn't.

MR. LINKO: Okay.

MR. SAVARIN: Mike Savarin, ICS Labs. Just a couple of things that I wanted to ask.

When you were making the assemblies, was

there any investigation into the packing density, or were they all kept at the same packing density and then you used the retainer rings to control the actual resistance of the unit?

MR. MONAHAN: When you use a sifter-film method, you get a dense-packed bed. And I think Jon can probably help me out on this a little bit on this.

MR. SAVARIN: Are you talking about the thing that looks like the snowstorm filler?

MR. MONAHAN: Yes.

MR. SAVARIN: Yeah, I'm familiar with that, but you can still get -- there's still room for packing the bed after you've finished.

MR. MONAHAN: If you -- the beds were compacted enough to create a solid bed. We tried not to distort the carbon by --

MR. SAVARIN: Yeah, I can understand that.

MR. MONAHAN: Yeah.

MR. SAVARIN: I would imagine that still needed some more investigation myself.

The canisters were fill volumes in

excess of 300 cc, right?

MR. MONAHAN: We used 300 and 600.

MR. SAVARIN: And 600, right?

MR. MONAHAN: Right.

MR. SAVARIN: I don't know if the intention is to, because I can't remember, is to have the C burns (phonetic) that are at that volume of 300 minimum. But if there was something less and then occupy more the cartridge type of definition in around the 250 or less cc, would you expect there to be any difference in some of the results that you saw?

MR. MONAHAN: We're suggesting to do a bed-depth study. This was strictly for base knowledge we were trying to do this. Everybody always talks, you know, depending on, in the industry about the effect of pressure drop on the cartridges. And it's not documented too well and we were just trying to get some data out there that shows what these effects are.

MR. SAVARIN: Yeah, that's the other thing that I think having controlled packing density would have also. That's the other side benefit is

that you should be able to reduce the distribution of variations in pressure drop.

But I have one other thing I want to just, not necessarily suggest but mention. Someone said they would like some suggestions on what we might be able to do.

One of the things that may be worth investigating is the effect of pulsed or sinusoidal flow rates on the cartridges, particularly in respect to the higher flows that we're talking about and will be talking about as this progresses throughout the day.

The higher flows are going to have some significant effects possibly, if you like, on service life. But a more realistic approach to testing the cartridges will be a different flow path I believe.

Thank you.

MR. PARKER: Jay Parker with the Bullard Company.

Mike, I recall at one of the previous meetings that NIOSH had proposed a maximum range of cartridge resistance of I think it was 5 millimeters

at 85 liters a minute. Or maybe that was just a concept.

MR. MONAHAN: That was, I believe that was the negative pressure.

MR. SZALAJDA: It was, yeah, we had -- in one of the earlier versions of the concept paper we had a canister uniformity requirement or potential requirement that was identified. And at least at this point, until we do additional research, we backed off on identifying a specific requirement.

MR. PARKER: Okay. Right. I was just -- that's exactly what I was wondering. So you're going to wait till you finish the research and then come out with a number?

MR. SZALAJDA: Right.

MR. PARKER: Thank you.

MR. SZALAJDA: Okay. At this point I think we're just a couple minutes behind schedule. Why don't we take a ten-minute break and reconvene.

(Recess taken.)

MR. SZALAJDA: What we want to do is to cover a couple additional topics before the lunch

hour. In particular we're going to address conceptual requirements for the canister, particulate testing and then battery requirements.

With that, Terry Thornton's going to lead the discussion on the canister.

MR. THORNTON: Didn't take long for them to get me back up here again. If everybody's ready, I'll go ahead and get started.

The canister requirements that we're going to go through, there's quite a bit of information in here, quite a bit of information that I'll be going through, so bear with me. We'll try to make this before lunch. We have an hour.

Canister requirements are really going to be based, for the PAPR are going to be based back on the work that we did for air-purifying respirators. We all remember the standard we came out with in March 2003.

The hazard list that we were actually working from was derived from earlier than that, from the CBR standards development work. So there was a pretty good history there of these canister requirements. This APR standard is available on the

NPPTL website, so it's pretty easy to find.

And on that website also there's preamble for the APR standard that gets into a lot of detail on the hazard analysis. So I'm not going to cover the hazard analysis real detailed as we have before. If you need any more detailed information about it, you can get with me during lunch or during a break and I can go through it.

Test representative agents that have been identified still as they were in the APR are for these families. There's ten chemicals and DOP. Seven are respiratory hazard families and six of them are chemical families. That's going to become a little more important when we talk about our protection stacking.

As you look at this, the one that really stands out is the acid gas family. And you can see in acid gas, there's five test representative agents that make up the acid gas family.

These are the requirements and these are, again, directly from the APR. This is the actual test representative agent with the challenge concentration that's used for that agent and the

breakthrough concentration that we look for.

Two items stand out there for the breakthrough concentration, nitrogen dioxide. We're actually looking for two chemicals, either 1 ppm NO2 as a breakthrough or 25 ppm NL. We monitor for both of those, the breakthrough.

Hydrogen cyanide, even though it's not marked up there, is a 4.7 ppm. We're actually looking for hydrogen cyanide or a combination of that and cyanogen to generate 4.7 ppm.

Test times, that's always been a big, hot topic. How long are we testing these for? Using those concentrations, NIOSH is going to kind of identify a new terminology that will be used here. And this terminology even goes back to the APR. It wasn't discussed in the APR standard, but this is how the APR canisters are being marked now.

One of our concerns was having a time limit on there of 15 minutes on the canister. What NIOSH has done is we've looked at marking it as a capacity. And as you see, we have capacities 1 through 6. 1 through 4 are 15-minute intervals. 5 and 6 are based on 30-minute intervals.

So the filter capacity for capacity 1 is the test concentration of that specific chemical times 15 minutes. Same as for a capacity 2 would be the test concentration times 30 minutes. The new APR standards that are out there approvals that it went out are marked with capacities and not just minutes.

Again, we're going to look at some PAPR types here. The constant flow pressure demand, as we've seen, we're going to look at moderate and high breathing rate performance of both of those. The canister requirements are going to be a little bit different. Right now in the concept, the requirements are different between constant flow and pressure demand.

I'm going to go through the constant-flow PAPR concept first. Again, for the canister requirements, constant flow, the manufacturer is going to apply for either moderate breathing rate performance, high breathing rate performance. Went through both of those earlier.

And you'll apply for a capacity. You're going to tell us what the capacity is that you want,

1 through 6.

The airflow for service life. This is where a lot of work is still being done to determine what the airflow is going to be tested at, what the canister will be tested at. As you can see, the service-life testing will be performed at the airflow of the blower.

In other words, we're going to measure how much air the blower is putting out. And then we're going to use the higher rate for the minimum. And you can see for moderate breathing rate, that minimum's a hundred liters a minute. For a high breathing rate performance, it's 261 liters a minute. That would be the minimum.

So if the blower comes in for high breathing rate performance, it's blowing at 300 liters a minute. If it comes in at 250, we would test the canister at 261 liters a minute. That would be the minimum.

We are still looking at how we're going to evaluate that airflow from that PAPR, whether we'll be measuring it directly, whether we're going to put it on a breathing machine, or how we're going

to measure that.

The requirements are going to follow again along with the APR standard in what we've done the previous work. So that there will be three tests at the low humidity capacity requested, three at the high humidity, and three for the crisis provision capacity. As you see, there's really nothing listed there for crisis provision. We're going to hit that a little bit later. Those were always run at 25 degrees C.

For multiple PAPR configurations, in other words, where there's a manifold that has two or three or more elements on there, we'll take that airflow, divide it by the number of canisters, and use that airflow to test the canister itself.

So if it's a 300-liter-a-minute PAPR, it has three canisters, each canister can be tested at 100 liters a minute individually. Of course if it's a single-element canister, we would test that canister at whatever the airflow is.

For demand responses, it's going to go about the same way at the beginning. You'll apply for a moderate or a high breathing rate. And again,

you'll specify the capacity 1 through 6.

What are the flow rates for the demand responsive? Before we get too many moans and groans on here, we are still looking at these flow rates so they are not set in stone. They're still a concept that is evolving.

But for right now, the moderate breathing rate performance, the canisters would be tested at 115 liters a minute. That would be the flow that the canisters are tested at. And I'll remind you, as we have a canister or a system that comes in with two or more canisters, we would take that 115, divide it by the number of canisters, and test the actual canister at that flow.

For a high breathing rate performance, that value goes up to 300 liters a minute. But we're still looking at both of those values and we're looking for any information you can give us to help us evaluate on how we're going to perform that test.

The test, the canister itself will be tested again as with constant flow as the APR, three tests at high humidity, three at low humidity, 25

degrees C. We're also going to perform three tests at crisis provision capacity.

Again, we say the same thing for a single element or for a multiple canister. We'll change those values proportionally. And remember, the minimum will always be there for both the high and the moderate breathing rate.

I've mentioned a couple times crisis provision. And before I go to this next slide, remember we're still looking on, we're still evaluating this airflow that we're going to use for crisis provision. But for right now our concept, we look at the crisis provision as whether it's a constant flow or demand responsive unit.

We're going to test the crisis provision all the same. Three tests, 430 liters a minute. We're going to go ahead and put the humidity back to 50 percent. That kind of falls along with what we had done for crisis provision before. It's right in the middle. 25 degrees C. We're going to stick with that time of five minutes.

So it's the same challenge concentration for each chemical, but the service -- I don't know

if service life's the best words to use there, but the time for that test is still five minutes. Again we're evaluating that 430 liters a minute.

We've seen some studies that come up that talk about some airflows. And we're continuing a study that Mike Monahan talked about that may help us narrow down that number. But as we say, we're always looking for other comment on what would be an appropriate airflow to test crisis provision.

We see in the concept paper for 1 April, we have a provision in there for stacking, stacking of protection. All right. There's the base CBRN testing that will be done. But we feel like the manufacturers may want to come in and have some additional protection added to the canister beyond -- still staying within the realm of CBRN, but instead of just one capacity across the board, you would want to raise a specific chemical or group of families up to a higher level capacity.

You remember, as I pointed out when we looked at the TRAs, acid gas has five chemicals. So if you want to increase any of the families, you would have to pass the test at that higher capacity

at each of those test representative agents. For acid gas there's five.

A quick example of that would be for protection of CBRN capacity 1 with an increase of acid gas capacity up to 2 and maybe an OV capacity up to 3. Now, this is just an example we kind of -- we kind of pulled out of the air. The testing would be performed, for CBRN capacity 1, we'd test NO2, formaldehyde, phosphine and ammonia at 15 minutes.

The acid gases would be tested at the 30-minute value, 30 minutes. And then for the OV, since it's a capacity 3, capacity 3 is equal to 45 minutes.

That's kind of everything that's covered in the concept paper as it's written right now, 1 April. But of course as we're still evolving with everything, we're trying to look at what else we may need to make the standard complete.

And as Mike had talked about, canister uniformity is one of the things that's being considered. Back at the last concept, or last public meeting, we put this out and I think somebody had mentioned a measurement of 5 millimeters. And I

believe that's what we had put out earlier.

So what we'll do for canister uniformity, we see that -- we really feel like the canisters need to be uniform across the board, and at a prescribed flow rate. So probably that will be about 85 liters a minute. But we're not specifying the flow rate yet.

What we'll do is we'll take all the canisters that come in for service-life testing. And that's approximately 125 to 150 of them. We'll do the initial resistance tests on all those. And we just collect that data as we're doing the testing. And then we'll average that, get a baseline for that manufacturer of that particular canister.

And then the requirement will be, as you see, the variance between the population must be at a defined range. And we're saying defined range right now because we're not sure how we're going to specify that measurement, whether it be plus or minus 2 millimeters of mercury or 2 millimeters of water pressure, or maybe just a percentage of that resistance.

So we're looking for information on how we can set that. Now, that defined range will not only be the population that we've generated, the 150 that we've tested, but that range will have to be continued throughout the manufacturing process and will have to stay that way.

So quality assurance will have to be able to be involved to ensure that throughout manufacturing process of producing hundreds or thousands of these, that that range within that defined range is held.

Some more additional things we're looking at. Our tests to determine that the airflow from the individual canister connection on the manifold, and Mike had alluded to this, that we've looked at manifolds that may have two or three canisters. The air coming into those may not be equal, even though it looks like it's an equal distribution there.

We're concerned about that. And we need to devise some type of test to determine if that's an appropriate flow for each canister connection. And we could do that with an engineering evaluation

that would look at that manifold airflow.

We may not have to actually physically measure that. But we're going to need to take that into account when we talk about service-life testing, especially the time of service-life testing.

So these are our ongoing concerns on how we're going to do the testing. And Mike Monahan had pointed this out, that we're looking -- there's a difference between testing as a systems and testing as individual canisters. All right. And our concerns there are the uniformity of the canister, the uniformity of the manifold, and, hard to believe, but we also look at, we're very conscious on the time and the cost for the service-life testing.

So we really have three concepts or three ideas that we're looking at right now on how we're going to perform the service-life testing on the individual canisters or the system.

And you can see these are pretty simple. We're going to do either individual canisters where all we test is the canister itself,

we'll do a systems testing, which would be all the chemicals, would be complete systems testing, the manifold with the canister as a whole or a combination of it.

For individual canister testing if we'd go that route and look at specifically individual canister testing, these are some ideas that we would have on how to do that. Of course we'd stick with the concept of three canisters at high humidity, three canisters at low humidity, three canisters at crisis provision.

But you see we would have to maybe take into account the airflow differences through the canister and through the manifold. So we would have proportional airflow to the blower plus an increase in either the flow or time to build in a safety factor.

We would also have to do some type of evaluation for that equal flow characteristics on the manifold, whether that be engineering, design look at it, or actually do some measurement testing. We would need that to help define the percentage of increase of flow or time.

For systems testing, we can see this is kind of what we do now. If a manifold comes in with two canisters or three canisters, we put it in as a complete unit, put it into the box, everything would be exposed to the concentration at the same time, to that challenge concentration. And we would just use the airflow of the blower. Again, we would do the three systems, high humidity, low humidity and the crisis provision.

It's pretty easy to figure out what comes next, the combination of doing this for both individual canister and the system combination testing. All right. So we would do individual canisters at that high humidity, low humidity, and the airflows of the blower are proportional to the blower, and the three canisters at the crisis provision. Right now that crisis provision stays the same constant flow, 430 liters a minute.

But beyond this testing of the individual canisters, we recognize that we would need to look at the system as a whole and test it all at one time. So for this we would need to do some type of complete manifold with the canisters or

the cartridges in place. And here's where we're really looking for some opinion, some help.

