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

Wednesday, December 15, 2004

CONTINUED DISCUSSION for Concepts of Powered Air-Purifying Respirator (PAPR) Standards and Introduction of Concepts for Closed Circuit, Self-Contained, Breathing Apparatus Standards Development Efforts Used for Respiratory Protection Against Chemical, Biological, Radiological, and Nuclear (CBRN) Agents

Commencing at 8:32 a.m. at Sheraton Station Square, Pittsburgh, Pennsylvania.

PROCEEDINGS

MR. BOORD: Okay. You know, to start the meeting, I just need to relate a little experience here.

About a month ago, my son -- my son got married, so we had the traditional elaborate wedding. I was in Doylestown, Pennsylvania.

So -- so we had the, as I say, the traditional wedding where we had the ceremony. And then about an hour, hour and a half later, we had the reception.

So we went through the ceremony, and everything was fine. And I need to put a plug in. My two little grandchildren looked really spectacular at that wedding.

But then we went from the wedding to the reception.

And we were all meandering about in the reception shaking hands and talking and having a good time, and there was this one couple that was there that seemed to be off to the side.

And so we went up and started talking to

them. And it turns out that they were in the right place for a wedding, but on the wrong day.

So we made sure that they did participate in the reception and had all of the goodies and so on and so forth.

But in that spirit, I would just like to make sure that everybody realizes that we are here today for the public meeting to discuss powered air-purifying respirators and closed circuit self-contained breathing apparatus.

So if anybody is in the wrong meeting on the wrong day or at the wrong time, now is your chance.

Obviously, the opening remarks are reserved for Rich, and I need to extend a -- an apology for Rich. He had another commitment that there was no way to change it or otherwise I'm sure he would have been here. So I would like to extend the regrets for Rich.

And also to again re-emphasize that the purpose of the meeting today is to discuss the concepts that we have relative to powered

air-purifying respirators and closed circuit self-contained breathing apparatus for CBRN applications.

The spirit of the meeting, as with past meetings on these topics, is one of information presentation. So the concepts in the draft requirements that you have been looking at on the concepts on the website will be presented and discussed.

In addition, some of the work that has transpired in recent weeks and recent efforts will be discussed as well, and we do encourage the exchange.

As I have said previously at these types of meetings, the exchange is very, very helpful. And as we go through the process of identifying draft requirements and developing those requirements, the information exchange and dialog is certainly a critical part in bringing the requirements to a proper perspective.

Another topic I just want to touch bases on is there has been quite a bit of discussion

relative to how these requirements and standards will be implemented.

Those of you who attended the public meeting that we had on total inward leakage several months ago, the discussion and explanation on this -- in this area really comes down to the point that at this point in time, the department is not 100 percent sure which of the alternatives available for doing this will be followed, and those avenues are constantly being reviewed.

But the important part of what we are doing is that the technology and the technical portions of developing the requirements doesn't change.

And that's where we are right now. We are in the process of identifying draft requirements and developing those requirements to an acceptable point.

So I think we want to keep that thought in mind as we go through the process today and continue through the meeting.

So to close out the welcome and the

welcome to cold and snowy and icy Pittsburgh, I just want to restate that the purpose of the public meeting is to discuss the draft concepts for the CBRN powered air-purifying respirator and to present the CBRN closed circuit self-contained breathing apparatus draft concepts.

Thank you.

MR. SZALAJDA: Good morning. My name is Jon Szalajda. I'm currently the team leader for the CBRN standards development programs at NIOSH.

And at least far as we have a -- in telling you what we are going to do today, we have a pretty ambitious agenda that we are going to try to follow. And it may take a little longer or a little shorter, depending on how long-winded we get and the type of questions or comments that you in the audience may have.

What we are going to focus on through lunch time is to address the requirements that are currently being considered for the CBRN powered air-purifying respirator, the PAPR.

There is a couple of things that we

wanted to cover this morning, and you will have to forgive us if we jump around a little bit in the agenda.

One of our speakers, Terry Thornton, has the flu, and we felt it was best for him not to present a biological hazard to you during the course of the meeting today. So he is at home recovering.

And Dave Caretti was feeling a little under the weather yesterday, but I see he is here, and he will give his presentation later on this morning. We thought we might have to jockey that around a little bit.

But we plan on running through lunchtime. And then after lunch, we will wrap up the PAPR as follows, at least as far as dealing with some of the tests and the provisions that people who are involved with the CBRN program are familiar with, with how we do environmental -- are planning to do environmental and human factors type evaluations as well as special CBRN tests.

And following that portion of the meeting

at the end of the day, we are going to introduce our concept for the closed circuit self-contained breathing apparatus, and that discussion will be led by John Kovac, as well as input from Frank Palya and Nick Kyriazi of NPPTL.

As far as some of the logistics are concerned, I think everybody either had preregistered or signed up on the way into the conference area this morning.

If you didn't, if you could please see Betty Robey or Marlene at the table outside the conference room at some point during the day to make sure that you are registered.

The meeting is being recorded. Copies of the transcript will be available through the NIOSH docket office at a later date.

And for the most part, with the exception of me presenting for Terry Thornton, we are going to run through the agenda as it's currently provided.

After each presentation, there will be an opportunity for questions and answers as well as

comments from the attendees. And we would ask that you come up to one of the microphones in the center aisle and introduce yourself and any organization you represent and then make your comment.

There is also going to be a couple of opportunities during the course of the day for presentation -- or for public comments, any comments that individuals may have for the docket, as well as opportunities to make presentations.

I wasn't aware of any -- at the start of the meeting, I wasn't aware of any individuals that wanted to conduct a presentation today.

If you do have something you would like to present, please see me at some point during one of the breaks, and we will work to accommodate you during the opportunities for public comment.

Administratively, there really aren't too many details with where we are. There will be two breaks during the course of the discussions. There will be some light refreshments provided at the back of the room.

As far as lunch is concerned, you are on

your own. Fortunately, with the location of this meeting, there are a lot of opportunities either in the mall across the street or with the different restaurants up and down the concourse for you to find something to eat.

The restrooms are around the corner going back towards the lobby.

Other than that, I think it's pretty -- today's meeting is pretty simple as far as logistics.

As far as formal comments that you might like to provide to us through the NIOSH docket office, here is several different ways for you to get in touch with us.

One thing I did want to note and make sure that -- and you will hear it from me again at a couple of points during the day.

There are two different control numbers used for collecting the comments to the docket for the PAPR. The control number is ten. And for the closed circuit self-contained breathing apparatus, it's 39.

So depending on the comments that you may have regarding our concepts, you know, please make sure you reference the right docket number.

And I think in general, we usually begin the presentation talking a little bit about the processes and some of the background information related to the standards development.

And today I wanted to spend a few additional minutes to discuss some of the historical background of the standards development program, in particular paying some attention to how we did the vulnerability assessment as well as the selection of the test representative agents.

I know for some individuals, you know, that have been consistently attending our meetings, this is old information. But, you know, in light of the public becoming more and more aware of the CBRN standards and with their adoption and other -- by other federal or private organizations as standards for equipment, we feel it is appropriate to, at this time, to go over and briefly discuss some of our rationale that was conducted early in

the program just so that everybody is back up to speed with the -- with the process that was used to generate the requirements for the different standards.

But in the beginning, which I guess there are some other things that start that way, but -- there was a need -- there was identified a need within the stakeholder community, the respirator stakeholder community, for coming up with a new set of requirements for respiratory devices.

And this was based on the fact that in an evaluation of the potential respiratory hazards, that responders could see that neither NIOSH industrial respirators nor military respirators completely met the requirements for protection for responders in dealing with a CBRN terrorism event.

And in looking at the -- in focusing our efforts, there were really some very obvious differences between the industrial respirators as well as the military respirators. And they fell into five main categories: Purpose, the user groups, the hazards, how they were used in

operation, and then the protection that the respirators provided.

And in looking at these types of protections, the hazards -- the hazards and what the responders would see fell in between what the military may see in a battlefield situation, when you are dealing with uncontrolled, uncharacterized events, and what NIOSH would see in terms of an industrial respirator operation where hazards are known and controlled and quantified.

And part of our effort was to come up with a process that we have consistently used throughout the development of all of our respirator standards.

The key, up front, was to do a comprehensive hazard analysis, which we did, in conjunction with the old Army Soldier Biological Chemical Command, now the Research Development and Engineering Command.

We looked at the protection levels that would be required for responders, you know, whether you were working -- you were dealing with an IDLH

or above-IDLH type of event, or in a type of event where the hazards were a little more known and controlled, and you were in an area where respiratory protection was required, but the benefits of having a self-contained unit weren't necessary.

We also saw as part of our evaluation the need to identify specific requirements to ensure a degree of ruggedness for the equipment.

And in this case, we looked at human factors types of requirements which addressed the ease of wearability for the systems with the potential users as well as environmental factors, trying to anticipate a wide range of storage and transportation conditions that the respirator could potentially see as part of its use.

We have also incorporated something called a standards concept, where we share with the stakeholder community via the internet our current thoughts as far as what the requirements of the standards would be.

And this document is available either,

you know, through the internet, or we have made copies available at the public meeting. And you should have received copies of our current concept paper with your information packet when you entered the conference today.

But the standards concept has been very important for us because it provides an opportunity for the stakeholders to give us real-time feedback to what we envision the requirements to be, whether you think that we are on track or off target or if there is other aspects of the requirements that you think we should consider as part of our process.

And in conjunction with that, we looked at the requirements for how we are going to certify these systems and -- once the standard has been fully defined, test requirements with regard to, you know, the actual requirements that we will be evaluating and using standard test procedures as part of the certification program.

Also doing research where it is appropriate to fill data gaps, where the data may not exist between the stakeholders involved in the

process, and focusing our research and applying it to helping us define the requirements for the standard.

And finally, we have really tried to promote doing the standards -- standards process in its most visible and public means as possible. This is, I believe, the sixth public meeting we have had related to the CBRN standards development program.

NIOSH has also done other public meetings with regard to the Total Inward Leakage program as well as some of the efforts on the industrial respirators.

We have tried to make extensive use of the internet as far as using that tool as making -- making the information available to the stakeholders for your consumption and your comment, and we will continue to do that as we go forward.

We also really encourage you to come in and speak with us individually if that suits your needs better, that our door is always open to the stakeholder community to come in and share ideas

with regard to what the requirements of the standards should be.

And this effort has been ongoing for a few years now. The very first meeting was conducted on a similar day in Morgantown back in 1999. I think there was a little more snow involved with that event.

But the whole focus of this chart is looking at partnerships and the fact that we at NIOSH have realized that this not -- this endeavor is not something that we can do alone, that we have needed to develop quality partnerships with the manufacturing community as well as the stakeholder community, the users, to fully identify the requirements necessary for these systems.

As well as making sure that we identify the protections levels as well as identifying the technology constraints and helping to do the research that's necessary to bring the technology forward to allow us to have respirators that meet the responders' needs.

There were several partnerships that we

formally established as we have gone forward. I think a couple of the early memorandums of understanding and interagency agreements that we established were with the National Institute for Standards and Technology, the Army, Occupational Safety and Health Administration, and also with the National Fire Protection Association, the NFPA, who as a standards development activity has been very instrumental in working with us in the development of standard requirements.

We have also received a lot of resource requirement support along the way. Initially through seed funding provided NIST by NIJ and now the Department of Homeland Security, as well as funding through Centers for Disease Control to allow us to complete our standards development effort.

Another thing that I think is very unique for this program, for those of you who have been working with NIOSH for many years, is that for the first time in the CBRN program that NIOSH uses a -- does not do the actual chemical warfare agent

testing or the laboratory protection fit level testing themselves.

These are things where we have contracted and established a relationship with RDECOM, with the Army at Aberdeen Proving Grounds, to conduct these tests for us. And we really see this as part of the overall strategy for NIOSH as the years go by as the first method for introducing the possibility for third-party testing for doing our certification work.

And I think some of the key things that have come along as part of our process is that the standards that we have developed have been recognized and implemented on a national basis. And in particular, two organizations have stepped up and adopted the use of these standards as part of other requirements.

One is the Department of Homeland Security who, back in last February, adopted the CBRN self-contained breathing apparatus, the gas mask and escape respirator standards, as requirements for consideration in spending grant

money for the purpose of personal protective equipment.

These respirator standards have also been adopted by the NFPA as part of their standard protective clothing standards when you look at the respirator as part of the individual personal protective equipment ensemble. And at the -- the standards there are referenced as part of those ensembles, whether they be for the self-contained breathing apparatus or for the gas mask.

Also part of what we did early on was a comprehensive hazard assessment, which has not only been used for the respirator program, but also has been used by NIST and RDECOM in looking at the overall strategy for developing all types of personal protective equipment technologies, from clothing to detectors to decontamination, the list of programs that are being administered by NIST as part of their arrangements with the Department of Homeland Security.

And in looking at conducting our hazard assessment and the potential respiratory hazards

that could be seen by responders in an event, we determined up front that the chemical warfare agents and the toxic industrial chemicals would represent the most critical challenges that a responder and his equipment may see on site.

And what we identified as part of helping our program move along is a list of 139 potential respiratory hazards that we are not providing protection for as part of the CBRN standards.

And in testing -- as part of the test program, in looking at those requirements, we identified ten chemicals which represent 107 different potential respiratory chemical hazards as well as one particulate test representative agent which represents another 32 particulate hazards to provide the individual protection against a CBRN type event.

And testing against these 11 test representative agents ensures that the respirator will provide protection for these identified hazards and also other organic vapors. And we will talk about that a little bit more in the course of

our presentation today.

The focus -- really the focus of the standards effort early on was to look at completing our hazard assessment as well as doing an analysis of the human factors types of criteria that would be necessary to ensure that the respirators had a degree of ruggedness that would protect the responders at the time that the devices were needed.

And at least as far as a little background regarding our development process that we went through working with the Army and looked at a lot of different multiple scenarios with regard to the dissemination of either chemical warfare agent material or toxic industrial chemical materials.

And what became apparent to us going through the process was that for outdoor events, you have a lot of natural events that are taking place which allow the dispersal of an agent, you know, whether it's environmental conditioning, wind, other activities that would cause the agent

to disperse quickly.

So we focused the hazard assessment on looking at indoor events because we expected to experience higher vapor concentrations because those dispersal factors weren't available to remove the -- to move the agent.

And we looked at -- during the course of the process, we looked at I believe it was 27 to 29 different events where different either toxic industrial materials or chemical warfare agents could be deployed.

And the intent -- and I know people have worked around the most credible event terminology. But the intent of looking at these different scenarios was to establish a concentration that we could use as part of our evaluation process, not necessarily one that reflected the worst case scenario or the best case scenario, but one that we felt a responder could potentially see in dealing with one of these types of events.

And to -- well, I guess I just said that so you -- I won't read this chart for you people.

But where we ended up at the end of that process was that all of the information that we collected was rolled into the first standard that was released, the SCBAs.

And the requirements were based -- in looking at how the requirements were based and the hazard assessment, we developed a three-tier approach that we have carried forward with all our standards development processes for CBRN.

The first is that we look at our requirements identified within 42 CFR, Part 84, for applicability to the standard.

And second, we look at existing national or international standards to help provide the human factors and environmental conditioning protections that we feel are necessary for the respirator.

And in the sake of the SCBA, we found that the tests that were conducted by the NFPA as part of their SCBA, open circuit SCBA standard, fit the bill for what we were looking for to provide that consideration for human factors and

environmental conditioning.

And then the third tier of our process are special CBRN tests.

And in particular, for the SCBA, we looked at establishing two tests. One was testing with chemical warfare agents, which we heard and continue to hear from the responder community that they wanted to be sure that these devices work if they deal with chemical warfare agent scenarios or potential hazards.

The other was a laboratory protection level test which is done at Edgewood for us where we looked to ensure that the respirators provide a degree of fit to the individual as well as provide a wide range -- or fit a wide range of the population. And we use -- currently use the Los Alamos panel for doing that part of the program.

At this point, we have approved, I believe, the current number of 46 different SCBA models, as well as -- from six different major respirator manufacturers, as well as 16 different upgrade approvals where we evaluated kits that

allow fielded items to be upgraded to meet the CBRN configuration.

And the website that is listed at the bottom of this chart -- or you can follow links through the NIOSH webpage -- will provide you a list of those models.

And the second aspect of our standards program was to look at the requirements for air purifying respirators, and we released the standard for the gas mask back in March 2003.

And this project was unique in a couple of different manners that, one, also in response to stakeholder feedback, that we heard a requirement for one -- that there was a need for one canister which provided multihazard protections; that when responders came to an event, that they didn't need to -- or didn't have the time or didn't want to logistically deal with trying to identify or use multiple -- or sort through multiple canisters to deal with the potential hazard.

And the system that was set in place identifies protections for 139 potential

respiratory hazards and the CBRN canister.

Also for the first time that -- with this standard, we established a provision for interoperable mask and filters, acknowledging that NIOSH is still approving systems or approving respirators as a system, this -- by requiring or putting in a requirement, a design requirement in this standard, that we are allowing the potential for interoperability to be conducted on site, where, if you have approved CBRN respirators, that you could use different filters with -- or different canisters with different masks, depending on logistic needs and giving that flexibility to the incident commander and OSHA on site to allow the use of interoperability.

And also with this system, we looked at establishing a crisis requirement to address high physiological flow through the canister.

And we established a requirement to look at excursions for individuals where they may be dealing with a secondary device and potentially higher concentrations of a hazard as well as

addressing physiological demands of the individual where the canister would need to provide protections at a higher work rate or higher work demand that an individual may be putting on the system.

There are two manufacturers that have submitted and received certification on gas masks, and I believe we have three models that have been certified to date. And again, you can identify which models are available through the website link.

And the last set of standards that we released were for the escape respirators. And in this we addressed both air purifying and self-contained types of models.

And this was truly a challenge for us because the focus of who these respirators were developed for was a little different, that these respirators were developed to protect the general working population and not the emergency responder community.

And when you look at potential escape

strategies, there are really a wide range of, you know, how individuals may see the need for respiratory protection as part of their risk assessment that they would need to do in identifying why they need to have respirators in the first place.

And to that end, we ended up developing three different protection levels for the escape respirators: Two related to the air-purifying device and one for the self-contained device.

And in general, if you look at the requirements of the standard, they pretty much track, in terms of the physical testing -- with the test representative agents as well as with the chemical warfare agents, they track what was done for the self-contained breathing apparatus for the self-contained escape respirator, and then the gas mask to support the air purifying types of respirators.

But what is different for us in looking at the protection level for what we call the specific category, is that any of the air-purifying

respirators provide for a degree, a specific protection level which addresses the ten representative agents as well as testing for particulate.

And what we have done is we have allowed the flexibility between the manufacturing community, as well as the user community to increase specific chemical challenges as part of the requirement.

I guess ammonia is a good example, as far as -- ammonia is one of our test representative agents.

And the thought process there was if you lived, you know, next to an ammonia plant, or if you have a business next to an ammonia plant and you feel that is there a need for you to provide respiratory protection against that specific hazard, we will test and approve, certify the requirement at a higher level that you -- your respirator would have a degree of additional protection at that specific level, in addition to the other test representative agents.

And so where that brings us today in the focus of the first part of our meeting is to address the current concepts for the powered air-purifying respirator.

And in looking at the comments that we have received at other public meetings and dockets, we went back to our original goal statement. And that's why emergency responders is highlighted on the chart.

Now, when we looked at why we were developing these types of respirators, who the focus -- who the target user community was for these products.

And when NIOSH initiated the standards development program in lieu of using formal rule making, we used provisions -- policy making provisions that are allowed to us under 42 CFR to specifically generate these requirements for emergency responders.

And to that end, as part of our evaluation, we went back and looked at our hazard analysis in relation to what protections are

required for emergency responders to use powered air-purifying respirators.

And I think in general, when you look at the emergency responder community, which we have defined as the fire service, law enforcement, and emergency medical technicians, that we envision that they would need the same types of protection that would be afforded by the gas mask.

And as part of that evaluation, we felt that only a tight fitting respirator, one that covered the eyes, nose, and mouth, as well as sealing to the face or the neck, met those requirements; that loose fitting types of devices that may be more inherent for use by people that have been called first receivers or emergency departments at the hospital, as well as, you know, medical staff, that those types of systems wouldn't be appropriate -- the loose fitting systems wouldn't be appropriate for use by the fire service, law enforcement, or emergency medical technicians.

So that the focus of the standard is

going to be looking at the tight fitting respirator.

And in consideration of that, I think -- please keep in mind that, you know, this is not just the face piece, but also hooded systems with neckbands, you know, the things in the respirators that meet the tight fitting requirement, whether it's a face piece helmet or hood with -- or devices with tight fitting neckbands that would meet the NIOSH definition of a tight fitting respirator.

And continuing along with the standards development process, we are doing to follow our three tiers of requirements in looking at 42 CFR national and international standards as well as identifying specific CBRN type of requirements.

In looking at what is applicable from 42 CFR, we have identified these paragraphs would be appropriate for consideration as part of our standard.

And these subparts and paragraphs address things such, you know, the general provisions for respirators, quality control, the process for

application for approval, general construction and quality control types of requirements.

Some of the paragraphs look at definitions, labeling and marking, the exhalation valve leakage requirements where, you know, tests have already been established and defined in 42 CFR that are appropriate for use on this type of device.

In the second tier, we start addressing national and international standards.

And I think one thing to keep in mind today during the course of our dialog is that, you know, all of those standard concepts are dynamic at this point.

And the key -- some of the things that we want to be sensitive to -- and I think if, you know, you have looked at the docket comments and how the concept paper have evolved, is that we have been sensitive a lot of the things that the stakeholder community has said with regard to the different requirements.

And I think what you will hear during the

course of our discussion today is where docket comments have been addressed as part of our evaluation.

You will hear from the different presenters, how those comments have either been accepted or modified, or why we are not choosing to consider them for this application.

The other thing to keep in mind -- and one of the things that our standards development team has been working with as we are going along is how to effectively test these respirators.

And part of the focus that we are trying to address is we want the testing to be as representative as possible to what individuals will see while these devices are being worn.

And to that end, that leads us to be more inclined towards doing testing where the respirators are operating. You know, for example, for the PAPR, doing a lot of the evaluations where the blower is running.

Now, however, we also acknowledge that there may be provisions that we want to consider

where the blower is not running, you know, that the blower may have failed and you are no longer getting the benefits of forced air through the filter and whether or not we should consider testing requirements where we look at the respirators in those scenarios.

But you will hear a lot more detail about those as we move along through the program today.

In particular, there is a lot of information that has been generated since the last time we met in May in terms of benchmark testing that looked at the need for indicators on the system and the battery requirements as well as operational controls for the respirators.

We are also going to have a discussion in which I will try to give Terry Thornton justice to look at the breathing performance of the respirators and how we are addressing defining the test requirements for those types of systems.

Then we have also the other human factor types requirements, the field of view, the ability -- the haze, luminous transmittance, and

the abrasion resistance that look at the ability of the respirator wearer to see through the unit.

Other tests such as noise levels, hydration, carbon dioxide, all considered; and you will hear more about these as part of the discussion today.

Also, we will be discussing with you the special CBRN requirements looking at the gas life testing as well as presentations by Dr. Lynn Hoffland from ECBC to discuss the recent chemical warfare testing that was done on powered air-purifying respirators at Edgewood.

One aspect that we weren't going to cover in a lot of detail today is the practical performance requirement that we are conceptualizing for the standard.

