NIOSH/NPPTL Public Meeting to Discuss Standards Concept Development for Powered Air-Purifying Respirators to Protect Emergency Response Workers Against Chemical, Biological, Radiological, and Nuclear (CBRN) Agents

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P R O C E E D I N G S

RICH METZLER: Good morning. Welcome. Good morning, ladies and gentlemen and partners for improving occupation safety and health. It really is a pleasure to see so many friends of NIOSH and of NPPTL here with us today at this public meeting. I'm Rich Metzler, Director of the National Personal Protective Technology Lab, and want to give a few opening welcoming remarks for your public meeting today.

I want to encourage active, proactive actually, participation. Today we're introducing a new concept for powered air-purifying respirators with protection against CBRN threats. But we're also bringing to close in the second meeting this afternoon our final concepts for a quality assurance module. That module will move forward in the next 90 days through the internal process of getting approved to be announced as a proposed rule.

With regard to the PAPR module, we're really at the beginning of setting standards. We have a concept which is trying to bring a balance among technology and users' protection needs and their needs for interoperability, and that balance is a difficult one to achieve. I point that out early so you are all aware we understand the issues and we welcome your comments not only here today in this recorded public meeting, where a transcript will be made available to

you on the docket, but we welcome your comments and your guidance, data, that you can provide to a docket office as this process moves forward.

I want to call your attention to a recently completed project that NPPTL had been working on with Rand in their Office of Science and Technology Policy, which is an activity we are conducting through the National Science Foundation. They had done two studies for us looking at personal protective equipment needs for emergency responders. The first document has been available since May of last year. The second document in the lower right-hand corner is available for you to take a copy with you today. It is an extension of the early work we did in questioning responders from the World Trade Center, the Pentagon, and Oklahoma City as to what their personal protection equipment needs are relating to structural collapses, to expanding that to all emergency responders in any source of events. And you can see in these documents what the emergency responders personally feel about their personal protective equipment.

Rand is continuing to work with us in completing this study which will bring together the information from the emergency responders themselves with database information on injuries and fatalities, and this information will be used to help us identify priority research for the laboratory.

I also want to thank everyone who have been attending these meetings over the past couple of years and just give a very brief summary of where we stand with regard to our activities related to standards development for CBRN threats.

In January 2002 we began accepting applications for self-contained breathing apparatus. Today we have three manufacturers who hold approvals on 21 models, 15 approvals for those models. Interspiro, MSA, and Scott. Scott also has an upgrade kit, CBRN approved, to bring their traditional firefighter equipment into compliance with CBRN. Other manufacturers have discussed with us their intents to apply. And from what we see in the specifications they are discussing, it looks like as though there will be more approvals very shortly upgrading traditional SCBA.

Gas mask standards were implemented in March, and there are five applications in-house, and all those applications have had the preliminary testing against the permeation tests against chemical warfare agents, sarin and mustard, and have passed the preliminary screening tests and are in various phases of the certification process. Things are looking good for having equipment available in the coming months.

In October we implemented the standards for escape hoods. In November we'll be accepting applications for escape hood certification.

This work that we have completed could not have been done without establishing quality partnerships. A major philosophy for the laboratory that I initiated was built around the fact that quality partnerships enhance safety and health. To carry out the program and accomplish what we've accomplished was not something done alone. The process was initiated with the Department of Justice and the National Institute for Standards Technology, who had the foresight as early as 2000 to provide initial funds to NIOSH and NPPTL to begin the process of looking into hazards associated with CBRN response.

SBCCOM, as you know, our Army brother/sister organization, is working with us in conducting tests and evaluating the equipment, as well as helping us establish the standards. They recently changed their name to RDECOM, Research Development Evaluation Command.

OSHA we have partnered with to identify cautions, limitations, restrictions of use, guidance on enforcement. And recently the Department of Home and Security has provided $3 million to continue the development of standards for PAPR's, combination equipment, closed-circuit, long duration apparatus.

This also could not have been done without the cooperation of NFPA. As you know, our program tends to be a tiered program, where NFPA requirements are required to be

met, NIOSH approvals, in additional to military testing.

I'd also like to thank those in the private sector. The ISEA has been very supportive. Individual manufacturers who come to these meetings and many stay quarter meetings that we hold on one on one at the Pittsburgh Complex, the International Association of Firefighters, the International Association of Fire Chiefs, and many others who attend these public meetings.

And in closing I want to just say today we have a special guest with us. Many of you have worked very closely with John Dower. John retired at the end of September. He lives in the Morgantown area and was able to come over to meet many of his friends. The accomplishments that I've described were achieved by all these partners really started with John's activities in helping to establish the interagency board, in networking closing with NIST to bring you early money into the program. The early funds started somewhere around $500,000 from DOJ and NIST, and over the past two years have been funded by a variety of sources up to $18 million.

So I'd like you to recognize, John, if you'll stand up, and recognize that we are here today and accomplished what we have done because of his initiation and -- (applause) Thank you, John, God bless you, and I hope you have a very enjoyable meeting.

Speak up. Go to the microphones. Let's hear from you. I know I don't have to tell many of you that. Thank you.

ROLAND BERRY ANN: Good morning, everybody. I want to reiterate what Rich said about welcoming you here. We're glad everybody could make it and be here. We're looking forward to active participation. I believe everybody got a copy of the agenda in their packet, if not, we can get one out at the table during break.

We're going to be covering the same type of requirements that we have previously in these types of meetings. I'm talking about the requirements, how they were derived, what they're based on. We've got a full day. We have an afternoon session. We'll be adjourning this meeting at 2:45 and have a short break, and then at 3:00 we'll be reconvening a second public meeting on the QA module that Rich spoke about.

If anybody has not signed up for that and is planning on staying, there's a separate sign up sheet for the QA Module Meeting this afternoon. Please do that at the reception table out front.

Meeting logistics, those of you who have been with us before probably are familiar with all the details of how our meetings are conducted. There's sign up sheets at the front for each of the two public meetings. Please sign up your attendance if you haven't preregistered. The meeting, as Rich

said, is being recorded. We have a verbatim transcript that will be available on the docket of the meeting. We're going to do our best to follow the agenda and get everybody out on time. We know that there's travel arrangements and such. And we do want to get to all the topic areas during the day.

We will have question and answer periods after each presentation. You'll have an opportunity to question and comment or make any comments you want. There's a microphone in the aisle that you can approach. Please identify yourself and affiliation with any comments that you make so that that can be captured by the transcriber. And you may be asked to provide clarification of your name, spelling. And if anybody here - we do have one presentation, I believe, who has preregistered to give a presentation. If anybody else wishes to give a presentation at the end of the session of the meeting where we have time allotted, please sign up at the desk out front and we'll get you on the agenda.

Okay. Just real quick, as Rich said in his presentation, we began this process in 1999. We have three standards that have been completed and released. Two of them we have applications in the process. One of them, the SCBA's, we have approvals issued. As a footnote to the SCBA's, we have the upgrade program for SCBA's that we have implemented as well this year, and we have one approval issued under that, and

other applications forthcoming. Today we're starting the journey on the next set, which is the PAPR's. And hopefully early next near we will have our concepts into a standard that we will be able to move forward with.

Again, just reiterating the beginning of the process where the needs were defined early in the process in 1999, and the partnerships that Rich talked about, and we believe we are fulfilling on those promises that were made early and following the course that was set. But we continue to ask for input to assure that we are on the right course on our priorities.

Okay. Again, Rich already covered with his brief statements, I won't belabor it, RDECOM has been one of our partners who are agent testing and are subject testing for the protection level testing. NIST, OSHA, NFPA, and Department of Homeland Security have been instrumental in helping us make our progress and be successful in our efforts. Again, the purpose of this public meeting is to provide our initial concepts on PAPR requirements, what we think are appropriate to continue the process of the CBRN standards, and we are hoping that we get active feedback and input to tell us where you think we are correct in our assumptions and our directions and where you think we need to reassess our initial concepts and improve our product.

Here's the address and information for the docket office. Again, that information is available, if you don't have it, at the front desk outside the room. And that concludes the logistics. Thank you.

JONATHAN SZALAJDA: Good morning. I wanted to spend a couple of minutes initially that follow along the discussions that Rich and Roland introduced regarding our standards development process. And really I think it gets around to, you know, what the first question we've had to answer in terms of why we need a suite of CBRN respirator standards as what's the requirement for a new standard. Well, I guess obviously the first thing that we look at is if you have a threat you're trying to address to look and see if there is an existing standard that could be applied to address that threat. If there's not, then you have a requirement from the standpoint that that type of standard doesn't exist.

I think there are a couple of other possibilities about why we develop new standards. And they really relate around technologies. I think the one aspect in dealing with CBRN events is the identification of new hazards, you know, and the aspect that terrorists are very iterative people by what we've seen in events not only in this country but around the world. And a lot of different things can be deployed in different manners to create a hazard for responders.

I think the other aspect though of technology and in consideration of new requirements for standards is the protection, the equipment controls protection elements that are identified, being respirators or other protective ensembles, that include the design and products that evolve to address the hazards that are associated with the different threats and the response through personal protective equipment and how to protect against them.