How many times would we do that? Would we do it for the worst-case chemical, which either we could define as a worst-case chemical or we could look at preexisting data that comes in for the manufacturer to define which of the ten chemicals would be the worst case, or possibly it could be just a short list of the chemicals. OV, one of the catalytic reaction chemicals.

So that's one of the places we're really looking at studying this. And we would welcome any input to determine what type of chemicals and how we would do that.

Some pros and cons. This is pretty easy to look at. Cost for individual canister testing, the cost, there's fewer dollars in chemical cost, fewer canisters used for testing. Fewer canisters used for testing also goes with the durability. There would be less that would have to go through the durability.

But does not account for the flow variations of manifold and canister resistance, the

flows that we are talking about through there. And it sort of deviates from the traditional requirements described in 42 CFR.

The other way to look at it, the systems testing, as Mike referred to, preliminary cost estimates would raise that cost if we're going to test all ten chemicals, three systems for each high and low humidity, maybe three to five times the cost as of now of testing the canisters individually.

So much higher cost in chemical. More canisters would be required. If the PAPR comes in with three canisters on a manifold, and you tested the system on all ten, high and low, that's a lot of canisters. There may be additional costs of test manifolds would come in with that.

But it would take into account all the variations of the flow through the canister and through the manifold that would be built into the system. And it's also traditional with what 42 CFR calls out now.

Combination testing is going to give us the best, probably the best of both worlds, lower costs, fewer canisters, which relates to lower

costs, fewer test manifolds.

Probably the combination is the best way to go as far as time in the laboratory. As we know, that laboratory testing takes quite a bit of time. And that will account for all the flow variations in the manifold and the canister resistance.

And that would be all for canister requirements. So if we have any questions, I'll be happy to attempt to field. There may be one or two from this.

MR. BERNDTSSON: Goran Berndtsson from The SEA Group. Couple of questions here.

One of the things you said we shouldn't mention here because you are still considering it, but I think you really need to think a little bit about the breath response for the positive pressure demand system and compare it, because the way it is drafted now it is not very good at all.

I would like to have an explanation why you have -- you had in the February draft, you were looking on seeing the max capacity of the PAPR, evaluate that and then testing the filter quality. What's the reason for dropping that?

MR. THORNTON: I think you're referring to, for the pressure demand, we were going to attempt to find the maximum airflow that that unit was capable of delivering.

MR. BERNDTSSON: I didn't read that to be only the positive pressure demand. I thought it was all the PAPR was going to be looked at.

MR. THORNTON: And I think some of the real questions came at the pressure-demand units. If you attempt to push these to the upper limit, it could be built beyond what humans will respond to, what they will ever breathe. So testing them at that maximum unit just didn't seem logical on how to do that.

Constant flow is a little bit different because constant flow is constantly coming through there and we know how much is coming through the canister. And everything that comes through the canister needs to be appropriate, needs to be purified or cleaned or filtered, however you want to look at it.

So I think we have kind of shifted to performance and looking at the unit itself and

evaluating it based on that breathing performance.

We would connect it to a breathing machine that's at the appropriate speed and look at the total volume over a certain amount of time that comes through the canister. And that seems to be the best approach on how to determine the capacity that's needed for that unit and those canisters that are connected with it.

MR. BERNDTSSON: But maybe I'm missing something, but that's not how the standard, how the draft is written now, because you have limited that to be tested at 115, or 300, 261 liter, I think you said, divided by the filters.

So for example, if I make a constant flow PAPR where flow's 400 liters, estimate that higher, then of course if you're testing at 260 liters, there's not going to be any relevance to how long the filters last in real life out there.

MR. THORNTON: No, the 261 would be a minimum. If that unit comes in and blows 400 liters a minute, we would use that 400 liter a minute to develop the -- or to determine the capacity.

MR. BERNDTSSON: Then I misunderstood

how it was reported.

MR. THORNTON: Yeah, those are minimums for moderate breathing rate and high breathing performance. Those are minimums. The 100 and 261 liters per minute are minimum values. If the unit is beyond that, we would evaluate it at the flow that that unit produces.

MR. BERNDTSSON: Are we -- you also had in the early draft that it had to be tight, snug-fitting respirator. That was dropped out.

MR. THORNTON: I think it has -- I think we're allowing both loose-fitting and tight-fitting in this concept now.

MR. BERNDTSSON: But can you explain the logic in panic mode for a non-tight-fitting respirator?

MR. THORNTON: Well, I think the crisis provision always needs to be evaluated. No matter what the person is wearing, he could get into a crisis provision -- or a crisis area and he needs to leave the area.

MR. BERNDTSSON: But what I'm saying is that if you don't have a tight-fitting respirator

and it only supplies 320 liters, and if you require more, it's not going to be drawn through the filter, it's going to come from somewhere else. So it kind ever doesn't make sense.

MR. THORNTON: Well, you're correct, it's a positive-pressure unit. And so there should be enough pressure inside there to take care of the overbreathing.

But it is something that we need to study and develop a little better understanding of how we're going to draw the standard for that.

MR. BERNDTSSON: I'm going to sit down.

(Unidentified man walked from floor to dais microphone.)

UNIDENTIFIED: Just a minute. Goran. Two comments.

First of all, on the tight-fitting and the specification for tight-fitting, you're absolutely right, with the panic demand, you're breathing flow is pretty high, 430 liters per minute. So the ability to meet that with perhaps a loose-fitting design is questionable.

So by means of having a panic demand at

a high-flow rate, we're really using a performance requirement to establish the overall performance. It's tough to see perhaps how a loose-fitting design could comply with that. So it's performance-based.

Second thing, on the max flow. In the February issue, yeah, we did specify that we would test the max flow of the system, of the blower system. What actually happens there is you get into issues of fan laws and how do you determine the maximum peak flow capacity of a blower system.

And rather than get into that technology, we decided to step back from it and look at the flow delivered by the unit when it's operating at a specified breathing rate. So we're kind of balancing, I think, technological requirements there. But your points are well taken.

(?) MR. NAYLOR: I have a couple of points.

Probably the simplest one first. The range of resistances of canisters, if we have multiple canisters on a unit. I'm a little bit concerned about if that is an absolute value.

Logically, I would have thought it ought to be a percentage. Clearly the effect of having a 5 millimeter variation on a canister is only 2, 20 millimeters is much greater than if it's 80 millimeters.

And the other point I'd make is that that kind of requirement does already exist in the European standard and has for many years. So the levels that it talked about there are reasonably well established in industry and complied with. That was the first point.

The second point, which I've not heard raised, I haven't been to many of these meetings, but one concern I have is for the user and how they understand or more likely fail to understand the use time of these respirators. And by that I mean the multiples of 15 minutes.

Is the user to assume that at 15 minutes the canister has to be replaced every 15 minutes in a CBRN scenario? And if that is the case, is that realistic for a PAPR? That would probably prevent using the PAPRs if they have to change the canisters that frequently.

And then secondly, that leads on to my comment that if we're having this stacking with multiple use times for different chemical groups, that's really going to be too much for the user to understand I think. And I've talked to a number of users and this 15-minute principle has not got over to the user community, and clearly it's going to give them a serious problem.

MR. SZALAJDA: Hold on. I'm going to get lost in all these questions.

MR. NAYLOR: Go ahead. My next comment is unrelated.

MR. THORNTON: Go ahead, can you do the first one?

MR. SZALAJDA: What was the first one?

MR. THORNTON: Hell, that's why I'm asking you to do it.

MR. SZALAJDA: We'll take the second one first regarding the capacity. And one of the reasons why we went to clarify or save on the canisters, identifying a capacity, was try to get away from the issue that, well, this is marked 15. It's only good for 15 minutes. That's not the

intent.

And you have to keep in mind with where these systems are going to be used that you have active monitoring, or you should have active monitoring going on, where you have identified and quantified and controlled the exposures and you know what the concentration is in the environment of a potential contaminant.

By identifying, we feel by identifying the capacity of the system, that we're giving a tool for the hygienist on site to develop a change-out schedule appropriate for the concentration of the environment that the responder may be dealing with.

And we're in the process right now within our group of developing guidelines to make available to the community that hopefully clear up any misconceptions or confusion about capacity related to what the change-out sched -- they're developing change-out schedules for the canisters.

One of the things that leads -- the other issue about the stacking, and one of the things that we've seen with the testing that's been done over the past several years is that, depending

on the type of canister that a manufacturer may use or the types of carbon or how the canister is constructed, you may see significant differences in how long a canister may perform for, pick on acid gas for example, that it may meet the minimum requirements for organic vapor, but we could test for 120, 150 minutes on acid-gas capabilities and the canister will still continue to provide the required protection.

And we felt in instances like this where the technology of the canister may have been established to provide additional protections, that it would be a penalty to both the user community as well as the manufacturer not to be able to market their product and let the market drive the need or the capabilities for the stacking provision.

We completely agree with you on the concept about the confusion level. And I mean to be honest with you, I think that's something that, longer term, we need to do in terms of, and will continue to work on here over the next several months with regard to the labeling that goes along with these items.

I mean any time you pick up any canister, it's an alphabet soup with regard to the labeling and, you know, what the different letters, the letters mean. And part of our intent as we move forward is to try to clarify what the, on the labels what particular protections are provided for each type of canister.

I'll see if I can get back to try to remember what your first, the first question was.

MR. NAYLOR: Sorry, resistance.

MR. SZALAJDA: Oh, (inaudible) on the resistance, yes. Actually, that's a very good point as well in looking at the resistance, that as we move forward and continue to do research throughout the summer, that will give us a better indication of whether or not that we can use a percentage in terms of identifying that and also looking at the other standards that are in place that may uniform -- that may use a uniformity criteria.

MR. NAYLOR: Okay. Just come back on that, on the first point, before I move to my third point, accepting what you say about the use times, could we assume that you're going to be looking at

those issues with regard to the APR standard and also the escape hood standard as well?

It would seem logical if that was applied across the board, and in terms of the education process that we're going to have to go through with users, that there's a common theme in terms of the use time of the devices and, you know, this cost level seems logical. I question whether we really need six, but that's something that we need to know that we're going to have to get that across to users.

MR. SZALAJDA: That's a very good point. As we like to say, the process is very dynamic. And obviously, as we learn more, if there's impact on other standards we would certainly consider that.

I think one thing, though, just before we move along, on the escape respirator, one of the considerations on using the 15 is that we were looking-- or the, how the labeling is conducted on escape respirators is that we were trying to take into account for the type of population that would be using the systems, that when you're talking about

the gas mask or the PAPR, you're talking about users that have familiarity with the respirators and follow the proper procedures and meet the OSHA respiratory protection guidelines and have a different knowledge base than the individuals that may be using the escape respirators.

So at least with regard to the labeling for escape products, we weren't too concerned about 15 or 30 with regard to what the potential wearer may be, with the emphasis on being if you need to put one of these devices on, you need to egress as quickly as possible.

MR. NAYLOR: Just my final point.

I think the most fundamental issue about the standard, and the one that's very, very finely balanced and needs to be correct for the whole community to go forward is this balance of the flow rate testing of canisters.

And I think that's going to need some work. I think everybody's aware if we go one way, we're going to wind up potentially with products that are very, very heavy and don't provide the benefits that we expect. If we go the other way, we

wind up with products that (inaudible) insufficiently tested.

And two things I would just comment. One is that there doesn't seem to be a provision for the breath-responsive unit that is nonetheless not positive pressure. And these kind of systems have existed for some time. And the fundamental benefits of those systems is that the air is provided at varying rates according to the demand of the user.

And the canister is smaller because the total flow through that canister is generally lower. So I would not like to see that benefit lost.

The second point I'd make is on this crisis provision, the 430 liters a minute. We've seen where that number comes from. And I think everybody accepts that number. But I'm curious as to why -- clearly this is a one-off kind of flow rate. It's not something that the canister will experience maybe more than once during its use and certainly no more than once each breathing cycle.

So it seems to me that to test the canister at that constant flow rate is overburdening

the canister requirement very considerably and we really need to look at something that mimics the breathing rate performance at that panic situation, which is after all a breathing pattern, not a constant flow.

The other thing that we really need to think about is are we going to test canisters at constant flow or sinusoidal or some other flow rate? And there's a lot of evidence now that sinusoidal flow rates make a huge difference in the result you get from canister performance.

MR. SZALAJDA: Thank you.

MR. LINKO: Bill Linko from Micronel U.S. Quick question on the mechanical side of a C2.

I'm assuming we're talking about a C2 type of filter with a treaded input; is that correct? When you say a canister, you know, mechanically, does it have a treaded input essentially with an aperture at 1 square inch outlet?

MR. SZALAJDA: We don't have any connector requirements.

MR. LINKO: Well, the current ones that are being used aerodynamically bother me because we look at the pressure drops. If we look at the pressure drops (inaudible) for orthopedic surgeons we use three double-A's to give them protection. At .97 -- 97 percent at .3 microns at 24 hours of operation. That's only particular. (inaudible) but we don't, not constrained by the 1-inch apertures. For 32 per minute is not a problem. If you're talking about 300, now you're starting to talk about big pressure drops. So if there's flexibility, you can do a lot of things.

MR. SZALAJDA: Right. Thank you. That's a good comment.

One of the things that we've at least initially heard from the user community is that interoperability of canisters for the PAPR application isn't really a requirement much -- which is different than what we did on the gas mask.

MR. DUNCAN: Paul Duncan, Scott Health & Safety.

Mentioned at the last public meeting. I think it's this one thing I'd like to repeat. If

NIOSH is intending to pursue the uniformity requirement between filters, I'd encourage you to consider provisions for allowing the manufacturers to group filters as operating units where their quality system controls the range of pressure drops within an operating group.

You know, for instance, if you have a two-filter system, to package your filter in pairs where you're controlling the quality between those pairs and the user instructions indicates they're going to be used in those operational units. That's just one comment.

The other comment, just real quick, something that Jim was saying, caution NIOSH in establishing the sort of best in class in using some of the EN standards, EN benchmarks, to make sure that they're considering EN test methods. Because there are some instances where the benchmark gets pulled from the EN standard, then the NIOSH test method gets applied to it. And you end up with a totally different requirement. It's actually even a little bit more tighter.

MR. SZALAJDA: Good comments. Thank

you, Paul.

MR. SIMON SMITH: Simon Smith, 3M Canada. Just a question sort of linked into operability.

You have high flow and moderate flow systems. And are you making any provision to prevent mix-up of the canisters that are intended for moderate flow to be used on high flow systems?

MR. THORNTON: Well, that's a comment that we've heard before. And yes, we are trying to take that in consideration and determine a way to prevent or help prevent that mix-up.

MR. SIMON SMITH: Thanks.

MR. SZALAJDA: I thought you guys were going to get an early lunch break there for a second.