And in general, the focus behind this type of evaluation is going to be to integrate these type of requirements into any test where human subjects are used, whether it is the LRPL or if we end up doing a manned test for carbon dioxide or evaluations like the fogging criteria, that we

would consider human -- performance -- practical performance aspects as part of those evaluations in looking at developing a standard test procedure to address those as we move along.

Again, you know, we welcome your comments. We encourage you to visit our website to follow our progress through the use of the concept paper.

I know with the -- usually there is several months in between iterations of the concept paper, but I think historically people that have been involved with this business see, as we get closer to the standard, that we may have several concept papers in a row, you know, on a monthly basis that, you know, define -- that further refine and define the requirements for the system.

Just a couple of words in general with regard to this type of item.

We have had two public meetings so far on the PAPR. This is the third today. At this point, we do not envision whether or not we will have a fourth public meeting to discuss the PAPR.

I think a lot of the rationale going into scheduling another one with a public meeting will be to -- once we complete the results of our benchmark evaluations with breathing performance will I think give us an indication of whether or not there will be a need to get back together to discuss in a formal setting the requirements for the system.

And we have had some active submittals to the docket, you know, with regard to technical content that we should consider as part of the system.

And what we have done in terms of our process today in looking at these different topics is that we have decided to address these as part of our continuing evaluation and presentations to give you an idea of how we are addressing your comments.

You know, in the past, we have heard that, you know, people have been concerned that the docket is a black hole; that information goes in and nothing comes out. And I want to assure you that we take very seriously any comment, any

criticism, any constructive input that you may have regarding the content of our standards.

Here is some of the other items that we have received comments on.

And with that, I'm finished. If you have any questions at this time, I would be glad to take them. Otherwise, Dave Caretti will be next and give us a discussion of some of the research that he has been conducting for us in support of the CBRN standards efforts.

And following Dave, he has the pleasure of introducing our first break, but we will see how we are in relation to time.

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

One question. You said that the data that you collected concluded that loose fitting PAPRs are not appropriate for first responders but may be appropriate for first receivers.

Is there anything on the NIOSH agenda to look at the potential for evaluating loose fitting PAPRs for first receivers.

MR. SZALAJDA: Thank you, Frank. That was a good question.

And I think a couple of things I wanted to bring up, you know, with regard to that subject is, one, is with the OSHA -- OSHA has a document out on their website which looks at best practices for -- basically for emergency departments dealing with mass casualty incidents, which is currently in a draft form, but pretty specifically addresses the requirements of what a hospital may encounter in dealing with a mass casualty type of event.

There has also been some research done by Horton and others that look at the potential for cross-contamination from casualty victims coming into emergency departments. They have looked at that, I guess, over a four- or five-year period as far as, you know, the effects on the responder community.

I think at this point in time, in looking at the focus of why we started to develop the requirements that, you know, the focus for CBRN was to provide those protections to emergency responder

community.

And I think as we move forward, you know, in looking at the other classes of respirators, you know, to follow, as well as the specific needs of other communities, whether it be the first receivers or other aspects of respirator users, that the potential is there to do an evaluation of those concepts.

But at least at this time, in the short term over the next three years, our focus is on the emergency responders.

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

Jon, I have got a question. You talked about this is really the last anticipated public meeting.

Do you anticipate another draft of the standard coming out prior to release, or are you going to go right to the release of the standard, and what is the current anticipated date for release of the standard?

MR. SZALAJDA: You are stealing my

thunder for later on, but that's okay.

I envision there is probably going to be several more updates to the concept paper.

With the paper that is currently out on the web, I think we have asked -- and somebody can correct me if I'm wrong. I think we have asked for formal comments back to the docket within 30 days from this public meeting.

We envision that once we get those comments back and as well as, you know, looking at existing research that is being done and will be done over the next couple of months, that there will be another concept paper out probably in the February, March timeframe.

And then I would assume there will be a few more following that as we move forward and continue to do benchmarking and looking at the high flow type of testing.

In terms of the standards release date, we are anticipating September of 2005.

And part of the aspect that goes along with that is we have, you know -- I guess like the

stakeholder community, we have learned a lot as we have moved along too.

And one of the things that we really want to focus on is making sure at the time of the release of the standard, that all of the test procedures been developed and are in place for the manufacturing community to have at the time of the standard release.

And we know that has been a shortcoming in the past with some of the other standards that we have released. The SDPs all weren't available for the community, and it has made it very difficult for manufacturers to develop and get their products ready to bring in for certification when those tests aren't in place.

So our intent over the next several months, and -- you know, like I said, September is probably a good date, though. It could be sooner depending on how our research goes. Our intent is to finalize the supporting documentation to go along with the release of the standard.

Okay? Well, our next speaker is going to

be Dave Caretti from ECBC, who has -- I have known for several years, and he is going to provide to us some updates on his research work in support of the standards.

And, Dave, if it's 10 o'clock when you are done, you can have the pleasure of introducing the break.

MR. CARETTI: Good morning to everyone.

This is becoming your regular routine, so you have probably seen this several times. If you have seen this before, I apologize.

I'm going to try to run through a brief update of my portion of some of the research that we have done for NPPTL and NIOSH related more so to the literature review and trying to get ahold of what are realistic expectations for breathing rates in the workplace.

And then I will fumble through the second part of this related to the filter efficiency testing, since that is not my area of expertise, but I tried to get some good information from my colleague, Paul Gardener.

If you have questions to that effect, you can ask, and I will make sure I get them back to Paul to get some answers.

For the workplace breathing rate assessment, we were approached by NPPTL to really try to take a look at what is in the literature, what would be expected in workplaces for ventilation rates.

The main focus being things related to minute volumes, the amount of air exchanged in a minute, essentially. And issues related to peak flow rates. And for respirators, probably our main concern is peak inspiratory flow rates.

So what we have done is we have gathered a lot of literature, and we have gathered even some more recent data related to actual respirator wear from different research houses, both university settings and company settings, and tried to really analyze that data to see what it can tell us.

Happy to report that the literature review and analysis has been published in -- as an Edgewood report. We have not gone through the

process through NPPTL.

So what we have done is we wanted to get the information in a document for ourselves in-house. I do have a few copies of that with me if you are interested. It is released -- approved for public release.

I just caveat that it is probably not the end-all of the discussions, but it probably represents, we believe, a good compilation of information currently available that is in the literature, and it includes some analysis of some of that data beyond just regurgitating what others have reported.

To do this task, we did find there was very limited empirical data to meet the main objectives. There aren't too many studies out there where people will allow you to come into a workplace, whether someone is wearing a respirator or not, instrument them with some type of flow measuring devices so you can actually record ventilation.

It probably makes sense they don't want

their worker productivity to be degraded because you are trying to run a study. So very limited information out there.

So we made a lot of reviews of other types of literature related to energy expenditure studies, which are a little easier to administer without interfering with people doing their work.

And we have made some -- we have made some relationships or examined relationships from some of that information based on different metabolic values.

What we did is we adopted approach for estimating minute volumes from energy expenditure literature, and we looked mainly at relationships of minute volume to oxygen consumption.

Basically, oxygen consumption is an amount of oxygen required to do the work, and there is a relationship that you have to breathe so much air to consume so much oxygen. So that is essentially what we were looking at.

The literature review we went through, we have actually adopted a couple of different

equations for making these estimations.

And I will emphasize the point they are estimations. Every human responds differently to the same type of work. It is really difficult to pinpoint that everyone in this room would breath at the exact same rate doing the exact same task. It just doesn't happen.

We believe it is better to have a range of values, at least to show what the low ends may be and the high ends may be for individuals performing certain types of tasks.

By the same token, there is very little literature out there related to peak flow rate values because peak flows really are more related to probably clinically diagnosing somebody with some kind of a respiratory problem, a restrictive lung disease or something along those effects.

It doesn't mean there isn't any data out there in the literature. And the information related to peak flows become a little more -- people have become more interested in that in the past few years, especially as how it relates to

filter performance and efficiencies related to respirators.

Again, we looked at the data. We made some relationships and came up with the range of peak flows related to minute volumes.

Just a brief graph of a couple of relationships in the literature relating oxygen consumption to minute volumes that serve to develop our upper and lower ranges.

These curves are somewhat exponential -- well, these are exponential. We have evaluated existing literature data on how they fall in between these values, and all of that information is in the tech report.

We basically relied on these equations to establish our ranges.

Again, I will say this probably is not the end-all to the discussion, but we believe it provided us reasonable information related to minute volumes and the relationship of minute volume and oxygen consumption.

Just a brief graph to show the curve of

data that we used to estimate peak flow rates. And you can see, there is an upper and a lower bound related to the dash lines. And some of the plots in there are actually empirical data to how they fit into that range.

And, again, we used the linear fit of the data to give us an estimate of peak flows based on minute volume values.

And the upper and lower lines represent the prediction intervals that we used for estimating, again, multiple values for a given minute ventilation. Just because you inspire a certain minute volume doesn't mean you always have the same peak inspiratory flow value.

In reviewing the literature, what you have in the graph here is just a frequency distribution of minute volumes found related to occupational task performance.

This is a compilation of actually measured minute volume data from the workplace and our estimations of minute ventilations related to energy consumption or energy expenditure using

oxygen consumption data and the equations that we talked about previously.

If you take a look at the data here, it's really skewed to the left only because there is one article that we reviewed where there was an estimate of a minute volume of 162 liters a minute, which skews it way out to the -- it shows that one data point way out to the right.

This is just to show all the data that we had in the analysis. Here is a breakdown of the data.

In the distribution of minute volumes, the average of what we found was about 39 liters per minute. The median was roughly 34 liters per minute. The 95th percentile, about 73 liters per minute. And that peak value of minute volume was 162.

This, again, is the literature related to workplace energy expenditure for reported minute volumes.

Using these minute volume values, we estimated the peak flow rates based on the equation

or the linear relationship we showed you before.

And, again, really what we are showing here is a range. And based on the values that we have in minute volumes, we really could not estimate anything over 120 liters a minute. So it really only eliminated one data point in our analysis, but we came up with a range of expected or anticipated peak inspiratory flow rates of roughly 270 to about 390. So that really does show that in the workplace or workplace type activities, you can have high peak flow rates.

To try to say what those values really mean, we went and looked at literature related to peak human performance. We really only did that to say, Well, these are values that are reported in occupational settings. How often or what is the likelihood that in an occupational setting without a respirator on, how close are you going to get to peak human values that are possible?

Reviewed mainly literature related to exhaustive short term work for people normals, meaning they were apparently healthy individuals,

different age categories.

And some of the data presented here is right out of certain articles where it's a good average of basically the most fit in general population of subjects, males in the 20-29 year age group.

And maximal minute values reported for those individuals, roughly 114 plus or minus about 23 liters a minute. It can go higher than 114, but 114 is a pretty high value for minute volume.

Females lower generally due to differences in body size. But there are extremes reported in the literature under peak performance conditions where we have seen minute volumes that can go up to about 200 liters a minute.

In trying to find peak flow rates under similar work conditions, we found some literature related to maximum exercise values for healthy individuals around 300 liters per minute.

We have recorded some values higher than that in our laboratory for some testing without respirators, and there have been some reports in

the literature of extremes in excess of 500 liters a minute.

What does that mean? It means it's quite possible to have a high peak flow rate.

Does it mean it's sustainable, the question is? The answer to that question is probably not, but it can occur.

So in summary, what we found in the paper, for occupational tasks, minute volumes will rarely approach maximal capabilities, at least what we found in the literature that we reviewed.

We felt that 73 liters per minute is a sufficient representation of the upper limits of minute volumes anticipated in the workplace, and probably 114, give or take, is a reasonable estimate for maximal minute volume values.

Some of the predictions that we came up with are estimates for peak flows based on these minute volume values correspond with some literature. And using that max VE value of 114 suggests that an upper limit in the workplace, if you are doing maximal capabilities to exhaustion,

is in excess of 400 liters a minute.

It is important to note that higher minute volumes can occur. Higher peak flow rates can occur. But based on the literature review, it seems that these instances are not the norm, and it is not something you would anticipate happening all the time.

The second part of the analysis of the literature related to occupational minute volumes -- and the fire alarm is going off.

The -- we got some data from other sources on more recent investigations that have been done with respirators. Work has been done from different intensity work rates, but a lot of it done at very high intensity work rates, in excess of 85 percent of someone's maximal cardiovascular capabilities.

We wanted to get this information to try to validate or update our current knowledge on ventilation during respirator wear and to identify data gaps for further research.

We have populated a database, and we have

defined all the parameters, and we initiated some of the data analysis. And we anticipate to finish this up in January with a report to follow.

Just briefly, what you have here might be hard to see, but on the X-axis is inhalation resistance. This is imposed resistances either with a full facepiece respirator or a half-mask.

Whether it is with an off-the-shelf type of a cartridge or some kind of an orifice that is blocking flow, it doesn't really matter. We took the values at face value related to actual resistance in centimeters of water/liters per second.

On the Y-axis is minute volume. And what you see is just a distribution of some of the data for those specific resistances that were tested for inhalation resistance.

It is just a summary graph. I can't tell you what it means right now. Just this is data on more recent respirator examinations that have been done by four laboratory sources.

It is just interesting to note that there

is quite a variability in the minute volumes that are capable depending on resistance. And if you look at this particular graph, it kind of begs the question that some of the lower minute volume values are at the lower resistance levels.

So this is my quandary right now in trying to analyze this data, so we are going to go through and try to see what that means. But we just wanted to show that -- what some of the data looks like just at face value right at the moment.

This is a similar graph, but it's peak inspiratory flows based on inhalation resistance. And we had a little more consistency in the data there.

Interesting to note that peak flows are still capable of being quite high, even with high inhalation resistance conditions.

And this is just another way to show the peak flow data as particular inhalation resistances down the right-hand side. These are representative of individual studies or different resistance conditions within one or two studies. And that is

just a frequency distribution of some of the peak flows that are out there.

But if you go back to the 430 liter per minute estimate of probably an upper value for peak flows in the workplace, you will see most of the data falls below that value. And this is, of course, under resistance breathing conditions.

Part of the purpose of doing the literature review on the flow rates was to try to provide some moderate to high flow rate conditions for a second study that we are currently conducting for NPPTL.

We are doing some filter efficiency testing to assess the impacts of moderate to high flow rates on performance of particulate filters, particulate filters. These are not combination filters. These are not gas filters. These are particulate filters.

And we are trying to compare efficiencies measured under constant and cyclic, meaning breather type flow conditions.

Another part of this is we are comparing

efficiencies measured using inert, or simulants, and bioaerosol challenges. Okay?

The current test plan involves eight approved N95 and P100 filters. Again, these are all air-purifying respirator particulate filters. We have four cartridges and four filtering facepieces.

We are using different challenge aerosols depending on the particle sizes. That is probably because of the limitations of the equipment we have, but we are looking at submicron and supermicron particle sizes.

For the N95s, for the solids, we are using sodium chloride and the -- and PSLs. And for the P100s for the oil, we have got DOP and Emery 3004.

The sodium chloride and DOP are being used for submicron particles, and the others for the supermicron. And, again, those are limitations due to our equipment. There is really no difference in the particles other than they are materials, but they are all being used for the same

sizes.

So we have particles below micron and supermicron, and we are testing solids and aerosols and oils through that range from .02 to 3 microns.

We are doing some bioaerosol challenge to see how we compare with the inert to the bioaerosols. And for the bacterial particles, we are using BG spore simulants. And for the viral, we have got the MS2 phage.

A lot of this work is being conducted in house, and then we do have some of the biological aerosol stuff being conducted outside.

But the link back to the aerosol sizes and the flow rates goes back to the review of the literature that we did for the occupational flow rates.

Under constant flows, it is pretty straightforward. We are trying to use flow rates to span the range of moderate flows to high flows.

Peak inspiratory flow of a constant flow test is the same as mean inspiratory flow. But when we get to the cyclic values, we are using the

peak inspiratory flow values and the minute volumes that are associated with that.

And the mean inspiratory flow would be -- I don't have a pointer. Is there a pointer?

Peak flow -- and this is inhalation. This is just a sample of a sinusoidal curve, but this is peak flow would be the highest value as related to that inhalation phase.

And mean inspiratory flow would be somewhere in here, depending on the breathing pump that is being used, whether it is a pure sine or if it's a Silverman sine wave.

Mean inspiratory flow is the same as root mean squared of that curve, and that's what these values are reflecting here.

For the constant flow testing, it is important to understand with the cartridge types of tests that if the cartridge is designed to be on a respirator that is a dual cartridge system, the flow rates are halved because we are only testing one cartridge at a time.

And this is just a graph to show the

match of the flow rates being used in testing. The 40 liter per minute is close to the mean minute volume that we found for the occupational ventilation rates, 85 liters per minute, current test standard for resistance testing.

The 115 is representative of the maximal minute volume values, and the 135 is representative of the maximal value plus one standard deviation. Why are they not exact 38 and a half to 38 and a half? Just limitations of the breathing pump in the tests.

Just some preliminary findings. Again, I apologize for not being the expert here, but this red line is the efficiency, 99.97 percent for the particular cartridge that was being tested, a P100.

This represents a DOP test under constant flow rates, and you have different particle sizes being tested on the X-axis.

And it's just a curve of efficiency. The flow rates are halved under constant flow because it is a dual cartridge system, so this is for one cartridge. What the data shows is, under higher

constant flows, we lose some efficiency of the particular filter.

Same cartridge, just a comparison of the constant versus the cyclic flow data. For the conditions here of constant flow, again, that is half of the 270 value versus doing cyclic where we have a match of peak inspiratory flow to the constant flow. Those would be the light blue bars.

And here we have a match of the mean inspiratory flow to the constant flow.

Preliminary data suggests that cyclic versus constant, the match is constant for mean inspiratory flow value in terms of efficiency.

This data is all very preliminary. This is just a first look at what we have here. Just wanted to show some of that just to highlight what we found to date.

The status of the testing is the submicron aerosol testing has been completed, and we have initiated the supermicron particle testing, and we anticipate this testing to be completed in February.

Testing with the bioaerosol, the cartridge tests have been completed with the Bg spores, and we are currently conducting testing with the filtering facepiece systems. All of the MS2 phage testing will commence once we have completed the Bg trials.

For this research, what we anticipate for future directions is, in terms of the workplace breathing and respirator ventilation data, any new literature that comes to light, we will try to make sure we get it and review it and see how it relates to what we have reported in our tech report.

We really would try to -- like to, one day, try to get into some occupational settings and actually measure ventilation in the workplace for a full range or complete range of actual occupational task performance so that we don't have to rely so much on in-house laboratory testing.

We would use that information to try to validate and/or update the relationships that were used in the literature review for estimating minute volumes.

For the filter testing, the next step that we anticipate is down the road, testing the combination filters to be more representative of the CBRN type of filters that are being used or being certified.

And we would also like to determine efficiency based on waveshapes and/or other types of breathing profiles.

To date, all of the particulate filter testing has been done with sinusoidal flow curves for the cyclic tests. Humans do not breath just sinusoidally, so we would like to take a look at different waveshape impacts on filter efficiency.

One other project related to some of the research for NPPTL is we have initiated a human factors review of issues related to the closed circuit self-contained breathing apparatus, and that information will be summarized into a report to support that particular CBRN standard development.

At this point, that's all I have to say related to those projects. I apologize for some of

the brevity related to the filter efficiency testing, but any questions you may have, I will entertain those at this time.

MR. BERNDTSSON: Goran Berndtsson from SEA.

I don't really have a question. I would like to applaud this research you are doing. It is a very good presentation, and we are getting some very interesting results coming out, and it's about time.

Very good.

MR. CARETTI: Thank you.

MS. TOWNSEND: Dr. Mary Townsend, ME Townsend and Associates and the University of Pittsburgh. I have a question about the minute volume.

Is it actually the integrated amount of air that is moved in a minute, or is it based on like the flow rate that -- like, say, for a second, that has been multiplied by 60 in order to get a volume?

Because it's not --

MR. CARETTI: I will tell you how we do it in our laboratory.

MS. TOWNSEND: Okay.

MR. CARETTI: We actually sample data for 30 seconds.

MS. TOWNSEND: Okay.

MR. CARETTI: And then we will calculate breath-by-breath minute volumes for all the complete breaths in a cycle, and then extrapolate that to be a minute.

So it's a time-weighted value for each breath.

MS. TOWNSEND: So what --

MR. CARETTI: The controversy of what is the actual volume in the whole minute --

MS. TOWNSEND: Uh-huh.

MR. CARETTI: -- or is it fair to take a ten-second sample and just say that is the minute volume.

I believe that's accepted that as long as you have gotten a good portion of a minute to make that estimate, basically under steady state

conditions, that should be fairly uniform. It does not mean you can have size and gasps and other things that can change those values, but that is how we handle that information.

MS. TOWNSEND: Okay.

MR. CARETTI: The minute volumes in the literature, we took great pains to review the procedures that were used and to look at the flow measuring devices that where used. We discussed many of those options in the paper.

Essentially, if the data -- it was a lot of data, but the method used might have been questionable.

We made sure that we said, Well, they used something out of the ordinary, but these are the values that were recorded.

MS. TOWNSEND: I was struck by the histogram that you had where you said that part of it was your projections and part of it were measured -- minute volumes, they were low, weren't they?

I mean, is that reflecting that the

places that were studied are fairly -- that maybe they only have peaks of rapid breathing? Were there fairly sedentary occupations?

MR. CARETTI: That's a good point. And in actuality, there was a full gamut of types of occupations.

Some of the heavier occupations that were actually measured values, some of the logging industry, felling trees, moving things around. You would probably know as well as I do that when you want to measure somebody doing something, they may not perform the way they normally would, so there could be some dampening of values to that effect.

But by the same token, there is also the white labcoat syndrome where sometimes people get a little more nervous, so their ventilation may be even higher.

The best I can answer to that is the literature we reviewed, it's all -- the parameters are all in there. It was lower than I had thought it would be.

But an interesting side to this is in the

standards for the chemical agent testing where we were exposing them to the TB and HD, that is a 40-liter-per-minute minute volume, and our average was 38.

By chance? I don't know. But that kind of says, Well, that's a good representative flow for the majority of the occupational tasks.

It doesn't mean there are stages in a work day where people work at much higher rates.

MS. TOWNSEND: I'm wondering how that would relate to the emergency situations, that all of -- you know, that this is all about, all of this CBRN.

MR. CARETTI: One slide that is not in this presentation today was presented in May -- I believe that was the last public meeting -- where we broke out what we identified as first responder type activities.

And I won't tell you exactly what that value was in terms of the mean and the 95th percentile. That data was related to firefighters, but I don't believe the mean was much more than the

mean that was presented here.

I think it may have been in the low 40s, but I don't have that with me, so I won't make that guess. But if you want that information, I will be more than happy to provide that.

MS. TOWNSEND: So you are probably looking at peaks, then. But when you integrate them over the whole minute then, it ends up being a kind of low value?

MR. CARETTI: Yes.

MS. TOWNSEND: Good. Thank you very much.

MR. CARETTI: Sure.

MR. BERNDTSSON: Goran Berndtsson from SEA.

I think you said that in the beginning of what -- when you responded to this, that if you take a too short sample, that will mean that you might not get the right minute volume, and that is maybe what happened on some of the earlier studies.

And if you look on them, they very often took a couple of breaths and estimated -- predicted

the entire minute on a couple of breaths. And that could have been a couple of large breaths, or it could have been a couple of small breaths.