I think the bottom line for where we stand today is that, and we've said this in the past, that military standards or existing NIOSH standards don't totally fit the bill for developing appropriate protection for CBRN events. NIOSH standards are principally for certification of product to ensure that performance required and some quality assurance requirements are present and maintained in the product that's used by the worker population. Military standards are geared towards identified design performance criteria that were identified to meet an operational requirement for equipment used by the military.

Looking at the user group populations, you know, when you talk about NIOSH industrial type respirators, that we're looking at the general working population groups that have been identified that are required to have respiratory protection as part of their day to day functions as

engineering controls. Now, obviously for the military standards, the standards are geared towards protecting military personnel in defined scenarios for where they would need personal protective equipment.

For the hazards that we are dealing with, I guess through with NIOSH, that, you know, you're looking at toxic industrial chemicals. And I think we're to some extent, you know, that these types are hazards are quantified and identified and PPE respirators are incorporated as part of engineering controls to minimize exposures to the workers. With the military standpoint, you know, in speaking from a perspective on the respirator development, that their requirements for the respirator were built around defined battlefield scenarios knowing what the agents were that the adversary could deploy and what concentrations could be generated in a battlefield scenario, how to appropriately protect against several of these instances where chemical warfare agents may have been deployed.

I think when we're looking at terrorism though and given the unknown perspective in dealing with terrorism events that one of the that we've tried to consider is the full range of CBRN warfare agents. And chemical warfare agents as well as the deployment of toxic industrial chemicals as a potential weapon, biological, radiological, nuclear particulate matter.

And as well as, as I mentioned, the concern about the extreme use of toxic industrial materials being deployed as a terrorism weapon.

I think some of the other characteristics in looking at the difference between the military and NIOSH standards include protection characteristics, as far as defining the criteria and the protection necessary for the responder in dealing with these events. From the historical NIOSH perspective, you know, we've built requirements around the use of REL's, PEL's and unacceptable exposure when it's defined over a 40 year period. And the military requirements are built around the myosis effects of the chemical warfare agents and the effects on military personnel.

I think when we look at terrorism we're encompassing a wide range of potential responders that we've seen from time. The definition of responder has really evolved over the past several years and in this field that we've considered people such as the fire services, law enforcement, emergency medical technicians, construction engineers, and engineers that would be supporting cleanup activities, as well as even people such as telephone and those type of workers that are trying to reconnect basic services that may have been interrupted as the result of a terrorism event.

But I think what we always try to do in terms of working on new standards is to identify a goal for the project, because as Les Boord who usually gives us this type of discussion says if you don't set a goal for yourself, you know, any road can take you to lead any - lead you to any type of accomplishment you want. And in terms of this sytem we felt that the goal needs to focus on protecting emergency responders against potential inhalation hazards and other terrorists hazards that could be seen by a responder at an emergency of using CBRN type of materials.

And I think just to kind of follow up on what Roland and Rich and had said earlier, that this is our first meeting to discuss the CBRN PAPR concepts, and we really want to encourage your review of the concepts and your engagement with us in discussions on the process in order to maximize the feedback and the ideas that you may have from your community, whether it's a manufacturer or from the user side, so we can make sure or at least work towards ensuring that we can address those aspects as part of the standard.

Where we envision this sytem being used is pretty consistent I think with traditional methodology and where air-purifying type systems should be used, that we anticipate that PAPR's will be used in warm zone type environments where there is a controlled - hazard's been identified, it's been

quantified, controlled to some extent, but it's still at the point where it's above a permissible exposure level for the responder that the air that the responder is dealing with needs to be purified to reduce the effects of contamination.

I think some of the aspects that have historically been seen with the warm zone operations include your long-term support activities like decontamination, traffic control around the perimeter of a site, as well as in supporting rescue and recovery type operations as well. One of the things that we felt was important based on some of the earlier work that was done with the standards development effort was to provide for crisis provision in terms of the capacity of the canister infiltration. This system is used where there's a potential for high physiological flow through the system. And also we wanted to identify a capacity in the system for dealing with secondary type of devices or pocket of entrapped hazards that may not be readily recognizable in the warm zone, but could be there and made present and still provide an adequate protection for the responder so that he could escape from that type of scenario.

And I think at least in terms for this meeting I wanted to go through and spend a few minutes in terms of talking about the process that we've been following and trying to consistently follow, starting with the SCBA and moving through

the APR, as well as the escape products, and now into the PAPR at least in terms of the types of activities that we're considering in our process for developing the CBRN PAPR standards. And I think at least off the top the need for a hazard analysis is inherent with the process. And I think one thing to keep in mind up front is that the hazard analysis for the CBRN PAPR uses the same criteria that we established for the CBRN air-purifying respirator and gas mask.

This work also builds upon the initial work done in the hazard assessment and the vulnerability assessments that we've conducted in 2000 and 2001 with the soldier biological and chemical command, now RDECOM. Vulnerability factors that were assessed as part of this early work included an evaluation of the toxicology and the hazards, potential delivery methods a terrorist could employ to deliver that hazard, challenge concentrations of the hazards that could be generated as a result of the deployment of the device. And then also the identification of the protection that would be required for a responder in dealing with these different events.

The modeling efforts that were generated by the Army in support of this assessment showed that the toxicities of the toxic industrial chemicals and the chemical warfare agents span corridors of magnitude and value. It wasn't an easy problem to solve by any means. We also found that the

challenge levels that are generated were venue specific. And by that I mean that as part of the assessment the modeling considered I believe the total was 28 or 29 different potential venues in the deployment of chemical warfare agents, and also evaluating the deployment of toxic industrial chemicals. And we found that depending on the venue and the scenario, the things I mentioned, that it concentrated - challenge concentrations vary widely. And in terms of how we develop our challenge criteria for the chemical warfare agents, we identified something at the time we call incredible events and looked at the range of concentrations that could be generated as a deployment of these types of materials and select the challenge concentrations appropriate for what we felt would be most like seen by a responder in dealing with these environments.

And I think to leave from the hazard analysis to protection is that in part of the process in doing this assessment was looking at the protection that was required for the responder, and that was dependent on how the respirator would be used obviously in IDLH type scenarios we're looking at self-contained breathing apparatus, which was the initial standard that we developed in looking at less than IDLH type conditions in warm zone type operations. We look at APR's and now PAPR's.

The protection that's required, you know, I think the tie in with that is that once you have the - you've done this assessment and you've quantified and identified the hazards and you can apply the appropriate protection level in terms of respiratory protection, whether it's provided in a supply air system or an air-purifying system to provide the required protection for the individual that needs to wear the respirator. Along with the hazard, going through this type or part of the process with the hazard analysis and the assessment of the protection evaluations, we go through a process in our standards development concepts of identifying and evaluating human factors and environmental factor characteristics and concerns.

And I think human factors are pretty well known to the community. They're referring to aspects such as communications, speech intelligibility, the field of view, whether or not the respirator will fog during operation, the ruggedness of the lens, how the lens will resist abrasion while the respirator is in use.

Environmental factors are addressed to assess the different types of conditions that the equipment may be exposed to in its life cycle. To that extent we've used other standards in terms of looking at requirements that were identified by NFPA for NFPA approved equipment, as well as

looking at things like military standards, Mid-Std-810 for environmental condition is one example.

But as we go through, and one thing I wanted you to appreciate in terms of the process, in going through these different steps that as we go through the hazard analysis and the determination of the protectability that's required, and consideration of these other factors, we're working to define these conceptual requirements on what we call the concept paper. And this is the device and instrument that we initiated as part of the air-purifying respirator standard development. And really we like to think that the concept paper up to the point where we implement is a standard is really a living document. And it's easy - I guess it's easy enough to say that, but what we really, from our perspective, we see this is a good mechanism of translating our thoughts and our thought process to the stakeholder community in terms of things that we're considering in terms of requirement, and looking at the stakeholder community to come back to us and identify where we're on track or maybe where we might need to consider some things to redirect the requirements generation.

Buy anyway, once we would get out and start identifying the concepts, then we start looking at the perspective as well as taking those concepts and then translating them into the standard and the supporting activities that need to go along

with the certification, the certification that products that NIOSH receives for evaluation meet the requirements of the standard. And along with that we're looking at trying to look at the development of procedures, testing procedures, from a certification point of view to make sure that we have a consistent method of performing the tests and evaluate the products against the requirements.

I think the next aspect along with that is looking at any special provisions in terms of quality assurance that need to be addressed in terms of the certification activities as far as when we implement the standard, if there are any other special criteria that we need to consider would be manufacturer and community needs to consider in terms of the product that's being provided.

And finally, the last aspect of our process is to try to do this is a public forum. And I think we try to do the standard development in an as open environment as much as possible. We courage the exchange of information between stakeholders and other representatives of the community and any interested party that may have an interest in our process. And I think, you know, public meetings like this one are an example of that type of process, as well as any of the open discussions that Rich and Roland mentioned that we welcome to have with members of the community.