MR. THORNTON: Here's the bad news. Since you've heard my voice before, I won't even introduce myself. I'm going to jump right into it. They put me up here kind of a back-to-back. I guess that's to get me off the stage so they can continue.

This, the subject I'm going to cover now

is particulate testing. And as you can imagine, service-life testing and particulate testing kind of goes hand in hand because it gets back to the airflow studies and how we're going to set those airflows, what we're going to look at. Not only how are we going to set those airflows but how are we going to measure those airflows with the PAPR units.

So for particulate testing -- I'll try to run through this so that Ted can get up here and finish you off for lunch. Particulate testing, very similar again to the APR and the APER for particulate testing. It's a P-100 filter.

And the first comment I always hear is, well, PAPRs have high efficiencies. Well, for CBRN standard, we're going to test those as a P-100 filter. It will meet 99.97 particulate filter efficiency against DOP. So that will be the test agent.

The testing, as with previous, will be done after the durability conditioning. We'll stick with the number that we've done for APRs and APERs, which is 20 canisters tested against the DOP.

The additional nine canisters from the cyclohexane test, service-life tests, after cyclohexane service-life tests, those canisters that have been exposed to cyclohexane go back for DOP testing. There's nine of those. That's the three high humidity, three low humidity and the three from crisis provision.

The flow rates, constant-flow PAPR tested at the airflow of the PAPR, in other words we'll measure it to determine what it flows at, use that number to test it. For multiples canisters we'll do the same thing, and take the proportion.

Demand-responsive, again we're looking at those same values of 115 liters a minute for moderate breathing rate, 300 for high breathing rate. Same concept though. Multiple configuration, we cut those proportionally.

And we do, as -- we've stated this, it's kind of repetition here, but we're going to develop, try to develop ways of measuring the actual volume of air through the canister over that specific period of time. And that's probably done in relationship to the breathing performance, the

breathing machine it's going to be used on.

We're aware that we need to perform particulate tests, the same airflow as the PAPR units supply. Right now all testing for DOP is done at 85 liters a minute. But we're trying to look at ways to develop tests to test it at the actual airflow. So we're going to look at the amount of air that comes through that canister.

Two separate concepts again that we're going to look at. And we're looking at these both at the same time, kind of evaluating both parallel to see which is the better concept to use.

The first one sounds very easy. We'll just have new equipment developed to perform DOP testing. So we'll take the ones that we use right now that are zero to a hundred liters a minute and we'll just buy some new things to go from zero to a hundred liters a minute.

The other concept that we can use is to stick with the equipment that we currently have now, which is the 8130 for DOP testing, and it uses it at -- right now it can do approximately 110 liters a minute and generate roughly 100 milligrams per cubic

meter for DOP. Kind of go through both of these concepts. You can see the differences and see what questions we have and what our concerns are.

The first one, the high flow tester equipment, again, we would use just the same airflow of what the PAPR unit actually uses, use that in proportion for the canister. So we'd be testing the canister individually.

An example of this, measured it -- or a PAPR with 240 liters a minute, three canisters, single canister would be tested at 80 liters a minute and the loading proportionally reduced to 67 liters a minute. And that's currently what we do now.

The other example is if a unit comes in with a single canister, 240 liters a minute, we would test the whole unit at 240 liters a minute with a loading challenge of 200 milligrams.

The second concept that we're trying to work -- and to go back to the first concept, that is if we can purchase and have equipment that will allow us to do the high flow testing, allow us to perform high DOP testing.

The second concept kind of comes in if that equipment cannot be produced, cannot be maintained, we would look at just using the same test equipment that we have now. And we're going to introduce a kind of a different testing idea. We're going to test test units sized proportionally for the same effective surface area and geometry to the airflow of the PAPR that's produced in production. And this is equivalent face velocity.

So this is something we're looking at. We're going to study this. We'd be able to test those at the flow rates of approximately 100 -- or approximately 85 liters a minute. And we have a kind of a range there of 85 to 100 liters a minute that we'd be able to work with the existing data.

The test units will be provided by the manufacturer. They would be built with the same specifications, just reduced in size, so that we would test them at that flow range, 85 liters a minute. The same geometry would need to be in place also. So whether it's a fluted filter or a folded filter, you would have to keep the same geometry. We're just going to reduce the space.

To give you an example of this, a PAPR with airflow of 240 liters a minute, two canisters, and each canister has a surface area of 100 square centimeters. You would produce test units that have an area of 71 square centimeters. And they would be tested at 85 liters a minute. The loading would also be to reduce to 142 liters a minute -- or, I'm sorry, to 142 milligrams.

And that's not -- that's a little confusing. And I'll go through the calculations as to how we come up with those so we can kind of narrow down to how this calculation would be performed.

In the example was 240 liters a minute with two canisters. So each canister tested 120 liters a minute. That's beyond what our capability would be. Set up a ratio, and sulfur X, you get 71 centimeters, or square centimeters.

Therefore the test unit, the effective surface area would need to be built at 71 square centimeters. And that's effective surface area, so you'd have to take into account the glue that's used to hold that medium in place. The same proportion

would be used to reduce that challenge to the appropriate value of 142.

Along with this concept, using our existing equipment, we would need to test the 20 test units against the DOP at the 85 liters a minute. We'd also test 20 production canisters after the durability testing. And that will pick up -- that means we will actually test what's in production. We'll be able to see the gluing that's used there and the efficiency of the production canisters.

And also the additional nine would come from the cyclohexane testing to the DOP testing. Those additional nine, if we look at those, the three from crisis provision will and should be exposed to a much higher flow rate. So that will also test that medium to see that it can stand up to that higher flow rate.

So requirements how we'll do this, for the first one, it's easy. We go out and buy some high flow DOP testers. That sounds very easy. But actually getting DOP testers at high flow that can generate the right DOP and that can be used and

maintained for certification is something we really need to look at.

Second concept, we need a more thorough study of this equivalent face velocity technique. And right now we think we can do that, but we will have to study how we're going to perform that and then do some benchmark tests of test units.

So the question is how are we going to make the decision which one to use. This may not be an easy decision. But the first thing we're going to look for is what we're doing right now, which is input from the manufacturer and the user community. Do we agree that this can be done, this equivalent face velocity, or do we think that high flow DOP testers can be used.

We'll look at analyses of purchasing and maintaining those high flow DOP testers. That takes some time to do. We have to go out and find manufacturers to manufacture them and determine that they can maintain them correctly for certification.

And we'll also need to do benchmark studies for equivalent face velocity testing.

So those are the three areas we really

need to look at before we can establish this particulate testing. Again, airflow of the unit is an important piece of information in there also.

And that would be it for this presentation. So if there's any questions?

MR. BERNDTSSON: Goran Berndtsson from The SEA Group.

I'm getting really confused here. Your second alternative, are you telling us that you want us to make special filters that was not produced in the ordinary manufacturing just so you can test them?

MR. THORNTON: Yes.

MR. BERNDTSSON: So what kind of certification does the end user have that this is going to be what he actually is buying at the end of the day? I mean you're going to have to hand-build some filters because you can't expect us to build special production units just for the sampling.

MR. THORNTON: We are going to have to look at that also. That's a consideration we have to take into account is can those test units be produced.

MR. BERNDTSSON: Goes against all principles of testing respirators, doesn't it, to build specials for approval, special type of filters for approval. It's difficult, if you want to take samples out for verification of quality, et cetera, how do you do that?

MR. THORNTON: Well, we are going to test the 20 production filters also. And so we're not just testing the test unit and then saying it passes, it's certified, it goes out. We'll test the test unit and we'll do additional testing to cover the production to see how they're built and make sure the quality is in there.

MR. BERNDTSSON: I hope that we solve it through the first option because it sounds like a nightmare to me.

MR. SZALAJDA: I think keep in mind though too with looking at the equivalent face velocity, you're looking at just the filter media and not building mock canisters with the, necessarily with the charcoal included, that we're looking at the filter media.

And I think when you look at the

concept, you know, obviously doing something like this is very different than what we had traditionally done in certifying respirators.

(?) MR. NAYLOR: (Inaudible) support what Goran just said. And I would add that one thing that you will have to take account of is the possibility that you will receive product which has a single filter and nevertheless is a demand system capable of very high flow rate. So the translation from a small filter to that kind of filler is quite a big leap of faith.

The second thing I would say is that the filter performance of particulate filters is not just arising from the media. The media performs very, very differently when you put it in a filter. And you cannot evaluate the performance of a particulate filter just by looking at the media. There are a number of effects that are not fully understood, but they are big effects, order of magnitude effects.

The other thing I want to say in support of the first option is that if you put this in the standard that this is a requirement, then I'm sure

that the filter test manufacturers will look to develop that very quickly because all the manufacturers are going to want to buy them.

MR. THORNTON: Thank you.

MR. SZALAJDA: Thank you.

MR. KOH: Hello. My name is Krank Koh. I'm from the University of Maryland. Just a quick question.

Most of these PAPRs are battery-charged. Are you going to be measuring the flow rates when it's fully charged or at 80 percent of its max? Just wondering how you're going to determine the flow rates and what, I guess, charge.

MR. THORNTON: Right now we would use a fully charged battery. We'd follow the user's instructions on how to charge that battery appropriately.

MR. BERNDTSSON: This raises another question. I mean, the performance, I think Krank was very -- it was very important what he said here.

The performance you're looking for, is that going to be also -- I mean are we not talking

about filter here now, we're talking about the entire unit when you're saying that we want to maintain positive pressure? Is that at the end of the battery life or the beginning of the battery life, or an average of in between or -- how are you going to ensure that?

MR. THORNTON: Well, it would be, the operational battery life is what the -- right now the concept is for the breathing performance to be performed over the operational battery life. And during that operation, whether that be four, six, eight hours, maybe even two hours, we're not sure, it would need to stay positive during that.

Now, we would start with a fully charged battery, again, going back to the user's instruction manual on how to charge the batteries, start that with a fully charged unit.

MR. BERNDTSSON: Okay. In other words, during the length of the battery, it has to perform. So if it is a four-hour battery, it has to perform to meet a positive pressure requirement at four hours?

MR. THORNTON: Correct.

MR. SAVARIN: Mike Savarin, ICS Labs.

One thing I just feel I should say in case there are some people who may not be aware of it, the use of surrogate filters to perform and stand in for actual filters is a completely, I won't say well-understood, well-practiced principle and behavior, especially when looking at particulate filters and how well those devices fit the user in the establishment of that fit.

Very often a surrogate filter is made, and it should mimic in some way the flow characteristics of the parent device. It's just a small bit of data that goes in to support the entire approval. So this kind of approach where, oh my God, I don't know what's going to happen, it's a nightmare, is just completely untrue.

The other thing is there are a number of problems with trying to find high flow devices, particularly with certain agents. The current protocol requires the use of DOP, which does have obviously some effects that are -- that if we can avoid it, you know, we should try to avoid it as much as we can.

There are a number of devices out in the marketplace that look at very high flows and high concentrations of aerosol generation, but very frequently will necessitate the use of a different type of particle with different characteristics, which is a whole new nightmare itself. Much more, much more the nightmare than you might currently think.

If we could get, especially the big players, because this is the kind of device that's going to be significant cost. If we can get the big players in the marketplace to chase up and come up with a device, that would be fantastic.

But normal cycle times for these kind of high flow devices operate in years. So you've got to factor that in when you say, hey, yeah, let's go for the first option. We'll have a machine in six months. Dream on, you know.

Reality is that it's going to take some considerable time. There are some big problems with trying to get high flows, maintaining the distributions of particles and keeping those things in a shape that means they can be used in accurate

test modes and are not changed by the nature of the media.

So you have to kind of factor all this in when you're trying to say we should go for one option versus another option.

Oh, one other small thing. I've always had a mental issue with the use of taking instantaneous DOP measurements in relation to the use of HEPA filters or HEPA classification filters. I heard something that was like a good step in a really good direction that goes we're moving away from the concept of a HEPA filter to using the P-100 filter.

Now the current description for the P-100 filter does necessitate that a loading characterization is performed on the filter media. Unfortunately, there was no mention of that. We're just going to use a P-100 filter. You're going to supply the 20 filters, and then we're going to do a test which is basically instantaneous, unless I've misunderstood something.

Now, if that's true and you don't measure the characterization, then actually you

haven't established that it is a P-100 filter.

MR. THORNTON: Well, just to make a point real quick, I think you did misunderstand this. We would be doing the loading and looking into filter efficiency. On the -- in the back table back there, there's a letter to manufacturers that talks in great detail about the actual P-100 testing.

MR. SAVARIN: Okay.

MR. THORNTON: And that would be very beneficial. You may have already seen the letter before.

MR. SAVARIN: Yeah.

MR. THORNTON: But yes, we are going to follow that P-100 testing like that. We will load the filter and look for the efficiency.

MR. SAVARIN: Okay. Because that was missed out from. And there may be people who didn't understand that, because that in itself is quite -- that's important too.

MR. THORNTON: Yes, is it. And P-100 testing is, there's a lot of detail that's --

MR. SAVARIN: Right.

MR. THORNTON: -- very specific.

MR. SAVARIN: Okay. I just think a loading comment should have been placed in the record.

MR. THORNTON: And thank you for your comments before because that kind of wraps up what the concern is. It is very difficult. Either way has its good points and bad points.

MR. SAVARIN: Right. That's it. Thank you.

MR. SZALAJDA: Thank you very much.

We'd like to move ahead with the next -- oh, okay. Last one.

MR. BERNDTSSON: Have you considered raising the allowable leakage from 99.97 to 99.997 of the ordinary flow rate? And that rate going through you'll see what's happening? And that's another way of probably testing it.

MR. THORNTON: Are you saying lower the efficiency or raising?

THE ARBITRATOR: I'm saying raise the efficiency. In other words, today we are asking for 99.97. If you have 99.997 of the ordinary testing

flow rate and maybe do some correlation, see what happens if you go to that. Then we could use the same equipment as you're using today.

MR. THORNTON: Yeah, I don't think that's a concept that we've thought about and looked at yet. So we would welcome any comment on that. And we'd have to investigate that.

MR. SAVARIN: I think it's well worth investigating. I think it's a great idea.

MR. SZALAJDA: Thank you.

And this will -- Ted Klemetti will be our last presenter before lunch.

MR. KLEMETTI: Hi. I'm going to talk to you today about battery requirements for the new PAPR concept.

Background into these battery requirements. I looked at several manufacturers' capabilities within the battery manufacturing industry, within electronic device industry and within electronic component industries.

Numerous manufactures state the ability to maintain all of our requirements or meet our requirements. These requirements are somewhat based

or similar to the CBR and SCBA and industrial PAPR in that with the SCBA you have a percentage time warning or a percentage of cylinder remaining, will do the same thing with the battery.