I mean, as you have been measuring entire minutes now, you see the variation can be quite different within that minute, even if it is that work. Because you have sneezing and a few other things.

And then if they are on that, it could take just two of those, there will be a misprediction.

MR. CARETTI: That's true. Many of the studies with the data may have not had a large enough sample time. But if they are sampling every minute doing a constant rate type of activity and there is not a large fluctuation minute by minute, you can get some comfort in that the data is fairly reliable.

And this all went into the thought process and the paper.

MR. BROCHU: I'm Lieutenant Commander Paul Brochu from the Marine Corps Chem/Bio Incident

Response Force, and I applaud you for your work.

And as I appreciate that, the -- one of the studies that was done was done at CBIRF in Maryland, and it's the coughing study, which I know you are aware of, Dr. Caretti.

In that study with a young healthy population, a good chunk of our population, over 42 percent, were seeing minute volumes in excess of 100 liters per minute in that study. And I know you took that into consideration and referenced it in your study.

And really, it's just a comment that I wanted to make that in certain populations, which you are addressing, there is that chance that you are going to exceed certainly your estimated 95th percentile of 73. And this was sustained for a 20-minute period during the standard firefighter's agility test.

So in some cases you could be seeing, you know, even higher rates than possibly this overall literature search, you know, revealed.

MR. CARETTI: I thank you for your

comments.

But just one clarification on that study is those high values were actually sustained for three minutes. That was the peak respiratory period during the heaviest activity of that 20 minutes.

There were excursions to that level during other tasks, but the overall average through that whole period wasn't reported. It was only reported on the region of peak respiratory interest.

But, again, those were in excess of that 95th percentile. They were over 100 liters a minute.

MR. BROCHU: That's correct.

MR. CARETTI: Yes.

MR. BROCHU: Thank you.

MR. VIJAYAKUMAR: Vijay from Air Techniques. I have two comments, two questions concerning filtration, the testing you have done.

There has been a lot of studies for many, many years concerning filter efficiencies at

different flow rates and different particle sizes, especially the most penetrating particle sizes.

Have you compared your data or compared your data with published -- with commercial and technical -- technically peer reviewed publications?

The second question, when you are measuring filter efficiencies on a cyclic flow rate, are you sampling a cyclic flow rate, or are you sampling for measurements on the steady flow rate?

I mean, the instrument that you use to measure concentrations up and downstream, are they cycling as well?

MR. CARETTI: Your first question about comparison data in the literature, yes, that was the basis for all the testing. All the literature that existed was out there.

The only thing that was missing that we could not find -- if you have a source, we would love to have that -- was actually with the Bg or MS2 phage under cyclic conditions.

So that phase of the study with the inert particles was to revalidate what has been done and then compare what has not been done to those revalidated values.

As far as the equipment, I don't have a direct answer to that. I believe it's sampling continuously through the cycle, but we can check and let you know.

You have got my number, Vijay, and we can give you that information.

MR. HAUSER: Hans Hauser from Safety Tech International.

We saw different numbers of possible peak flows, and my question is now in the draft for discussion of October, you mentioned that whatever will be the peak flow, it will never exceed the breakthrough of the filter.

Is that the statement, is that still valid, or how we can understand it?

MR. CARETTI: I don't know that I have stated that if you exceed peak flow that the filter is still okay.

I guess I need to understand your question a little bit better.

MR. HAUSER: Yeah. We have a certain breakthrough time and flow -- maximum flow for a filter.

And now that panic mode exceeds most of the time, especially the numbers we have seen here, will exceed the breakthrough capability of the filter.

But it is written here that the peak flow should not exceed the breakthrough capability of the filter.

MR. CARETTI: That's in the concept --

MR. HAUSER: My question is now, is it the statement, is that still valid, or is that a misunderstanding from our side or ...

MR. CARETTI: Okay. We will have to get back to you on that when we see the section in the concept paper.

MR. BERNDTSSON: Goran Berndtsson from SEA again.

You quote that the median flow rate, that

was based on a sinuous curve, wasn't it? I mean, when you talked about the peak flow rate and then you -- I think you also put a medium flow rate during it.

It was a sinusoidal --

MR. CARETTI: Actually, Goran, all of the data in the paper is based on what is in the literature collected under human ventilation parameters.

So there is not a lot of -- not everyone is reported -- they didn't measure just the flow curves. They reported values.

The peak flow values that were on the one relationship, the linear relationship, were actually empirical data that were just plotted versus minute volume. I can't tell you what the curve shapes were for those values.

The filter testing right now is all under a sinuous curve.

MR. BERNDTSSON: Yeah.

MR. CARETTI: And the next step that we would like to do is change that waveshape to make

it more representative of what you would see under high intensity.

You would not see a sine curve.

MR. BERNDTSSON: That was going to be my point, next thing. Because as you make a more squares (phonetic) curve, which is more relevant to most people how they are breathing, especially when they stopped working a little bit, you will get a higher level on that median number?

MR. CARETTI: The median number, yes.

The peak flow won't necessarily be higher.

MR. BERNDTSSON: No. No. But the median number will be --

MR. CARETTI: Yes.

MS. SWANSON: Hi, Meghan Swanson, Mine Safety Appliances.

Dr. Caretti, you mentioned 430 liters a minute for a peak performance rate, and you said that wasn't very sustainable.

I was just wondering if you had any idea how long a person can keep that rate up. Is it two

seconds or two minutes?

MR. CARETTI: Less than five minutes. Usually, under very heavy intensity exercise, running up a flight of stairs at full speed.

The actual maximal sustained time is a great question, okay. What you have to factor in is what is somebody's cardiovascular fitness level. If they are wearing a respirator, how familiar are they with that respirator. How heavy is the -- how much does the respirator system weigh.

But those heavy intensity exercises in general are generating the highest minute volumes, generating the highest peak flow rates. You could mimic the peak flow at rest sitting in a chair at high if you really wanted to do it voluntarily. But at rest, when you do that a few times, you will become lightheaded.

But under heavy exercise, I would have to say five minutes. I don't think it can be exceeded to that effect. And I don't know if that is every breath in that five minutes that you can exceed that 430 liter per minute peak flow.

A lot of times those values are related to, in a full minute you will see flow curves, and you may have a spike because somebody takes a real deep breath, and then it goes back down a little bit lower. So it may be one excursion to that peak value in that five minutes.

I don't have the answer to that question. It all goes to the variability in breathing. Even under a constant rate exercise, little things can make big changes.

So I guess that's the best I can answer that question.

MS. SWANSON: Thank you.

MR. SZALAJDA: Thank you very much. Thank you, Dave.

Let's take a 15-minute break, and we will start up again at 20 after 10.

(A recess was taken.)

MR. METZLER: I think a lot of people may have already noticed our technology branch has several posters set up in the lobby, and there is also several individuals from the branch here as

well today that are prepared to discuss the posters in some more detail. So during the break or during lunch, the opportunity is available for you to see some of the other activities that are going on at NPPTL.

One other aspect I forgot to mention this morning, there will be an attendees list put together for the meeting. It is going to be available during the afternoon break.

So you can keep that in mind that there will be a list, and it will be available during the afternoon break.

We have fallen a couple of minutes behind schedule. We will work to get back on track and address some of the requirements, one of the research projects and the some of the requirements for the PAPR that we are considering.

Mike Monohan is going to provide a presentation that -- a project that he is undertaking with looking at the canister resistance and impacts on service life for CBRN canisters.

MR. MONAHAN: This is the second part of

a study that we presented at the last public meeting, and it has to do with differences in resistances and what happens to the flow -- to your service life -- if I can get this to work.

This work was contracted to AJE Testing and Research. And the object of the study is to determine the effect of differing canister resistances on the service life of a PAPR by artificially altering the pressure drop to pairs of simulated cartridges.

We tried to target a fairly wide range of pressure drops from basically matched pairs at zero to 25 percent difference.

I'm going to go over this part fairly quickly since it has been gone over once before. And if anybody has any questions, please stop and I'll try to -- stop me, and I will try to answer the questions for you.

Our test conditions were 25 degrees C, 50 percent RH, and the test concentrations that we used were -- are the same as for the APR standard.

And the test gases were cyclohexane,

sulfur dioxide, phosphine, and cyanogen chloride.

The -- basically, what we tried to do is we picked the cyclohexane as a surrogate for the -- your organic vapors, sulfur dioxide for your acid gas, and phosphine as a catalytic type of challenge, and the same with cyanogen chloride.

The test cartridge we used was five inches in diameter, and it has -- by adjusting the fill, you can adjust the bed depth.

This is only a preliminary study, so we chose to use just one carbon. And we chose a URC 12 by 30 that is manufactured by Calgon Carbon. And we looked at different bed depths, and these are represented by the fills of 250 and 300 ccs for the low flow rate of 115 liters per minute. These are steady state flows.

And 500 and 600 cc fills for the high flow rates.

The effluent and break points were both determined on each cartridge of the tested pairs. Break times -- the system break times were calculated -- is a calculated value based on mass

balance.

This is a diagram of the cartridge that we used. By varying the bed depth, you can actually -- with these retainer rings, you can tighten down and get a uniform pressure on the beds. And they were quite consistent in our results with these.

The apparatus we used was a typical service life apparatus with some modifications on the back end where we were actually using mass flow meters before the test started to get the differences in flow rates and -- with the resistance. And each -- each canister had its own detector so that we could see the differences in breakthrough.

When we calculated the actual end point of the particular service life test, we used a mass balance, and this is the calculation we used.

For the one example, we had the different concentrations at any particular point. And this one, I had a flow of 63.4 liters per minute for the one cartridge, and 51.6 for the other. So there is

a lot -- with a total of 115.

This is actually what happens with a high and low resistance cartridge. You have your low resistance cartridge here, which has your highest flow, and the high resistance cartridge here, which is your lower flows.

And this is the calculated service time at any particular point on the curve. And these tests were run to twice the breakthrough concentration because the effects of one cartridge is basically contributing all or most of the leakage at one -- at any particular time.

These curves are for the different flow rates and bed depths. Your low flow rates are here.

Basically what you see is as the flow rate increases, your service life decreases, and the -- for any particular bed depth.

We saw very similar conditions or results from when we looked at both cyclohexane and sulfur dioxide.

At any particular point, even though the

service lives were different, the percentage difference on the pressure drop versus the percentage difference in service life were approximately the same for both cyclohexane and sulfur dioxide.

But when we got into cyanogen chloride, there is more of an effect with the higher flows in the service life. It was more -- there was more effect to it. I think it is because there is somewhat of a catalytic effect to it.

When we looked at phosphine, we got some very interesting results. Basically what we are seeing here is that we had instantaneous breakthrough on three of the four tests that we ran, and we got a dramatic service life drop-off.

And when we looked at it, what we saw was -- there is a minimum amount of time necessary for the reaction to take place to get a successful test. And basically it comes out a little less than .3 seconds residence time is required to get a successful test.

You can see here, this is just about

where it drops off. And you are getting -- your time is a little less than .3 seconds. As soon as you reach that -- that residence, if you don't have enough residence time, you get almost an automatic breakthrough.

When you look at a single cartridge, you can see where you have an induction period with your cartridge. And if you don't have enough bed depth, like in this particular case, you have almost an instantaneous leakage. And then as the reaction -- it's a catalytic reaction. As it picks up, your efficiency or your cartridge gets better and better.

But since the end point of the test is -- well, you can't see it here. Whoops. Well, you can't see the Y axis, but .03 is right around in this area, which would be your end point of your test.

So for this particular challenge, you must have at least a minimum amount of bed depth in the cartridge to get the test to pass.

The conclusions that we were able to draw

from this study was that the differences in resistance between canisters will cause changes in air flow patterns between the cartridges or the canisters, which will result in lower service times.

The type of contaminant does have an effect. With cyclohexane and sulfer dioxide, we didn't see a significant change in the reduction of the service life due to the contaminant challenge.

These also were basically physically or chemically absorbed compounds. And, as I said before, the amount of reduction in service life is just about the same for whether it was chemically absorbed or physically absorbed compound.

For cyanogen chloride, we saw that higher flow rate conditions produced larger differences in the service life. And this mechanism of absorption is probably a combination of both catalytic and chemical absorption.

Phosphine, as we saw, it requires a sufficient residence time within the canister to effectively remove the contaminant. And this is --

this is a catalytic reaction, either in whole or in part.

And other absorbents will probably show different types of results in that they may not all show the same types because of the amount -- what type of impregnates are used and the amount of pure carbon involved. You probably will get different results, but they should be fairly similar to what -- the results that we have here.

And the last one is standard implications.

We are going to require a canister uniformity with a resistance variation of approximately 10 percent. This 10 percent is very similar to that -- if you look at EN 141, they have the same tolerance.

And we were looking at -- there is two different options we are looking at in relation with this canister uniformity.

When you look at -- after a system is certified, we do checks to make sure that the systems are still working right.

And one of the things we were looking at was that once you certify the respirator, when you go back to look at and make sure that they are operating right, how would you check the -- to make sure that the uniformity is still there?

And we come up with two options. The first is that you take the average resistance of the canisters within what I'm calling a package use unit. We will probably come up with some other crazy name for it.

But basically what we are talking about here is that if you have -- if the PAPR has three cartridges, you would package them so that three cartridges are in one package so that when a user goes to use it, the cartridge will be relatively uniform.

It will be easy to do since when you are manufacturing them, you would probably do this serially, and you would probably get very little variation amongst the cartridges at any particular point in your manufacturing.

The second would be a little tougher to

do in that if you decided you wanted to -- the manufacturers wanted to sell cartridges separately, since you would have no control over when -- or which cartridges were used.

In other words, you could have one laying on your shelf for possibly a number of years and a fresh one from two different lots and slightly different manufacturing conditions. You would have to have some basis to test the uniformity.

So you would probably end up having to base the uniformity on an average resistance that would have to be given by the manufacturer and approved by NIOSH as to its validity. And then you would have -- all your cartridges would have -- they would be tested -- after the certification, would have to meet this plus or minus ten percent.

These are our options right now. We would like to have your comments on this, and that's about it.

And the last part of it is a systems service life test.

We feel that -- we were looking at both

individual cartridge testing and systems testing. And based on some of the information that we have found out through our benchmark testing -- which I think Ted is going to talk about later on as far as the manifold, the effect of the manifolds' -- we are proposing that -- we are going to do a system test with the manifold and canisters as they would be used in regular use to determine what the service lives are going to be.

And that's all right now.

Anybody have any questions?

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

So when you talk about the systems service test and you mention the manifold, are you referring to the PAPR manifold as part of the respirator or a standard NIOSH set up for a manifold?

MR. MONAHAN: No. We would use the manifold that the manufacturer uses in his system.

We would try to keep, if at all possible -- the new test rigs that we have been

putting together are large enough that we can put whole manifolds in with hoses to accomplish this.

MR. DUNCAN: And then I ask just to confirm that, what you are talking about, if my understanding of Option 1 is correct, there is -- I think I suggested this before, you are allowing or considering a provision that the manufacturers can package filters in groups for designated use where they maintain that the resistance tolerance is within the specification.

Is that correct?

MR. MONAHAN: Yeah. In other words, in the package use configuration, the allowable difference would be 10 percent within those cartridges.

MR. DUNCAN: In both of those cases, I applaud you guys.

I think that's a very practical approach to all of this, and I think it is very well thought out and well done.

MR. MONAHAN: Thank you.

MR. SMITH: Sorry. Just one further

question. Simon Smith, 3M Canada.

With the systems service test, as you showed there, what would be the implication for the number of samples of systems and canisters that would have to be submitted?

Would you do the service test on every gas and in multiples?

MR. MONAHAN: Is the question how many we would use for test certification testing?

MR. SMITH: Yes. What would you need in terms of submissions?

MR. SZALAJDA: It would probably be the same as we are doing now. Three --

MR. MONAHAN: Yeah. There is -- when you look at the different -- we do three at the low humidity, three at high humidity, and then three at crisis demand.

MR. SMITH: For every gas?

MR. SZALAJDA: Yes.

MR. MONAHAN: Yes.

MR. SMITH: And in multiples on the manifold?

MR. SZALAJDA: Yeah.

MR. MONAHAN: Right.

MR. SMITH: So quite a large number, then.

Thanks.

MR. MONAHAN: Thank you.

MR. SZALAJDA: All right. In Terry's absence, I will try to give his presentation the due credit it would deserve.

The thing is, as I mentioned this morning, in looking at the gas life requirements for the PAPR canisters, the testing is going to be based on the requirements that were developed for the gas mask.

And we have discussed that and several of the requirements for the gas mask, and the development for that standard as well as with the escape respirators.

I think one thing I did want to note I guess in relation to some of the other comments from this morning, all of our presentations from the previous public meetings are available through

the NPPTL website.

If you go to the website and follow the links back to the public meeting, it is segregated by the type of respirator that addressed it. And I think I had mentioned in particular Dave's presentation -- the comment about Dave's presentation from the May meeting, you know, and some of the detail regarding the peak flow rates can be found in that document. As well as you can get the transcript from the docket office with what was said and by whom at each of the meetings.

And this morning, I had mentioned the fact that we had identified test representative agents for the 139 potential respiratory hazards that this device will protect against, and here they are.

I think for the most part, everyone is familiar with those. The manufacturers that have been submitting devices for evaluation are familiar with these tests and the concentrations and the breakthrough rates, the breakthrough concentrations.

And in general, when we looked at defining the canister requirements from an engineering standpoint, I'm not an industrial hygienist to tell you how to use the thing, but in terms of the canister itself and the equipment, you know, we focused on capacity and dwell, you know, knowing how much goo the filter, the canister can absorb or adsorb, and how long it takes things to break through, you know, as far -- and what the effects are in relation to the physiological demand being placed on the respirator.

In setting these concentrations for -- and the breakthroughs for this device, for the air-purifying device, that in general the challenge concentrations are based on multiples of the IDLH and the breakthrough concentrations are based on half of the permissible exposure level, or the recommended exposure level.

And that is not entirely true in all of the cases because, again, when you get back to the philosophy of looking at capacity and dwell, you know, where it makes sense from a test technology

standpoint to test at a higher concentration and allow a greater breakthrough concentration, we are solely looking at, you know, the ability of the canister to do its job.

One of the things that we intend on doing as a part of completing this standard is looking at -- identifying a concept which looks at the different operational technologies. And what is currently defined in the concept paper are constant flow -- are requirements for constant flow, PAPRs, as well as breath response of PAPRs.

And one of the comments, or some of the comments that we received through the docket have addressed the inconsistencies with how we have used some of the terminologies with the system and how we described things.

And as we are moving along now, I want you all to be aware that we are going to be very sensitive to, you know, the terminologies.

I think in general, when you look at how the concept is evolving, we are planning on being consistent with current defined NIOSH terminology

that you would see in 42 CFR, you know, and using that type of terminology, and carrying it forward through the standard development process.

One other thing on this chart, a lot of questions have come up with regard to capacity and how -- how the devices are supposed to be used once they are fielded and in the hands of the responders.

And, again, it gets back to, you know, we are looking -- you know, in defining the requirements, we are looking at capacity and dwell. And to that end, now that we have established, you know, physical parameters that the respirators will provide protection for, part of our policy and standards group, being led by Heinz Ahlers, is in the process of developing guidance documents to help assist the emergency management community and hygienists in how to apply the information that is available regarding these types of devices.

You know, what capacity, you know, capacity one means in terms of the protections being afforded by that type of device.

I think we -- you know, we acknowledge the fact that there is not a linear relationship between the -- how the capacity is defined and how things may be used in a workplace environment.

And part of the guidance documents that we are developing are to take a look at the existing -- the existing requirements and translating them into products that the responder community will be able to use in selecting the respirator and knowing how long that the device will be good for in operation.

The service life for the respirators will be -- will include testing with -- of the air flow of the blower or minimum flow, depending on the manufacturer specified breathing performance, whether it is a minimum value or rate specified by the manufacturer.

And as I had mentioned this morning, one of the focuses that we are trying to carry through with this system is to replicate how the testing and how the devices will actually be used.

And to that extent, as Mike had mentioned

in his discussion, that we are looking at testing the manifold and the canister as a system in our operation.

You know, we will be doing the traditional gas and vapor evaluations with the test representative agents, three at a low relative humidity, three at a high relative humidity, and also three at a crisis level, which is still to be defined in terms of the development process for the concept paper.

I think the -- I think one of the key points here in looking at how we are going to be doing the testing is that we want to meet the traditional systems testing requirements that NIOSH has always promoted for evaluation of respirators.

And as well as, you know, by doing the testing of the system, that we will be able to account for flow variations in the canister resistances as part of our evaluation.

In addressing some of the public comments, we submit -- on stacking, we submit that we thought it was a good idea to be able to allow

certain chemicals to -- or be able to provide the provisions within the requirement to allow for certain chemicals to be stacked and tested at higher concentrations, knowing that, you know, inherently carbon-based canister systems are going to provide, you know, longer service lives for certain materials than others.

But in looking at the development -- looking at this in concert with the development of the guidance documents and the information that the manufacturers generate with regard to service life of the canisters, we think that, you know, the -- the concept of stacking can probably be addressed, you know, through guidance documents, as well as the user documents, and in allowing the user to know exactly how long the specific item may be good for.

And this -- the crisis provision has been more challenging than we originally thought, and we have gone through a couple of iterations of what the -- we think the requirements should be based upon information that was generated for the gas

mask, as well as some of the research that has been done, you know, including the work that was done by Dave Caretti that was presented at the last public meeting, as well as this public meeting.

And I think to address the one question from this morning with regard to the breakthroughs, the breakthroughs that would be considered for the crisis provision, it's not based on time, that we are looking at the concentration that we will be looking through is a breakthrough concentration, not a time.

And I think it's a little confusing in the concept paper, and that will be clarified as we move forward with the next edition.

But part of our concern in looking at how the testing is done is twofold. You know, one -- one that we are looking at, trying to do the evaluation using existing testing concepts that have been used in the industry for many years.

And again, it gets back to constant flow testing where it may not be truly indicative of how a respirator is used, but it defines for us the

capacity and the dwell for how well the canister will work in an application.

As we have moved forward in developing the CBRN with the gas mask and with the PAPR in general, in looking at these, the potential for these high peak excursions of, you know, up, you know, 430 liters per minute, you know, at various points in time, there is a question of whether or not that testing a constant flow will be able to address and provide protection, you know, in those instances, when an individual, you know, under physiological duress will stress the respirator and challenge it with a higher -- a higher flow, a higher physiological demand, whether it be a short-term or long-term effect.

And part of what we are looking at doing over the next several months is to conduct a research program to look at whether or not, through the use of constant flow testing, that we will capture, you know, those peak excursions and provide the necessary protection for the user.

And if -- and concurrently with that, we

are also going to be looking at the potential of doing a cyclic type of evaluation where, instead of testing at a constant flow, we will consider using testing at a cyclic flow to replicate individuals breathing and establish the peaks that way, and then measure the concentrations that -- the breakthrough concentrations to determine the acceptability of the canister.

And this is something, you know, something that has been discussed, I guess, in other circles. And at least we are looking at moving this forward over the next several months as part of our research effort to bring some answers to those questions.

With regard to the particulate testing, we tested the manifolds -- or when we conducted particulate testing that will reduce -- let me start over again.