So having done that, to set the stage for what we want to talk about in terms of the PAPR, I wanted to bring up front some of the points that are features of the concept that we are thinking of building the standard around. And some of these - and with the team working and trying to identify and having seen some of the other issues that were identified with some of the other standards development efforts, we decided to put forward a couple of concepts for the community to consider. And really this is where we need to get the feedback not only from the stakeholder communities, but also from the manufacturers in terms of how the technology, the PAPR technology could be employed within the development of the standards.

I think one thing up front that we felt was important because of the nature of CBRN agents that we felt that the protections that were afforded by a tight seal to the face was important for a responder. And so the first thing that we felt was important for responders in dealing with a CBRN event was to specify a tight fitting, full facepiece PAPR. And this includes I guess by definition some of the neck dam systems where NIOSH has made a prior determination, the neck dam could be applicable as a type of - tight fitting, full facepiece. It's a lot to spit out this early in the morning. But that type of system would be appropriate and fit the category of a

full facepiece type of tight fitting PAPR.

The other aspect along with looking at the protections, based on some of the user - naturally there's significant user feedback with the development of the CBRN and APR requirements. And the user very articulately defined the need, the desire for interoperability or to allow the interoperability of filters as could be determined onsite, with the site commander working with OSHA and other agencies to make a determination that you could exchange filters between CBRN approved APR's and the canisters that were developed along with those APR's. And what we're conceptionalizing at this point is to continue to built around that feature for the system and to translate the requirements that were identified with the CBRN APR with a gas mask to the PAPR as well.

I guess from the user perspective it seems that this would be desirable because one of the big concerns was to minimize the number of filters, the number of canisters that responders would have to deal with onsite. And by requiring the same, identifying and requiring the same connectors and physical parameters of the canister, and as well as the gas life requirements of the canister between the systems, we're working towards providing that potential for interoperability.

Another aspect that's come to light with this approach is

that it simplifies the testing technology that's required for this type of system. And to that extent that we're using and evaluating these types of systems where we'll be using the same test technology and the same procedures that have been defined for the APR, you know, that we would simplify the process at least with regard to how the canisters would be evaluated.

A couple of the other requirements that we addressed in going along with that is a determination of a minimum flow rate for the PAPR. And we're using the 115 liters per minute, which was identified as part of the 42 CFR requirements. And in following our logic process for using this airflow, that leads to the identification of two - a minimum of two canisters, a minimum of two filtration systems that would be necessary for this type of device.

I think I probably jumped ahead of myself in that discussion a little bit. But in terms of the requirements that were established for the gas mask, for the APR canisters, we pretty well identified that as in working within the development of the concept paper and then the establishment of the standard for the APR. Looking at really building off the mechanical connector design that was specified in the statement of standard, both the male and female connectors that are associated with the face plank as well as with the

canister. Also we're continuing to consider using the parameters that were defined for the gasket and mechanical connector. And for those of you that were involved or tracked the APR process, I think you'll recognize that we developed those parameters around the military requirements that were used on the M-40 and the NCU-2P masks which were shown to be effective as the result of evaluations done by the Armed Services.

The canister and the dimension and weight again tracks with the development and the efforts that were indicated in the gas mask standard. And looking at a limit of 500 grams for the canister and then fitting within the size envelope that was defined and the requirement of going through a five inch diameter hole. And I think the other thing to keep in mind, as I mentioned, was that we're looking at doing the same gas life, the same particulate testing that's done with the APR canister, the requirement for the P-100 filter media to effectively remove the biological, radiological, and nuclear particulate matter, the same gas life challenge concentrations, and the breakthrough concentrations that were identified with the APR.

549 To follow-up on that thought, and Mr. Thornton will
550 follow me and he'll talk a little bit more about the hazard
551 list, but in looking at the hazard analysis that we conducted
552 as part of our early work in vulnerability assessment, the
553 PAPR continues to follow and build upon the hazard list that
554 was identified as part of our early vulnerability assessment
555 and hazard assessment work that was done.
556 To that extent we looked at a variety of lists that have
557 been promoted within the community, the ITF-25 and now the
558 ITF-40, lists that been promoted by the CDC as well as the EPA
559 and other federal agencies, lists that were generated by law
560 enforcement agencies. But again, in defining the requirements
561 for this standard we're looking at providing the same 139
562 protections that we identified for the gas masks for the APR
563 standard. And one thing to keep in mind though with this
564 analysis is that though our assessment here is a dynamic
565 process, as information is generated and comes available we
566 continue to review these lists and conduct benchmark testing
567 and other evaluations where necessary to follow up on the
568 requirements and the protections that this system could
569 provide for responders.
570 And again with following with the work that we've done
571 with the gas masks, we're using the concept of test
572 representative agents to simplify the certification testing as

far as the number, of using a small number of materials, of chemicals or particulates to protect against a wider population. Terry will get into that in his presentation.

And I think if nothing else I think people will say that NIOSH has been consistent with a three-tiered approach to a standards development. We introduced this with the SCBA. We've continued it with the gas masks and the escape respirators. And now we're going to use the same methodology for the powered air-purifying respirators.

And in looking at the requirements that have been identified in 42 CFR, Part 84, what we're envisioning right now is to use applicable sections of the document. And by that I mean the sub parts A through I believe it's F, which deal with the general construction requirements, the QA requirements, things of that nature, as well as probably sections of sub part I to address the requirements that were identified for powered air-purifying respirators for the tight fitting respirator.

It looking at the requirements derived from other standards and specifications, one of the things that we've tried to do with the development of these requirements is where existing standards are in place to use them to the maximum extent possible. And I think when you look at some of the things that we've defined in the first concept paper, you

know, we're continuing to make use of EN-136 and looking at the requirements for the mechanical connector. We're using ASTM methods in identifying the testing requirements for the mechanical gasket.

For the field of view and the abrasion and some of those other parameters, we're using requirements that were identified in EN-136 as well as in guidelines that have been issued by the American Medical Association for visual acuity. And I guess then another aspect that jumps out is with the environmental conditioning, using the requirements and procedures that have been developed as Mil-Std-810 and tailoring those requirements to be applicable to how we envision this device being carried and used by the responder community.

And then the last part of our triad of our tier of requirement is the special CBRN requirements that are inherent with this type of system. Now, obviously in testing for chemical warfare agents is one of them. And that's been something that the user community has been consistent and vocal in their desires that this equipment be evaluated against the real thing, that it will protect against the chemical warfare agent. We're also continuing along with the implementation of a respiratory fit test in a laboratory setting which we call the LRPL. I know I'll mess this up, but

it's Laboratory Respirator Protection Level testing. And this test is done for us by the Army as our test agent. And I think for the manufacturers and the stakeholders that have been involved with the process that you'll see that the overall protocol for this device isn't new, that we are translating the same protocol that was developed as part of the initial work with the SCBA that's been continued through PAPR and the escape mask and tailoring that protocol to meet the specific parameters associated with the respirator in this case. Now we'll be looking at tailoring the requirements of that protocol to meet the LRPL requirements. And then the last part of the special requirements gets into the gas life testing, the testing against the test representative agents that were identified for filtration and the canister.

Some of the other things that we're really looking for feedback from the community on as we move forward over the next few months are other requirements that are unique to the powered air-purifying respirator. And as I had mentioned earlier I think with - and as we conceptualize right now, because of the nature of the CBRN threats, you know, we're looking at the protections that a tight fitting, full facepiece respirator can afford. With the harness requirements, and by harness we mean the aspect that where the respirator components are held against the wearer's body, and

along with that, the design of that harness, you know, how easily the components may be removed or replaced or work within the system.

Some of the other things that have been traditionally considered with the PAPR's are container requirements. And by that I mean the designations that may be applied regarding the system, things like indication of the battery requirements, the indication of flow, of the airflow through the respirator. And then also with the labeling that's incorporated as part of the container requirements, but things I guess along the lines of information about the battery or the flows, things like appropriate cautions and limitations that could be applicable to this type of device.

Some of the other things that we want to evaluate and get into and get feedback from both stakeholder community as well as the manufacturers are other construction requirements of the respirator. I guess one thing when we look at the battery requirements, you know, what should we identify in terms of the service life recommendations for the system. We also want to be able to - we're conceptionalizing how we want to evaluate the rating requirements and verify those requirements for service life of the battery and whether we should define battery requirements based on - for duration based on motor drive, the load that the battery sees and the condition of the

battery where you may have rechargeable batteries that maybe used with they system. These are the types of parameters we want to evaluate.

Some of the other things that come to mind are the indication of the charge of the battery, you know, whether or not it would be appropriate to include a low battery light indicator with the system.

The flow indicators are another aspect of the requirements that we're considering. I think inherently we're looking a probably providing some sort of visible indicator or some other means for the responder to know that they're getting the proper flow through the system. Whether or not that indicator is based on a low flow capability or a monitoring of the ongoing flow, that's still to be determined. I think part of that process needs to be looking at the range of the flows that could be associated with the respirator and how best to monitor that.