Requirements for the battery. It will be tested to operational battery life plus 20 minutes. This is very similar to what Terry talked about earlier with the breathing performance.

We're looking at doing this under similar conditions to silica dust loading or actually silica dust loading. Under a worst-case condition, we would simulate a load level that's equivalent to the low flow indicator or just before it, and test the battery life at that, with that method.

And then the third methodology would be to do battery performance testing based on maximum total draw of each of the components within side the PAPR; i.e., the motor, the LEDs, the chips, so on and so forth.

Based on the worst-case condition or the equivalent silica dust testing, we would have to develop a resistance curve for silica dust or an

equivalent total load, and apply either the total load or the resistance curve over the operational battery life. Very similar to what Terry was talking about earlier.

Another requirement that we put in for the battery or for the PAPR in relation to the battery is a 15-minute operational battery life remaining warning. This must be apparent and allow for an additional 15 minutes at the desired flow rate, which is the flow rate that maintains the positive pressure within the face mask or the breathing zone.

This 15-minute warning would be tested during operational battery life testing or in a similar method after operational battery life. For instance, if you don't happen to hit upon the 15-minute warning within the operational battery life for whatever reason, we would continue the test or start with a not fully charged battery to accommodate the 15-minute warning.

And this, the PAPR would also have to be capable of demonstrating operational service life and/or battery expiration date.

For a nonrechargeable battery used in a PAPR, indicators may be active, which would be an indicator that alerts the user when the 15-minute warning is reached; or passive, in layman's terms, or in my opinion, it alerts the user when 15-minute warning is reached.

Oh. That's not right. It alerts the user when the -- up until the point of where the 15-minute warning is reached. So one is the light comes on when you hit the 15-minute warning. The other way would be the light is constant till you hit the 15-minute warning.

For the nonrechargeable battery, you'd also have to have the expiration date. It would have to be visible on the battery. Once again, we hit on the 15-minute operational battery life remaining warning.

Rechargeable battery. Likewise, the indicators may be active or passive. We're looking into some sort of end-of-cycle life or a number of recharges being noted somewhere in the user's instructions or on the manual or looking at doing this in the quality assurance. And it also must

have a 15-minute operational battery life remaining warning.

The user's instructions must list all applicable battery information. Remaining operational battery life must be sufficient to sustain desired flow rate. And methods of warning shall be specified by manufacturer and in the user's instructions.

Another requirement for the PAPR is the low flow indicator. It will be tested using the same mechanism that tests operational battery life or similar mechanism to lower the flow level until we reach the flow that should indicate the -- or should activate the low flow indicator.

Once again, this can be passive or active, similar to the battery requirement, the 15-minute battery. It can be flow- or pressure-based, and must be fully explained in the users instructions.

Some of the shortfalls towards looking at a particulate loading equivalent testing would be needed time to evaluate resistance changes during current particulate filter testing. We'd also have

to develop a method to add the resistance change over the operational battery life.

We'd have to ensure that this method has appropriate flexibility to incorporate new technologies and designs in PAPRs. And this is a potentially very time-consuming test procedure. I.e., you have a 12-hour battery life. That means this test lasts 12 hours, 12 hours and 20 minutes.

For developing a battery load test, we're looking at -- and once again, this is something that we're doing simultaneously. We're looking at both at the same time.

This would be to develop a method to determine full load or current draw of the system for all potential PAPR designs; ensure that the method has appropriate flexibility, similar to the previous test; evaluate reducing test time dramatically over the total operational battery life.

There are methods out there to do battery testing where you only have to run the battery for two hours to evaluate the total life of the battery. And time required for test equipment

ordering and validation testing is another shortfall or consideration.

Time lines. To complete the particulate equivalent test, analysis of resistance curve associated with particulate testing completed June '04. Test method to apply the resistance curve, we're looking around July this year. And verification testing would happen sometime around August or September of this year.

For the battery performance test, or the total load test, current draw determination procedures, sometime between May and June. Hopefully earlier in June. Test method to apply the current draw completed around July. Equipment ordered and delivered, August-September time frame. Verification testing completed September-October time frame.

Any questions?

MR. LINKO: Bill Linko from Micronel again. A quick question.

In a case of rechargeable batteries (inaudible), are you going to specify the lowest battery voltage allowable, i.e., you know, from 4.2

down to 3 or 2.6?

I can play tricks with that by going down to 2.5 and getting more hours of operation. But it limits the number of charge cycles I can do with a battery. So if that's not defined, I can play tricks with that.

MR. SZALAJDA: They're good points. Thank you.

MR. BERNDTSSON: Have you had any -- Goran Berndtsson from The SEA Group.

Have you had any thought process around how to verify for the positive pressure demand system (inaudible) using a system with a motor accelerate and deaccelerate? The biggest load and highest killers of the batteries is of course this accelerations which draws a lot of amps.

Have you had any thought process how you're going to be able to look on that now? I don't have a solution. I guess that --

MR. SZALAJDA: That's a good point as well. That's one of the things, since we haven't really done any benchmark testing on the battery yet, that's something we can consider during the

benchmark testing for that.

MR. BERNDTSSON: You're welcome to communicate with our guys on this one.

MR. SZALAJDA: Thank you.

MR. KOH: Krank Koh from University of Maryland again.

Just curious, battery characteristics may be different for each manufacturer. Some may exponentially decline. Some may actually be plateau and then drop after a certain period. When most of these manufacturers, they specify 12 hours, they normally don't sustain that flow rate for that whole 12 hours.

Are you going to set some standards so that if a manufacturer warrants let's say 140 liters per minute for at least 12 hours, that that would not qualify, in other words? Because the battery life would probably not sustain 120 liters for 12 hours. It would start going down.

MR. KLEMETTI: I think the answer to that is that that's what we're looking at doing in the battery performance testing. That is we're looking at ensuring that we're going to have the

flow rates to maintain positive pressure throughout the entire stated battery life by the manufacturer.

MR. LINKO: Another quick comment from Bill Linko.

On the alarm indication, like if you have a choice of visual, audio or vibratory, in the event of having it on your back where you can't see it, visual isn't any good, okay. Hearing, the noise atmosphere, audio's no good. Vibratory, maybe all conditions. So do you want all three (inaudible)? You want one.

MR. SZALAJDA: I think sort of the intention was to leave it up to the discretion of the manufacturer given the particulars associated with his equipment. Because one of the things that we're looking at in terms of technology is that, you know, say potentially a heads-up display in your facepiece that, you know, a light could be an appropriate warning, you know, for that type of thing. So at least at this point it was left open to the discretion of the manufacturer.

All right. Well, thank you. I think it's about 10 after 12:00. Maybe we can reconvene

at 10 after 1:00. Thank you.

Excuse me, one again, there's lunch outside the doors. There's also a Subway and a Chinese restaurant out in the parking lot and Jackson's around the corner.

(Lunch recess taken from 12:10 p.m. until 1:15 p.m.)

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A F T E R N O O N S E S S I O N

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MR. SZALAJDA: We'll go ahead and start now.

Frank Palya is going to review our conceptualizing for the human factors and the durability testing.

MR. PALYA: Thank you for attending. My name's Frank Palya. I'll be discussing some of the human requirements.

Human factor requirements that I'm going to be discussing is the field of view requirement, the fogging, the communication, and the haze luminant transmission (sic) and the abrasion requirements. These requirements are -- and test

procedures are the same requirements as the air-purifying gas mask for the CBRN.

First thing I'd like to discuss is the field of view requirement. In order to pass the field of view requirement, a PAPR must obtain a score greater than or equal to 90 points. This will -- part of one of the pieces of test equipment will be the aptermometer (phonetic) that meets the requirements of EN 136 or equivalent.

This will be used to perform the field of view test. And what we're going to do is get a respirator size that best fits the head form of the aptermometer. It will be the average score of the best of three fittings of that same respirator size.

The visual field score was derived from the American Medical Association guidelines, 90 points, which translates basically, functionally basically into a normal vision.

This slide represents, is a sample respirator that we tested for field of view. This particular one got a visual field score of 96. As you can see, there's 22 points in the upper two

quadrants, 27 in the third, and 25 in the fourth quadrant.

The grid assigns at the 7 -- 70-degree mark, it assigns 110 points. This is about the 70-degree point right there. And there's 110 points within that fixation. And when you put the respirator onto the head form and you illuminate it, it will shine and it will -- you mark the outline of the light generated. And then you translate that and you go ahead there and count the points confined within the perimeter of this.

The next requirement I'm going to be speaking of is the fogging resistance requirement. The requirement is that the average, the subject's average visual acuity score must be greater than or equal to 75 points.

Three visual acuity scores will be taken. This will be when the subject will first walk into the environmental chamber, don the respirator, a visual acuity test will be given. And then after five minutes of exercise on a treadmill, during that two-minute rest period after a five-minute exercise, another visual acuity test

will be provided.

And then after another five minutes, another visual acuity test will be administered. And it will be an average of all those scores there. And each subject will have to get above the 75, greater than or equal to 75 points.

The test conditions and the equipment that's going to be used. We're going to have the environmental test chamber set at minus 21 C. There will be two PAPRs of each size cold-soaked in the environmental chamber. So when the subject enters the chamber, they can go ahead there and don it and start the test.

The human subjects must have an eyesight that is better than or equal to 20/40 vision. As you can see, there's some of the test equipment, the environmental chamber, the treadmill, the low acuity chart. This acuity chart has a 22.5 percent contrast. There are other ones out there that have 10 percent contrast, but this one has a 2.5 and that's the one we've been testing with.

The next requirement is the communication requirement. For this requirement,

the overall performance rating has to be greater than or equal to 70 percent. This test will be conducted with the motor blower operating.

The communication test. When we test this requirement, we will be using the modified rhyme test. The background noise will be 60 decibels, consisting of a broad band of pink noise. The distance will be 10 feet from the speaker group to the listening group.

There will be 10 MRT trials, yielding 15 scores with the respirator and 15 without the respirators. The listening group will consist of three listeners and then five speakers. Each group is required to have a female subject.

The last requirement I'm going to be talking about is the haze luminous transmittance and abrasion resistance. The initial haze, when we get the samples in, they will have to have -- pass an initial haze requirement of less than or equal to 3 percent or initial luminous transmittance -- or and initial luminous transmittance of greater than or equal to 88 percent.

Then once those are performed, we will

abrade the specimens and then the haze shall not increase by no more than 4 percent nor should the luminous transmission decrease by 4 percent.

This is some of the test equipment that NIOSH uses to test this requirement. It's the haze guard haze meter by BYK Gardner, Model HB 4727. An equivalent could be used. This is done in accordance with ASTM D-1003.

And for the abrading machine we use the Taber abrasive machine or equivalent. But we typically use the Taber one. And that's in accordance with ASTM D-1044.

For the specimens that are acquired, there's going to be four -- three specimens required, three abraded, three unabraded. These specimens are 4-inch square. These specimens are not going to be actually cut from the lens material, but it will be the same type of material and the same protective coatings will be applied as in regular production. And it also shall have the same nominal thickness as in the dominant viewing area.

After the lenses are abraded, they shall be cleaned in accordance with ASTM 1044, or as

suggested by the respirator or the PAPR manufacturer's user's instructions.

Again, the test methods are ASTM 10 or 1003 for the haze and luminous transmittance. And for the abrasion, surface abrasion, we use the ASTM 1044. The abrasion wheel will be a CS10F Taber wheel and the load will be under a 500-gram weight. It's going to be 70 revolutions.

The issues and testing and time lines, this time we really don't see that many issues with it because, again, these are the same tests that we were using in the CBRN gas mask and we've been performing these tests, kind of refined these testing methods.

However, we will still get some benchmark testing done. We're going to go do some benchmark testing to get three to four PAPRs per manufacturer with a minimum of three manufacturers. We'll go through the procedures. And we believe that the verification testing should suffice, will be the same for the benchmark.

Time lines we figure around September 2004.

So in summary, these are the requirements for the human factors requirements and test procedures that were used.

At this time I'll address any of your concerns.

MR. SAWICKI: Jack Sawicki, GlobalSecure.

Your intention here I guess is to get rid of out, of the marketplace of any of the hooded-type products that the hospitals are using primarily now?

MR. PALYA: That wasn't our intention. Are you referring to the haze luminous transmittance (inaudible)?

MR. SAWICKI: Well, possibly that, but like the abrasion and like the cold-temperature tests and things like that.

It seems like there is an area in the market that this is sort of going to do away with. And a lot of those are really popular products. So I was just wondering how you'd address that.

MR. PALYA: Right. Well, that was not a consideration. That was not an intent.

MR. SAWICKI: Because this seems more directed towards a mask version of a PAPR. And this would sort of put you towards a like Affirm or the Swedish TSI-type hood rather than the continuous flow which is throughout the marketplace now.

MR. PALYA: Correct. You're right. A lot of these were written around the tight-fitting facepiece or traditional tight-fitting facepieces. We really have -- again, we're going to try to do this benchmark testing. So we're going to learn a lot from that. And then we'll see how that all turns out.

MR. SAWICKI: I had previously put a comment in suggesting that a category be established similar to the escape hood with characteristics -- or escape respirator I guess that you had previously. Was that taken into consideration at all when you developed this?

MR. PALYA: Not really, no. We were just going to go ahead and look at these requirements. And again, we'll look at some of these and see how they pan out later.

MR. DUNCAN: I apologize for walking in

late and if you guys mentioned this, I severely apologize.

Paul Duncan, Scott Health & Safety.

I would like to encourage you guys to consider changing the abrasion resistance requirement as instead of having an increase as to instead have an absolute value. The way the current standard it written, for instance, let's say if a manufacturer has a hood or facepiece and luminous transmission prior to abrasion is 95 as opposed to somebody who's 88.

And they both -- let's say the one that's 95 increases by 5 and goes down to 90; whereas the one that's 88 only increases by 4 and goes down to 84. You've actually by your test procedure have disqualified the mask that actually has a net better luminous transmission.

It seems like, you know, that we should look more what best serves the end user. Is it the increase or actually the absolute value that's really to base the performance standard on.

And the same thing with the haze, you know. If a person starts out -- if a manufacturer

starts out with a haze requirement that's only 1 and it increases 5 up to 6, or if somebody starts at 3 and it increases 4 up to 7, you've knocked out the person who has a lower final haze value just because of the standard's written. So I'd really encourage you guys to reconsider that for the next standard.

MR. PALYA: Yeah, well, we were -- we thought of that during the development of that. And what we were looking at when we actually do the abrasion resistance, we were looking at the feature of the lens material to really abrade resistance, okay. We weren't really looking at the end value, but just so much the ability of the lens material to abrade the resistance, the difference in it after being abraded by that.