We are going to be using the P100 requirements for CBRN protection. And it's part of the parameters that we set up early in the program and are continuing through the -- all the standards

that are being developed.

You know, when you look at the industrial certification program, the NIOSH industrial PAPRs use high efficiency particulate filters.

And for the difference between that type of device and this type of device is the focus on making sure that the CBRN PAPRs meet P100, the minimum P100 requirements that are identified in 42 CFR.

But as far as the testing goes, you know, constant -- with constant flow or breath response of demand responsive type units that will test at the air flow of those PAPRs as part of the evaluation.

And keeping in mind that when we do the particulate loading, that if you have three canisters on your filter or on your system and we do the particulate challenge against that canister will reduce the air flow by three. So if you have a 300 liter per minute PAPR, each canister will see 100 liters per minute as part of the testing.

Now, we will be using the standard

diosophalate (phonetic) challenge. And also we are going to continue forward the post durability challenging of the filter, the durability challenge, environmental conditioning, testing, taking some samples out of that and evaluating them against the organic vapor cyclohexane.

And this addresses a concern that was raised during the CBRN gas mask standard development process, that certain -- certain filter medias aren't all created equal, and that there needs to be a means to ensure that, after exposure to particulate, that the filter efficiency against certain gases hasn't broken down.

And we implemented cyclohexane as a test for that.

Also, in look at the particulate testing, one of concepts that we had explored was to use a -- an equivalent face velocity where we would look at sections of the filter media that was provided as part of the canister for effectiveness against DOP.

But in general it seemed that, after

reviewing the comments that were received regarding that concept, that it was just too much research that needed to be involved, and we dropped that part of the concept.

And I had mentioned back in the May public meeting that, you know, with regard to completing the requirements for -- well, completing the development of the requirements for the PAPR standard, that the high flow testing equipment was the critical path for bringing this standard to conclusion.

And we were correct as far as that being the path -- the critical path for resolving a lot of issues related to the testing.

We have had contracts awarded, and are currently expecting delivery of two different systems. One is from Air Techniques in Maryland. The other is from TSI in Minnesota.

And my understanding is that basically these are adaptations of existing testers that are used for flow evaluations in the industry, that they are being modified to allow testing up to

flows of 450 liters a minute.

And we are expecting delivery of those items in February of 2005. And we will begin our evaluations after we do a shakeout evaluation of that equipment.

And one thing I did want to note in conjunction with this slide and a comment I had made earlier regarding the test procedures is that we acknowledge this is a very critical piece of information for the stakeholder community with regard to how we are going to do these evaluations as we move forward.

And in the development of our test procedures, we will identify the equipment and the parameters associated with the equipment. So you can -- in particular, the manufacturing community can make some decisions regarding, you know, what to do in terms of your pretest development.

But having said that, though, with the limitations of not being able to get the equipment quickly, we have done some evaluations internally using our existing equipment within the lab.

And there were some studies run where we increased the flow rate of our existing TSI equipment to approximately 100 liters per minute to evaluate the particulate testing.

And we did show that for the limited number of samples we did, that there was a consistency with the P-100 requirements.

We have also looked at doing some limited laboratory evaluations with the gas life at the higher flows.

And, again, these were -- these were basically done using the crisis demand type scenarios that we established for the PAP -- or for the gas mask requirements that the -- the crisis demand for the gas mask is 100 liters per minute, and we have the capability to run evaluations at those levels. And we have completed some studies in that area.

In general knowing that -- acknowledging that the canisters, you know, weren't specifically designed for that purpose, they did perform fairly well.

And that information, unfortunately, we weren't able to get complete in time for this public meeting, as far as specific test results, you know, to present at this meeting because of Terry's illness, but I will look into making that -- when the slides for the presentations from this program are made available on the internet, we will look at having that information included as well as part of the presentation.

And where we are headed over the next several months, is to do additional benchmark testing at the higher flow.

And so with that, I have -- I'm complete. Anybody have any comments?

I'm shocked.

MR. BERNDTSSON: Goran Berndtsson from SEA.

Can you go back a couple of slides where you looked on -- maybe five slides back or something where you had...

MR. SZALAJDA: This one?

MR. BERNDTSSON: Yes, that's right.

MR. SZALAJDA: Okay.

MR. BERNDTSSON: You thought that was good to talk.

We are -- I'm a little bit -- not -- next one actually, go forward one. Another one.

That's the one.

MR. SZALAJDA: This one?

MR. BERNDTSSON: Yeah.

Demand responsive PAPRs canisters tested at 115 liters for moderate breathing and then 300 liters, why are you sticking with ...

Okay, why are we sticking with the constant flow for demand respirators?

I mean, in the draft paper here, you are actually requiring higher testing constant flow for demand than you do for a constant -- it's 261 liters against 300 liters.

Do you see the logic behind that?

MR. SZALAJDA: I think maybe the slide is not very clear with how it is presented.

But I think in general, we are looking at a minimum flow or the value specified by the

manufacturer as part of the testing.

And in concert with that, what we will be doing is developing a test procedure that is going to look -- that is based -- I believe, it is on STP -- NIOSH STP No. 12, which determines the flow rate of the PAPR.

And we will be using that test procedure to determine flow rate, which will carry forward into the other tests.

MR. BERNDTSSON: When it comes to the absorption of the gas cartridge, the gas part of the cartridges, isn't that true to say that there is two parameters that you have meet.

You need to meet the peak flow, and that you do with the filter there. And then you need to meet the capacity, and that is the volume over there.

And both of those have to be tested or meet some kind of requirement.

MR. SZALAJDA: Right. And that's where we will be -- when we do the manifold, we will test the -- well will run the evaluation as a system.

You know, we will put your manifold and your canisters into the chamber and run the -- run your device as a system.

MR. BERNDTSSON: That's fine. I don't disagree with that. That's fine.

But when you have a demand type of respirator, you will not run -- you will meet the peak flows, but you will not flow the volume through the filter.

So in other words, I mean, to meet the peak flow of the 300 liters, you maybe have an interactive flow of 100 liters, just as an example. So, yes, you need to meet the peaks at the filter depth, and then you need the flow for -- the capacity is only 100 liters.

MR. SZALAJDA: And I think that is part of the research that we are looking at as we move forward, you know, with determining how exactly the tests are going to be done, whether or not by testing at a constant flow if we are going to capture those peaks, or if we need to do something different in terms of the cyclical tests where we

may, you know, by varying the flow rate, that you put more of a demand on the respirator to address systems like you are describing, you know, to evaluate the efficiencies at the higher flow rates.

MR. BERNDTSSON: So did you -- in conclusion of that, what you are saying is that you haven't -- this is not settled in any way.

MR. SZALAJDA: Oh, no, no. By -- again, it is all -- it is still all a concept at this point, and, you know, it is still limited, you know, by what we have been able to do with the equipment -- the equipment in-house. And we certainly haven't been able to address anything above 100 liters a minute yet.

MR. PFRIEM: Dale Pfriem, ICS Labs.

Jon, just a question, realizing that this isn't final, but just to get a stable, current view of what you have.

In this present slide, you have got the constant flow PAPR is going to be tested at the airflow of the PAPR, and you had mentioned that that airflow is going to be determined by the

reference STP.

MR. SZALAJDA: Okay. I think --

MR. PFRIEM: Okay.

MR. SZALAJDA: Yeah, I think the way -- I'm sorry, Dale. I'll let you finish.

MR. PFRIEM: So are we going to work at the measured airflow of the PAPR, or are we going to work at paragraph 5.3.4, in either a medium flow criteria or a maximum flow criteria, testing either at 100 or 115?

MR. SZALAJDA: Okay. Well, I think when you look at particulate testing, I think the way the concept paper is written out, it says we are doing the standard 85 liters a minute.

MR. PFRIEM: Well, that was my next question. And this goes back to 85.

MR. SZALAJDA: And part of -- and part of, you know, the reason for showing the chart this way is there is still information that we are trying to generate to determine the feasibility of testing -- do the particulate testing at these higher flows, and we just haven't had the

capability to do that.

The other aspect of that is to look at the research that has been developed, you know, in concert with the type of protection that is afforded for particulates in different flow rates.

And one of the things that I know, looking at, you know, the work that Dave has done and ECBC is doing for us, looking at different particulates, but also looking at that literature, you know, and there is a lot of -- a lot of differing opinions in the literature as far as, you know, efficiencies at various flow rates.

And a lot of that data we still need to crunch through before we make a determination of what exact flow rate we are going to evaluate.

MR. PFRIEM: Okay. So right now, it is indeterminate, 85, 100, 115, or at the exact performance level of the PAPR?

MR. SZALAJDA: Right.

MR. PFRIEM: And I'm not sure if this is the appropriate time, but since we are talking about particulate performance, and I had a chance

to talk with Dave briefly on what he presented before, what is the rationale with the -- behind the current proposal of dispensing with any kind of a loading test for the media, either dolomite or silica dust?

MR. SZALAJDA: Right. Actually part of Ted's presentation is going to address the loading tests that we are envisioning in relationship to the filter and the indicators, the low-flow indicators.

MR. PFRIEM: Right. Because it's an instance both of the filter performance and of system performance where we have got 30, 60, et cetera, failure notice criteria and performance specification, but they are done under nonload conditions.

MR. SZALAJDA: Right.

And part of the issue that we have seen with doing the actual loading is with the silica dust test that is currently used by NIOSH.

And what we are trying to leave open in terms of the concept is looking at other avenues

to -- other than that test to replicate how it -- you know, the results of that test without having to go and do the particulate loading.

MR. PFRIEM: Thank you. I will wait.

MR. SZALAJDA: Okay.

MR. BERNDTSSON: Goran Berndtsson, SEA.

Just another comment which I would like you to consider. And this may -- I don't know if this is the right time for doing it.

But on all your parameters, for example, we are using 25 plus/minus 5 degrees Celsius, and we are using a fairly broad plus minus number.

I would like that you go through the entire document and tie it up as much as you possibly can to make it more specific.

I mean, it is 25 degrees plus/minus five is much broader than you need with a new modern equipment that you put into the lab today. That could probably be plus/minus two and which means that it makes much easier for us to make things to meet the requirement without overdoing it.

MR. SZALAJDA: That's a good comment.

Thank you. That's, you know, one thing that, you know, I -- why -- I should have mentioned with -- when I mentioned the -- talked about the, you know, the terminology differences that you may see in the document, that, you know, we are trying to be sensitive to those types of requirements, as well, in the documents.

Thank you.

At this point, Ted Klemetti will continue the presentation with battery requirements and carbon dioxide.

MR. KLEMETTI: My presentation is going to cover the battery requirements as we have them right now in the concept paper.

I'm going to start off with some public comments and our responses to them for all of the different battery requirements within the concept paper.

We have had comments that this is a difficult test to perform, consider standardizing it. We are planning on performing these tests in standardized conditions using manufacturer

submitted equipment.

Test low flow indicator against both conditions, a fault caused by a low battery or by clogging or filter loading. On both conditions, we are planning on testing both conditions, if appropriate.

Changes in work rates require -- or cause a change in battery life. Our plan is to test to a minimum standard and have -- require in the users instructions explanation of the effects of changing work rates on the battery life.

We have had comments to both require only the low flow indicator and/or to only require the low battery indicator. We are going to at this point in time require both to alert the user to more fault conditions.

We have had suggestions that the manufacturers should provide data on extreme temperature use and other pertinent issues rather than testing to a -- to extreme temperature conditions.

Our plan at this point in time is to

require some level of minimum testing at these extreme conditions, as well as require the data into the users instruction, and then also to leave the indicator battery alarm or low flow indicator method of signaling optional.

Our plan is to require one, a form of indication, but no specific form, i.e., it could be a visual or an auditory alarm or a vibratory alarm, but we are not going to say that it has to be any one of the three or that it only has to be one.

Now, we get into the first test which is the battery performance test. Well, actually this is a description of the three major tests that we foresee in this section.

We have the battery performance test, which is the test performed at minus 30 degrees C to ensure the functionality of the system at this temperature.

The second test is the low battery indicator test, which will evaluate the PAPR's ability to alert the user to a low battery condition.

And the third is the low flow alarm test. This is used to evaluate the unit's ability to alarm user prior to negative pressure.

This will kind of also fall into the whole loading condition. The intent is to test the unit to ensure that upon a certain level of loading, that it will actually alarm the user prior to negative pressure.

Here is some of the results from the benchmark testing that has been performed to date.

For the battery performance, the only testing done there has been a preliminary test of whether or not current PAPRs on the market are able to run while being in the temperature condition.

We had a couple that ran periodically throughout a 72-hour cold soak period, and we had some that ran periodically throughout a 12-hour cold soak period.

They weren't run constant through any of this. Four hours, 12-hour increments. They would be tested, turned on. Some of the devices that had methods of indicating flow rates, indicated that

they were operating in the proper flow area or realm.

For high flow testing for the battery performance, we have not completed any testing there yet.

For breathing performance, which is a similar test the battery performance is performed at, 25 degrees Celsius rather than the minus 30.

As you can see, we have ran several different systems and have different running times, and that test is dependent upon the negative pressure inside of the facepiece.

Low flow alarms, as you can see it has only been run at the ambient condition, 25C. We had two systems in particular that had that ability, and they appeared to alarm in the correct times of the pressure, the low pressure.

At minus 30, we have not run any of those tests yet. That will be done at a later date. The low battery indicator, this test is requiring a minimum of 15 minute at the 25 degrees C to a 45-minute alarm prior to negative pressure.

As you can see here, we have roughly 10, 12, 13 minutes prior to that negative pressure after the alarm.

That's for the audible alarm on these systems. They have varied levels of battery indication throughout the time, and some of those different levels were well within the 15- to 45-minute period showing that this is something that can be accomplished with current technology.

Battery performance test concept criteria: It must maintain positive pressure in the breathing zone while breathing at the manufacturer selected breathing performance rate, whether it be moderate or high performance, 40 or 103 liters a minute.

Each individual PAPR will be required to meet this positive pressure condition for 35 percent of the rated battery life; and the average of all of the systems tested for this test will have to meet at least 40 percent of that operational battery life.

This test will be performed at minus 30

degrees C. And the plan is at this point to cold soak the systems for four hours prior to beginning the test.

As you saw the benchmark results earlier, we have done benchmark on breathing performance using both breathing rates, multiple PAPR systems, and using both the Posicheck and the NIOSH breathing machine with the Silverman cam.

There was very little difference between the two systems as far as what the results look like, and preliminary testing on the ability to work in low temperature conditions have been performed.

Future direction for the battery performance test. We will perform benchmark testing on several PAPR systems, finalize standard test procedure, and perform verification testing. This is for the minus 30 degree test for battery performance.

For the low battery indicator, the concept criteria is it will be either a moderate or high performance test at 25 degrees C. And the

requirement is that it will passively alarm the user at least 15 minutes prior to negative pressure, but no more than 45 minutes by passively alarming -- I mean, it's -- it will alarm the user to where you don't have to go looking for an answer.

If you're busy doing something, it's going to alert you to the low battery condition, not you have to go find the condition.

Likewise, this test will be performed at minus 30 degrees with the same criteria, with the exception of the time limit after the alarm goes off prior to negative pressure. There will be no minimum or no maximum time.

The test conditions, at this point we are looking at 25 degrees C plus or minus 5 degrees Celsius for ambient conditions with the breathing machine operated at the manufacturer's specified breathing rate of 40 or 103 liters per minute, although it says 2 up there, with a relative humidity of 50 plus or minus 5 percent.

And then at the minus 30 degrees, plus or

minus 5C, we are looking at a relative humidity of 20 percent plus or minus 5 at this point in time.

Benchmark results, we have performed tests at 25, as you saw earlier. The alarms -- the PAPRs with built-in alarms showed the ability depending on when the alarm -- or what part of the alarm you used as your decision maker in the 15 minutes.

And the PAPRs without built-in alarms could very easily be adapted with the current technology that is there to meet the standard or concept criteria.

There is an example at the end of the pressure, at the end of a battery indicator test. It is showing the last couple of minutes of a breathing performance test.

As you can see -- well, not really well, but the line that is right above the sample numbers that are going across on the X-axis is actually the -- is the minus .2. The next line above that is zero.

You can see distinctly where it goes

below zero and begins to increasingly go downhill and stay negative on the inhalation portion of the breath.

Future direction is to perform benchmark testing at the low temperature criteria, finalize the standard test procedure, and perform verification testing.

The last condition within the battery requirements is the low flow alarm. This is really a two-part test to test both the causal factors of a low battery and causal factor of loading or clogging of the filter.

The first part of the test will be performed similar to the breathing performance or battery performance test, having a breathing machine running. When the battery gets low, it goes off -- the low battery alarm goes off. At some point prior to negative pressure, does the low flow alarm go off.

This brings up an interesting question. What if our alarms are integrated, i.e., the low battery and low flow alarm, there is only one

signaling method or component for both of those.

If that happens to be the case, for this instance, as long as the low battery indicator went off at the appropriate time and that indicates to the user that they need to leave and the low flow alarm indicator could be considered part of that low battery indicator.

For part two of the test, we are looking at adding additional resistance with an adjustable orifice to the level of where it reaches negative pressure to ensure that an addition of resistance or loading, simulated loading causes the low flow alarm to go off so the user knows that he is in a negative pressure or approaching a negative pressure condition.

Concept criteria.

It alarms the user upon or just prior to negative pressure in the breathing zone for both conditions or both parts of the test.

As we saw earlier in the benchmark results table, initial evaluation of PAPRs with low flow indicators have shown the ability to provide

the required warning on the couple that did have that feature currently available.

The other ones, there is distinct breaks in where the pressure went below zero, leading to the decision that this could be something added to any of the current PAPRs with today's technology.

Further testing will be performed, and this will eliminate the need -- and this last statement is back on the thing that I said about if the low battery and low flow indicator are an integrated alarming system.

You would only need one of the two to indicate that there is a fault needing to leave the area for the low battery causal condition of low flow.

Here is an example of the pressure readings during a -- during a couple of low flow alarm tests. Throughout all of these, as you can see, there are peaks that reach below the zero line. The PAPRs that were tested during each of these peaks did alarm.

Future direction is to evaluate the

effects of instantaneous negative peaks in the breathing pattern, perform low flow testing at a low temperature condition, finalize the standard test procedure, and perform verification testing.

As Jon stated earlier, I was going to touch on the removal of the loading or clogging test, or filter loading test that we are doing.

Right now, we are looking at using an artificial simulation of a loading to facilitate that you still have the proper flow upon a loading.

This concludes my -- well, no, it doesn't. Moving on to the next -- well, let's go ahead and take a break here for any questions before we get too far ahead.

MR. BERNDTSSON: Goran Berndtsson, SEA. Couple of questions here.

You said the cold test was going to be done after four hours of cold soaking. Does that include the batteries?

MR. KLEMETTI: Yes. That falls in line with our fogging test.

MR. BERNDTSSON: Okay. And the next

question is maybe stupid, but I don't necessarily know the answers to it.

How does the filter perform at minus 30 degrees Celsius?

MR. SZALAJDA: Could you repeat the question?

MR. BERNDTSSON: Does anyone know how filters perform at minus 30?

I mean, do we have a problem with some humidity freezing in the filters so they don't work too well when they come down to minus 30?

Have we done any verifications test that it does work?

MR. SZALAJDA: I think part of that -- when you look at the -- how the requirements for the battery were defined, you know, we took the approach of looking at doing the worst case type scenario, the effect on the battery itself in looking at the minus 30 and seeing where it was applied in other standards, like the NFPA standard, use a minus 30 application.

I think with the effectiveness of the

filters, you know, obviously, we do all of our testing at 25 degrees, you know, with varying humidities. And, you know, the effectiveness and the part of, I guess, where we look for help on that is to go back to the manufacturing side and looking at where your recommendations are for where the system should be used.

You know if it is something that, you know, the tests shouldn't -- you shouldn't use this device at temperatures less than 10 degrees or over 110 degrees or some range, you know, in your user instructions for the device.

Again, it gets back to, you know, looking at setting a minimum performance criteria in testing the filters, the canister's effectiveness, you know, at room temperature.

And I think the one thing when you look, like again, with the battery, you know, we are looking -- we know -- we know that cold temperature is going to affect the battery, and, you know, we try to structure the operation to allow, you know, a certain amount of degradation of the performance

of the battery as part of our evaluation.

So I don't know if that really answers your question or not or ...

MR. BERNDTSSON: I think that I understand where you are coming from, but it is fairly useless if we get the batteries to work at minus 30, but the filters don't.

I mean, what we need to do is get respirator who works at the certain temperature, and if minus 30 is right or wrong, I'm not the man to say that it is. But we have to be concerned on the total system at those extreme temperatures somehow.

So I think that -- spending a lot -- and I think you are doing well. You should be doing it, spending a lot of time investigating how it is working at certain temperatures. But we really need to look at the system as total. Otherwise it doesn't help the end user in the end of the day.

And, I mean, we -- minus 30, four hours cold soak, it is going to be really, really difficult to get anything to perform very well.

The battery technology is difficult down in that area.

And I haven't done any testing on filter performance down at that temperature, so I don't know the answer to the question.

And of course, in the activated charcoal, there is some humidity in the beginning in the charcoal embedded to get it to work.

And if that humidity freezes, or it would be freezing, and if that affects, I don't know.

MR. KLEMETTI: Okay. Thank you.

MR. VIJAYAKUMAR: Vijay from Air Techniques. I have some comments on this -- what Goran has mentioned.

There has been some work done on filtration at extreme temperatures. The lower temperatures, your performance will be great, even for a standard filter. But even more important, when you have a requirement to test performance low temperatures, the cycling will affect the construction of the filter.

I can almost bet that if you take

commercially available canisters and cycle them up and down to minus 30, it may lose its integrity between the fact you have in the filter it seems the differential expansions.

A lot of work has been done, both for the military, for the NASA, and to put filters up in space, as well as for the nuclear industry.

MR. KLEMETTI: Thank you.

MR. SZALAJDA: That's a good aspect. And I think when Frank gives his presentation probably after lunch, he will address this part of the environmental conditioning of the filters.

MR. GOSSWEILER: Otto Gossweiler, Safety Tech International.

You are stating that the breathing pressure is measured inside the mask and specified that it is inside the breathing zone.

Can you expand on this?

MR. KLEMETTI: The pressure will be measured in the same place -- same general vicinity that the pressure is measured in for the current NIOSH carbon dioxide testing, which is STP64.

It is a port right below the nose, in between the nose and the mouth port within the filter, or within the mannequin head form.

MR. GOSSWEILER: Okay. Thank you.

MR. HAUSER: Hans Hauser, Safety Tech International.

To follow this question, if you say you measure it exact at the nose, what is the meaning behind?

I say as a manufacturer, as long as we have all pressure in the entire mask, we are safe. You haven't to measure it just by the nose or whatever point.

We shall measure it inside the mask somewhere because we have everywhere except inside the nose, mouthpiece, the same pressure. Even says as long as all pressure in the mask, we are safe.

I suggest to alter this and to change it.

MR. KLEMETTI: We will have to look at that. Thank you.

All right. No further questions? We will move on to the carbon dioxide requirements for

the CBRN PAPR.

Some public comments we have received for the carbon dioxide testing identify the standard test procedure used for this test.

As Jon stated earlier, we are planning on having the standard test procedures completed at the same time that the standard will be completed so that -- and referenced within the standard so that all of that comes out at once.

What flow rate will be used for this test? Right now we are looking at the standard NIOSH CO2 flow rate, which is ten and a half liters a minute.