With operational controls I think you're looking at protections within the system to keep the user from accidentally turning on - I'm sorry, turning off the respirator while it's being worn. I think another aspect of concern for us with this type of device is how do we make sure that we keep unpurified air from entering the breathing respirator either through the fitted respirator around the

face or potentially through the seal of the neck dam.

Noise levels has been a concern as well in the past. And I think obviously with anytime you have a blower or a mechanical system you're going to be generating some sort of noise. And we certainly want to keep that to a level where it's not providing damage or doing damage to the respirator wearer. And we'll be looking at monitoring for noise around the ears of the respirator for what a responder, what a user may see while the blower is running.

And with the airflow I guess the concept, and falling back and continuing on from the identification of using the requirements that were defined for the CBRN APR canister, what we're envisioning is that the - we want to monitor and ensure that the face velocity through the canister, through the filters, doesn't exceed the face velocity achieved during gas life testing of 64 liters per minute. And again, this is where we welcome your feedback and your ideas as far as how best to achieve the potential for defining interoperable, potential interoperable canister, yet working within the context and the technology that the powered air-purifying respirator can provide.

What we're going to go through today in terms of some of these special requirements, and again, part of the intent of what we want to do here today in addition to introducing the

potential for interoperability in the airflow concepts was to do a review of what envision as the CBRN unique testing that would be required for the system and discuss those parameters up front, and as we move through the process that we'd like to spend more time in the evolution of the PAPR unique performance parameters and performance requirements, and maybe not as much in reviewing and rehashing the information regarding special CBRN requirements except where there may be changes made or modifications to protocol, the protocols that have been established that the community should be aware of.

What we're going to cover here over the next few hours, and then we'll talk about the gas life testing then, Terry Thornton, a research chemist within our organization, will review the parameters that have been established for the gas life and particulate testing for the canisters. Ray Lins from SBCCOM and myself are going to address the chemical warfare agent, testing the penetration and permeation testing that's done to evaluate the respirators. The focus on that is - at least the topic we discuss the identification of the challenge and breakthrough requirements for the respirator. And Ray is going to discuss from his perspective some of the experiences he's had in the past evaluating powered air-purifying respirators with his equipment, as well as the capabilities at his lab.

741 And Mr. Berman, Mike Bergman, from our lab in Pittsburgh,
742 is here to discuss the LRPL requirements. And I think what's
743 very novel regarding Mike's presentation is as we continue to
744 learn and evolve as part of the accumulation of a lot of
745 different information regarding physiological characteristics
746 of individuals and how that relates to the proper fit of
747 respirators that this has been a very dynamic process in terms
748 of developing these requirements, both in looking at evolving
749 studies and information that's being generated regarding the
750 working population of today as well as trying to leverage
751 information that the Department of Defense has been generating
752 regarding physiological face seal fit, neck sizes, things of
753 that nature, to try to incorporate all this information and
754 review it and make recommendations for sizing parameters and
755 determination of fit requirements based on a whole slew of
756 both new and old information.
757 Again, as I had mentioned in the review of the process
758 that we're going to develop a standard in a public forum, you
759 know, meetings such as this, individual one on one meetings,
760 participation in other development activities around the
761 country that may be related to Tech Chem evaluations or other
762 features of respiratory protection. We're going to be
763 involved. I would encourage you to speak up at this meeting,
764 make your points known. And I'd also encourage you to work

with us. If you're not comfortable in doing it in a public forum, we encourage one on one discussions, your feedback, your data, your thoughts, your engineering expertise is invaluable to us in developing the characteristics associated with what we should consider for the requirements of the standard.

We're going to continue to use our concept paper. We have to apologize. The first one was out I guess the end of September, and it was our error, it took longer to get it through the processes and then available to the community. We're going to work, continue to do better in getting that information out quicker to the community. And to that extent I think you can expect that we'll have concept papers, a new paper on the Web site every 30 to 45 days. My intent for the next paper is based on the discussions that we hear today and the feedback that we receive from the community, that the next paper, the next concept paper will be available within 45 days on the site.

Part of what we're going to try to do in terms of the use of the Web site, as we go through and identify requirements where we promised you that, that something will be available for developing a test protocol, if we're developing some other requirement that we're going to require feedback, if there's a delay in getting that item out to you, we're going to go ahead

and establish the length, we'll put some sort of message there, whether it's under construction or something along that line, to let you know that we haven't forgotten, you know, that we are working towards the development of that product and as soon as it's available it'll be on the site. And hopefully that will be a good tool that you'll be able to use to track what we're doing.

And where we're going in terms of a schedule and how it circumvents, I guess are conventional processes to some extent. I did want to let you know that we have planned and are in the organization stage for the next public meeting, and we're looking at conducting that in Pittsburgh at the end of January. There's a flyer. There's a flyer available in the back at the registration desk that you can pick up related to this meeting. We are going to go through, you know, we're beginning the development of, you know, what we formally need to do through the Federal Register to announce this meeting and the particulars associated with the meeting. But given the interest in the CBRN respirators and development of the requirements, we did want to bring to your attention and for your planning purposes that we're in mission in getting together again at the end of January.

One of the things - another milestone that we're trying to identify up front is the engagement of our internal NIOSH

peer review group to evaluate, we hope at that March time frame, is to evaluate the requirements associated with the standard. This is part of the process that we've done internally with all of the respirator standards, staring with the SCBA and continuing through the APR's, as well as the escape respirators. That will continue and knowing their involvement and meeting with them and getting their feedback will continue through the development of this standard.

Don Campbell from the Division of - I know I'll mess this up - Respiratory Disease Studies, thank you, is one of our peer review members. Rick Niemeier from Cincinnati, NIOSH in Cincinnati, is another peer review member. I don't know if Nancy Bollinger made here today or not. Nancy is the Deputy Director for the HELL Division located here in Morgantown. Captain Frank Earl used to be with NIOSH in Morgantown, now is with the office of the director in Washington, is another reviewer. And Angela Webber, who's with the Health and Field Safety Evaluation Office, is our final peer review member.

In terms of what we're going to do with the standard, again, we're currently conducting the same process that has been used with the other CBRN respirator standards to solicit public input. And we are currently discussing concepts within NIOSH on how best to follow on with the implementation of the standard. And as we move forward with the process over the

next several months, as we get some answers regarding the implementation phase of the standard, we'll bring them forward to the community.

And with that I'll open it up for any questions you may have. Our next presenter will be Mr. Thornton, Terry Thornton, from our lab. But again, if you could come to the microphone, state your name, your organization, affiliation, and your comments.

PAUL DUNCAN: My name's Paul Duncan, Scott Health & Safety. Something I think should be considered in developing - or considering the interchangeability portion of the PAPR and with the battery specification, it's necessarily intuitive that some PAPR's have a direct relationship with filter resistance and battery life and some of it inverse. There are ones out on the market where if you put a lower resistance filter in there, the battery life actually decreases because of extra draw on the motor, whereas ones that you put a lower resistance the battery life will increase. Now as we start talking about interchangeability between different manufacturers' filters on different manufacturers' PAPR's, you start misleading the, I think, the end user about the detecting of battery life.

JONATHAN SZALAJDA: Thank you.

GORAN BERNDTSSON: Good morning. Goran Berndtsson from SEA. I hope I misunderstood what you were saying here, because the concept is not going in the spirit I was told earlier that this was going to go. For example, it sounds like you are intending to write this down that based on the simplicity of testing the interchangeably in preference for performance and protection of the user. Then you are limiting to say, for example, that filters is not going to over the face because they are still testing it. How are you going to control that in air (unintelligible) respirators. I mean you're going to penalize PAPR's, (intelligible) that constant. I hope that we can come to some arrangement where we are changing the testing procedure to meet the requirement of the manufacturer's claims.

JONATHAN SZALAJDA: Yeah. I think - I don't want to give you the wrong perspective that part of the development of this requirement was just solely from the simple indication of the test program quality. That's a byproduct. If we can successfully proceed with using, taking and translating the requirements of the filter into - from the APR into the PAPR, you know, that's a benefit, but that's certainly not the main driving factor towards the development of the criteria. Again, I think part of one of the things that we're grappling with in terms of trying to translate the requirements and

knowing what the technological capabilities and the capacities and capabilities of the PAPR is how can we translate user desires in terms of interoperability and still be able to accommodate and include technology evolutions and feature positive features, positive by meaning good features of the PAPR into this type of requirement.

JACK SAWICKI: Jack Sawicki, Global Secure Holdings. Just a general comment. I believe the standard is - the direction you're going in is really overly design restrictive. And specifically, and I guess this is a question, do you really anticipate being able to take a canister from the PAPR and plug it into an APR? Is that the interchangeability you're talking about?