MR. DUNCAN: Again, in answer, you're sort of evaluating material instead of evaluating the performance requirement and how it affects the user. That's why that --

The other comment I would make is I'd appreciate if you guys would consider better clarifying protective coverings or overshields and things like that. You know, I've seen some things

out there where, you know, maybe protective coatings on something or an accessory which you put over your primary lens.

I think for everybody that may be submitting options like or trying to take that approach, you'd better clarify as how you're going to handle the haze test and the luminous test and those requirements with regards to additional coverings.

Okay. Thank you.

MR. SZALAJDA: I just wanted to add something I guess on the comment that Jack had made about that he made at the last public meeting.

I think one of the things that in reviewing the comments that came in that we try to keep in mind for PAPRs in general is that we want to define minimum requirements that could be used across the board, whether it's an escape PAPR or, you know, tight-fitting or loose-fitting, whatever the requirement may be.

And I think once we get in and get to evaluate some of them in the benchmark testing and see how things perform, it will, that will shed some

light onto that topic.

MR. PALYA: Okay. Continuing on, I'm going to be discussing the durability requirements for the PAPR.

What I would like to talk about first is the purpose and the goal, the assumptions that we made when we developed these test requirements, the minimum packaging configuration, and the battery. It's also going to go, undergo the environmental testing and the transportation testing and its minimum packaging configuration.

Some of the rationale we came up with when we were developing these test procedures. The purpose of this test is to perform the environmental storages and the shock tests was to quantify durability and to detect any initial life cycle failures. We wanted to ensure that after it underwent this, that it would provide adequate respiratory protection, and also to ensure that there was integrity inherent in the design of the PAPR.

Some of the assumptions on driving that was these test conditions were going to be induced

by the user that they may experience at the point of issue. So the PAPR will experience these conditions from the point of issue.

And also we want to look at that there's still going to be maintenance inspection shall be performed in accordance with Department of Health and OSHA regulations. This is for an industrial -- this is not for industrial-use scenario, but for CBRN emergencies.

The test conditions were tailored to U.S. meteorological weather conditions and U.S. roadway conditions. Also that, you know, some people will say that, well, the PAPR will never experience these conditions.

Well, we really don't know that. There is a potential for these PAPRs to go ahead and experience these conditions, just because of the different operation missions that the users may -- that may be using them in. These tests are not intended to represent the entire life cycle, but rather just again to identify some initial life cycle failures.

Now, we used Mil Stand 810-F as the

principal guidance document because a lot of these test procedures were already established. And plus Mil Stand 810 requires that when developing these tests you go ahead there and look at the operational, the potential operational platform that they could be used under. And you design your test around the potential conditions that they may experience.

Right here is the flow chart of the testing. As you can see, the PAPR and the battery and the canisters, they all go through high temperature, low temperature, humidity and vibration. And then after that, the canisters alone get subjected to the rough handling drop test.

After the durability testing, they will be performance -- they'll just undergo the regular performance testing. Specifically for this one, it will be like a lot of the agent permeation resistance as to the GB and HD. And for the service life, it will -- the canisters will undergo their gas and service-life testing.

These, the CBRN PAPR and canisters will be subjected to the durability testing and minimum

packaging configuration. And minimum packaging configuration will be recommended by the manufacturer in its user's instructions.

The batteries will also be conditioned in this minimum packaging configuration. And that also will be as recommended by the manufacturer of the PAPR in the user's instructions.

I wanted to point out here that after they, the PAPR and the batteries and the canisters go through the environmental storage and the transportation storage, that the batteries will be either installed into the motor blower unit, or if they're not already installed in there, that they'll be put in.

And then a functional test will be required where you go ahead there and turn on the motor blower unit. And there's no time limit. It's just required to function. Even if you go ahead and turn it on and an alarm sounds, that will be adequate to pass this test.

We're doing this so that we can go ahead there and determine any interface problems or operational problems with the units after it went

through the durability testing.

The batteries. After this functional testing, the batteries will be recharged if they're rechargeable batteries, or replaced if they're replaceable batteries. And then they'll go to their subsequent testing, GB and HD testing.

The minimum packaging configuration is protective packaging that the end user shall store or maintain the PAPR and the components inside after they are issued.

The user's instructions shall identify the minimum packaging configuration and shall direct the end user how to store and maintain the PAPR and the components while it's in the possession of the end user. The level of minimum package configuration is left to the discretion of the PAPR manufacturer.

Any overcases, packaging over and above the minimum packaging configuration will not be durability tested. In other words, we'll just go through, conduct the durability tests and the minimum packaging configuration.

And the end user will be the person who

will derive protection from the PAPR by wearing it. It is assumed the end user will store -- will be responsible for storing it and maintaining it and having it in his possession.

The high temperature, these are the ones, the conditions that we're proposing. The high temperature storage will be performed in accordance with Mil Stand 810-F. And this will be for a three-week period. It's a diurnal cycle, so at the highest temperature there at 160, it will probably be there maybe an hour, hour and a half out of a 24-hour cycle and then it will cycle back down to 95.

This will be conducted for a three-week period. Then after that high temperature cycle, then it will go, be tested for low temperature storage according to Mil Stand 810-F, Method 502.4. But this will be a constant cold at minus 31 C for three days. And then after that, the humidity will be for a five-day cycle. And that also will be on a diurnal cycle.

After the environmental storage, then the items will be transportation-tested for

vibration according to Mil Stand 810-F, Method 514. It will be conducted in the vertical, longitudinal and the transverse positions. It will be done for 12 hours.

Typically how they do this, they'll test it for 12 hours in a longitudinal position. And then what they'll do is they'll rotate this item, because the table normally just shakes left to right, so they'll rotate the item and then they'll test it for another 12 hours. And then at that point, then the table will be, have an up-and-down motion. That's when they'll test the vertical. And that will be a total of 36 hours.

The next test, the canisters are just going to undergo, this is a rough handling and drop test. That will, the canisters will be dropped once on one of the following three axes. This -- it will be from a three-foot drop onto a bare concrete surface.

The first rationale we get, just the high temperature simulates the storage in the trunk of a vehicle. And we were looking at different areas within the United States, areas such as like

New Mexico, Arizona. And we felt there wouldn't be unusual for a responder to go ahead there and leave their PAPR in the back of their car or outside in these conditions.

We went ahead there and we chose a three-week period because of prior RDECOM's experience, whereas that if there was to be a problem with the respirator, it normally pops up within the three-week period.

Then the low temperature test, again we're looking at climate areas within the northern United States. And then the humidity regions will be areas such as Florida. They were -- the test period, three for cold and five for humidity, again, that was out of -- recommended by Mil Stand 810-F.

And the vibration simulates the transportation over 12,000 thousand miles of road. It's not an extreme rough-handling condition. These items are tested in the unstrained configuration.

Some of the issues, testing and time lines we foresee, perhaps we'll perceive some battery survivability maybe in the test fixture itself. Maybe testing the containment fixture we

might have to build another one so it will accommodate the larger size PAPRs. Maybe the test procedures may have to be tweaked a little bit.

But again, we're going to go do some benchmark testings on four to five PAPRs per manufacturer, and with a minimum of three manufacturers, and then see how they turn out. And then we might have to, either we could use the same STP as the air-purifying respirator or maybe, we may have to develop another standard test procedure. But after that, then we'll do the verification testing on that particular test procedure. And that should be done somewhere around October.

So in summary, enclosed is the matrix for the proposed durability testing. We feel that these tests are critical to ensure the CBRN PAPR is durable enough to adequately protect the user and that there is integrity inherently built into the design of the PAPR.

This concludes my presentation. At this time I'll take any questions. Thank you.

MR. BERNDTSSON: We aren't going to let you get away without having any questions, eh?

MR. PALYA: Yeah, that's unusual, isn't it?

MR. BERNDTSSON: Yeah, that's right. That's right.

Goran Berndtsson, The SEA Group.

You had the slide, the slide before the minimum packing, can you bring that back up again?

MR. PALYA: Sure. That one there?

MR. BERNDTSSON: Yeah. You had something where you said it has to start, you have to put -- after the testing, the APR to start. But it didn't have to --

MR. PALYA: Okay.

MR. BERNDTSSON: Okay. So what immediately after durability and ambient conditions. Then you say required to be functional. What do you mean by required to be functional? Coming up saying that I don't function? Is that functional?

MR. PALYA: Well, I mean it has to be either an alarm sounds or it operates. I mean if you turn it on and, you know, I mean we're looking at things that maybe the battery housing will crack

or --

MR. BERNDTSSON: If you have a function built into your respirator and self-test it and it comes out and it says oh, doesn't work any longer, is that a powerful failure?

MR. PALYA: I'm sorry?

MR. BERNDTSSON: If you have function built into the respirator that it self-tests and the answer that they come up and say sorry, I'm not functioning, I don't have enough power or whatever it is, that is a power --

MR. SZALAJDA: That's correct, because the, really the intent is because of where and how the PAPR will be used, that the user will be able to make a conscious decision if he wants to put the system on or not.

And part of the rationale here is that you're testing the functionality, that if the answer is the system's not ready, that's okay. But the purpose, the point is to get some sort of answer.

MR. BERNDTSSON: The other thing that's going to be a challenge of course is that if you're taking it out of this cold environment and expect

batteries to work straightaway, that is -- I didn't really understand if that was the purpose with some of the cold testing. Are you going to be -- is it required to be working straight after coming out of minus 21 degrees Celsius or?

MR. PALYA: No, no, that's after all the durability testing.

MR. BERNDTSSON: That's all the durability.

MR. PALYA: Right. Then after all the vibration, after the vibration.

MR. BERNDTSSON: You also said something about that each user was going to have to look after the batteries. Was that something? I mean for example, if you have a large fire brigade using PAPRs, they might need to have some battery maintenance function (inaudible), otherwise it won't work when they are needing it. So that is -- is that going to be part of the approval system in that case if you have --

MR. PALYA: Well, what we were intending was that the PAPR, what the user would have after it was issued to him would be whole. It would be the

complete package. So it would be ready to use. Not so much going off to some sort of a supply room or something and getting it. Because again, what we're trying to do is we're trying to cover a whole broad range of operational users.

MR. BERNDTSSON: Some of this, I mean, personally, I think it's unlikely that you put a high performance PAPR in a car in the back of the trunk sitting there for 12,000 miles and expecting it to work. You might do that for a face mask. But a PAPR, it is -- you need to make sure that the batteries are conditioned all the time.

And if it will sit eight days in a boot, you're going to -- it maybe lost 50 percent the capacity already there. So it can't really be done realistic scenarios I think when it comes to high performance PAPRs.

MR. SZALAJDA: I appreciate your comment on that. I think just some of the things, the input that we've gotten back from the users, the user community on that that we've heard in a major metropolitan area was buying PAPRs and planning on putting them in their police cruisers because they

didn't want to deal with other aspects of using gas masks.

So I appreciate your point on the issue. But I guess the part of our, our concern is in looking at setting up minimum requirements is that we need to make sure that the PAPR, regardless of its design, meets certain minimum criteria. And that's what we're working through with this set of requirements.

MR. BERNDTSSON: Some of that could be dealt with in the marketing, the marketing of the product. I mean, for example, if you can't have it functional after sitting in the back of the car, the battery's a problem for everyone. It doesn't really matter which manufacturer it is. If it's going to be sitting in the back of a car, it's not going to work when you come straight out after a few days. And that I think is a marketing issue.

MR. SZALAJDA: That's a good point.

Paul?

MR. DUNCAN: I agree. As a follow-up to that, I mean maybe we should be considering PAPRs more like SCBAs and less like gas masks. I mean an

SCBA has to go -- undergo a functional check.

You know, if it's sitting in the back of a jump seat, it typically undergoes every 24 hours a check to make sure your air pressure is there. If it's a wallhanger, it's certainly checked less frequently, but it's nonetheless checked.

And to sort of expect these to go through this and be functional after some period of time is I think a little unrealistic.

The other comment, I didn't see this really addressed in the previous slide, previous presentation, was also, as part of the fogging test in the way the requirement is worked, these batteries will be cold-soaked to minus 21 degrees for four hours, then expected to be fully functional for a fogging test.

Is there any thought given to that? I mean is there -- you know, do these things just have to pass the fogging test after four hours at minus 21 or is it --

MR. PALYA: Correct, yeah. The fogging test is not going to be that long of a test. I mean with the fogging test we're testing the respirator

for resistance to fog or clear the respirator.

MR. DUNCAN: Okay. We're still expecting the batteries to deliver some level of airflow after cold-soaking it at minus 21 C for four hours?

MR. PALYA: Correct.

MR. DUNCAN: That's a little rough.

MR. PALYA: Well, again, we were looking at some of the research and we found that some of the batteries would operate in that functional range.

MR. DUNCAN: Have you actually tested that as like an over -- is that just like a generic study on battery technology or has that actually been bench-tested against PAPRs cold-soaked at minus 21 for four hours?

MR. PALYA: No, that was just some of the batteries, the battery technology.

MR. DUNCAN: Okay.

MR. PALYA: But again, you know, that's why we're going to do a lot of this benchmark testing, so.

MR. DUNCAN: All right. Thank you.

MR. SZALAJDA: Okay. Thank you.

MR. LINKO: Just a quick comment. Bill Linko from Micronel.

In the event the unit has negative pressure inside, may I suggest you check for leakage? Could be micro-cracks in the material. Or if it's under pressure, leak down again. I spent hours talking with GE about various polymers and their cracking, particularly if subjected to let's say to polycarbonate oils, they cause cracking. And while the leaks may be small, still in some cases, 1 part per million is important.

MR. PALYA: Yes, sir. That's why we're doing this test. A lot of those will be picked up and the permeation penetration testing will undergo the GD and HD.

So again, I mean we're testing the integrity of the design of the PAPR, the materials. And without this testing, a lot of those problems may crop up without us knowing it. So that's why it's very important for us to have this testing.

(Mr. Linko spoke from his seat.)

MR. SZALAJDA: Thank you.

Next Mike Bergman is going to discuss some of the special tests that will be done under CBRN.

MR. BERGMAN: The presentation I'm going to give is on the chemical warfare agent testing that we do. This is done at RDECOM down in Edgewood, Maryland. So I would just like to thank and acknowledge their help in this project.

The two agents we test are sarin and sulfur mustard. The challenge vapor concentrations are equivalent to the CBRN APR standard. They use the Smart Man upper torso mannequin which is connected to a breathing machine.

The current concept has the battery installed for testing. The test itself is an eight-hour test in the live agent chamber. But there are also additional time for leak testing in a cold system as well as quantification of the chamber itself.

So the concept is here to have an alternate power supply which would either be a longer-life battery or an electrical plug-in in addition to the battery installed.