And will the PAPR be tested in the power off mode? At this point in time, we are not planning on testing the PAPR in the off mode.

Concept criteria for the CO2 machine test. The average carbon dioxide inhalation level must be less than 1 percent. Oxygen level 19 and a half percent, must be greater than.

It will require both levels to pass the test, and the test will be performed with the

blower operating.

Test conditions. Temperature range is 68 degrees Fahrenheit to 80 degrees Fahrenheit. Gas levels will be averaged for at least five breathing cycles. The breathing machine will run at ten and a half liters a minute.

The exhalation air from the breathing machine will contain 5 percent carbon dioxide. And as far as the equipment, the PAPR, the filters, all of that will be as received for the testing.

There will be -- with the exception of environmental conditioning, there will be no other -- there will be no loading of the canisters prior to this test.

Benchmark results. Preliminary testing has been performed. This test was performed with just the carbon dioxide analyzer attached to the system. There was -- the oxygen analysis wasn't performed nor was the pressure sensor used.

Four different PAPR systems were tested. Here are the results from that.

As you can see with the blower on, all of

the PAPRs are roughly zero that were tested in this.

We did perform the test with blower off, which is currently not part of the concept criteria, and those PAPRs that were tested on this test were not sized to fit the head form, per se. Some of them may have, but it wasn't intentionally designed that way or performed that way.

Future direction is to perform additional testing with equipment to determine repeatability and equivalency to current testing procedures and then to finalize the standard test procedure.

Human subject CO2 test. The criteria is less than or equal to 2 percent carbon dioxide, 19 and a half percent oxygen. It requires both levels, and this will also be performed with the blower operating.

Test conditions approximately 68 to 80 degrees Fahrenheit. The gas levels will be averaged for at least five breathing cycles. Two trials, one stationary and one walking briskly at three and a half miles an hour. And once again,

the equipment will be used as received.

For the human subject testing, we need to perform benchmark testing, establish the standard test procedure. We are looking at basing this off of STP 0454, which is the escape human subject breathing gas test, and perform verification testing.

Any questions?

MR. BERNDTSSON: Goran Berndtsson, SEA.

What is the logic behind not doing CO2 testing for the power off when we are doing LRPL testing with power off?

MR. SZALAJDA: Part of what we are trying to come to grips with when you look at the on and off aspect of the blower is trying to address how the system will be used.

And you know, if -- in an ideal world, you know, the blower always works, and, you know, it's appropriate to test it that way.

What we are grappling with is this part of the discussion is is looking at the appropriateness of testing -- testing the item in a

failed mode, you know, where you may, you know, prescribe or identify as part of the PAPR use, you know, that you leave the respirator on to -- if the motor fails, you leave the respirator on for egress purposes.

You know, that's a little different than how NIOSH has identified to do business with the industrial respirator because if you are wearing the PAPR, you are in, you know, a less than an ideal type environment.

You know, we have told people, you know, as part of the instructions, you know, the system fails, you take the respirator off because of potential CO2 build-up and other factors, and you leave. You egress from the area.

You know, with this -- with the CBRN event, it's a little different animal. And what we are looking at in terms of the standards development is, you know, the appropriateness of including, you know, for lack of a better term, failed -- you know, failed equipment test in the standard.

You know, when we look at, you know, evaluations of blower on, blower off, LRPL, you know, blower on, blower off, and whether or not that is part of the instructions that we ultimately provide to the user, address the fact that you leave the respirator on.

And if we are looking at that aspect as part of the, you know, instructions saying, Leave the respirator on, then it is probably appropriate to do these tests with the blower off.

Now, however having said that, you know, you look from the other standpoint, yeah, that the system should always be working and then we should test it that way.

So that is something that we are going to continue to work on over the next several months. It's not a -- there is not a straightforward easy answer, but that's sort of the thought philosophy that we have here in trying to determine what is appropriate to test.

MR. BERNDTSSON: You just talked yourself into -- to include it, didn't you?

Again, it makes sense.

MR. SZALAJDA: You're right.

MR. BERNDTSSON: CO2 is a critical thing. I mean, if you have something that really builds up CO2, then the reason why we are doing LRPL testing with power off is we want to have that escape capability if it fails, but we don't want them to die because of CO2 death.

MR. SZALAJDA: Right. And that's the issue in looking at the requirements when you look at how NIOSH has traditionally, you know, specified or developed guidance based on these systems.

And in looking at this particular threat, when you look at the CBRN threat, that, you know, if the failure can be tolerated or not. And on one aspect, you know, we should challenge the manufacturers to say that, you know, the item will not fail, but we know in practice that that isn't true.

And when you look at how the systems are used in this type of environment, we have some very specific decisions to make over the next several

months as far as that blower off test being appropriate or not.

MR. BERNDTSSON: You are absolutely correct. It shouldn't fail, but even though, it does stop sometimes.

I mean, it happens. You know, it's ...

MR. BROCHU: Paul Brochu from Marine Corps CBIRF. Just following up on this gentleman's question.

You know, by God, I would like to have a warm fuzzy when that thing shuts off on me when I'm down range because you know very well that we just don't have that opportunity to take that baby off and happily walk out.

And I know you are aware of that, but I would encourage you to please test it as stringently as you can, even in this regard.

MR. SZALAJDA: Okay. Thank you.

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

Ted, I know we will discuss this at greater length, but correct me if I'm wrong. The

current PAPR, non-CBRN, the blower is off when you do the CO2 test?

MR. KLEMETTI: Actually, there are currently two tests, one blower on and one blower off.

MR. CARETTI: Okay. At that low of a flow rate with the blower running, how is NIOSH planning on identifying when inhalation actually starts for averaging CO2 because your pressure values are no longer useful for that.

In the current test with the blower off, you see a cyclic change in pressure where you are measuring that, and your shape of your curve may change dramatically.

And you showed values up there that were less than atmospheric on average for CO2. You know, .03 percent is what atmospheric is. So you are telling me that with your benchmark testing, it's even less than that.

MR. KLEMETTI: Part of that goes into the subtracting out the background.

Current NIOSH testing procedures

subtracts the background CO2 levels from the actual readings that you get. So that's why it is lower than atmospheric.

As far as where -- how we are going to determine the beginning and end of inhalation, that's something that we are seriously going to have to look at.

Right now, as I said, these tests were performed without the pressure sensors, so they were estimated, rough guess at where they started.

MR. CARETTI: That's fair. I just wanted a clarification on that.

One thing that is not specifically clear, as you say, average inspired oxygen level cannot be less than 19 and a half percent.

I will tell you in the human subject breathing gas tests, you can get averages below the 19 and a half percent, but at the end of inhalation, you are above 19 and a half percent.

So you need to be specifically clear what you mean by that value because they are two very distinctly different things. Because to eliminate

something that doesn't have an average of 19 and a half may not be correct.

And I know we will discuss it at greater length, but that needs to be clear when we go with the next concept paper.

MR. KLEMETTI: Thank you.

MR. WILLIAMS: All right. Jon Williams, NPPTL.

I might suggest, as far as when you are making your measurements during the power on part of the PAPR, as to when the respiratory cycle starts and ends, you could probably use something like plethysmography, link it up to a plethysmograph to look at chest excursions going in and out, and maybe have a marker that says, Okay, well, at the begin of this phase, the plethysmographer reads a certain amount. And then as your chest goes in and out, you can link it to those cycles.

Something to consider.

MR. SZALAJDA: Thank you.

MR. PFRIEM: Dale Pfriem, ICS Labs.

Just a point of clarification to your response to Dave's earlier question. Currently we don't assess -- currently you guys don't assess CO2 in a PAPR application at all.

And then second -- second on to that, the isoamyl acetate test is done in a power on condition, but there is no CO2 assessment.

MR. KLEMETTI: We do have standard testing procedures for both blower on and blower off for the PAPR.

I know there have been some instances where we have performed the test with the blower off for a particular application.

As far as beyond that, I'm not sure that we do do it on a regular basis.

MR. METZLER: Well, I think at this point, we are at 5 of -- almost five to 12.

Let's take a break for lunch, and we will reconvene at 1 o'clock and finish the PAPR concept.

(A luncheon recess was taken.)

MR. SZALAJDA: Next is Frank Palya, who is going to discuss the durability conditioning of

the CBRN PAPRs as well as human factors type testing.

MR. PALYA: May I have your attention, please? May I have your attention, please? We would like to get started here.

Okay. I would like to go ahead and discuss some of the durability testing requirements for the CBRN PAPR.

Most of you are familiar with these requirements, but I'm going to go ahead there and go through them just for the benefit of the people who are not what familiar with these.

I would like to go ahead there and discuss the purpose and goal of the types of tests and conditions of the PAPR when they undergo the durability testing, and address some of the previous public meeting comments.

The durability testing includes the environmental, transportation, and rough handling aspects.

The purpose of this test is to perform the environmental storage, transportation shock,

and drop tests on the PAPR to qualify the durability and to detect any initial life cycle failures that may occur from typical use.

And the goal is to ensure that the PAPR provides adequate respiratory after being subject to the normal use by the end user.

As you can see, these are the sequence of tests that is going to happen. There is the PAPR, batteries, and canisters will undergo high temperature. Then they will undergo low temperature conditioning, humidity, and then vibration.

Then the canisters will be rough handled, and that basically consists of the drop test. And then they will -- the required amount of canisters will come back in and be hooked back up with the PAPR systems, and then they will be tested for agent permeation resistance.

The other canisters will go through the life testing, the gas life testing in the manifold. Also there will be a cyclohexane testing -- or after the cyclohexane testing, there will be a

filtration testing. And that is to address the concern that some filter media may undergo deterioration after being subjected to organic vapors.

This is the matrix explaining some more detail.

It explains the test methods that are used to test the hot, the cold, the humidity, the transportation. Basically it's Mil-standard-810F. Then this is the details of the exact conditioning, the duration, and what's being tested.

These tests is the same test requirements as the air-purifying respirator. And most likely we are going to be using the same standard test procedure. There may be some modifications to it just to adjust to the size and load of the PAPR systems.

The test -- the CBRN PAPR and canisters will be subjected to the test conditions in the minimum packaging configuration as specified by the manufacturer in the user's instructions.

That has caused a little bit of

confusion, but what we are doing is we are giving the manufacturers the opportunity to let us know how to have the PAPRs undergo this durability testing.

As it undergoes this durability testing, this will be conveyed to the users of this product, and we will expect the PAPRs to be stored in that configuration. This configuration may be the bags, different thing, carriers.

So again, it may -- it is up to the manufacturer, and it is up to the manufacturer to specify this.

After the durability test, we will check it for -- the PAPR for functionality. And then before it gets -- goes on to the next test, it will be -- the batteries will be recharged or replaced before it goes into the agent testing.

We did perform some benchmark durability testing. We benchmark tested three PAPRs per manufacturer, and we tested three manufacturer's products.

Now I would like to address some of the

public meeting comments. There was a comment that NIOSH had considered durability test conditions that shall be set by the manufacturer.

The current test, the concept test for the durability testing establishes a standardized test conditions. If the durability test conditions were set by the manufacturer, it would defeat the whole spirit of a standardized durability test, and it would be difficult for the user or community to keep track of the various storage conditions for the various PAPRs that they may have.

Another comment was that it may be unrealistic to expect a PAPR to function after the environmental conditioning.

What this will happen is in this case the batteries will be replaced or recharged before the subsequent chemical warfare agent test.

There was a comment that stated that it would be important to perform leak testing on the PAPRs due to the cracking potential of the various materials of the different types of polymers used to produce a PAPR.

There is a leak test performed on a PAPR before it undergoes the agent -- the chemical warfare agent GB and HD permeation resistance test.

Another comment was concern that the extreme temperatures in the durability test requirements will adversely affect the sensor calibration and battery performance.

After doing some research -- and Ted touched on it earlier -- that there were batteries and pressure sensors that are available on the open market to withstand these temperature extremes. Keep in mind that the batteries will be replaced or recharged before it goes of to the subsequent test, the GB and HD testing.

The last comment, there was a comment that recommends drop testing the entire PAPR without packaging by performing multiple drops off the actual human subject, so it would be right on the floor.

We feel that dropping the entire unit multiple times without the packaging makes the test more severe, but we feel it's like borderline

abuse. Plus it's -- after this abuse, there are alarms to indicate if the PAPR isn't functioning properly if accidentally damaged.

Another thing one must consider is that if you want to go ahead there and make this thing that hardy, it would almost be gold plating it. In other words, it would -- you would have to beef up the materials and the cost of it where it would be very expensive, where it's just not needed.

At this time, I could answer any of your questions about the durability testing. Or, if not, I could just continue on with the human factors test, and I'll address any of your questions at the end of the presentation.

Moving onto the human factors. The human factor requirements for the CBRN PAPR is the field of view, fogging, communications, the haze, luminous transmittance and abrasion resistance test of the primary lens.

The field of view requirement is that the PAPR must obtain a visual field of view score greater than or equal to 90. How this is tested is

with the currently apertometer that meets the EN 136 standard, and it's derived after three fittings. And, again, it's the same standard test procedure that was used for the air-purifying respirator.

The next is the fogging resistance requirement where each subject's average visual acuity score must be greater than or equal to 75 points. And the number of human subjects tested is two.

There will be three visual acuity scores taken, one post chamber don, and then two minutes -- or after 5 minutes of exercise, there will be another set of scores, and then after another five minutes of exercise.

These visual acuity scores will be taken and derived for an overall visual acuity.

Again, this is the standard test procedure for the air-purifying respirator.

The next is the speech requirement and the speech intelligibility where the overall performance rating has to be greater than or equal

to 70 percent.

The PAPR motor shall be operating during this, and the voice conveyance system shall be operating at maximum if there is an active voice conveyance system.

And then the primary lens, haze luminous transmittance abrasion resistance requirements, again, is the same as the air-purifying respirator, and these are the requirements.

And that will be just done on the lens specimens. That will not be done on the respirator lens. In other words, we will not cut the lens specimens from the eyepiece of a respirator, but the manufacturer will send in flat four-by-four-inch specimens to be tested.

Discussing some of the benchmark testings. The field of view benchmark testing, what we did is we tested four PAPRs, three full facepiece types, type fitting full facepiece, and then the hood type, neck down type.

As you can see, they all passed the requirement of 90.

Next we tested the -- benchmark tested for the fogging. We tested three full facepiece types, one hood type. And, again, as you can see, they all passed the scores, passed the requirement of the overall performance requirement, sub 75.

The communication test, there was a -- from the full facepiece, there was two passive systems, an active system, and then there was a -- the hood type had no voice conveyance system or voicemitter.

There was these two type of -- one passive failed, and a system that had no voice conveyance system also failed.

When we originally tested this, there was -- we had the noise generator operating at the time. There was some comments that -- some people felt that there was comments -- had a concern about the noise -- there was excessive noise during this test.

So it didn't seem fair that this requirement would be the same as the air-purifying respirator because you had the noise generator

operating, plus you had all the PAPRs, or the test subjects operating. Therefore, the noise was excessive during the test itself.

And we changed the test procedure for that, and I will discuss that a little bit later.

To address some of the public meeting comments, the field of view test, there really were no comments provided on the current requirement and the test method.

As far as the fogging requirement, there was a concern that the batteries would not function after four hours of cold soaking at minus 21.C.

During the fogging test, the batteries worked adequately in all of the PAPR models after the initial four hours of cold soaking while performing the fogging test.

The communication requirement, there was a comment that the four PAPRs would generate excessive noise thus making the requirement more difficult to pass than the APR.

As I mentioned earlier, what we did was we have a proposed change that the test procedure

to have a minimum background noise of 60.

And how this works is that when all four PAPRs are operating during this test, if there is 60 decibels or greater noise level, the noise generator will not -- will not be activated.

If the four PAPRs during the test do not generate a noise level of 60 decibels, the noise generator would be activated to create this minimum of 60 decibels.

The next is the haze, luminous transmittance and abrasion comments. A lot of people -- there are some folks that would eliminate the abrasion requirement for the flexible lens materials that will be used in disposable one-time-use hood-type facepieces.

And after considering -- NIOSH is considering eliminating the abrasion test. However, we would still keep the haze, luminous transmittance requirement.

Next, there was a comment of how will coverings such as lens protective coverings and overshields be handled for the lens abrasion.

This requirement is just for the primary lens on the respirator, not for protective coverings, outskirts, or overshields that are replaceable.

Another comment was that NIOSH had considered changing the luminous transmittance and haze requirements to an absolute value.

In other words, have the absolute minimum, which is luminous transmittance of 84 percent and the maximum haze value at 75 percent instead of the current NIOSH requirements, which is there can't be a decrease in luminous transmittance by 4 percent, or the haze can't increase by 4 percent.

NIOSH will not adopt this absolute value. The purpose of this test is to test the abrasion resistance characteristics of the lens material which is independent of the initial luminous transmittance and haze values.

So, again, the characteristic and the spirit of this test is to test the abrasion resistance characteristics.

Another comment was some manufacturers felt that they should not have to provide the abraded lens.

NIOSH is considering waiving this requirement for the abraded specimens, but -- however, it's currently required just to determine to see if the tests are consistent between the manufacturers and NIOSH. It's just a good way of making sure that there is consistency.

And at this time, I will answer any of your questions.

Thank you.

MR. SZALAJDA: Frank.

MR. DENNY: Since nobody else is up here, just a quick question.

We just discussed a few moments ago that you guys are doing LRPL testing with the blower off as you are concerned with worst case assessment.

But then I noticed you are doing lens fogging with the blower on.

MR. PALYA: Yes. You know, that just struck me that, you know, when you go with the off

mode, does that mean that you have to do it with the off mode during a fogging test?

And, you know, there's a good argument for having it off while you are doing the fogging as well because you certainly don't want to be down range and have it go off and then come back blind.

MR. DENNY: Just something --

MR. PALYA: That's something under consideration. Thank you.

MR. SZALAJDA: Yeah. One thing I wanted to add to that was, you know, I think, keeping in mind how we are considering or trying to consider testing the respirators as they are going to be used.

And one of the features when you look at air-purifying systems in general is that the user makes a conscious decision whether or not he is going to put the device on before he goes into a scenario.

And with a -- in looking at how the fogging test is done, you know, the respirator could be cold. And part of that aspect is making

sure that, you know, is this part of the checks and balances that a user will undertake in evaluating their system before they put it on?

MR. TEELE: Bruce Teele, NFPA.

The comment and the response about the 60 DBA level for measuring the voice intelligibility through the respirator, the PAPR, having been reduced because it was said there was too much noise with the noise generator going and the PAPR is operating sounds to me like a fairly moderately quiet incident scene at that noise level. And to reduce it further, further complicates the ability of the emergency responders to communicate with one another while they are wearing PAPRs or any other respirator for that matter.

I don't agree with that position being taken because voice recognition, being able to communicate with the respirator on, has been, is now, and appears to continue to be a problem with emergency responders.

MR. SZALAJDA: Yeah. Well, we were just trying to establish a standardized baseline of

noise level when performing that test.

You know, as with the air-purifying respirator, that was pretty simple because the APR did not generate any noise.

And then, you know, again, we were just trying to go ahead here and establish the minimum value. We needed to take that into account because we wanted to check out the feature or test the communication features of the respirator.

MR. PALYA: May I respond?

MR. SZALAJDA: Yes.

MR. PALYA: It would seem, though, that the suggested change, not less than 60 DBA, leaves it wide open as to how you would conduct the testing and it may lead to inconsistent testing depending on the noise generated by the PAPR device or whatever other background.

It would seem like you would want to set a decibel level, and then everyone is tested equally.

MR. TEELE: Well, yeah, because the thing is -- okay. So there is a minimal level of 60 set

during the test.

And then if it would increase, you know, you would almost be penalizing the PAPRs that are run very, very smoothly.

If there are, let's say, all four PAPRs and plus the noise -- are generating a 61 decibel, by, You know, increasing their noise level up to a certain point than with the lower ones, it just would seem like it would penalize the PAPRs that run at a lower noise level.

MR. SZALAJDA: Thank you, Bruce.

MR. SMITH: Andrew Smith, SEA Group.

You specified that you were going to test active speech devices at full volume.

Could you explain?

MR. PALYA: Yes. Yes.

In other words, so that there would be no discrepancy by saying, Well, gee, you didn't test my PAPR at full volume. You only tested it at a fourth, or this person only tested at three-fourths. This way it would give it consistency.

MR. SMITH: And the consistency of the speech volume?

MR. PALYA: Pardon me?

MR. SMITH: The consistency of the person speaking, how loudly they were speaking.

MR. PALYA: That would be one of the test procedures. You establish the volume. The speaker is trained to go ahead there and speak at a certain level.

MR. BERNDTSSON: Goran Berndtsson from SEA. That makes it very difficult.

I mean, the whole purpose of having the volume is that some people speak very slowly or very low, and others speak very loud. And then, of course, you can adjust that by depending a little bit on the surrounding noise and how hard you are -- how loud you want to speak.

So if you are turning it up to the max, and someone speaks really hard in the microphone, it is going to be a lot of distortion.

I think you need to consider that it's not really fair to go to put full volume on and

then not considering because the whole purpose with the volume was to overcome his kind of thing.

MR. PALYA: Okay. Yeah, I understand a need for consistency, and thanks for the comment.

We will talk about this today.

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

Goran, to answer your question and the questions about speech intensity, the MRT test requires probably 60 percent of the time that you train the speakers to use the same intensity throughout the entire test.

So there are many efforts made to try to train people to do that.

It is always consistent? It is pretty good.

Is it perfect? No. But it is the nature of that type of testing.

I think the purpose of turning up the microphone all the way is once the speakers have been trained to speak at the same intensity with and without background noise and without a

respirator on and with a respirator on, is to give the benefit of the doubt to the speech conveyance system if it's an active system for whatever the manufacturer wants to use. So that's how we try to handle that information.

As far as the background noise combinations, that is still an outstanding issue, Bruce. I think we still need to discuss that. And that really addresses the minimum background noise. And correct me if I'm wrong, Frank, you are using some existing standard as to how loud a PAPR blower can be at the level of the ear before you will even do this test?

MR. PALYA: Yes. There is a requirement of, you know, in the 42 CFR.

MR. CARETTI: And that is what? 80?

MR. PALYA: That's the 80 decibels.

MR. CARETTI: The 80 decibels.

MR. PALYA: Right.

MR. CARETTI: And one question, too, one thing that is still outstanding is in terms of the breathe assist types of respirators, it is my

experience that when someone is speaking, and those things are ramping up, that background noise really shoots through the roof.

And we need to consider the impacts of that if the system doesn't have some kind of a speech transmission that is an active system.

MR. PALYA: Okay.

MR. CARETTI: Okay. Thanks.

MR. PALYA: The next couple of presentations that you are going to hear are related to tests where NIOSH has, I want to say licenses, isn't probably a correct term, but where we use the Edgewood Chemical Biological Center, RDECOM, as our test agent for performing chemical warfare agent challenges on respirators, as well as the LRPL.

Dr. Lynn Hoffland from ECBC is going to be discussing the results of some recently, I guess as of last week, completed tests of NIOSH approved equipment, NIOSH industrial requirements versus our conceptual PAPR agent challenges. And Ted Klemetti is going to discuss the LRPL results for

benchmarking that were recently completed.

One of the things that I did want to -- when you look at this aspect of the testing is this is a result of our three-tier process. The whole purpose behind the chemical war -- testing with the chemical warfare agents test was to evaluate the penetration and permeation resistence of the respirator versus chemical warfare agents.