JONATHAN SZALAJDA: Well, that's one of the concepts that we're trying to identify here. Obviously I think from the user perspective, if they can use one filter, I think that's what they would desire to do. Part of what we're trying to evaluate here during the concept development is the feasibility of being able to do that. Whether you can, I mean I think the desire is there to be able to use the same CBRN filter, whether it's with your canister between the two types of systems. Whether or not technology, you know, technologically that's achievable, we still need to address. I mean there may be, you know, along with some of the other

comments, and we are trying to be sensitive to I guess the earlier comment regarding limiting technology. It's a fine line and a lot of tradeoffs that we're going to be needing to evaluate. As part of the process how to move forward, you know, with still trying to meet the requirements and the desires for interoperability, but yet still leave the potential for technology evolution of the product open.

JACK SAWICKI: I guess my second comment was, and following Goran I guess that's a good place to be, is I really hope you will address in the testing the possibility of the pressure to the APR's rather than just constant level APR's. Because I think just running a test around what may be currently the standard on the low end of the industry really doesn't challenge the manufacturers to - it doesn't allow them really to do innovations. So I'm encouraging to continue to evolve these standards to allow perhaps a breathing machine rather than a constant flow and some other issues that might accommodate those types of designs.

JONATHAN SZALAJDA: Thanks, Jack. Again, I appreciate these type of comments that you have technical issues and other considerations that you feel are pertinent to the development of our product, as well any data, any studies that you may have done individually, if you could bring that forward to our attention it would be worthwhile in the

process.

JAY PARKER: Jay Parker with the Bullard Company. We were interested to see the exclusion of loose fitting hoods in this concept paper. That's interesting because it is a pretty serious design restriction. And I also notice that the concern there was there would be leakage, especially when the blower is not running. There is no test in the load without the blower on in the laboratory respirator detection level tests. So it's a little hard for me to understand why you want a tight neck seal and yet you're not testing it with the blower off. There are technologies available out there to provide good protection with a loose fitting seal to the neck.

I'd also like to comment on the battery life. I see you give an example of a one hour battery. I'm not sure one hour is long enough. You might want to go back to the existing PAPR requirements which basically require at least four hours because of the silica dust test duration. Also, on the low flow indicator, the thing there to be careful of is that low flow can be caused both by battery power and a loaded filter, and the lung will work differently depending on which one is causing it. So if you're going to test the low flow indicator, you need to test it in both conditions if you're concerned about a clogged filter being one of the potential causes of the low flow. Thank you.

JONATHAN SZALAJDA: Thank you for your comments. I did want to mention one thing, and Mike will be addressing this as part of his presentation, when we look at the development of the requirements for the LRPL, you know, what we initially put in was the requirement in the blown configuration, I think one of the things that we would like to solicit your feedback on is the valuations for the LRPL and an unknown, unblown mode, whether that's appropriate. I think when you look at what we developed for the SCBA there is some precedence there in terms of doing that testing, testing the SCBA facepiece and an unblown mode using a P-100 filter to evaluate the fit of the respirator. And in that type of criteria I think there could be some justification. And we welcome your feedback in terms of whether or not developing that type of criteria for the PAPR would be appropriate.

JOHN MORAWETZ: John Morawetz, International Chemical Workers Union. Following up on the question of interchangeability of APR's versus PAPR's cartridges, the test breakthrough concentrations has some inconsistencies between APR's and PAPR's. Can you comment on that, the different breakthrough concentrations?

JONATHAN SZALAJDA: Yeah. I'm not aware of any changes between the PAPR and the APR that - essentially the challenge concentrations are based on multiples of the IDLH and the

breakthroughs for the APR's are based on half the REL's. And in some instances where those don't translate there were some ratios established as part of the test technology to simplify the certification testing to develop the same capacity for the filter, but maybe not necessarily test and sample at those levels. And again I think that's part of the thing to keep in mind with the definition of the requirements for the canister is that we're looking in terms of the developing a capacity, a canister capacity for handling the quantity of gas that could be seen through the filter. And we felt that in identifying that capacity we were able to set up some ratios. I don't recall the chemicals off the top of my head, but there are some chemicals where we set up ratios of both to the challenge of the breakthrough that don't directly correlate with the multiple of IDLH and half the REL. I'd be welcome to sit down and review that with you.

JOHN MORAWETZ: I misspoke when I said the challenge. It really is the breakthrough concentration. Many of them are the same, but, for instance, hydrogen sulphide for APR's has a breakthrough of 30 ppm, for the PAPR's the proposed was 5 ppm, for ammonia it's 25 ppm for breakthrough for APR's, for PAPR's it's half that, 12½, so.

JONATHAN SZALAJDA: We'll look into that. I can get that out to you about the requirements. They should be the same

between the two.

BODO HEINS: Bodo Heins from Draeger. My first question that comes up is the first sentence you are stating there, the PAPR shall be identified as inhalation and possible terrorist hazards. Does that mean that we have to have also hair protection or full body protection? Or what do you mean here?

JONATHAN SZALAJDA: I'm sorry. I think with that it - you know, obviously I think with where this system is going to be used, we're going to use them in a quantified and known, identified and quantified environment, and in conjunction with that you'll be using the respirator, and in conjunction with appropriate clothing and other personal protective equipment.

And what we've done in the past with the other standards is as part of the cautions and limitations that we've identified that mean that the respirator needs to be considered in terms of the overall ensemble that's used by the responder in dealing with a particular incident.

BODO HEINS: So is this then that there's no hair protection required as for example for escape?

JONATHAN SZALAJDA: You means in terms of a hood?

BODO HEINS: Yeah.

JONATHAN SZALAJDA: At least right now that's correct. I think what you're looking at again with a full facepiece type system, we envision you may be using it with a hood, a hooded

type ensemble. You have a jacket with some sort of hood. You know, obviously with the neck dam system you are going to have some sort of hooded system. But I think in terms of as we develop the concept, you know, we'll be looking at these aspects and whether or not there is going to be a need to identify requirement for a hood if it's used in conjunction with clothing that doesn't afford --

BODO HEINS: So at the moment it's a possibility and not a requirement?

JONATHAN SZALAJDA: Right.

BODO HEINS: My second question is as far as I have seen you took the same resistances as in the APR standard. Why do you need a blower then?

JONATHAN SZALAJDA: Well, at least in terms of the requirement and trying to build around the standard for the canister we're using the same resistances that were identified for the APR.

GORAN BERNDTSSON: Goran Berndtsson, SEA Group. I don't know if you expect us to comment on everything we need to comment on, or do you want us to do that in a private meeting with you? I mean it's quite a large number of design restrictions that you have pointed out in this draft, which I hope that we can negotiate away from those. The aim must be to build better respirators, not build those respirators that

we have today. I mean according to this draft, some respirators which has NIOSH approval today cannot be approved according to this draft. I hope that is an honest mistake or something we can correct.

JONATHAN SZALAJDA: Well, I think that when we look at the NIOSH approval, I mean with - keep in mind that this is, you know, you're looking at a specific population that obviously when we looked at the APR, and I'll pick on the APR for example, you don't have to have 42 CFR compliance in order to get a CBRN certification for the APR. And at least initially that's what we envision for the CBRN PAPR, that you may not necessarily, you know, depending on as we go through with the hazards assessment and the determination of the type of protectability that's required, you know, there may not be the need to have a fully 42 CFR compliant PAPR. That may not meet the requirements that are identified for the CBRN. That's still - I think that's still in a part of the dynamics of the process. I think with regard to your first question as far as making the comments, we'll welcome these as we go through the presentation. If you have specific things that you want to bring to our attention regarding the topic, you know, we welcome you to bring them up at the end of the presentation where that aspect was discussed. Or, you know, you're always welcome to come and visit us and discuss these in further

detail. And also I guess the other aspect along with that is again the docket. We encourage you or any of the other interested stakeholders to make your comments known to the docket so we can have a formal record and be able to process them through our evaluations.

GORAN BERNDTSSON: I was not referring to those kind of requirements. You have requirements in here in regard to the inhalation/exhalation assistance which makes it impossible to make a positive pressure demand respirator. There is requirements on the filter resistance that makes it almost impossible to make. There's a number a number of things in here that really needs to be thought out a lot more carefully than it has been. And I think it's probably better that we sit down have one to one discussions about it.

JONATHAN SZALAJDA: Sure. And again though, we do welcome your comments either to us or through the docket. And again, I think in terms of what we were trying to conceptionalize was again to build on the concept of interoperability and how we can carry forward the design parameters associated with the protections afforded by the canister through the designs of this system.

SAM PITTS: Sam Pitts, United States Marine Corps/Chem Bio Incident Response Force. John, at the risk of exposing my neanderthal status, section 3.9 on the airflow, am I to

understand that regardless of power or negative pressure manifold system each filter will only be tested a maximum of 64 liters of air per minute in minute volumes?

JONATHAN SZALAJDA: Right. That's what we were envisioning was to limit the face velocity through the canister at 64 liters per minute, which is what we evaluate the APR canister, too. And then it would be up to the design of the particular respirator on how to channel the air through the filters at that velocity.

SAM PITTS: We would probably urge you that that is not quite connected to realistic, or respectively realistic respiration requirements, sir.

JONATHAN SZALAJDA: I think the one thing though to keep in mind is that we're looking at multiple filters I guess in terms of trying to identify a minimum number of connectors as the airflow goes up you can add additional connectors to compensate for the airflow that the filters may see.