Again, the sarin concentration is the same as for the APR. Those concentrations are indicated there as well as the breakthrough times. And the total test time in the hot system is eight hours, with the (inaudible) of vapor being generated for 30 minutes.

Mustard HD, again, the vapor concentrations are the same as the APR standard. Vapor is generated for 30 minutes and they apply the liquid in the last two hours of testing, with the total test time of eight hours.

So as a summary here, we would like to accommodate the use of an alternate power supply, either a longer-life battery with a ten-hour life as a minimum or the regular battery installed also having an electrical plug-in system to plug into the laboratory power supply.

For the HD liquid, there will be a standard number of drops on the facepiece. And then we'll have to determine the placement and the number of drops for the base assembly and accessories.

Summary time line, we'll be working on standard test procedures with RDECOM May and June.

And we hope to perform verification testing late this summer, August and September.

Any questions?

(Inaudible.)

MR. BERGMAN: Right. Again to acknowledge RDECOM for their assistance in performing the test there at their facilities as well as in having input into the concept and the standard test procedures.

The LRPL is a fit factor corn oil test. And the purpose is to establish a benchmark level of protection under laboratory conditions. It's not intended as an indication of protection in an actual response or CBRN scenario.

Here are some of the criteria for the test: Concentration of aerosol and the particulate size. The pass-fail level is greater than/equal to 10,000 for at least 95 percent of the test trials. It's evaluated over 11 exercises and it's the harmonic mean of the values from those 11 exercises. The concept is to test the PAPR in its operational condition; that is with the PAPR blower operating.

Here we have the 11 exercises. Eight are from U.S. Department of Labor OSHA standard exercises for quantitative fit testing. And then I've indicated there the three that are emergency response exercises that were developed over the course of CBRN standards development.

Looking at the human subject anthropometric parameters, these are the same parameters that we've considered for the CBRN escape respirator. Those are the neck circumference and head circumference, face length and face width, because these PAPRs as they are designed can have the sealing surfaces that would be effective for these parameters.

The subject panel is the same panel from the CBRN escape hood or escape respirator standard. The ranges were established through review of population data of head, neck, face length and width sizes. For the face length and width ranges of the panel, we are using the ranges from the Los Alamos panel report of 1974. That is the LANL panel.

And for the head circumference and neck circumference ranges we are looking at the latest

research by Dr. Zhuang of NIOSH NPPTL. And his survey is conducted for establishing new panels for NIOSH respirator certification and international standards. The subjects for his study were recruited from industries nationwide, manufacturing, construction, health care, law enforcement and firefighting.

There were approximately 4,000 subjects in the study. Over 2,000 of them had complete measurements for face length and width and head circumference and neck circumference. And in looking at the panel we've constructed, you'll see the face length and width row, that's the top row, that comes from the LANL panel. And then the head circumference and the neck circumference rows are from Dr. Zhuang's study.

In the case of a three-size model, we would look to use the individual size for each model, so. That is, for the small size we would look for the, for fulfilling the column of the small column, and so on for the medium and large sizes. For one-size-fits-all PAPR we look to fill the criteria from the whole panel.

This slide just shows how we extended the neck size ranges for the small and the large neck circumference up to 50th percentile of the population. 378 is the 50th percentile. And in doing that, what it does, it allows for a single subject to meet multiple criteria for that size range.

For example, if the subject had a small neck circumference, it would just allow that subject more of a statistical chance that he or she would have the small face circumference criteria.

Going back to the panel here for a second, what that means is you can use subjects that, if it were a small-size respirator, if they met all the criteria of the small column, that is they have a small face length, width, head circumference, neck circumference, you can fulfill all that criteria with the same subject.

If the subject had say for instance only a small face size and not a small neck size, you can use that subject only to fill the criteria of the small face size.

This is a new concept for the April 1st

concept paper is the idea of practical performance. And it's in the spirit of the CBRN escape hood -- or, I'm sorry, CBRN escape respirator requirement of the practical performance. That is, that as the subject is performing the LRPL, we want to make sure that that subject is able to wear the PAPR as it is indicated to be worn.

That is, when they're performing the LRPL, we want to make sure that they don't accidentally switch the PAPR off or that the hoses and electrical wires don't entangle and cause the facepiece or hood to move off of the head or move to a position where it's not indicated it will be in that position.

We are aware of the possibility that lubricants from the PAPR blower may be coming up into the facepiece, causing LRPL results that could fail the unit or just have lower results. So this is a consideration we're going have to think about in the development of the standard test procedure if we're going to try to eliminate this phenomenon or just consider that unacceptable.

Again, for the time line here, May and

June will be at SBCCOM -- or at RDECOM, working on standard test procedures and performing verification testing in August and September.

Okay. Any questions or comments?

MR. DUNCAN: Paul Duncan, Scott Health & Safety.

I'm a little clear (sic) what you mean by the aerosol coming off the motor bearings, you know, basically showing up as a photometer reading as being unacceptable.

Are you basically saying that you're actually considering failing units if motor lubricants actually give a false reading, what's actually known to be a false reading on the photometers?

MR. BERGMAN: I think what we're going to try to do is consider working that into the standard test procedure, where, if we can eliminate that from happening, that would be the best thing. And if we know it's happening and it's failing the unit, well, I'm not sure how to deal with that yet.

MR. DUNCAN: There are certainly ways you can eliminate it. I'm not sure if it's really

of a benefit to the end user to basically like say you're adding a feature, possibly like a filter or something, to actually purposely just pass a test, where we know that the aerosol readings really aren't any indication of poor fit.

I'd rather see some investigative work be done in maybe establishing baselines for the aerosols coming off the motor and then adjusting test procedures to factor out those baselines. I think that would probably be more -- I request that would be a more appropriate solution to the problem.

MR. BERGMAN: Thank you. That's a good idea.

MR. HEINS: Bodo Heins from the Draeger Safety. Could you explain please how you came to the fit factor numbers? When I remember the SCBAs have a fit factor from 500, the APR 2,000, and now the PAPR of 10,000. I would have expected the other way around.

Because in my opinion, the first responder will start with an SCBA. And then he will be followed by colleagues with an APR. And the colleagues outside at nearly clean air will wear an

APR and PAPR. So I have no idea how it has to be 10,000.

MR. SZALAJDA: Yeah, that's a good comment, Bodo, and something that we've thought before for a long time with this type of system.

I think when we look back and we look at history with the SCBA, in coming up with the 500 value we were looking at establishing a basis for the fitting, identifying good fitting characteristics of respirator, knowing that you were working in a supplied air mode.

You know, with the 2,000, when we go back to the APR and look at the requirement of 2,000, we selected a value that technology could accomplish, you know, through benchmark testing and evaluation of data, generated an SBC column.

The 2,000 number was something that technologically can be achieved today, you know, providing a good degree of fit for the individual that's wearing that respirator.

In looking at the PAPR, the consideration was we know that the PAPRs can be 10,000. And we've seen that with testing done at

the Edgewood facility. And I think the criteria here where we'd appreciate getting feedback from the community is whether or not that not so much if the, that value is appropriate, but maybe we need additional criteria. Maybe we need an unblown method for achieving fit.

And looking at establishing the 10,000 number, we're looking at that number across a whole variety of technologies, you know, from loose-fitting all the way to tight-fitting facepieces, and realizing the fact that systems, those types of systems can generate airflows to meet that requirement.

I guess the question that raises to me is that enough? Do we need to do something in a negative or an unblown mode to assure the degree of fit of the respirator. So any comments that the stakeholder community has on that would be welcome.

MR. HEINS: Obviously 500 hundred is enough. So why you need 10,000?

(?) MR. NAYLOR: What you said concerns me greatly, to be frank. It seems like the different standards are for different procedures for

setting the laboratory protection factor. That concerns me because of again how we have to present that to the user. That's the first comment.

The second comment is that we've been talking about positive pressure powered respirator systems. I think if we're going to have these systems, we'd like to be able to demonstrate their protection equivalence to SCBA in some way.

My third comment is that with PAPRs, you are looking at a wide range of different technologies and quite a number of different applications. And it's by no means obvious to me why they should all meet the same protection requirements.

And an obvious conclusion I would draw is that we ought to be offering more than one level of protection and that the distinction, the fundamental distinction between the positive pressure system and the other systems ought to be the protection level that they meet.

The 10,000 you've said is achievable by devices. And I'm wondering whether that is all devices that might be offered to the first responder

community or whether that's just certain full facemask devices for example. My experience would be that that number is potentially challenging. It's not always possible to include the -- increase the protection factor by a factor of five just by putting 115 liters a minute into the facepiece, for example.

So I think my basic point is we really should be looking at more than one class. And I think that's potentially what the user would expect.

MR. SZALAJDA: I guess, let me make just one comment then with regard to your comments.

I think the one thing that I don't want to mislead anybody when we talked about the generation of laboratory protection factors. And by no means are we circumventing established OSHA guidance for selection and use of respirators where respirators should be used.

When we get into the actual application of using a gas mask or using a PAPR, you know, the OSHA rules of the day for assigned protection factors are what would be used in the selection of

the respirators.

And in terms of setting a laboratory evaluation, setting a laboratory test, you know, I think a lot of the basis going into looking at the values that we were evaluating or looking at in the laboratory are based, you know, on what technology can provide.

But by no means do I want to give anybody the impression that, you know, we're circumventing the procedure, the already established procedures for selection and use for respirators.

MR. NAYLOR: If I may just quickly come back on that, some of the devices we're talking about today are novel. And I think they will need new selection procedures. And we know realistically that one of the things that people look at is that performance can't rely on existing OSHA rules to inform the selection of these device. Some of them will be quite new technologies.

MR. SZALAJDA: Thank you.

MR. BERNDTSSON: Goran Berndtsson from The SEA Group.

When it comes to protection levels, I

assume that the first responders, they all need to be protected from whatever. I mean theoretically you should have the same level of protection if they're going to be used for chemical or biological warfare.

However, what's different is the work rate they're going to be used in. So in other words, I think it's a little bit misleading when we are, if we are talking about different level of protection, different level of -- different level of protection based on different work.

So for example, the difference between the 115 (inaudible) low or medium work rate and high work rate here is really what kind of work the person is going to do (inaudible). But the level of protection has to be equal, whichever piece of equipment he is using. But he can't work too hard.

Does that make sense?

(Chorus of "No" responses.)

MR. BERNDTSSON: But that is what is going to make the difference. I mean if you're working harder, you're going to require more air. (Inaudible.)

MR. SZALAJDA: Yeah, I think a couple things to keep in mind with this test, there's one that's solely a laboratory test I think as Mike had stated early on, that I forget how you had it phrased on the chart, but it's not necessarily indicative of what somebody may actually see in doing actual work.

I think when you look at the, how OSHA assigns protection factor values, you know, you have certain values for the gas mask and now we're going to have new requirements for the PAPR based on technology evolutions over the past several years.

So I'm not sure if that's really answering your question, but I think part of this is when we talk about the LRPL, I think we have to look at it in context that doing -- you're doing a laboratory test in very controlled conditions. And in selecting exercises, you know, we're evaluating the criteria, coming up with a baseline criteria for which all the respirators are going to be evaluated against.

MR. BERNDTSSON: I don't think I'm making a question. I'm making more a statement.

In the end of the day, if you're a first responder, it doesn't matter if you have a breathing apparatus or full facemask or a PAPR, you want to he fully protected. That is the bottom line.

You don't want different level of protection. But you can use a different type of equipment, a different work rate, because it is going to maintain that protection at different work rate. You still want to be fully protected.

MR. SZALAJDA: Right. Well, we -- I think we agree with you that we definitely want to protect the responders. And I think part of all this gets into as well the proper selection of the respirator appropriate for the task at hand, whether it's an SCBA or a gas mask or a PAPR.

MR. BERNDTSSON: And appropriate information about the limitations of the different type of equipment is.

However, the reason I came up here was this background noise (inaudible), material coming off motors, electric motors or bearings in the PAPRs. It's fairly simple to establish that by running a dry test with no contaminants and

measuring what's happening. And then you get a baseline.

And then you do the same measuring with contaminants. And then you have one against the others and you get a totally (inaudible.)

And I really hope that you would implement something like that because if you're going to get good performance, you need to have bearings (inaudible).

MR. SZALAJDA: Right. And that's one thing I think the benchmark testing will show as we move along.

I guess part of the concern is just making sure that, you know, any byproducts of the system, you know, that if, you know, for example, if you use something in the manufacturing process with powders or whatever to preserve the components of the respirator, how those will be addressed and whether or not that's something that the user would be concerned about that prior to wearing it that they should run the system for so long to blow out those types of particles.

MR. PARKER: Jay Parker with the Bullard

Company. I'd like to go back to the live agent testing presentation for a sec.

You mentioned that you wanted to use a power supply to replace the battery because of the length of the test. How will the voltage be determined for that power supply and also how will NIOSH address the fact that once you do that, you might be eliminating components that could be affected during the testing such as battery cables, battery mounting systems that could be attached to the blower and could affect the blower and things like that?

MR. SZALAJDA: That's a good question, Jay. I think, you know, part of that's going to come to light as we do some additional benchmark testing.

Our original concept with doing this is that when you look at how we do the SCBA, that, you know, we ask the manufacturer of the component to provide the interface between the supplied air system that's available in the laboratory to allow the respirator to be run for the six-hour period for that test.

And in concept we're looking at, you know, the similar type of approach to allow some sort of adapter potentially to be added and provided by the manufacturer to allow the system to be run for that long. But that's something we'll consider during the benchmarking.

This is the guy who has all the answers to the questions about the LRPL testing.

MR. SIPE: This is Adam Sipe (phonetic) from ECBC.

Going back to the LRPL values on the SCBA, when that's tested, that's tested with just a P-100. It's not tested with the complete system. Whereas when we test the PAPR, that will have the complete system. That's why the LRPL pass-fail values are lower for that.

And the, with the PAPR is higher for the 10,000 because that's the complete system providing all the protection. Whereas, again, with the SCBA it's just the facepiece with just a filter in line. So essentially an APR for our LRPL test.

MR. SZALAJDA: All right. Thank you.

I don't know how everybody feels at this

point. After this presentation we were supposed to move to a break. Unless there's any objections, I'd like to just go ahead and press on and cover the last two presentations that we have and then the one from Janice Bradley and then open it up, have our open comment period.

There are some refreshments in the back of the room if you're so inclined. So unless there's any objections, I'd like to just continue to move forward.

(No response.)

MR. SZALAJDA: Okay. Thank you.

I'll tell you what, we'll let just everybody take five to go get something and come back. Don't go wandering off into the lobby or anything. We'll start in a couple minutes.

(Recess taken.)