And part of the intent in looking at the respirators was to, you know, do that evaluation on a Smartman head form, which Lynn will describe a little bit further. But basically it's not -- basically to try to focus -- the respirator to just act as it would normally do being worn by a wearer.

We are not testing the breathing resistance. We are not testing the -- if the breathing efficiency. We are testing to see if chemical warfare agents are penetrating and permeating through the equipment.

And one of the things that was a little different -- and Dr. Hoffland will explain it in his discussion -- is when we looked at the

different types of PAPRs, we evaluated the -- one of the breath response type systems where we considered raising the flow rate of the breathing machine inside the Smartman mechanism to surge it to allow for a higher volume of air, 60 liters per minute instead of 40 liters per minute, as part of the test cycle.

And part of our thought process here was that we wanted to see with regard to the equipment and knowing that there may be some changes in the respirator whether or not that -- that change in the breathing flow made a difference in how the respirator responded and whether or not things opened or closed, or, you know, may have loosened while the respirator was responding to the increased breathing flow.

We haven't completely analyzed all of the data, you know, associated with that. And probably between now and the next concept paper, we will be able to make a determination whether or not that that's really applicable for the standard or not.

So with that, Dr. Hoffland will give his

presentation.

DR. HOFFLAND: Thank you very much, Jon.

As he introduced me, we were given two copies of PAPRs manufactured by -- from three different manufacturers, and we just ran the standard as it was written to determine how they performed as received.

Okay. The test requirements are, we perform a leak test, 30 minutes on a clean head form in order to make sure that the PAPR will seal to the head form. And then that is repeated again on the agent head form before the test begins to make sure that it's fit properly before an agent test begins.

Breathing rate for constant flow is 40 liters per minute, which is 36 strokes per minute with a tidal volume 1.1.

If it's a on-demand unit, from minutes 15 to 30 of each hour, the rate -- respirations will be increased to 55 strokes per minute, which will increase the total volume to 30 -- or 60 liters per minute.

For GB, the agent concentration challenge is 210, plus or minus 10 percent. And the challenge vapor is introduced for the first 30 minutes of an eight-hour test.

And this gives the break for maximum peak, .044, and the break -- a CT of 1.05 milligrams per minute -- milligram minutes per meter cubed.

This is a typical challenge profile. So for roughly 30 minutes, we have an agent turned on. And then it's -- the supply is turned off, and it gradually decays as it -- the item breathes and purifies the air in the box.

We had three manufacturers. We designated them A, B and C.

And these are the results. The cumulative CT for the first one. The second one, it did very well. And the third one didn't do quite as well.

I can guess as to what the problem was in this case. I don't know if I should -- should -- I guess not. But, anyway, the third unit failed

about right at a little bit before four hours into the test.

For mustard, it has the same requirements for breathing rates. Again, if it's on-demand, it's increased for minutes 15 to 30 of each hour of the test.

Challenge concentration is 50 milligrams per meter cubed, plus or minus 10 percent. Again, for the first 30 minutes of the challenge, it's turned on as a vapor challenge. And then at hour six, we do a liquid application, and that's on for the last two hours of the test.

This gives you break times, maximum peak, .3, and the break is three milligram minute per meter cubed.

There is a typical challenge profile. And the three PAPRs, A, which broke about seven hours into the test. B, which didn't break, what is considered passing, although there was some agent getting into the mask. And C, which broke about three and a half, between three and a half and four hours into the test.

That's all I have.

Are there any questions?

MR. CARETTI: Dave Caretti.

I would lend just a comment. When you do the 60 liter per minute volume testing, I would recommend that you don't just increase the frequency. You have to change both the volume and the frequency to do 60 liters a minute because that's the way it would be in the real world.

And then a comment for NPPTL and everyone else to be aware of. We have two systems where we have moderate breathing rate of 40 liters a minute, but we are using very different title volumes and stroke volumes for those tests.

And you may want to have those to be consistent. You know, the moderate flow rate under the current concept paper is 24 breaths a minute, so it is roughly 1.7 liter tidal volumes. And then the testing doing at Edgewood is 36 breaths a minute, and it's 1.1 liters tidal volume.

And I don't think it would make a big difference in your test, but I think we should just

be consistent in that.

MR. SZALAJDA: Okay.

MR. CARETTI: Thanks.

MR. PALYA: Let me just add to Dr. Hoffland's presentation.

This pertains to the batteries. And in talking with some of the folks down at Edgewood, disposing batteries off an Army base is very difficult. Disposing agent contaminated batteries is near impossible.

So I think when we are looking into the standard test procedures is that we are going to try to keep the batteries outside the hot box and try to rewire and up hook up leads in there.

At this time, the standard test procedure is pretty fluent. We are trying to adjust it, and -- so that we wouldn't deal with those problems with disposal of hazardous waste with the batteries. And that has been working out -- from talking with the lab personalities, it is working out rather well.

MS. RICHARDSON: Irene Richardson with

the U.S. Army Center for Health Promotion and Preventive Medicine.

Just a quick question. Are there any plans that have any requirements in case the battery pack does quit as far as performance or protection against the chemical agents in case -- again, you just basically have a glorified APR instead of the actual PAPR if the batteries die?

MR. SZALAJDA: Go ahead.

DR. HOFFLAND: I guess that issue is to be worked out.

I know in this case, two of the manufacturers' PAPRs were supplied without batteries, and so we provide a constant voltage source for that unit, for those two units.

The third unit had batteries in it, but we also provide a constant -- they were provided with their charging system, and that was plugged in during the test.

So the batteries weren't challenged for these tests, but I don't know what the plans are.

MR. SZALAJDA: Yeah. Irene, that's a

good point, and I think that's something that, you know, with this test, as well as with the other, you know, the other ones that we have talked about that we are going to need to think of in terms of maybe evaluation and any decisions we make in testing a failed type mode.

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

Does the concentration that the batteries are exposed to have any effect on them, or do you know?

DR. HOFFLAND: No, not that I'm aware of.

The agent shouldn't permeate the battery. It probably shouldn't permeate the casing that the battery is in to begin with. But even if it does, I don't think it will have any effect upon the battery.

Liquid agent isn't applied directly to the battery itself, just the housing.

MR. DENNY: Thank you.

MR. BROCHU: Jon, can I make one comment?

MR. SZALAJDA: Okay, Paul.

MR. BROCHU: Yeah, just back to the battery issue. Something you may want to consider is you mentioned internal versus external batteries in some of the material questions here.

We can -- perhaps if there are external battery packs, perhaps those should indeed be exposed to the agent test. I mean, certainly mustard can do a number on a variety of materials. And, you know, rather than take that battery out of the picture, you may want to consider, as far as agent compatibility.

DR. HOFFLAND: That is -- thank you, Paul. That's a very good point.

And I think that reminds me of one thing to just keep in mind too, that as part of the evaluation, we look at the effects of the chemical warfare agent on the respirator as well as the accessories.

And if there are issues that we see with plastic degrading or components breaking as a result of the exposure, we can work out those issues as part of the certification. So that's a

good point.

Thank you.

MR. KLEMETTI: All right. This one is on the LRPL requirements as we see them in the concept paper as well as some of the benchmark testing that has been performed at Edgewood.

Some of the public comments that we have received so far are how are we going to deal with failures due to particles produced from the PAPR.

At this point in time, we are looking at -- our primary concern is what the material is made of that is coming off, an MSDS chemical composition of that material.

And then the secondary concern is looking at a way of evaluating the background or the particles caused by that, PAPRs, and being able to remove that from the actual result if this becomes an issue.

Rationale for 10,000 LRPL, same environment. We are currently not requiring 10,000 LRPL level.

Perform at minimum flow and with blower

off. The test will be performed with the blower on and off as the concept is now.

Confusion between different LRPL levels of respirators. The different is twofold, partially because of the different types of respirators that there are, and second fold is the idea behind which we run the testing. For instance, the SCBA is tested as just a facepiece with a P100 filter attached.

That is a use configuration that will never by used by that PAPR -- or by that respirator, and all we are looking for is a facepiece fit.

Consider one size fits all panel for the LRPL tests. At this time, we are following the APR panel for full facepiece PAPRs, and we are looking at the air-purifying escape for the tight fitting neck dam PAPRs.

Same protection at different work rates. This test is being performed over 11 exercises, both blower on and blower off.

The concept criteria for the blower on,

we are looking at a level of greater than 500 for 95 percent of the trials. And for the blower off -- that's backwards.

For the blower on, we are looking at a level of greater than 2000 for 95 percent of the trials. And for the blower off, we are looking at a level greater than 500 for 95 percent of the trials.

Our test conditions, we are looking at somewhere between 68 to 80 degrees Fahrenheit, relative humidity of 50 percent, plus or minus 10 percent.

The corn oil challenge concentration is 20 to 40 milligrams per meter cubed with a median mass air diameter of .4 to .6 micrometers. Oxygen level will be at least 20 percent during the test.

Two trials with each subject for each testing mode. In other words, we are going to run a trial blower on, a trial blower off; a trial blower on and a trial blower off with each test subject. Once again, this will be an 11-exercise routine.

And we get back into talking about the panels. At this point in time, they are the same as an APR for the full facepiece, like I said before, and the APER for the tight fitting neck dam PAPR.

Benchmark testing, we performed testing on three different full facepiece PAPR systems, completed both the blower on and blower off trial. Each PAPR system was tested by more than one subject. And of concern during the benchmark testing was the hair placement of the subjects prior to testing.

Here are the results. We have the subjects listed one through seven, which will be on subsequent slides. Respirators were X, Y, and Z. Values for the on and off mode.

The one failure you see here was caused by hair affecting the seal, which we would remove from the test and retest -- or remove that result and retest the subject as it stands right now.

Here is more of the results for subjects three and four. There is five and six. And there

is subject seven.

Future direction is address testing concerns from benchmark testing. One concern is, of course, the tight fitting neck dam, which we currently have not run a test on, as well as the hair placement or any other fitting issues.

Finalize standard test procedure, and then perform verification testing with final standard test procedure.

Any questions?

MR. BERNDTSSON: Goran Berndtsson of SEA.

When you do the power on, power off, you intend to take the person out of the chamber, refit it again, and then go back in again?

MR. KLEMETTI: Yes.

MR. BERNDTSSON: So you are not just turning on and off the power?

MR. KLEMETTI: No.

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

I'm sorry. You may have said before in other portions of the presentation -- I haven't

seen it yet.

What -- will you be applying -- or I assume you will be, but when will be discussed -- is there going to be a maximum inhalation resistance of the respirator with the power off?

We can all make blowers that can overcome quite the filter, but when you turn the blower off, the person is supposed to be able to breathe through it for these tests.

MR. KLEMETTI: That is actually in the concept paper.

There is a standard for the -- I believe it's for the complete system power off. It has minimum, maximum inhalation and a maximum exhalation, I believe.

I believe it's 50 millimeters, 70 millimeters for initial and final for the inhalation, and 20 millimeters for the exhalation.

MR. DUNCAN: All right. Very good.

MR. KLEMETTI: And that comes out of 42 CFR for the current industrial PAPR, I believe.

MR. DUNCAN: Well, it actually says here

that -- oh, okay, so those are actually -- and so if I got this right, I guess, we are talking about Section 5.6, here.

This refers to the 85 liter per minute is actually drawn through the respirator in the negative pressure mode?

MR. KLEMETTI: Yes.

MR. DUNCAN: Okay. All right.

MR. CARETTI: Dave Caretti.

Ted, can you explain to me the rationale? In the spring, the LRPL was 10,000 with the blower running. Now it's 2000 with the blower running. And isn't that not lower than an APR requirement?

MR. KLEMETTI: That is part of -- in looking at setting the requirement, what we had received through the docket after the May meeting was at 10,000, was the value that was too high for the PAPR, that we should use -- since the PAPR would be used in the same applications as the gas mask, we should have a similar or use the same LRPL value that we did for the gas mask, which is 2000.

And at least at this time, while I think

we all appreciate that PAPRs can and will provide protection factors significantly higher than 2000, we are still looking at whether or not there is a technical basis to require something higher than what we specified for looking at the APR.

MR. SZALAJDA: Well, it's 1:58, and we are two minutes ahead of schedule, which is pretty novel for us. So I will try to slow down the pace a little bit.

But I think in summary, what I would like to try to do is, at least, to wrap up I hope what you, you know, what you heard or you think you heard from us today, and open up, following my presentation, any comments that you may have from your perspective, whether it is as a user or a manufacturer or some other stakeholder involved with these products.

But in retrospect, I think it is probably always good to occasionally go back to where we began. And the goal is to develop a system for emergency responders.

And I think, at least as far as the

evidence you have seen today, I think you appreciate why we focused on the tight fitting types of requirements at this time and in looking at the three different tiers of requirements or -- that we were anticipating for the system.

There is still work to be done with regard to flow. We do see the potential for two possible types of system, one being a breath response panic demand, however we ultimately define it for traditional NIOSH methodology, and also constant flow type PAPRs.

Then we are going to continue -- with the equipment that we have coming in, we are going to continue our evaluations of these systems and at that higher flow rates both for gas and vapor testing as well as particulate type testing.

The hazard protection, we are looking at the same requirements that are used for the gas masks, the same test representative agents, the same chemical warfare agent challenges, the same type of testing on a lot of our human factors, and durability type testing that we are going to

accomplish during the certification testing.

I had mentioned this at the May meeting, and I think these issues still apply as far as things that manufacturers should be considering as part of preparing -- ultimately preparing for CBRN certification.

There are going to be some unique labeling requirements associated with this type of system. And I think in particular our concern, at least at this point, is with regard to the canister.

And knowing that a lot of manufacturers use 40 millimeter threads as part of their filter design, which we have also identified as a specific design requirement for the APR, for the gas masks, we need to make sure that we ensure through labeling and cautions and limitations associated with the piece of equipment that we are not going to inadvertently allow for interoperability between the gas mask systems and powered air-purifying respirators.

Acknowledging that, yes, it may be

theoretically possible that if you have developed a canister that is good for the gas mask, it could also be used for the PAPR, but we want to make sure that the labels are distinct enough that one system is for the gas masks, the other is for the PAPRs, and they are not interoperable.

Also that we are going to be looking to address the issue of uniformity with the manifold, and to look at your engineering evaluations of differences in manifold air flow.

And I think we have established some concepts for addressing how we are going to be doing the service life testing. And in looking at the requirements that we're anticipating for resistance in the canister as well as testing the system as part of the gas and vapor evaluations.

Where we are going to go from here? Sometime within the next 90 days, there will be a new concept paper.

Parts of what you are going to see in that document are going to be developed based on the ongoing benchmark testing, as well as new

benchmark testing and any inputs that we receive from the community with regard to what is currently in the standard.

And we also encourage you, as individual stakeholders, to come in and have discussions with us to let us know your feelings regarding the concept and where you feel different requirements or other considerations should be taken into account with regard to the system.

With the benchmark testing, as I had mentioned, during Terry's presentation earlier, it's going to be a very interactive quarter coming up as we get the difficult pieces of equipment in that will allow us to do the testing at the higher flows.

Some of the -- during the presentations, here, some of the other benchmark testing that we are going to be conducting here over the next several months, carbon dioxide testing and if we do go with a human subject type testing for making that determination as part of the concept.

Also doing the additional studies of the

battery performance at low temperatures will be ongoing and during the next quarter.

Target date for the standard, as I had mentioned this morning, is September of 2005.

And, again, please keep in mind that that's -- currently, that day is currently defined, given the -- our current resource constraints with the program and laying out what we need to do, who we have to do it, and how much money we have to do the test between now and September of 2005.

And all those parameters are subject to change one way or the other. Hopefully, it's sooner than later. But with regard to the completion of the different testing activities, as well as the STPs that need to be defined, we envision it is going to be a several-month process yet to complete the standard.

And with regard to your comments, please keep in mind to -- other than contacting us personally, please feel free to make formal comments through the NIOSH docket office. Reference Project 010, Project 10, to keep it

separate from any of the other standards efforts that are ongoing.

And with that, I would like to open up the floor for any comments regarding the standard.

Upon the end of the public comment period, we will take a 15-minute break. And then we will introduce the closed circuit SCBA project.

Thank you.

MR. HAFLING: Thank you.

Dan Hafling. I'm the Senior medical Advisor representing the Northern Virginia Hospital Alliance. We are a coalition of 13 hospitals in Northern Virginia that have come together over the last three years to work on disaster preparedness efforts.

So I guess I'm an end user, and I have some comments in the context of the excellent work that NIOSH and NPPTL have demonstrated thusfar on looking at these issues.

But, Jon, sensitive to terminologies, was a phrase that you used -- and I guess that that's one important issue that I want to bring to your

attention, at least vis-a vis the health care community.

And specifically the need, I think, to distinguish between emergency responders, which is really what this standards paper is focused on, and health care facility first receivers.

And I know that my colleague, Frank Denny, from the Veterans Administration, Veterans Affairs introduced that at the beginning of the meeting. But I think it bears repeating because this concept paper as it is in its current form I don't believe is appropriate, or I don't believe it represents appropriate standards for respiratory PPE for health care facility first receivers.

And the rationale is -- and I -- bear with me because I'm sure that this is review for all, but I think it is worth describing.

The rationale is that when we look at, you know, federal regulations with respect to response to hazardous chemical events or chemical terrorist release events, and we look at the hazlawfer (phonetic) standards, it is very clear

that those guidelines are specific for agencies responding to events, but hospital and health care facility personnel are really not included within that definition of response.

And in fact, this specific language in, you know, CFR -- 29 CFR 1910.120, states, "That emergency response or responding to emergencies means a response effort by employees from outside the immediate release area or by other designated responders to an occurrence which results or is likely to result in an uncontrolled release of hazardous substance."

That is really the audience that you are addressing with this concept paper. And I think that it's important to make that distinction from the first receivers, who are going to be, you know, on the -- literally on the receiving end of whatever response occurs.

And OSHA, as I think you are all aware, has recognized the "unique" situations of hospitals. And they have, in fact, affirmed the concept that hospital personnel who provide decon,

are not the same as scene providers.

And this, in fact, led to what is, I guess, in the final stages of a draft form, an OSHA guidance for the selection of respiratory personal protective equipment for hospital first receivers and this document entitled The Best Practices for the Protection of Hospital Based First Receivers.

So you know, I think then that specifically going back to these standards as you have worked them out over the course of the, you know, the many months that this process has been ongoing, including much more restrictive definition of personal protective equipment than is necessary or reasonable in the health care facility setting.

And the key issues of concern that I see here, number one, is that the proposed PAPR design is one that has to be tight fitting, and either tight fitting to the face or with a neck dam.

And the design that is most favored in hospitals currently is one with a loose fitting shroud to tuck into protective clothing. And these would not be approved under this current guideline.

The second issue is that in this proposed standard, the PAPR design must include a low battery warning and a low flow warning, which in the setting of a health care facility would require additional training, additional time for training, and possibly result in increased costs.

And because of the fact that the funding pool is so limited, we are very sensitive to whatever may drive up costs for unit of purchase.

And in the wording of this standard, it is explicitly stated that the use of NIOSH approved PAPRs would not be for entry quote, unquote where hazards have not been full characterized.

And, again, in the health care facility setting, in the setting in which we are literally the first receivers of victims from a release site, whether it's intentional or not, we are not going to know either what the agent -- threat agent is or what concentrations those threat agents will be in. So this is something that is very restrictive language in the context of health care facility setting.

And I guess bringing this all together, what is concerning from my perspective is that the Department of Homeland Security has set a track record of looking to NIOSH standards to set their own standards, which are then linked to essentially funding from DHS under their specific grant programs for purchase of equipment.

And although one might say that, you know, in the health care setting a lot of personal protective equipment currently is being purchased out of the health and human services HERSA grants, there are also a large number of cities that are receiving DHS specific grants in the context of the Urban Area Security Initiative grants.

And all of these purchases would be put in question and at the very least might set a confusing standard if DHS were to adopt these strict standards based on the language of this concept paper as it is written right now.

So I guess what I am, you know, asking NIOSH to consider, number one, is to request that the concept NIOSH PAPR standard reference a

requirement for development of a unique and distinct standard related to use by first receivers in a CBRN threat environment.

I think to the manufacturers who are represented here, you know, the corollary would be that manufacturers really need to begin to explore the development of PAPRs for use specifically in the health care facility environment.

And then the corollary to that -- and I believe, Jon, that you made mention of it at the outset of the meeting -- is that ultimately such health care facility first receiver PAPRs are going to require their own set of standards and review under NIOSH's leadership to make it clear that we are, you know, providing the best and safest for our workers in our unique situation.

So I thank you for the opportunity to make the comments. I look forward to working with you on this.

MR. SZALAJDA: Thank you very much, Dan.

MR. KJELLBERG: Bengt Kjellberg, ISEA Group.

Let's see if somebody can verify something for me. I don't know if the right forum here.

When we are talking about tight fitted hooded PAPR, will they be required to be fit tested on your people using that type of device or not?

MR. SZALAJDA: For loose fitting type systems?

MR. KJELLBERG: No. The one you specify here, a tight fitted hooded type of PAPR.

MR. SZALAJDA: Yeah. We anticipate that would be used as part of an organization's respiratory protection program --

MR. KJELLBERG: And they would be required to do fit tests?

MR. SZALAJDA: -- to require the testing.

MR. KJELLBERG: Okay. Thanks.

MR. DeSANTIS: Vic DeSantis, Safety Tech International.

Jon, you said early on that you had hoped that this would be the last public meeting and the possibility of two or three revisions to this

concept between now and your targeted September '05.

There seem to be a lot of issues that are still out there floating around to be resolved. We have heard that there is either test equipment that is going to be modified or test equipment that has to yet be selected and/or designed. Those are still moving targets obviously for the manufacturers.

I would like to recommend that we have at least one more public meeting, maybe Juneish, July, if everybody else thinks that is a good idea. I do because there is a couple of moving targets here still.

MR. SZALAJDA: Okay. Thank you, Vic. We will take that under advisement as we move forward with the standard concept.

MR. BROCHU: Paul Brochu from Marine Corps Chem Bio Incident Response Force.

There aren't too many end users here that we have really heard of, at least, on the responder side, so I just have a general comment.

There is really -- there is a long standing history of the partnership between industry and our war fighters. And war fighters, when I say that, extends beyond the military to our responders out there, and that is important. And I applaud the work that NIOSH is doing to help us out and all those who supported us.

What we need is concrete data on real human performance, physiological function, so that we can make educated decisions regarding our protection equipment. And this is going a long way to assist us with that.

This is important so that we can protect -- I can protect our Marines and sailors, okay, soldiers out there, and that they can protect your families as well, okay.

We are at war right now. And it is not just Marines and sailors and soldiers kicking doors and getting rid of scumbags overseas. It is right here on land where people are attacking, you know, our senior citizens. They are targeting our children. All right. And that's what this is

about.

Our first responders are trying to help assist in that endeavor.

So, you know, we need a standard, and we are happy to get it next September. And I appreciate the work that you are doing to support that, but I could use that standard today. And I know that there is a lot of other folks who could.

So if there are any delays that are coming down the pike or anything like that, you know, I would just like to say that the sooner the better. We can really use this so that we can help protect your families a little bit better.

And I thank you for your support in that, ladies and gentlemen.

MR. SZALAJDA: Thank you, Paul.