GORAN BERNDTSSON: Goran Berndtsson, SEA. Just a small comment (unintelligible).

JONATHAN SZALAJDA: I'm sorry, Goran, can you repeat that?

GORAN BERNDTSSON: Following that logic, we need to make PAPR's with five or six filters on them.

JONATHAN SZALAJDA: Well, I guess there is a potential there that we can make more filters. But we're defining a minimum of two at this point.

BODO HEINS: Bodo Heins, Draeger. On that point, in 2.2 there's written that this unit is for long-term use. But if I remember right the minimum service life is 15 minutes. Have you seen what a user can do with it in 15 minutes other than coming into a clean area to change this canister? So 15 minutes is nothing for it.

JONATHAN SZALAJDA: I think though when you keep in mind with the use of these systems is that, you know, in identifying the rating, where the rating is identified for the purposes of how we're going to evaluate the time durations that we're going to evaluate the canister for. In practical - in use in the use scenario, you know, assuming that you've got monitoring in place and you've quantified and identified the agent and you know what the challenge is that by identifying the capacity, at least our approach to the canister was by identifying capacity of the canister against these particular toxic industrial chemicals. The industrial hygienist that would be working onsite would be able to make determinations knowing what the concentration is in the environment and knowing and being able to determine how long the life of that particular filter would be for dealing with that particular

event and then determinating a change out schedule as appropriate based on his knowledge and monitoring of the event.

And again, you know, you have the whole premise behind the canister is in determining the capacity, not if you have a 15 minute canister you can only use it for 15 minutes. You know, the 15, the duration rating is indicative of the test time that we've evaluated against a certain challenge and a certain breakthrough. So we've identified a capacity for that particular gas or family of gases. And what we're doing in terms of trying to relate this information is developing a series of guidelines which we'll be making available for the community over the next several months to try to help take that information and correlate it into a methodology that a hygienist could use in trying to determine appropriate change out schedules for the filters.

I think we're probably about a half an hour behind schedule. I think maybe what we should do now is take a short 10 minute break and then we'll have Terry Thornton move into the canister requirements.

(Morning break.)

JONATHAN SZALAJDA: I think what we'd like to do, at least at this point, I know we're probably about an hour behind schedule because of our noncontroversial discussions here initially. And again I think, at least at the time I thought that the morning discussion was - you know, we're really I guess looking to the community for input regarding the perspectives and technical requirements associated with the appropriate flow rates and the evaluations with PAPR. And I think what I wanted to leave you with was an appreciation of the fact that we're still trying to standardize around the capacities that we've identified for filtration as part of the work on the gasmask standard. And to that extent where it's practical and possible we want to try to continue and translate those requirements through to the PAPR. But again, this is where we need the input from the community as far as the feasibility of achieving these requirements and how best possible to do that. And again, you know, you're more than welcome to make comment here. I also encourage you to submit information to the docket for our consideration, as well as meeting with us to discuss your concerns.

What we'd like to do, and I think we'll pay it by ear as far as how time goes along. We'll proceed until noon as per the schedule. And hopefully we can get through the canister requirements and the LRPL, then we'll make a determination at

that time if we're going to proceed with the chemical warfare agent testing either before or after lunch. At least for right now Terry Thornton is going to proceed through the canister requirements that we're envisioning for the PAPR. Terry?

TERRY THORNTON: My name's Terry Thornton. John informed you I was research chemist there. I'm going to go through the canister requirements. I'm going to try to make up a little bit of time here. Canister requirements are very easy for what we're using now. You can see the CBRN canister requirements for the PAPR are going to be the same as the requirements for the APR. That's our concept right now. Don't be confused. The statement of standard for the APR is not a concept anymore. That is a solid standard that we're going to use. Applying that standard to the PAPR's is the concept that we're talking about here. And we can see that the statement of standard we're using is CBRN full facepiece air-purifying respirator dated March 7, 2003. That standard is available on the Web site, but it is not available in the back of the room. In the back of the room there is a statement of the standard for the escapes. Don't get the escapes confused with the APR's. I think that may have happened earlier today when you looked at the breakthroughs. So the standard is based - the PAPR's concept is based on the standards statement for the

APR. And so this is a review for quite few of you who have been with the APR's for a while. The hazard list was derived during the CBRN standards development work previously, we had done all this. A good way to understand exactly how that was done was to look at the APR preamble. There's quite a bit of information in there on the hazard list.

For hazard analysis and selection the first thing was the initial vulnerability assessment list of chemical agents. We identified those for potential respiratory hazards. And that came up to about 159 different chemicals that were identified. And the sources of that is what we had talked about earlier, ITF25, the FBIC, CDC, and EPA list. We took those and broke them down into agent families, or classification into agent families. From there - and that was just dividing all those chemicals up. From there we looked at test representative agents required for each family. So we had a family and we picked the worst case or the best chemical that would represent that family.

Backup data is going to be generated for that list. Take for instance the organic vapor. There's a list of 61 chemicals on the cyclohexane is a representative for that. The other chemicals, there will be backup data generated using those chemicals to verify that cyclohexane is the best test representative agent. Biological and radiological agents were

addressed by the P-100 media.

So with a category grouping, when we broke down what we were going to be able to cover as far as the amount of chemicals, it comes to 139 materials we'll call them. That's 110 chemicals, 13 biologicals, and 16 radiological agents. These were divided into 11 test representative agents. Those 11 are what's tested for certification to verify that the CBRN canister is ready.

This is the way the 139 materials broke down. Sixty-one (61) organic vapor family. And those are vapor pressures less than that cyclohexane. Thirty-two (32) for the acid gas, four base, four hydrides, five nitrogen oxides, and formaldehyde family which is the only one of its member. It's kind of a special chemical to deal with. And then 32 particulate family. The 32 consists of the three chemicals and then the 13 biologicals and 16 radiologicals.

You've probably seen this before. This is quite a busy screen here. There's 61 chemicals listed there. And that's the organic vapor family. Now I know that's pretty difficult to read back there. But this information has been put out before in the meetings, so it's not new, and I believe it's on the Web site, NPPTL Web site. so you can get the information from there also.

When you go through the list here we'll see the acid

families. And then there's the nitrogen oxide, the base, the hydride, particulate, and formaldehyde. When we see particulate, that is the P-100 testing that's performed on the canister. And that's where the biological agents and the radiological or nuclear agents are.

This gives a list of the biological agents, the 13 that we've identified. And again, this information is on the Web site, so it's pretty easy to extract from that.

There are radiological and nuclear agents listed here. There's 11 test representative agents and this is how it's broken down. Organic vapor, cyclohexane is the test representative agent. For the acid gas we could not justify one chemical that would take care of the acid gas family, so you can see it's five there. Ammonia for a base. Phosphine hydride, nitrogen dioxide, formaldehyde, and then the particulate family is covered by the DOP testing.

The requirements of the testing, and again this is the APR, and I think earlier, like I said, there may have been confusion between what the challenge and the breakthrough concentration processing for the escape, which is the statement of standard that's available in the back, and the challenge of breaking concentrations that are used for the APR. And so these that we will use for the PAPR's will be the same as used for the APR. We'll test each individual canister

separately.

So to perform those requirements for the canister, again, the minimum service life is specified by the manufacturer. That's not something that we identify. We give them a choice of the 15, 30, 45, 60, 90, or 120 minutes. The manufacturer tells us what it wants it tested at. We're going to test three canisters at a low humidity, three canisters at a high humidity, keeping the temperature the same. And those are tested at 64 liters a minute. Following the standard for the APR we're also going to test three canisters at the crisis mode or panic mode, as it's referred to, and those are at 100 liters per minute, 50 percent humidity, but that service life is only for five minutes. So it's only exposed for five minutes at that high airflow. It does them for the same breakthrough concentration as the testing at 64 liters a minute.

Canister requirements are going to stay the same. Maximum weight will still be 500 grams. And the canister must be able to pass through a five inch opening with threads perpendicular to the opening. So it limits the size to the five inches.

Breathing resistances. Somehow I just know we're going to get comments on this. The PAPR unit mounted on a test fixture with air flowing at a continuous 85 liters a minute

both before and after each service life bench test. We can see that there's the initial 70 millimeters of water and the final 85 millimeters of water. Those are the same requirements for the PAPR, or for the APR. And that is without the blower operating. So the blower was not on. The exhalation will stay the same at and at 20 millimeters of water.

Again, the canister requirements. The previous slide was with the APR mounted on a test fixture. We will also be doing breathing resistance for the canister alone. And it's tested in the same way, where there's 85 liters a minute continuous airflow, and the 50 for the initial, 65 for the final.

Really one of the only changes in this concept is for breathing resistance. For the APR the breathing resistance there was just a maximum, you couldn't pass that up. For the PAPR we're going to look at the overall average of the resistance testing for the initial. So we'll take all the canisters that we do the resistance testing on, get those, obtain an average and the variance, high and low, it's plus or minus two and a half millimeters of water. So we're kind of restricting what that flow range could be. And that goes along with 42 CFR. And it says in there that two or more canisters parallel resistance will be essentially equal. So really for the CBRN we've strengthened that a little bit and

gave a specific range or variance that it could be between the two canisters, or between the population of the canisters.