MR. SZALAJDA: Before Frank Palya gives his presentation on the chemical warfare simulant project, one thing I did want to mention, that the list of attendees for the meeting will be available on the back table where the handouts are so when the meeting's over you'll be able to get a copy of the

list of attendees.

I also wanted to let you know too that our intent, like with the other public meetings, is to put the presentations up on the website. And I'm hopeful to have that up sometime early next week.

So with that, Frank Palya's going to discuss the current status of the chemical warfare agent simulant project.

MR. PALYA: I just want to give an update what's the status here on the chemical warfare agent simulant project. I want to go ahead there and mention our partners that are very instrumental in coming up with this. It's RDECOM, formerly SBCCOM, NIST, and they've been very instrumental in helping us get this project going.

How we came about on this project was back when NIOSH announced that they were going to use chemical warfare agent simulants -- I'm sorry, when they were going to announce that they were going to use chemical warfare agents GB and HD to perform certification tests, some manufacturers had some concerns that they asked NIOSH to identify simulants that they could test in-house.

So what we did was we decided to come up with chemical compounds that would simulate the permeation effects of GB and HD when tested on different barrier materials.

The project goals were to identify chemical compounds that simulate the permeation effects of GB and HD through barrier materials. And the barrier material is a base material that is used in the construction of a personal protective equipment.

We developed a laboratory procedure that can be used by stakeholders for estimating permeation breakthrough times using GB and HD simulants. I don't know if you got a chance or an opportunity to go ahead and view the chart back there, but I put on display the actual permeation cell that was developed and some of the procedures that we were using, some of the test equipment.

This method would provide stakeholders with a low cost rapid screening method for evaluating materials using available low toxic simulants. If you noticed on my slide here I have Phase 1. We went to a Phase 2 because the results

of Phase 1 were favorable, and so we decided to expand our research. I'll elaborate more on the details of Phase 2 later on in the presentation.

Some of the accomplishments of Phase 1 is that we have identified four simulants that can be used to simulate the permeation effects of GB and HD. As you can see, you have DCH and CEPS for HD simulants and DEMP and DIMP for GB.

Next, after identifying the simulants, we developed a test procedure for using the simulants. Basically this test procedure could be used for TICs as well, toxic industrial chemicals, as long as they are liquid. And you would go ahead there and test the permeation resistance of materials with TICs using this particular method.

Uses of new cell design that is developed and it could be used to test hard materials and soft materials up to 1 centimeters thick. The technique is called the flooded cell technique. And what happens is you go ahead and you put the challenging chemical, you flood the entire surface of the specimen inside the permeation cell.

Next what we did is we developed a

written test method which describes the procedures, the test equipment, data analysis techniques. Also included in this is mechanical drawings of the permeation cells. So when it becomes available, stakeholders can go ahead and manufacture the permeation cell and perform testing in-house.

Eventually we, our goal is to have it published as an official NIOSH-numbered document. Right now, we have it, it's in the peer-review process that's been initiated. And also what we're going to do is perform some verification testing to follow the test method and perform some verification test method.

If these turn out favorable, we're going to go ahead there and before it's published as an official NIOSH document, we plan to have it put up on the NIOSH websites, provided that the tests are favorable and we don't see any major problems with this test method. We figured we'd maybe have an interim draft somewhere around July of this year.

The project goals for Phase 2 was that we want to improve estimation and reliability of the flooded cell technique by testing additional

simulants with other barrier materials and determine the quantitative relationship between the flooded cell technique and the conventional loading.

The conventional loading was that 10 grams per meter squared where they just put droplets on the test specimens.

Also the project goal was to determine chemical warfare agent simulant adsorption/desorption of representative barrier materials. This would be beneficial in the area of decontamination. We could use a lot of this data for that.

Other project goals is to identify critical properties of permeants and barrier materials that control permeation. We're looking at things like density, cross-sectional areas of the chemical and the polymer material.

What we're going to kind of try to do is look at these certain key characteristic features of these materials and of the permeant or the challenging chemical, and from the material find out what features are desirable in the materials where you could just go ahead there and try to select off

of, you know, these physical characteristics and chemical characteristics of the material, and, just by doing some literature search.

And that would eliminate a lot of trial and error at first. And then you could go ahead and perform this, the testing using the simulants. And then ultimately you could probably test the material against live agent. But again, this method is great for doing a screening evaluation.

The project status, Phase 1, we completed all those, we had the written test method, so all that's been accomplished. And now we're going through the peer review.

Now we're on Phase 2 and the project status of Phase 2 is that we selected some more materials. As you can see, these are the materials that we were going to go ahead there and look at.

And also there were some preliminary comparison testing done with the flooded cell versus conventional loading with DIMP and DCH on butyl. And what we found was that the breakthrough times were essentially equal. Now, that's initial break. That is not full-state permeation.

In summary and conclusion, shown are the major accomplishments of the chemical warfare agent simulant project. Just to review them again, we developed a rapid, low-cost laboratory procedure that can be used to estimate chemical warfare agent permeations through barrier materials.

We identified four chemical warfare agent simulants for permeation tests so we can use them as testing. Developed the written test method that describes equipment, test procedures and data analysis techniques. And again, this is under the peer-review process that's been initiated.

Also we initiated Phase 2 of the chemical warfare agent simulant process.

At this time, I just to emphasize that NIOSH nor RDECOM does not guarantee that simulants identified will be suitable for all materials, nor does passage of the manufacturer's pretest with simulants guarantee passage of the official NIOSH certification testing.

So again, this is the tool to help the manufacturers to go ahead there and do a lot of prescreening and test the barrier materials that

they're going to be using in their personal protective equipment to see how it would resist agent permeation.

So at this time I'll address any of your questions or concerns.

MR. SAWICKI: Jack Sawicki of GlobalSecure.

I urge you to use some more polymers beyond the ones you're doing because the multi-laminate film protective materials, if you get polyester nylon, there's a whole long list of films that may react differently to the different simulants than they do with the agent, and you should try to correlate that data with each of those individually.

MR. PALYA: Do you have any in mind or particular that --

MR. SAWICKI: Polyethylene, nylon, polyester.

MR. PALYA: Right.

MR. SAWICKI: And you can go a whole long list. If you look at some of the patents for mulit-laminate films that are out there, do some

analysis of the suits that are in the marketplace, Saran, there's a long list of them, but --

MR. PALYA: Right. I think in NADIC (phonetic) at this time they're doing -- there's a parallel study going on up there also looking at the suit materials.

But we're tying to get a range of materials, so I hopefully it will cover. I mean it's going to be tough because there's a lot of materials out there. But even if we could start blocking certain materials off of certain simulants and learning each step of the way, it will be beneficial to all.

Jay?

MR. PARKER: Jay Parker with Bullard.

You showed two simulants each for each one of the test agents.

MR. PALYA: Yes.

MR. PARKER: Is there a benefit to using both or all four simulants or just two, you know what I mean?

MR. PALYA: Yes. What we found out is that with the nominal, on sometimes that, as you see

here GB, the DEMP, originally we thought that was going to be two simulants, the DEMP and the DIMP would be good for GB, to simulate GB.

And as you see, DCH and CEPS was for the HD. But then after looking at the data, we found that sometimes the DEMP may behave just like mustard, okay. So what was recommended was that if you go ahead there and test with those simulants, that the agent would fall in somewhere in between the mustard simulant and the agent simulant.

MR. PARKER: But you have a better assurance of performance by using both simulants for each one of these classes than just one.

MR. PALYA: Yes. Yes.

MR. PARKER: Thank you.

MR. PALYA: Okay. Thank you.

MR. SZALAJDA: I think to some extent calling this a summary is a little bit of a misnomer because there's some other topics that we wanted to address as part of the meeting and I'm going to cover those first.

Back in October and also was identified in Federal Register notice that part of the

information that we're currently soliciting is a confirmation of the schedule that we're currently following for the development of the CBRN and respirator standards.

Following the completion of the PAPRs, we intend on moving through the integrated systems closed-circuit supplied air. And then following supplied air, if there's anything else left over, then we would address that at that time.

Whether you'd be willing to make a comment here or submit something formally to the docket regarding the schedule, we would appreciate your feedback.

The initial response from the responder community in terms of identifying the SCBA and then the gas masks, those have been accomplished. So at this point we're moving forward. And any input that you folks in the community have regarding the schedule would be appreciated.

A second topic that's come up and we're going to be addressing here in the short term is a potential field retrofit for the gas mask for the APRs. It's come to our attention along the same

lines with the, with what was done with the SCBA program that the user community may desire upgrades of items that, which may have been purchased over the last couple years in response to the events of September 11th in providing for homeland security.

Now that we have standards in place for the gas mask to potentially look at developing a program to allow those systems to be upgraded to meet the CBRN requirements. Our intention is to develop a concept paper for the retrofit program and post it on the website by the end of May.

And I think for those of you that have tracked the development of the retrofit program for the SCBAR approach to the APR concept is consistent with what we've done with the self-contained apparatus.

I think primarily we're looking at the items that have been in service for less than five years, that this seems to have been a good break point for both the manufacturers and the users with regard to facepieces that could be readily upgraded to meet the CBRN configurations.

Another feature that we see as part of

the retrofit program is to allow the retrofit to be performed by a manufacturer-certified technician, whether it's the manufacturer themselves or one of their representatives that they've certified to do the retrofit.

And again, in looking at the design configuration at what is upgraded, the field item that is upgraded would need to meet the physical configuration requirements of the original CBRN certification. So that, you know, your two-year old mask has the same physical configuration as the item that's passed the certification testing.

I think in summary, I hope our presentations have been helpful to you, you know, with regard to some of the technological issues that we're trying to deal with here in terms of developing the conceptual requirements for the PAPR.

I think in summary, I think this hits on some I think the unique perspectives and the unique technology challenges that we're facing in terms of how we're developing these requirements. I think, obviously, I think from what you've heard and the

dialogue that you've provided today that how we address the flow situation with the PAPRs is going to be very critical in terms of developing our testing, our certification testing capabilities, whether we look at high flow testers and the development of high flow test testers that can be used within a community or if we use existing protocols and come up with other procedures for allowing us to use existing protocols.

I think something that is somewhat novel with this system when you look at the hazard protections, I think the stacking, having the possibility for stacking of protections opens up a lot of options for both manufacturers and users.

As I had mentioned earlier in my remarks this morning, you know, we've seen with benchmark testing and certification testing done on other canisters that we may be doing a disservice to the capability, the CBRN capabilities of some of the canisters. And I think through the use of the stacking provision that it will allow manufacturers to fully be able to quantify the capabilities of their items and enable the users or provide the

users of the equipment some capabilities of, or additional knowledge of the capabilities of the systems.

And some of the things that I'd like the community to think about as well as we move along, and I guess the one thing is we try to learn from our lessons as we've developed all these standards, but I think with the PAPR, I think at least right now we can envision there's going to be some very unique application content constraints that will be required in terms of the packages that we receive for consideration in the certification program.

One of these things gets into the labeling requirements, you know, where we're dealing with stackings, you know, we're developing an alphabet soup associated with how the items are labeled. And one of the things that would be of benefit to us is to get the feedback from the community as far as how to make that as user friendly as possible.

Another aspect in looking into labeling is the specific component labeling. We're looking at the batteries and other accessories for the

system, how best to accomplish that as we move forward.

I think in terms of the quality control plan, it's pretty apparent to us as a result of testing that we did that there's some, there's going to be a need for some engineering controls over how we handle uniformity, either in the canister or in the manifold. And we'll be looking for your feedback with regard to those characteristics.

But one of the things that we anticipate that we'll be seeing as we move forward and the types of information that we'll require in terms of the quality control plans, we'll need to address uniformity.

And where we see ourselves moving ahead, we're going to continue to use the concept paper as a means of sharing our ideas with you. At this point, you know, given the 30-day cycle for you to make comments based on the information that was presented today, I'd envision that probably within 45 to 60 days we'll post the next generation of concept paper based upon your comments with regard to what we presented today, as well as ongoing

testing that we're currently doing either within NIOSH or with our partners.

And again, one of the things that we really want to consider is our stakeholder relationships, our relationships with the manufacturer, our relationships with the other standards organizations as well as with the user community.

And, you know, obviously when we've talked about the formal approaches in terms of docket submissions and public comment, and I also wanted to assure you that if you have proprietary data that you would like to share with us for considerations with regard to the requirements, then NIOSH will respect that proprietariness of the information and not make it part of publicly available material.

I think the long, the critical path in our view with the upcoming benchmark testing is going to be addressing the high-flow-type testing with the availability of testers to provide high flow at the proper loading characteristics versus the equivalent velocity-type of approach.

And in looking at the time frames for accomplishing the work, that's definitely on our critical path with regard to moving ahead and getting the standard done in a timely manner. So I think this is an area where any and all expertise available in the community and input with regard to existing capabilities and what could be developed in the short term would be definitely appreciated.

I think you heard, and one of the approaches that we wanted to share with you today was our time lines for conducting benchmark evaluations and give the community a flavor for when you could expect to see results of our testings from doing the different evaluations and that we're going to be moving forward with our benchmark evaluations for the gas and vapor testing with the chemical warfare and LRPL, the battery performance.

I think you can appreciate that probably the time frames that were generated for those types of applications are probably fairly realistic given the state of technology and the type of testing that would be required.

Really the key to trying to meet a

December release of the standard is going to be completely contingent on addressing and resolving the testing at high flows issue. If that can be resolved within a timely manner within the next few months, then December is a realistic date.

If the administrative procedures for getting equipment and getting contracts in place prove to be more difficult than we expect, then that date is going to have to be flexible. But that's our target.

And I think over the next couple of months we're going to get a better realization of the feasibility of actually having a standard ready for release in December.

And again, that's something where we would appreciate your inputs. If there are things that you're aware of from a technology standpoint that you would think help us address some of the issues that we raised today, we'd appreciate hearing about that because really the intent behind generating the standard is getting this type of protection out to the responder community as quickly as possible. And to that end I think it's in our

best interests to provide that type of effort as we move forward.

Again, I think we envision probably having another public meeting, hopefully sharing our benchmark data with you for what we've developed over the summer, probably in the September time frame. We'll try to be sensitive to the scheduling of that meeting around any other national conferences, whether they be hygiene shows or an FPA or any other of those types of conferences that may be going on in that time frame. But we think late summer, early fall would be what we're targeting for our next public meeting.

And again, this is information that was in your packet this morning. We would appreciate any and all comments, whether they be public or if you prefer private, because our standard is only going to be as good as the combined efforts of our team, not only the government team working on the development of the requirements but our stakeholders and all our partners.

So with that, I think I'm finished.

I'd like to invite Janice Bradley up to

make her presentation. And upon the completion of Janice's presentation, if anybody else would like to -- has a presentation, if you can let me know, otherwise we'll have our open comment period.