MR. SMITH: Simon Smith, 3M Canada. Thank you for a most comprehensive discussion today.

One point is that exercises in training in full powered-air systems are considered very important by end users. And they are not likely to

want to go to the expense of full scale batteries and filters.

We were wondering if a manufacturer wishes to provide a battery for training, how would you approach to finding requirements? Would it be up to the manufacturer alone or a subset of the full approval needs?

Likewise for a filter. If a manufacturer wishes to provide a filter for training, would you have minimum performance specifications, or would you, again, leave that to the manufacturer?

And one might suggest for those you would require, say, P100 -- organic vapor plus P100, the filter, air flow resistance and weight.

Any thoughts.

MR. SZALAJDA: Simon, I didn't get the last comment. Could you repeat that, regarding the --

MR. SMITH: Oh, I'm sorry.

Concerning a filter -- sorry, this thing is way too short.

Concerning the filter, would you, again,

have some minimum performance requirements for a training filter, or would you leave it up the manufacturer to work out with the user groups?

One might suggest that the minimum for a training filter would be P100 because some training is done with tear gas, or organic vapor P100 and a filter of equivalent weight, and air flow resistance to the actual full scale CBRN approved filter.

MR. SZALAJDA: Okay. Yeah, those are good comments, Paul.

MR. SMITH: Simon.

MR. SZALAJDA: At least to date, we hadn't -- I'm sorry, Simon. Too many Pauls coming up to the microphone.

I think with -- but I think with regard to the training -- the training concept, I think that it has merit.

It is something that we really haven't considered as part of the standard yet. But I think when you look at it in context with how we have addressed training with the other standards, I

think there is probably room for us to consider how we would address that as part of the standard, whether it's captured and -- you know, via the accessories or -- some other manufacturers use documents, you know, some means of capturing that.

And we will be happy to look at that idea as we move forward.

MR. SMITH: Thanks so much.

MR. SZALAJDA: Okay. Well, thank you -- oh, I should have known.

MR. BERNDTSSON: Yeah, just one. Goran Berndtsson, SEA.

When I talked with some people from NIOSH over the last couple of months, I was left to believe that you would have a more definite knowledge by now if it is going to go rule making or not. I understand that decision.

Do you have any -- does that mean that the legal people haven't made up their minds, or is there a date where we will know which way it is going to go?

What do you foresee?

MR. SZALAJDA: I think I'm going to defer that one to Mr. Boord.

MR. BOORD: Well, the answer to your question is we don't really know. It is something, as I said at the beginning, something that is being reviewed by the department.

As you can imagine now, with the changes that are taking place within the department, the new replacement for Tommy Thompson and so on, the whole issue is just being addressed.

So I can't precisely say by such and such a date we are going to know what the direction is, but it is something that is in the process of being reviewed.

MR. SZALAJDA: Well, with that, thank you for your participation. We will close the PAPR portion of the meeting.

Let's reconvene at 20 of 3, which will give us 20 minutes for a break, and we will introduce the closed circuit topic.

(A recess was taken.)

MR. KOVAC: Okay, good afternoon.

We are going to change subjects and, in so doing, change our line of inquiry. And we are going to look at the standard development efforts for CBRN closed circuit self-contained breathing apparatus.

I need to remark here that this is the first time this has been presented in public. Much remains to be done; much remains to be discussed. Points are open for revision and reconsideration.

Our goal is fairly straightforward, to develop a NIOSH NPPTL full-facepiece closed circuit self-contained breathing apparatus standard that addresses CBRN materials identified as inhalation hazards or possible terrorist hazards for emergency responders.

Such advice would be used for long-duration missions involving entry into an atmosphere where contaminant concentrations are IDLH and which may not contain adequate oxygen levels.

We should remember that beginning at least as early as the early part of the last

century that first responders have made good use of closed circuit breathing apparatus, self-contained breathing apparatus at that.

Primarily they were by rescue teams, not only in this country, but elsewhere that had to respond to the aftermath of a major underground mine fire or explosion.

That technology has evolved. It has improved. And even today, mine rescue teams are so equipped that they too have made good use of such apparatus under high risk situations.

All the photos shown are the early history and the evolution of the devices to today.

We are going to talk about how the logic underlying how effective standards ought to be developed.

But just as there is a logic underlying scientific inquiry, scientific method, there is a process or strategy for developing effective standards.

Ideally, we begin with public process. This is the first of such meetings to date, and

that process should be transparent. We should identify key stakeholders and form partnerships with them.

Whatever we do ought to be based on best practice, grounded on good science, benchmark testing, research to fill in data gaps and ultimately peer review to validate our results.

And lastly we need to focus on the performance of the breathing apparatus beginning with the hazards analysis, a firm understanding of what human capabilities there are, making sure that at the point of manufacture, the devices have sufficient quality assurance in their manufacture that they will prove to be rugged and reliable, that they be reliable at end use. And then we need to investigate issues involving practical use of these devices.

All of this we are undertaking beginning today.

Our model involves three tiers of standards. NIOSH approval under the program will signify that a respirator is expected to provide

needed protection to first responders in situations where an act of terror has released powerful chemicals, pathogens, or radioactive materials into the air.

Approvals will, of course, be based on positive results from rigorous tests on sample units submitted to NIOSH by manufacturers and from stringent evaluation of manufacturers' quality control practices, technical specifications, and other documentation.

We talk about three tiers of standards, and we begin with 42 CFR Part 84, those sections which are applicable to closed circuit self-contained breathing apparatus.

Added on to that are NFPA standards involving operational performance in a fire environment as well as high work rate performance.

And I understand that the NFPA subcommittee on closed circuit self-contained breathing apparatus has been reformed, and we welcome their collaboration and participation in this activity. Dick there is a member of that

subcommittee, and I see at least one or two people who are so representative thereof.

And lastly we overlay on that special CBRN requirements in terms of penetration and permeation of chemical agents as well as practical performance.

I need to remark here that NIOSH policy regarding approving closed circuit self-contained breathing apparatus for a fire environment for high heat, high flame, open flame have not really changed. Right now we are discussing how to approve such a device, but the policy itself has not been changed at all.

Crucial to this undertaking is looking at how a closed circuit device performs dynamically. So our concept calls for adapting and translating the open-circuit NFPA requirement to closed circuit.

How that is best be done, we regard crucial to it, the use of an automated breathing and metabolic simulator for performance testing.

How the devices which are currently

approved function and perform under these alternate test standards, these alternate test schedules will be the discussion of one of our presentations.

And, as a point of reference, an ABMS is a computer controlled breathing machine that simulates human respiration.

That is pretty much all I have to say. I would like to introduce Frank Palya. He will talk about the standards requirements.

If there is comments and questions, have at them.

Frank.

MR. PALYA: Thank you for staying around to hear the concept standards for the closed circuit self-contained breathing apparatus.

The purpose of my presentation is to discuss the following requirements. The flame -- the fabric flame resistance requirement, fabric heat resistance requirement, thread heat resistance requirement, facepiece lens, luminous transmittance and abrasion requirement, communication performance, the CWA permeation and penetration

requirement, and the LRPL.

These requirements, here, were -- these concept requirements were from the relative sections of the draft National Fire Protection Association 1984 Version 94.

The first one I would like to discuss is the fabric flame resistance requirement. As you can see, the fabric average char length is less than or equal to four inches. The fabric average after flame is less than or equal to two seconds.

This will be conducted on five samples.

When tested with federal test standard 19 -- 191A, Method 5903.1.

The thing to make note of is that these are established and active tests that are currently being used to test products for the fire service.

Again, I want to briefly go through these because most of these are outlined on the concept paper.

Again, the fabric shall not melt or ignite when tested with the Fed Standard 191A, Method 1534. This occurs in a forced circulating

oven at an air stream temperature of 260C to 265C.

The same with the thread heat resistance requirement.

Next is the facepiece lens, haze, luminous transmittance and abrasion resistance requirement. It's -- the requirement is that the haze cannot -- the change in haze has to be less than or equal to 14 percent.

This standard, however, in test -- this requirement and test method was adopted from NFPA 1981 for open circuit self-contained breathing apparatus in the 2002 addition.

Next is the communication performance requirement. It's where the average calculated value has to be greater than or equal to 70 percent performance. It also was adopted from 1981.

However, the requirement and -- on speech intelligibility may change based on potential new test methods that are under investigation.

The next was the chemical warfare agent. These are the special tests that Jon was -- spoke of earlier.

For the chemical warfare agent testing, it will be the -- we are going to go challenge the apparatus with GB and HD.

The vapor in liquid concentrations are equivalent to the open circuit unit, the open circuit standard that was NIOSH developed for the CBRN open circuit system.

It's going to be used -- when we test this -- the apparatus against chemical warfare agent permeation resistance, it is going to be on the SMARTMAN that is used down at Edgewood, but we are going to integrate the NIOSH approved automated -- ABMS system with it.

To get into specifics, the sarin challenge will be the same as the open circuit. That will be at -- there is just one vapor challenge for the first 30 minutes at 2000 milligrams per meter cubed.

The requirement is the breakthrough. You cannot have three consecutive peak readings of 0.087 milligrams per meter cubed. The maximum breakthrough allowed is -- throughout the entire

length -- run of the test is 2.1 milligrams -- minutes per meter cubed, and that is measured in CT.

The requirement at this time is six hours, but this is the initial concept. It was initially based off the open circuit. But realizing in some testing limitations, this may change for the open circuit. NIOSH is considering changing the total test time to the rate of duration of the unit plus one hour.

Again, the breathing rates it refers to the tables as 100 liters per minute and 40 liters per minute. I believe that is on Table 2 of the concept standard. That is rather aggressive.

We may go ahead there and look at more sedentary rates just so that the unit can function for the entire test time in the liquid challenge because remember the purpose of this test, the requirement, is to check the characteristics of the unit to resist permeation to agent.

Again, the challenge is the same challenge that is on the open circuit, the 300

milligrams per meter cubed. That's the vapor.

But then there is the liquid challenge where you apply a total of .86 milliliters of droplets on the unit through various locations on the apparatus, interfaces between components, hoses, eye lenses, what have you.

But right now, the failure is .6. If there is any -- three consecutive peak readings of .6 or greater, it constitutes a failure.

The maximum breakthrough is 6 milligrams per minute meter cubed for CT. The vapor challenge lasts for the first 30 minutes. The liquid challenge is for six hours.

That is applied -- the liquid is applied. The chamber is sealed, and the time begins. So liquid is applied initially.

Again, we may go ahead there and change this. NIOSH is considering changing the total test time duration to a rated duration of the unit set by the manufacturer plus one hour.

Again, we may go ahead there and add a third column to Table 2 where we reduce the

breathing rate times so the unit will last longer for the entire duration of the test.

Next, special CBRN requirement and test method is the fit-factor corn oil aerosol or LRPL testing. This test measures -- takes the ratio of a corn oil concentration inside the facepiece to the concentration outside of the facepiece in a test chamber.

The purpose of this test is to establish a benchmark level of protection under laboratory conditions. It is not intended as an indication of protection in actual use scenarios for any work conditions.

The challenge in the chamber is the concentration would be 20 to 40 milligrams per meter cubed corn oil aerosol with a particle size of .4 to .6 micrometers -- micrometers, excuse me.

And the challenge -- or the requirement is set at -- each subject has to get a reading of over 10,000. And there is 11 -- this will happen -- this will occur -- the readings will be taken when the human subject will perform 11

exercises. And this will be testing with the self-contained breathing apparatus in operating mode.

These are the exercises that are -- that the human subject will undergo through the LRPL testing.

If you notice, with the -- with the plus sign, that's for emergency responder exercises, and those will be included in the tests.

And at this time, I will take your questions. Any questions, answer any questions.

MR. SELL: Hi Frank. Bob Sell, Draeger Safety.

Maybe I missed it, but for the mustard test, the liquid droplets applied to the pneumatic system. Now, for the open circuit, that's applied -- since all of the pneumatics are exposed, that's applied in all various points --

MR. PALYA: Right.

MR. SELL: -- both the Bio and the Draeger are a closed system, not that the gas wouldn't get in, but how do you propose to apply

liquid agent to the unit?

MR. PALYA: Right now, we are currently looking at -- it's not like we are going to open up the unit and put them on the individual.

Whatever is exposed in a natural response scenario.

So if it's in a closed case, we would apply the liquid droplets to that, maybe the seams on the closed case or whatever is exposed outside of the case.

MR. FLYNN: Bill Flynn from Biomarine.

We have been through some experience of this nature. And what the Army did in their testing was test worst case situations, that if you did lose your upper housing or your cover, then they would deposit the droplets internal to that.

But in normal operation, obviously, there is no pneumatics exposed whatsoever in either system.

So I think that if you are going to test with the cover in place, you would obviously have to place the droplets elsewhere, you know, so there

is no exposure to pneumatics on either one.

MR. PALYA: Right. Well, again, initial thinking is to go ahead, there, and whatever is exposed to go ahead, there, and put the droplets on.

MR. HODSON: Dave Hodson, Draeger Safety.

On the LRPL test, it indicated 10,000 as being the reading. Why so high compared to that from the open circuit SCBA?

I think we have already discussed it on the PAPR that we were going to drop it down, anyway.

MR. PALYA: Yeah. For the closed circuit, we are testing the entire system.

For instance, the open circuit, we were just testing the facepiece, the quality of the facepiece itself. And it was being tested in the negative pressure mode, so ...

MR. HODSON: Okay. Thank you.

MR. PALYA: Mr. Nick Kyriazi will be discussing some of the operational performance requirements on this closed circuit self-contained

breathing apparatus.

Nick.

MR. KYRIAZI: I am going to be talking about the NFPA side of this proposed standard and anything that has to do with simulator testing or closed circuit apparatus.

The goal of this standard is to -- or the goal of this whole project is to establish a new standard for closed circuit apparatus by adapting the relevant sections of the FNPA1981 standard for open circuit apparatus.

So in general, we attempted -- or I was on the old NFPA1984 committee which was chartered to come up with a standard for closed circuit apparatus. And in general, what we attempted to do was to keep it identical unless it was impossible for some reason because of the design of closed circuit -- or the difference in design between closed and open circuit.

The 1981 standard, the major performance criterion was very simple. In the face of all these different treatments, the breathing circuit

pressure had to remain positive at the -- at the NFPA recommended ventilation rate at 100 liters per minute.

And the air flow performance tests consisted of simply connecting an open circuit apparatus to a breathing machine, a simple air mover, at a rate equivalent to a ventilation rate of 100 liters a minute under ambient conditions, which we assumed.

And in this test the breathing circuit pressure in the face mask had to remain between zero and 89 millimeters of water. And it had to remain within that range until it was expended, which for a 1,200 liter apparatus, quote, unquote, 30-minute rated unit, would happen in 12 minutes.

The major obstacles and application of this standard to closed circuit were these.

The -- on open circuit apparatus, at least a 30-minute rated unit would be expended in 12 minutes, and that is certainly within the realm of human possibility. But for a longer duration apparatus, it was not.

So we couldn't just say, Well, it had to remain that way for four hours. Of course, they wouldn't last that long, but certainly longer than 12 minutes.

And the positive pressure or the -- yeah, the positive pressure limitations were going to be more difficult for closed circuit since they are more complicated than open circuit, both devices have demand valves and relief or exhalation valves. But closed circuit apparatus also have CO2 absorbent canisters and coolant canisters, both of which add resistance to breathing.

And in addition, the 1981 standard listed no metabolic parameters, so we had to come up with some.

The solution to the obstacles was to test on a breathing and metabolic simulator instead of a simple air moving breathing machine at two work rates alternating between the high work rate, the NFPA 100 liter a minute ventilation rate, and the NIOSH ventilation rate of 40 liters a minute, according to this protocol.

The two work loads, the NFPA, which is workload A, the high one, and B was the NIOSH one.

It's easier to see graphically -- well, maybe not in this case. But I will point out the first 12 minutes here are at 100 liter per minute ventilation rate. And then for the rest of the half hour, it goes back down to the 40 liters per minute work rate.

Then the next half hour continued at 40 liters a minute ventilation rate. For the last five minutes of that half hour, go back up to 100 liters a minute to make sure it's still remaining positive.

And then for the next three half hours, the same pattern is repeated, 25 minutes at the 40 liters a minute, and the last five minutes going back up to 100 liters a minute to check to make sure that it was still behaving at the high work rate.

And then after those four rounds -- four half hour rounds were done, then you just continue -- it was proposed to just continue at the

40 liters a minute work rate until the apparatus is expended.

These were the metabolic parameters that we recommended to go with the two work rates, the two ventilation rates. These are subject to revision depending on what we find when we try it on -- go further down the path with performing the treatments on apparatus and running the tests.

We have run some tests on new apparatus at this work regimen, but these are the proposals today.

I would also call your attention to that the ventilation rate is listed in liters a minute, absolute volume displacement, or just ambient conditions versus the VO2 and the VCO2 are listed in terms of STPD conditions, standard temperature pressure dry.

This is a picture of the breathing and metabolic simulator with an apparatus mounted on it.

This is a schematic of the simulator, and I will try to just cover the main systems of it.

Here is the lungs -- the simulated lung piston in a cylinder operated by a stepper motor, and it connects to a mouth port over here so that air goes back and forth like this.

And at the mouth, we are monitoring the gas concentrations of oxygen and carbon dioxide as well as breathing pressure and wet bulb and dry bulb temperatures.

Here is the humidity loop and the heating loop. We drain water out of the bottom of the lung into a water reservoir where it is heated, pumped up, and rained in on top in a plate, and it rains in evenly so that we heat and humidify the air.

The metabolic system is composed of three needle valves which are connected to a CO2 cylinder, nitrogen cylinder, and a vacuum pump. So the CO2 is added here. The oxygen consumption simulation is effected here through this needle valve.

And since we can't be selective about what exactly we are removing, we are inadvertently taking nitrogen out as part of the oxygen removal

process. So we have to add nitrogen back in, as well as some CO2 that we are removing inadvertently.

These are all measured by the CO2 and oxygen analyzers and the computer, and of course, the whole thing is controlled by a computer.

At the moment, there are two presently approved closed circuit entry positive pressure apparatus, although I should mention, as is typed up here, that they are not approved -- since they are positive -- they are approved except in -- for areas of open flame and high radiant heat because of their status of being positive pressure and "100 percent" oxygen systems.

So many things have to be changed to accommodate the new proposed standard.

The preliminary test results are -- were not surprising. The two models we tested, Model A exceeded the inhalation and the exhalation pressure limits immediately. This was at the -- of course, at the 100 liter a minute work rate, ventilation rate.

And Model B, surprisingly, it exceeded the inhalation pressure limit. It went negative, but it seemed to have met the exhalation pressure limit. It was just a little bit under the 89 millimeters of water pressure.

And like I said, they were -- this was not expect -- I mean, this was definitely expected, that they would not meet the test since they were not designed to past this test.

Here is a graph of the Model A breathing pressures with the breathing pressures on the Y axis and time on the X axis.

You can see that the pressure is increased over the first 12 minutes from a little over 100 millimeters up to around 200 millimeters of water pressure at the high work rate, dropped down to around 40, 45 during the 40 liter a minute ventilation rate.

And for the inhalation pressures in the first 12 minutes at the high work rate, were down around 45 -- minus 45 millimeters of water pressure. And this was repeated throughout the

test.

Model B, you can see that -- the scale is different by the way, I should point out.

You can see that the first 12 minutes, it was -- the exhalation pressure was just underneath 90, just underneath 89, and it hit on inhalation minus 25 millimeters of water pressure.

And in the 40 liters a minute, it was within the recommended pressure range.

There are -- NFPA also does a number of treatments to their open circuit apparatus that they want to be NFPA certified. And some of these are not -- some of these do not use the simulator and some do.

I'm going to talk -- actually just mention the ones that are performed on the apparatus and -- performed on the breathing apparatus and then tested on the simulator either afterwards or during.

Here are the five treatments.

The temperature conditioning, the testing consist of four different -- four different

treatments. Soak it cold and then run it cold. Soak it hot, which means make sure the apparatus is stabilized at that temperature, and then run hot. Cold soak and hot run, hot soak and cold run. The temperatures are identical to the NFPA, minus 32 degrees Centigrade and positive 71 degrees Centigrade.

This is the current NFPA 1981 vibration test.

This is the accelerated corrosion test.

These are right out of the 1981 standard, I believe.

Particulate test.

And the heat and flame test. This one is the one everybody is afraid of. Not only the manufacturers, but the people who are performing it.

In fact, nobody has done it yet on a closed circuit apparatus. But this is what NFPA -- oh, some people have done it apparently. I'm not sure if they did it when the apparatus was operating.

MR. SCHUELER: Yes.

MR. KYRIAZI: Well, that's news to us.

And they are here to tell about it.

The test as proposed by -- or as done by NFPA is that there is a 15 minute exposure at 95 degrees Centigrade while the apparatus is operating at Workload B, which is the 40 liter a minute ventilation rate.

And then you take it out of this oven, I suppose, and put it in front of the flame throwers, where you have a direct flame exposure for ten seconds. And while you switch to the high work rate at 100 liters a minute, then after the ten seconds of the flame test, you drop it six inches.

And accept for a consideration that the drop may cause a pressure spike, otherwise, the apparatus has to remain within the stressor limits. And that after the flames shut off, there shall be no afterflame greater than 2.2 seconds.

That is the proposal. And if there are any questions, we have plenty of time for them.

Well, I don't see anybody, so --

MR. NEWCOMB: Bill Newcomb, NIOSH.

Do you expect that the requirements for the temperature inspired air to be different than they are now because of the different tests?

MR. KYRIAZI: The requirements for this or for the -- for 42 CFR 84?

MR. NEWCOMB: For the CBRN closed circuit breathing apparatus.

MR. KYRIAZI: So you are asking -- you mean during the heat and the flame test or the temperature conditioning test?

MR. NEWCOMB: During the metabolic simulation test.

MR. KYRIAZI: For new units or for treatments or during one of the treatments?

MR. NEWCOMB: For the new units.

MR. KYRIAZI: So you are asking is it going to be any different than the present --

MR. NEWCOMB: Yes.

MR. KYRIAZI: All right.

MR. NEWCOMB: Once you start going to the higher work rates, do you expect it to be any

different than they are now?

MR. KYRIAZI: The -- we -- I don't think I saw -- in the tests that we have done, the preliminary tests, the temperatures were not exceeded.

I think it's 45 degrees, isn't it, the recommendation for this standard, anyway. It's 45 degrees wet bulb temperature.

And I think neither the apparatus exceeded that temperature during this test from beginning to end.

So I don't -- like I said, before, these may not jive with present 42 CFR 84 stressor limits, and those will eventually be resolved. But right now, the two apparatus that are currently approved, the temperature limit did not pose a problem for them.

Now, whenever you -- we put them in a chamber at 71 degrees, they are not expected to maintain that same level or maintain, you know, within -- remain below 45 degrees wet bulb temperature.

MR. HEINS: Bodo Heins from Draeger Safety.

How do you handle it, this your breathing machine? As far as I can remember, the apparatus has to be tested at as well minus 32, also at 71.

Is your breathing simulator in the same chamber then?

MR. KYRIAZI: No. How we are envisioning it, unless I'm missing something, is to simply encapsulate the apparatus outside of the simulator because the simulator we do not want to put under those conditions.

MR. HEINS: Because I try to imagine what happens to a sea of water in your breathing simulator in minus 32 degrees C.