And really that's it. That covers the APR canister requirements. And that's the concept that we will use for the PAPR's. If there's any questions.

GORAN BERNDTSSON: Goran Berndtsson, SEA. I suppose I should keep my tradition up. You said that the APR inhalation/exhalations (unintelligible). You said that about that inhalation. You meant that on the exhalation resistance test as well (unintelligible), is that correct?

TERRY THORNTON: Yes, sir.

GORAN BERNDTSSON: And the last comment you had about a two and a half millimeter of water difference, I think that we probably all - I can probably talk to all manufacturers, it will be very difficult to meet that requirement because any variations of (unintelligible). I assume you have looked at this when (unintelligible). Have you?

JONATHAN SZALAJDA: I'm not sure how many we've looked at for that. And remember, this concept is out there. We're looking for information, for feedback. So that really the range is five millimeters.

GORAN BERNDTSSON: I understand that.

JONATHAN SZALAJDA: We've also discussed possibly using, instead of taking the average, just looking at a range of five

millimeters to see if all the canisters fit in that range. And so that's another discussion we've had.

GORAN BERNDTSSON: The other thing, I'm wondering what an object is when it comes to particulate - I mean we are very concerned about the maximum flow rate for the gas cartridges, but aren't concerned about the maximum flow rate of the particulate. I mean that has (unintelligible) 42½ liters. We're talking about panic needs on the gas (unintelligible), but there's no panic needs for a particulate. Do you have any logic for that?

JONATHAN SZALAJDA: And I'm not sure if there's any logic of why we didn't look at a panic mode for that. We used the current 42 CFR requirements for the particulate testing, and we just stayed with those.

GORAN BERNDTSSON: I found that very strange when we all know that particulate is (unintelligible). So I mean it is - at the end we know that performance in the field it is going to be dependant on the flow rate, when we on the other hand know that we not particularly showing - most of the gas testing is not particulate on the flow rate. But the particulate we know are, and that one you haven't even considered.

JONATHAN SZALAJDA: We'll have to take that in consideration then.

BODO HEINS: Bodo Heins from Draeger Safety. As said before, this zero resistance as you require now, it's not possible to make a unit that's (unintelligible) inside the mask several time. In Germany, for example, we have PAPR's which are developed for asbestos and that's required to positive (unintelligible) at every time (unintelligible), and it's going for one shift, which is eight hours. So do you think about a version with positive pressure in it?

JONATHAN SZALAJDA: I'm not sure what we discussed on that. I think with, again, I guess to kind of reiterate what we're doing with this concept and the different resistances that, you know, again, with the concept that we're envisioning, looking at this in the context of trying to build upon the canister that we've already developed. And we understand and we appreciate there are some concerns related to the development or the application of PAPR technology where it does and doesn't fit in well with the concept of using the interoperable canister. And that's something where, you know, if you have specific data or specific information that you think we should consider in terms of a requirement, we would appreciate getting that from you.

I did want to add one thing about I guess the comment that Goran made regarding particulate. And again we're relying on using the test criteria and defined as part of 42

CFR and the flow rate 84 or 85 liters per minute testing that's done there. There's some aspects of the filter that we considered in terms of flow rate, and we looked at a lot of, as part of the gasmask requirements, we looked at a lot of literature sources related to work that was done with capturing particulate matter through filtration. But based on the analysis that we've done of those sources, we felt that the identified test was appropriate for identifying the P-100 filter media that would be effective for filtering potential particulate hazards that could be seen.

Another thing to keep in mind, too, with regard to particulate testing is one of the things that we're considering as well for this standard is with the gasmask we identified a particulate challenge following testing, gas life testing, with organic vapors with the elements to determine if there were any degradation of the media as a result of exposure toward any vapors that would allow increased potential for particulate matter to get through the filter. And that is one thing that we do appreciate the comments and concerns on that, but that is one thing that we continue to evaluate as other information comes available to us. But we do have a high degree of comfort in the requirement for the P-100 filtration for this system.

BRUCE TEELE: Bruce Teele, NFPA. Just let me verify

something before I chuck my foot in my mouth. The breakthrough testing on the canister is done at 64 liters a minute for the rate of duration of the canister?

JONATHAN SZALAJDA: That's correct.

BRUCE TEELE: Okay. And the 100 liter a minute test for breakthrough is only conducted for five minutes?

JONATHAN SZALAJDA: Right. That's correct.

BRUCE TEELE: The emergency response community is looking for PAPR's as their stepdown respirator from SCBA, CBRN and SCBA, and the working times through many of these incidents will far exceed the canister durations that are given here, but that's a separate subject. I don't think it's acceptable to test breakthrough at only 64 liters a minute where past breathing rate studies have shown consistently breathing rates in the 100 liter a minute sustained breathing flows and peaking at up to 300 liters a minute. So I would suggest that we take another look at the testing and the breakthrough at 64 liters a minute, and I understand that's what APR is doing, but now we're talking PAPR's, and to up that to at least a continuous duration 100 liter a minute testing and perhaps peak flow testing for a shorter duration to assure that the breakthrough protection is there.

The second items was, I would suggest that you consider dropping the 15, 30, and 45 minute duration canisters, as they

probably don't have a real practicality in the emergency responder setting. By the time you get up, get in, try to do something, and then come back out, an hour seems to fly by. My suggestion would be a minimum of 60 minute duration.

JONATHAN SZALAJDA: Thank you for your comments, Bruce.

JAY PARKER: Jay Parker with Bullard. Just one quick question in the section on airflow. It says you have to have a sufficient number of mechanical connectors, but in the early part of the standard it does specifically say you have to have at least two filters. So my question is, why not refer to filters, number of filters, in the airflow paragraph also? I don't understand why you're couching it in terms of the mechanical connector.

JONATHAN SZALAJDA: I see your point. I think part of the thought process there was identifying mechanical connectors since we had identified that as feature of the APR and we translated that requirement.

GORAN BERNDTSSON: Goran Berndtsson, SEA. I'm pleased to hear that you have considered looking at particulates at high airflow rate. However, (unintelligible). That maybe doesn't mean that much, but it might. I mean is where you see this going?

JONATHAN SZALAJDA: Well, I think part of the data that we analyzed was received from a variety of sources and includes

the stuff that was in the literature, as well as other studies. And in overall without I guess getting into trying to remember the detail off the top of my head, I think the consensus or the bottom line that I remember was that in all the evaluations that we saw that the P-100 media was sufficient in terms of capturing the particulate matter, you know, to the levels we were afforded the appropriate protection to the user of the device.

GORAN BERNDTSSON: I might be surprised. I don't think there is that much published documentation on high airflow rate available.

JONATHAN SZALAJDA: I'd be willing to share the published literature with you that we accumulated with the APR development. And I'll make sure that we get those reports for you.

BODO HEINS: Bodo Heins from Draeger with a question to the weight limit. I guess you took this 500 grams out of a European standard. If you have a two cartridge respirator you couldn't wear it on your face, so we have to wear it at the belt, and then the 500 gram amount, it makes no sense to limit it to 500 gram.

JONATHAN SZALAJDA: Well, I think when you're looking at the tightfitting, you're following on with the concept of the tightfitting full facepiece, that there would some sort of

manifold that would be harnessed somewhere on the individual and necessarily that the filters wouldn't be harnessed directly to the face piece.

BILL NEWCOMB: Bill Newcomb, North Safety Products. A couple of issues that I'd like to address. One is the duration. I've read several comments about the duration on these units. If you look at the canisters that are developed for the APR's with the 40 millimeter connector, most of these fit within the size requirements are going to be 15 minute canisters, might be able to make it 30 minute, but most of them I believe are going to be 15 minute. So if you were to look at the PAPR's and put three of them on the PAPR, the most you're going to get out of that is the 30 - 45 minutes, and NIOSH has added a 20 minute flow requirement in excess of that. So we're talking an hour. To get something that's going to be four hours, I don't think we're going to do it with the type of canisters that have been required for APR. And if they're going to be interchangeable, which seems to be a desire of the user community, I feel that people should know that we're not talking long duration units here. Because you're not going to have units with six or seven canisters on them. Maybe somebody will make one. But for the most part they're going to be relatively short duration units.

As far as the resistance requirements, plus or minus two and a half millimeters, I don't see that as a big requirement within the manufacturing groups. But the resistance of the canisters does affect the flow. And if you have a manufacturer who is making canisters to be ensured at 10 millimeters resistance versus somebody that's making one at 49 millimeters, it is going to be a much different flow. And although I don't think that's a danger to the user to be interchanging these because of the difference between actual use and testing requirements, I do think that it is not prudent to set a range of resistance that manufacturers have to make their filters through. I think keeping a maximum of resistance is a better way of doing it.