MS. BRADLEY: If you've had PowerPoint overload, you can just rest and listen to my droning voice put you to sleep as I proceed toward the end of the day.

My comments are based on the April 1st draft. And I've tried to edit them appropriately based on the comments from the NIOSH staff and their partners that were presented for us today. If I didn't edit out all the issues that were answered, forgive me, but, anyway, I'll proceed.

I am representing -- my name is Janice Bradley. I'm the technical director at the International Safety Equipment Association. It's the leading organization representing manufacturers and suppliers of personal protective equipment and apparel.

We offer the following comments in response to the NIOSH concepts for CBRN PAPRs.

Regarding the scope, in the April 1st

concept paper, in paragraph 4 of this section specifically mentions only tight-fitting and loose-fitting facepiece designs. We believe that this proposal should include hoods and helmets, which have not specifically been referenced.

The definitions as provided in the concept paper exclude PAPRs with loose-fitting hoods and helmets from CBRN applications. Loose-fitting respirator inlet coverings have many benefits over a tight-fitting mechanisms and should be included in the standard.

The definition for respirator inlet covering should be changed to include hoods and helmets with neck dams. And NIOSH should include the following definitions for these devices in Section 3.1 of their concepts: Hood being a respirator inlet covering that completely covers the head and neck and may cover portions of the shoulder.

A helmet is a hood that also provides protection against impacts and/or penetration. And loose-fitting facepiece is a respirator inlet covering. It is designed to form a partial seal

with the face, does not cover the neck and shoulders, and may or may not provide head protection.

The statement in, which I quote, "ensures that only purified air reach these areas," unquote, should be removed as this information offers no discussion as to whether the PAPR is turned on or not, implying that the PAPR must do this even when it is turned off, thus requiring fit tests by all users.

Regarding respirator use as currently stated in item C does not require that filtering elements be discarded after use. Once the cartridges have reached their end of service life or when used for even a very short time against chemical warfare agents, they should be discarded.

NIOSH should define the term "use" and require that a change schedule be established by the user similar to what is required by the APR CBRN standard.

The language regarding liquid chemical warfare agent, which is I believe item D, should be consistent with other CBRN standards, specifically

the following CBRN APR language should be incorporated into the CBRN PAPR draft, quote: "The respirator should not be used beyond eight hours after initial exposure to chemical warfare agents to avoid the possibility of agent permeation. If liquid exposure is encountered the respirator should not be used for more than two hours."

Regarding the section on hazards, NIOSH should not imply that devices certified to the standard provide protection only against the 139 respirator hazards identified as potential weapons of mass destruction. Based on the testing against cyclohexane these devices will be at least as effective as -- against organic vapors with a vapor pressure less than cyclohexane even if that organic vapor has not been identified as a possible chemical warfare agent.

NIOSH did not indicate the respirators under this approval category are not effective against them. We suggest rewording the statement to, and I quote, "Testing against these 11 TRAs ensures that the respirator provides protection for the 139 identified potential weapons of mass

destruction, respirator hazards and other organic vapors."

Regarding respirator containers, I believe it's Section 511 requires that CBRN PAPRs be equipped with a container bearing markings which show the applicant's name and the type and commercial designation of the CBRN PAPR on all appropriate labels.

Manufacturers view this requirement as a significant change in existing NIOSH policy and seek specific rationale for this requirement if it is indeed retained in the final version of the standard.

Regarding labels, manufacturers believe that the language in Section 521 may be confusing to the user and that NIOSH should provide additional examples of other suitable locations for clarity's sake for the user.

Regarding the low-flow indicator, this is a function of the motor battery and particulate loading, not the gas loading of the canisters. And as written, this could give users a false sense of security that saturated canisters are still usable

by simply relying on an indicator to leave the area.

Regarding operational controls, while we agree with NIOSH on the importance of readily accessible, better protected switches and controls, it would be difficult to evaluate this requirement for product certification. What is immediately accessible to one person may not to the next.

We suggest that NIOSH eliminate this requirement because this is a feature that needs to be determined by the user and ultimately becomes a market-driven issue.

Regarding breathing performance, the transducer response time is not indicated. The two machines identified have two different transducers specified between NFPA and NIOSH. And the NIOSH version is faster than the NFPA version. These details need to be addressed before a final standard is published and NIOSH indicate these requirements that apply to only the CBRN PAPR requirements and not all PAPRs.

Regarding the respirator inlet covering lens haze luminous transmission and abrasion

requirements, manufacturers note that abrasion resistance was lifted out of the full facepiece specification. And it should be modified to include a different provision for hoods based on the materials used for hoods or eliminated altogether.

ISEA believes that manufacturers should not provide the abraded samples. And this is Section 564. If it is indeed to be performed by third-party testing, NIOSH or its designee should be the party that is abrading the samples that are supplied by the manufacturer.

Regarding noise levels, manufacturers request that NIOSH explain the rationale used to reduce the noise level from 80 dba to 75 given that the noise level in 42 CFR is 80.

Regarding canister capacity, we recommend that NIOSH delete the reference to ppm per minute as this will confuse most people reading the standard. It does not provide any useful information to the concept paper.

On Table 3 of the concepts, NIOSH has identified the peak flow rate for two types of CBRN as the basis for determining the flow rate to be

used for canister capacity testing. NIOSH should explain the rationale behind the choice of 87 percent of this value or the constant flow rate of the PAPR, whichever is higher, as the test flow rate.

Despite the absence of rationale for this value, it is not clear why they are needed at all. It seems more appropriate to use the constant flow of the blower as the flow rate.

NIOSH should not have to specify the minimum flow rate for the test if the flow rate of the blower is sufficient to pass the NIOSH positive pressure test and the LRPL test. It becomes a design specification rather than a performance specification which should be eliminated.

ISEA also questions the choice of flow rates selected for the demand response of PAPR. It would be more appropriate to test the unit at the maximum designed flow rate. Essentially the user flow rate of these devices is unknown to NIOSH. The only way to ensure that the capacity is sufficient is to use the maximum flow rate of the device.

ISEA also requests the details of the

test procedure based on STP 0012 as noted on page 9 specifically clarifying the terms stacking and family capacity as they are referred to in the TRAs.

The current text for adjusting the flow rate based on the number of air-purifying elements should be changed to, and I quote, "The filter canister capacity airflow rate shall be divided by the number of filter elements used on the PAPR."

Regarding particulate and aerosol canisters, Section 633 should be revised to read, and I quote, "When the canisters do not have separate holders and gaskets, the exhalation valves shall be blocked to ensure that valve leakage if present is not included in the filter efficiency level evaluation," unquote.

PAPR filters and canisters do not generally have values on them. The values are present on the facepiece.

And regarding the panic demand provision, PAPRs should not be different than the CBRN full facepiece APR devices. In the APR statement of standard the flow rate used is 100

liters per minute, 50 percent relative humidity plus or minus 5 percent, and 25 degrees C plus or minus 5 degrees, for each of the gases and vapors tested.

This requirement is not applicable as a test flow because if the wearer does not need the amount of air, all of it's not going to be drawn through the cartridge. This is particularly true of loose-fitting hoods and helmets.

Regarding communications, the proposed communication test is the same as that for the CBRN full facepiece APR, but does not take into account that there will be four CBRN PAPRs running at the same time in the test room. This additional noise should be included in the steady background noise of the 60 dba consisting of the broad band pink noise.

Chemical agent permeation and permeation resistance against mustard and sarin, this section should specify whether the CBRN PAPR is running during the test. The PAPR is off. The proposed test airflow rate is appropriate for moderate breathing rate PAPR but not for high breathing rate PAPR because the high flow rate could affect vapor permeation. This PAPR should be tested at the

higher flow rate during the mustard and sarin chemical gas tests.

Regarding the laboratory respirator protection level test requirement, manufactures believe that the APF of 10,000 for this test is excessive. The required LRPL of 10,000 could eliminate hoods without a neck dam.

And our market data indicates that first receivers and many -- which are many of hospital personnel, prefer these loose-fitting types of equipment. If these devices were eliminated, the vital needs of the first receiver communities will not be addressed by the standard.

Loose-fitting hoods and helmets are most likely to be provided in just one size. This criteria needs to address the panel requirements when the respirator is provided in only one size.

Durability conditioning, the final note of Table 7 should more clearly state that the low battery indicator must still work after conditioning.

Practical performance requirements that were added, NIOSH needs to define acceptable

practical performance and how they plan to measure this requirement. The inability to accidentally turn off the respirator is very subjective and could be very dependent on the test subjects chosen.

The requirement for identifying the inability for hoses and electrical wires to tangle causing the respirator position on the wearer to move to an improper position such as the respirator facepiece or the hood being removed from the wearer's head will be captured during the LRPL test and therefore is not necessary. And we recommend that NIOSH delete this language altogether.

Before NIOSH finalizes this concept, the other factors that NIOSH plans to evaluate under this practical performance heading must be identified and the test procedures written and reviewed by stakeholders. Many of these items of practical performance are design features that the purchaser evaluates when selecting a device and should not be evaluated for product certification.

Regarding cautions and limitations, they need to be established and reviewed by stakeholders before the standard is published instead of being

finalized as NIOSH is accepting submissions.

And I thank NIOSH for having this meeting today and giving me the opportunity to provide my comments. Thank you.

MR. SZALAJDA: With that, at this point in the program, I wanted to open up the microphone in the center for any comments from the floor regarding considerations that you think we should be addressing in terms of the concept as well as any of the information that we discussed today.

MR. HEINS: Bodo Heins from Draeger.

I learned today that you will require the maximum which is available for the PAPRs. But you shouldn't forget the costs. If you require too much, the cost of the respirator will also be very high. For example, the abrasion test, it came from the APR. But if a PAPR is perhaps only a single use unit, so it makes no sense to have this requirement.

MR. SZALAJDA: Thank you.

MR. DUNCAN: Paul Duncan, Scott Health & Safety.

The comment, first I think it's a very exciting, interesting time to be a manufacturer of

respirator equipment. A lot of these standards are driving a lot of things that normally wouldn't have occurred.

I have to raise just this general comment. I would encourage us to, as we look at the standard development, to think, instead of terms of what is best in class, to instead think in terms of what is needed by the user.

I think by reviewing some of the best in class and picking that as a standard, we are eliminating access to certain technologies that quite simply do the job and do the job well and have been proven to do the job well over a number of years.

I think we need to review -- I applaud NIOSH when they were developing certain elements of the other standards like the fit factor requirement for the escape hood by using a scientific method to say, okay, based on sarin exposures, we're going to determine the fit factor levels in the oral-nasal region to be this and for ocular exposures to be -- the fit factor to be this.

I encourage you to continue to use that

kind of science, you know, to further the work that Mr. Caretti's doing to determine flow rates and really base the performance standards on what is needed to protect the user instead of what is necessarily best in class. Thank you.

MR. THORNTON: Thank you, Paul.

MR. BERNDTSSON: Goran Berndtsson, The SEA Group.

I'm going to respond to that. And one of the problems with flow rates and accelerated flow rates, what David said this morning was that he didn't see any significant difference in speech as compared to maximum hard work rate. And that is absolutely true.

Then you come down to very low work rates. You have an enormous increase in speech. So the peak flows of speech and low work rate is significant. So I think that what we're doing here is actually writing standard (inaudible) that's just being able to communicate, doing the hard work as well as doing simple, not-too-hard work and still communicate and be part of a group or team who need to do things out in the work rate.

So it is difficult to kind of looking for a lower level of peak flows because you don't limit it. So even these people who's the medical people actually who's going to communicate with potential harmed persons has to think about the possibility of speaking. Even when they're not working hard, they will be having some significant peak flows.

MR. LINKO: Bill Linko again. (Inaudible).

I'm on the staff of the Loma Linda (inaudible) radiation center. And most men will probably have prostate cancer in their lives. And if that happens to you, we'd be more than happy to answer any questions concerning their protocols. And they're very effective protocols.

Getting off that subject, Micronel U.S. is a manufacturer of fans and blowers. And in a nutshell, we have capacities up to 1400 liters per minute or 50 cfm at zero pressure; pressures up to 5,000 psa or 20 inches of water at zero flow; cfm per watt up to 50.

We also have motor operation goes from 4

millimeters to 100 millimeters, both brush, brushless (inaudible). So if we can be of aid to you, be more than happy to do so. E-mail Micronel.com.

Thank you.

MR. HASKELL: Bill Haskell from Battelle Natick Operations.

In reading the front page of the concept paper defined the cold, warm and hot zones. And one thing that sort of confused me in reading it is depending on the event, whether it's a warfare agent, industrial chemical or biological threat, one event's hot zones might be totally different than another event hot zone.

And then it goes on to define where you would wear an air-purifying respirator. And I think that just sort of sets a tone that sort of confuses you when the use of the respirator maybe should be depending on the incident and the type of threat. And you're sort of steering you away from a hot zone. And in a biological incident, you know, maybe you can use these types of protective equipment.

MR. SZALAJDA: Thank you.

MASTER SGT. AVERY: Master Sergeant Avery from CBIRF.

And we of all people appreciate what NIOSH is doing. However, we do wish we would continue in the area of higher flow rates, somewhere around 150 and above.

MR. DUNCAN: Paul Duncan again.

Something that's been touched upon a couple times in this meeting is we started discussing flow rates. But I don't see a move to really address it. And we may not in the standard. I see a gap on our thinking where we fail to address what happens to the end user, what happens to protection if there is no battery or the battery fails or if the user is in a situation where the battery runs out.

You know, we've done a lot to move toward, distinguish between constant flow and breath-responsive PAPRs. But we're leaving the whole concept or the whole wide difference between tight-fitting facepieces and loose-fitting facepieces totally unaddressed.

I'm not sure if some of the test

standards and test procedures that come out will make more distinction between the two. I hope they do because I think we may be doing a disservice to the end user community to not address that issue specifically and maybe call these out and you call a separate class or have certain tests to make sure there are distinctions between how these products protect the user.

MR. SZALAJDA: Thank you, Paul.

Anyone else at this time?

(No response.)

MR. SZALAJDA: Well, I think I definitely agree with the one comment that I heard that it is a very exciting time to be working within this technology. And I encourage you to continue to let us know of your concerns and things that you think that we should be aware of as we move forward.

And thank you very much for attending and we'll look forward to seeing you all in the fall.

(At 3:25 p.m., the public meeting was concluded.)

REPORTER'S CERTIFICATE

I, Eloise L. Hess, do hereby certify that the foregoing 229 pages are a true and correct transcription of my stenographic notes taken at the above-captioned NIOSH/NPPTL Public Meeting on Tuesday, May 4, 2004.

Eloise L. Hess, Reporter

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