MR. KYRIAZI: Yes. I would not want to do that.

So the apparatus would be encapsulated in some sort of an environmental chamber, but it would be -- the simulator would be outside the chamber.

MR. RICCIO: Louis Riccio, Global Secure Safety.

This may be way early to even bring up the question, but --

MR. KYRIAZI: Next.

MR. RICCIO: Thank you, Nick, I appreciate that.

The metabolic simulator, I understand, is the perfect way to measure the performance of the closed circuit, but when it comes to actually being exposed to CW agent in a fume hood, you are proposing that it be very complicated to get a metabolic simulator to operate the unit.

So I'm wondering why we couldn't substitute it at best this time, when you are in the CW agent mode, that you just put it through the same kind of breathing cycle that current breathing machines would allow.

This way it would simplify the test. And you're just testing for leaks anyway. You are not testing for the actual efficiency of the CO2 bed and all that.

So I'm just suggesting that maybe the test doing the CW agent could be simplified.

MR. KYRIAZI: That is quite possible.

And I think I mentioned that, and some of the people who are experts in that told me something which just went over my head.

So all of these will be considered in due time.

MR. SZALAJDA: Yeah, that's a good comment, Lou.

We are actively working with ECBC right now to look at the integration of the breathing simulator into their operation to support testing of the self-contained escape respirators.

And as we get smarter with the operation and the impacts of doing that type of testing on self-contained type units, we will be able to make some determinations if we can do what you suggested.

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

Additional question, please, to your breathing machine, if it's extending outside, how do you handle the different dead space if the

machine is outside of the breathing apparatus to be tested inside?

It must be distance between --

MR. KYRIAZI: What is dead space?

No. Just kidding.

MR. HEINS: The dead space in your tubes or hoses in which you are connecting the apparatus to your machine.

MR. KYRIAZI: Oh, yes. I understand.

They are pushing -- they just got the environment chambers in this past year, and we are just simply pushing up the simulator right up to it.

And I don't think that it's going to be the trachea -- the simulated trachea is going to be extended from what it is now. If it is, it will be very a minor extension.

So it should not affect the metabolism. But whenever we actually do it, and it's up and operating, then we will have more information about that.

MR. SCHUELER: My name is Peter Schueler

from Draeger Safety.

I just want to add some information on this heat and flame test.

We actually performed this during our European approval, which is pretty much the same as you described here.

And because there was the question about flame and oxygen, we had the same discussion in Europe. And because these steps are more and more used in fire service, we made a test with the defined leakage on the mask and performed this flame test just to see if the flames are going inwards.

And we even performed that test. So if you are interested, we can provide you with the context or the result of the tests just to support this here.

MR. KYRIAZI: Oh, yes. We are definitely interested.

MR. SCHUELER: So that's the first point.

Secondly, you showed the results of the breathing resistance when you make the 100 liter

tests.

The first question is is this workload checked against the human ability over a time period of four hours?

Yes, that's the question.

MR. KYRIAZI: Say that again.

MR. SCHUELER: When you make the load test, 100 liter per minute, 40 liter per minute, over four hours operating this test.

Is it proven that a normal working man, first responder, can do this physically from the strength because this is different than open circuit where you just have 12 minutes, as you said.

MR. KYRIAZI: Yeah. I don't know.

The last time -- the last version of the 1984 standard was in '96, and it was operated between '87 and '96, 1987 through '96.

And at some point, of course, that question was brought up, is this humanly possible, and there was some responses that it doesn't matter; that's what NFPA wants and this is what we

have to get them -- give them.

And other -- I think people -- we had Rich -- I can't -- I remember there was a firefighter on the committee, and I think we actually had him do it, and I can't remember exactly how long he went.

But I'm sure that there are some people who could do that. They may be in the 99th percentile, but we -- I don't recall anything specific where somebody actually had to perform this test for four hours or do the test and then -- I don't think the apparatus would last that long, but I don't recall if somebody actually ever -- had ever done it.

MR. SCHUELER: The second remark on the temperature testing. As you know, we have to communicate the CO2 with the soda line, and the soda line has to have a chemical direction, and this is obviously slowed down by low temperature.

So would it be possible to say because of the technology involved, that the unit can be stored at room temperature and then used outside at

minus 32 degrees because that, at least, would solve the chemical issue.

MR. KYRIAZI: Yeah. That has been thought of before.

I'm not sure what the resolution is. Do we get to the point where we mold the standard to what the apparatus can achieve on the one hand versus the laws of physics.

There are some -- there is going to be some -- a need for improvement in technology, but you can't change the laws of physics. And if there is no chemical that can pass this test, well, then we should probably simply stipulate on these apparatuses that they cannot be stored at these temperatures because there is no -- it is not possible to store them at that temperature and have them function.

That is one of the essential differences between open and closed circuit. Closed circuit are dependent upon CO2 absorption. And if there are no chemicals that can absorb or can operate at a cold temperature, then you are between a rock and

a hard place, and something has to go.

MR. SCHUELER: And the last point is the breathing resistance, as you have shown. And this is also known by us.

You will not have -- you will have a higher breathing resistance on the current design, than point -- no -- 89 millimeter water column.

This can only be changed by reducing the breathing resistance by increasing the diameter of the hoses, making the cartridge bigger, so we will end up -- and this is also related to our laws of physics -- with a much bigger unit to fulfill these requirements.

Is this still -- can this still be thought through?

What is the best way? Having a bigger set, more heavier, just to get the breathing resistance down, or is there also a compromise of what is more important, the breathing resistance or the weight and the size of the set?

MR. KYRIAZI: Well, we show that one of the units already passes that test. So obviously,

it's physically possible without any advance in technology.

The other one -- the other apparatus manufacturer can simply adopt the same methods that his competition adopted to achieve that standard, so that does not seem to be a problem at this point.

MR. SCHUELER: Sorry. The one unit performed at the 40-minute breathing rate, that's right. But at 100 rate it was negative and -- it went negative.

So at 40, you are right, that can be achieved, but --

MR. KYRIAZI: No. Here we go, here is Model B. And you can see that the upper points here --

MR. SCHUELER: Yes.

MR. KYRIAZI: -- here is 100 millimeters. Here is 90. And you can see it's slightly underneath 89.

And this is at the 100 liter a minute work rate here, here, here, here, and here. So it

passed.

MR. BERNDTSSON: At the bottom, those are negative.

MR. KYRIAZI: Oh, it goes negative, yeah. I thought he meant the exhalation side.

MR. SCHUELER: No. Inhalation.

MR. KYRIAZI: Pardon me?

MR. SCHUELER: The inhalation side.

MR. KYRIAZI: Oh, the inhalation side, oh, yeah, definitely they both failed the inhalation, but only one of them failed the exhalation.

I'm sorry. I misunderstood the comment.

MR. HODSON: I think Peter's questions result in the simple question. Is it really necessary -- excuse me, is it really necessary that at the 100 liter performance, the unit has to perform the same values as with 40 liters?

MR. KYRIAZI: Well, the 40 liter came in only because it was felt that to require the apparatus to remain at 100 liters a minute until it was empty was not a logical thing to do for closed

circuit since people could not maintain a workload with a ventilation rate of 100 liters a minute until closed circuit apparatus were expended.

So the 40 liter a minute was not -- it is not really a -- the 40 liter a minute is even subject to changing, but the 100 is what the NFPA insists that an apparatus remain positive under.

And before you go on, let me just say that I come from the mine rescue and the mining part of the closed circuit apparatus. And before positive pressure came in, I mean, since 1910 or even before the turn of the last century, there were closed circuit apparatus, and they all went negative, and that was never viewed with any alarm.

But I think mine rescue teams were very well trained, and especially trained well in getting good face seals. And I guess with firefighters you would think they would have a -- well, a lot of times firefighters went into fires without apparatus.

And I forget when -- or without breathing apparatus.

So they don't -- I think they don't take it maybe as seriously going into burning buildings and such, as mine rescue teams because mine rescue teams knew that they were dead if they didn't have a good face seal.

But firefighters, perhaps they don't pay that much attention to a face seal, getting a good face seal. Therefore, the positive pressure requirement was a way of accommodating that cavalier attitude and to compensate for it.

MR. HODSON: That's right. But in -- as the case of the new standard now, you are combining two different standards, one is 42 CFR Part 84, and now the Siemans (phonetic) standard.

And if you have to follow both regulations, it's not possible with the breathing resistance, for example. You are requiring the 42 exhalation resistance of 5.1, and then the Siemans standard 8.7 millibar.

To fulfill the 8.7, you have to manipulate your unit so that you can perform this resistance, but then you will not meet the 5.1.

And there is -- not only there is the 100 liter, which I'm talking about. It is all -- also all the other requirements. How can you expect that if you go with a unit into a 71 degree C that your inhalation resistance temperature would still be 45 degrees C.

MR. KYRIAZI: Oh, well, that's not -- well, that would be waived, of course, in the actual -- I mean, in the temperature test.

And, again, all of these are subject to change depending on what we find when we actually perform the tests on closed circuit apparatus, including all of the treatments.

But the 5.1 millibar, 51 millimeters of water pressure is -- that is on a breathing machine at 40 liters a minute. So it would -- and it has to be positive if you want to get the positive pressure certification.

But the 89 millimeters of water pressure, we are permitting it to go 39 millimeters higher at the higher work rate. So I don't see that that's a conflict right now.

It may be difficult. It may be impossible, but I don't think it's contradictory.

MR. HODSON: To make it possible that you have to be at the 100 liter, 8.7 millibar exhalation resistance, you need a special spring load which gives you the pressure inside your system.

But just as in a calculated for the 100 liter, and it will be above the 5.1 from the 42 CFR because you cannot change in any kind of spring load.

MR. SZALAJDA: Yeah. I think sort of at this point, instead of completely designing the standard right now, we will move along.

I think one thing that you can appreciate was the complexity of this type of system. And we look at trying to identify the requirements and falling back to our philosophy in how to -- how we have been addressing the development of the standards when we are -- we look to the 42 CFR requirements first and then other standards, other national or international standards to support

that.

And as we move through the project, we will be able to, you know, further refine the tests and the capabilities, and, you know, the requirements of the concept as we learn more about the equipment in relation to what we think the requirements need to be.

MR. KYRIAZI: Also, one last comment. The 89 millimeters, I'm not exactly sure where that came from other than NFPA, but I don't know where they got that from.

I understand the positive pressure, their consideration of the importance that it remain positive, but 89 millimeters is certainly not the tolerance limit for a human subject. We can go much higher than that.

MR. KOVAC: Well -- this is John Kovac.

All these matters are very complicated, and debating them now, this isn't the best forum.

We cannot design a regulation today or a standard today. These are just the first fundamental and important steps on fleshing out

what a robust enough standard, a logically sound standard for closed circuit self-contained would have to be.

But between now and six, eight months from now, much is likely to change. And right now, we are trying to debate details, and there will be a time and a forum for doing exactly that.

MR. PALYA: Let me just add to that.

As always, we always welcome data input from you that we will take into consideration as the concept evolves.

So if you have something for us and if you think it would help, we would certainly appreciate it.

MR. KOVAC: Certainly bring forward whatever information, whatever inquiries, whatever studies you have made because they are going to help resolve the ambiguities that are inherent in doing this piece of work.

So we appreciate the efforts that Draeger -- the good work that Draeger has always done in this regard.

MR. BERNDTSSON: Goran Berndtsson from SEA.

This piece of equipment is going to be an alternative to an open circuit breathing apparatus for first responders. Is that correct?

Is that the idea with it?

MR. KYRIAZI: Yeah, that's the idea.

MR. BERNDTSSON: As such, I would expect it to have to meet the same type of requirement because otherwise it won't be an alternative.

I mean, the requirement is built of a need of the first responder that is what we have already identified. And if we are going to have another piece of equipment giving the same type of protection in the same type of environment, it has to perform to the same type of rules.

So otherwise we start writing standards around products, and that was not what we were supposed to be doing.

MR. KYRIAZI: All right. Thank you.

MR. TEELE: If I may take the opportunity, I'm Bruce Teele from NFPA.

Just a clarification in case you missed it in Nick's presentation. NFPA 1984 was a draft document within the respiratory protection committee for closed circuit SCBA. It was within that committee, and the task of which Nick sat on and worked on for probably eight or 11 years, depending on who is counting.

And it came to the point in the system where the emergency responders essentially fed back to the committee, We are not interested in closed circuit SCBA; there is too much baggage that goes along with it.

And the committee, through our correlating committee, stopped efforts on developing a standard that would probably be very -- have very little use and application in the field.

If there is a need for it here in these type of emergencies, which I won't debate here for a moment -- there certainly may be -- then there are many considerations that have to come before NIOSH and before the user community and with the

manufacturers to assure that we get a respiratory protection package out there that is equal to its counterpart in open circuit SCBA CBRN certified.

Thank you.

MR. KOVAC: I agree.

None of this is going to be easy. We have simply taken the first steps.

We are here in a public forum. We are starting work on developing an appropriate standard for CBRN closed circuit self-contained breathing apparatus.

We encourage meetings with stakeholders, with manufacturers to help us reconcile our views with theirs to help us clarify what we think ought to be the case. We certainly welcome the participation and collaboration with the NFPA subcommittee.

Our website is listed below, where copies of the concept papers could be found.

What else has to be done? First and foremost, we are going to revise and post our concept for what a standard ought to be.

We will obviously continue stakeholder discussions. We are going to undergo development of benchmark testing, and primarily we are looking to translate open circuit standards to a closed circuit equivalent.

So we are going to be conducting research into acceptable breathing resistance. We are going to have to look closely at integrating our simulator into test protocols.

And lastly, we are going to look at validating the way that we conduct our research.

Benchmark testing will be done not only at the NPPTL in Edgewood, but we will also turn to external laboratories for conducting those tests which are outside our span.

Our next public meeting is scheduled sometime in September, next year. And a target date for the standard is December of 2005.

There is a number of administrative details, where to submit comments for the docket. The docket number is 039.

And basically, having said, I think we

have said quite a bit this afternoon. So now it is the time for comments, questions, criticisms.

The mike is open.

MR. FLYNN: Bill Flynn, again, from Biomarine.

Of course, we are not going to set a standard here or argue breathing resistance or things of that nature, but I just have a couple of general questions that would affect how we would issue comments in the near future.

First, early on, someone said there was a limit on time for agent testing at Edgewood, that it would be probably the rated time plus one hour.

Can you explain or elaborate on the limits of the time because our experience is that you can go well beyond that.

I don't remember who made the comment.

MR. PALYA: Well, we were doing -- as you can see, the concept paper has six hours on it.

MR. FLYNN: Uh-huh.

MR. PALYA: And, I mean, it would be unrealistic to go ahead there, and they -- closed

circuit is only rated for four hours to expect the apparatus to operate for the entire six hours.

So that's why we were going to go with rated unit plus one hour.

MR. FLYNN: So the limitation was not the lab. It was the apparatus?

MR. PALYA: Right. It wasn't the laboratory. It was the apparatus. Because we wanted to operate fully for the entire period of time at a lower breathing rate, so it would for the whole time.

So what we are doing is we are testing agent permeation and penetration resistance in the unit, but yet we still want all the components functioning in there in case it has some negative or adverse bearing on it.

MR. FLYNN: Pardon my ignorance for not understanding some of the standards that are already existing, but for a one-hour rated open circuit system, what is the length of the test in the agent test?

MR. PALYA: It would be --

MR. FLYNN: At six hours?

MR. PALYA: Yeah. The six hours for the open circuit.

MR. FLYNN: Right. So that's on the one-hour operating apparatus. But for that test, you are going with a six-hour duration, an agent challenge for six hours.

MR. PALYA: Right. Okay.

What happened, we were looking that the responder be operating or working for that time, but he would be changing his air bottles out.

MR. FLYNN: Okay. So --

MR. PALYA: Yeah. That's where that --

MR. FLYNN: Okay.

MR. PALYA: All right.

MR. FLYNN: The standard, is this intended to be for an escape and entry or --

MR. KOVAC: Entry.

MR. FLYNN: Entry only. So no escape apparatus in this standard?

MR. KOVAC: That's correct.

MR. FLYNN: The last thing is this is for

first responders, going back to the discussion about the NFPA 1984.

We are not trying to duplicate an open circuit system to do the same job that an open circuit system is doing.

So I just want to comment that, therefore, why would we be saying we need to duplicate the requirements in 1981?

I don't fully understand the reasoning behind that. It is being used by the same people, but it's not doing the same job. So therefore, we have to keep that in consideration when making comment on all of these standards.

Thank you.

MR. KOVAC: Thank you.

MR. NEWCOMB: Bill Newcomb, NIOSH.

Jon, I hate to jump on the resistance issue again, but having spent many years of that 1984 committee myself, one of the requirements that NFPA had in their 1981 standard and the 1984 standard was what the apparatus be NIOSH approved before it could be NFPA approved.

And because of that, there was a conflict in the resistance requirements. It could not be NIOSH approved and still have -- and meet the requirements of the NFPA. This being a NIOSH standard, that should not be an issue.

Thank you.

MR. KOVAC: Thank you, Bill.

MR. HODSON: Dave Hodson from Draeger Safety.

Again, two points. First of all, on the LLPLs, you are saying you are going to do complete units at -- for inward leakage testing.

It's going to be an awful lot of complete units.

MR. PALYA: Yes. And at this time we are working out with ECDC on exactly how we are going to do that.

MR. HODSON: It's a fair number of facemasks in closed circuit.

MR. PALYA: I understand.

MR. HODSON: And finally on this, this is more of an appeal about all sorts of standards.

It comes up on the PAPR standard. It comes up on the open circuit, and it also comes up here on closed circuit.

At the moment when we look at trying to combine NFPA requirements with NIOSH requirements, one of the biggest conflicts that we have as a manufacturer is to maintain the quality of our product and to try and do that with the various types of breathing machines that are used.

We have now got the NIOSH breathing machine, which is a piston one. We have just managed to get rid of the piston one out of the NFPA, which was an old Chevrolet engine.

We have now gone to the compliant lung. We now have a metabolic simulator now, which, again, I would guess is a compliant lung system -- no, it's a piston system. Yeah.

One of the real difficulties for us as manufacturers is all these variations in lungs and in the ways in which we measure within those lungs.

And I would like, perhaps, the committee, everybody here at the moment, to consider some way

of perhaps standardizing on a system of testing the breathing.

We spent a long time -- and Bruce will agree with this -- on the last NFPA committee changing from our Chevrolet breathing machine to a compliant lung, and it has worked.

I think the other thing as well is when you go out into the first responder community, they also have to be able to test the equipment. And at the moment, they have the posi check. Again, a compliant lung.

So when we as manufacturers want to maintain the quality of our product, which one do we test it on, or do we test it on them all?

It's a real dilemma, and it does need to be addressed.

Thanks.

MR. SZALAJDA: Very good. Thank you.

MR. KOVAC: The only comment I would make on that is that a number of manufacturers, a number of test houses have breathing machines, breathing simulators.

We are trying to initiate a round robin testing regime looking at the simulator that NIOSH currently has and other technologies.

Obviously, who cares about the details of how that simulation is achieved. What you are looking at will -- different machines generate the same results or at least results that can be reconciled one with the other.

We will undertake an activity of that nature. That is important, yes.

MR. BERNDTSSON: It's not the same as that because if you come here -- Goran Berndtsson from SEA.

If you would compare the piston breathing machines to, what do you call it, compliance breathing machines, you have -- depending on how your breathing was designed, how sensitive and how well it interfere with the -- or interfere. How well it interacts with a human being, if you get a rough breathing machine, that doesn't work, and that is a problem.

I think that every manufacturer who make

high quality products in the self-contained breathing apparatus field, et cetera, had this problem around the world.

Even if you are stipulating everything else, then you can correlate all the other data. But if the technology is different, it will affect how it works.

MR. KOVAC: That's why we are going to compare the technologies, learn how to reconcile the outcomes, the experimental results, learn how to handle variability, learn how to handle uncertainty of the results so that we can compare them in a fair technical sense.

MR. FLYNN: Bill Flynn from Biomarine, again.

One question I forgot to ask. It's the critical one. When will we have cost estimates on these tests?

The sole estimate -- or some cost -- we saw costs yesterday, but any idea on when you will have a -- obviously, the cost from Edgewood.

MR. KOVAC: Not right now. At some

future time.

There will be a cost estimate, but, again, that remains to be seen in terms of fleshing this out.

All we have now is a skeleton and some components on that skeleton. We need to flesh it out.

Once we reach a more refined version of this, reconciling your comments against our thinking, then we can begin talking about costs incurred for testing.

MR. FLYNN: It is crucial. It's crucial for any manufacturer when you are considering the total cost versus the number of systems that are going to be sold.

MR. KOVAC: I understand.

MR. FLYNN: And it's not as if Edgewood has not been through this testing.

They have been through this type of testing. They have been through it on closed circuit systems. They have been through it, obviously, with a number of open circuit and a few

other items.

So I'm just questioning at this point if there is any way they can generate estimates. We would consider them estimates when they are given to us, but they are needed for consideration.

MR. KOVAC: I understand. Thank you.

Jon, some concluding remarks?

Everybody, happy holidays.

MR. SZALAJDA: I promise my comments will be brief, but I thought it was appropriate to at least wrap up before we left as far as what we think we have committed to you to accomplish over the upcoming months as far as our programs.

Again, as we had said back last May, our critical path is related to doing the evaluations with the high flow testing, with the acquisition of the machines, as well as looking at the test protocols and developing how we are going to address high flow as part of the PAPR standards.

Over the next several months we will be completing other benchmark evaluations as part of our process, as well as the development and

verification of test procedures all supporting a standards release later in 2005.

Now, please also keep in mind in formally contacting us, the PAPR docket is No. 10. That will insure that the information is properly filed and we will get it in a timely manner to address as part of our document development.

The closed circuit, as John has just said, there is no -- this is the initial fleshing out of the concept, you know, looking at building upon the tiers of requirements.

You know, we looked at documents that were currently available, whether they were NIOSH requirements or NFPA requirements or draft NFPA requirements, I should say.

And we realize that, you know, direct application isn't always possible or desirable. And as we continue to learn more about the technology and the test procedures that are necessary to support that, we will make course corrections in the concept paper as are necessary.

With the closed circuit, the target for

our next public meeting is September. We anticipate there will be a lot of benchmark data developed and evaluated between now and then leading to a standard later in the year.

We also understand the concern of the stakeholders regarding the potential for another discussion to address the PAPRs. And we will definitely take that under advisement as we move forward and refine the concept.

And for the closed circuit, Docket No. 39.

And with that, I want to thank you on behalf of NPPTL and our standards development partners.

I want to thank you for your participation in the public meeting. These discussions are very beneficial for us, and we hope they are for you as well, and we look forward to working with you guys in the new year and best wishes for the holidays. Thank you.

(Whereupon, the proceedings in the above-captioned matter were concluded at 3:54 p.m.)

CERTIFICATE OF REPORTER

I, Joseph A. Inabnet, do hereby certify that the transcript of the foregoing proceedings was taken by me in Stenotype and thereafter reduced to typewriting under my supervision; that said transcript is a true record of the proceedings; that I am neither counsel for, related to, nor employed by any of the parties to the action in which these proceedings were taken; and further, that I am not a relative or employee of any attorney or counsel employed by the parties thereto, nor financially or otherwise interested in the outcome of the action.

Joseph A. Inabnet

Court Reporter