Another issue that I was going to bring up earlier, it doesn't have to do with service time, but it does have to do with the performance of these products, is the low flow indicator. It makes it sound in the post-concept paper that the low flow indicator is a realtime indicator of flow. And I submit that most PAPR's, especially tightfitting, when the user is not breathing there is no flow. Flow in these units is cyclic similar to a non-powered air-purifying respirator. So I'm not sure how these are going to be tested and whether that requirement is a realtime requirement. But I think what we're looking at is an indictor of the capacity to have that

flow and not necessarily an instantaneous flow measurement. Thank you.

JONATHAN SZALAJDA: Thank you. Thank you, Bill. I appreciate your comments. And again, you know, I think the thing to keep in mind with this is in terms of our conceptional requirements that, you know, we appreciate your feedback and your inputs. And if you have additional data or anything you'd like to share with us or through the docket office we would appreciate that.

TERRY THORNTON: Let me address this two and a half, plus or minus two and half airflow resistance between the canisters. That was added in the spirit of that we didn't want multiple canisters on the blower and having one canister with an extreme low resistance that it would break through first. So that's why we had to control that somehow. And as John just said, if you guys have ideas, we certainly welcome you to go ahead there and try to control that so that there would be a consistency through the air flows for each canister, so that the airflow for each canister would be equal. So we welcome your comments. But that's why that requirement was put on that. Thank you.

PAUL DUNCAN: Paul Duncan, Scott Health & Safety. Just a comment regarding the filter ratings. I think something we're possibly overlooking is, I think you all understand this, is

that these concentrations and the durations are basically the way to characterize a filter. We're talking about a 15 minute filter, but meanwhile it's being tested at twice IDLH. That's for establishing just a benchmark. These filters in the PAPR will not be used in twice IDLH concentrations. So this is a respirator with use in non-IDLH concentration. So it's up to your respiratory protection manager to identify how long a particular filter can be used in a certain environment, and based on the how the filter is characterized by NIOSH at twice IDLH concentrations at 64 liters per minute.

GORAN BERNDTSSON: Goran Berndtsson, SEA. The two and a half millimeter thing, if you want suggestions, I mean the problem we have with two and a half millimeters based on tests, you administered a number, and then production is not going to go outside two and a half minutes. But if you say within a batch, because it is mostly likely that the filters will be used in the paper are going to come out of the same batch. So the variation within a batch should be more than two and a half. If it is against what you have in your records, it can be difficult to keep that going for years to come. That was my concern.

JONATHAN SZALAJDA: Thank you. And let's take one more and then let's move along to the next presentation.

VIJAY AKUMAR: I'm Vijay Akumar from Air Techniques. I have a strong suggestion. I understand the need for urgency to get a new standard out and thereby using your existing P-100 standards for canister. But it seems to me that standards by the time they get published are already one step behind technology. It seems to me that every new standard NIOSH writes should be going forward, like if you take the analogy of software. New editions are backward compatible. You don't need to be forward compatible. I strongly recommend looking for new standards for the canister that backward compatibilty be backward and not forward, that way all these issues of ours can be addressed. For example, in particulate testing. Particulate testing, there's a large body of knowledge available for probably 30 years and all kinds of flow rates for all kinds of poisons. And most filter manufacturers can give you that. Many have been published.

JONATHAN SZALAJDA: Thank you. And again, if you have any specific recommendations you'd like to share with us, we appreciate you explaining it to the docket. I think with that we'll move along and Frank Palya will discuss the environmental and durability considerations for the respirator.

FRANK PALYA: Thank you, John. I think most of you are familiar with this, but I'm going to rehash it. A lot of it's

from the air purifying standard. But for the benefit of the people that didn't attend the previous meetings I'll go ahead through it again. As Jon said, I'm going to present the proposed concept for the durability test for the CBRN PAPR.

Durability testing consists of three parts, the environmental, the transportation, and the rough handling. I'm going to discuss the purpose and goal, the assumptions, the types of tests, and the rationale for the tests.

The purpose of this test is to test the PAPR for durability and to detect any initial life cycle failure modes. As discussed earlier, most likely these PAPR's will be worn by the first responder community and multi-discipline personnel and with a range of variance operational missions and also different use scenarios. So obviously it's pretty hard to predict exactly where a particular PAPR will be used and what kind of environmental and transporation conditions that they may be stored in while they're being used.

The goal is to ensure the PAPR provides adequate respiratory protection after being subjected to normal transporation and environmental and rough handling conditions induced by the user. Also to ensure that the integrity is integral into the design of the PAPR.

I'd like to go over some of the assumptions here. The following assumptions were made about the operational

conditions of the PAPR. The test conditions - the test represented conditions induced by the user that the PAPR may experience throughout its - from the point of issue. In other words, we're not really testing the manufacturer's packaging. We're going to assume that when the user receives the PAPR that it's in excellent condition and that it has not sustained any damage to the point of issuing.

The conditions mainly represent the storage conditions imposed by the user, such as in back of his emergency response vehicle or some other condition that they may experience. Again, it's very hard to predict to how these PAPR's are going to be used, so therefore we're looking at some of the extreme conditions. The PAPR will be tested at the ready-to-use configuration as recommended by the manufacturer. Others can be loose, could be in a carrier or some sort of container. We assume that the PAPR's will undergo the required maintenance and inspection procedures required by OSHA's regulations.

The assumption is that the test conditions are tailored to realistic United States meteorological weather conditions, and also the U. S. roadway transportation conditions, and that a typical first responder's use of rough handling that the PAPR may experience. These tests are not intended to represent the entire life cycle rather than to just identify some of the initial failure modes that it may experience.

Also that we did a lot of the - we used Mil-Std-810 as the principle guidance document. Again, I don't want to imply that we're going to test these respirators or PAPR's as tough as the military does. Mil-Std-810 requires that you tailor your test to the platform that the PAPR will experience.

Here's the draft test protocol that we're recommending. The high temperature test will be conducted in accordance with the Mil-Std-810, Method 501.4, and that's a hot-dry diurnal cycle. Diurnal meaning a 24 hour cycle. And that's for a three week period. Then after those three weeks then it would go to a low temperature, and that's basically the basic cold temperature, and that would be for a duration of three days. Then after it gets exposed to that, then it would undergo the humidity. And that is a natural diurnal humidity cycle, and that's for a five day period.

Next is the transportation. That's basically the vibration which represents the U. S. roadway conditions. Again, this is conducted in Mil-Std-810F, Method 514. And as you can see that it - if you vibrate it on all three axis for 60 minutes that represents a thousand miles. So what we're going to do is vibrate it for 12 hours per axes at the vertical, the transverse, and longitudinal positions for a total of 36 hours which will represent the 12,000 miles. And that's going to be at the unrestrained condition, just as if

the PAPR was in the trunk of a car or another type of vehicle.

The drop test will be on just the canisters only, and they will be in their packages and containers. And then they'll be dropped once on one of the major axes as indicated.

Some of the rationale for the tests is the high temperature simulating storage in the truck equal to induced conditions would be pretty typical of say a policeman would carry his PAPR in the back of his trunk in New Mexico or Arizona and this representative induced climate conditions. And then the low temperatures representative of minimum temperatures in the northern regions of the United States. And that's basically a basic cold. And that comes of Mil-Std-810. And the duration is recommended by the 810.

The humidity represents the natural diurnal cycle of such humid regions such as Florida. The fibration simulates the transportation of 12,000 miles over U. S. highways in unrestrained conditions. And the rough handling simulates the drop of a canister and packaging can from the trunk of a vehicle or a tabletop.

Here it is indicated in the flow diagram. As you can see both the PAPR's and the canisters will undergo the high temperature in this order, high temperature, low temperature, humidity, vibration, and then the canisters will be subjected to just the drop test alone. Then after they go through the -

then they'll be subjected to the requirements of the CBRN PAPR standards. And as John mentioned earlier, that the filtration will be tested for filtration on the P-100 requirement after cyclohexane - I believe it's six canisters of the organic vapor.

So in summary this is what we have. Basically in the same order as well. So that concludes this presentation. At this time I'll be happy to attempt to answer some questions. Please o airflow questions.

GORAN BERNDTSSON: Goran Berndtsson, SEA. I wish that every police car was buying a PAPR. That would be fantastic. I think it's highly unlikely. We have a concern with the high diurnal temperature. It is very difficult with most, and particularly battery life, after running them through this very high and very low temperature. I don't think it is realistic to think that those kind of equipment is going to sit in the back of a truck or a police car for 12,000 miles. I think it would be stored in a container ready to be used in case of an incident. So I think you should - I would appreciate if you would reconsider some of these requirements.

FRANK PALYA: Particularly the low temperature?

GORAN BERNDTSSON: Particularly the low temperature, yes.

PAUL DUNCAN: Paul Duncan, Scott Health & Safety. A brief comment. I think there probably needs to be some better specification on how the filters are tested, environmentally tested, in their packaging. And a more formal representation to the end users of how those respirators were tested. If there's a situation where a respirator is tested, environmentally tested, particularly vibration tested in its plastic packaging and then deployed to the end user, the end user not realizing that that respirator passed its testing in that packaging then takes it out and deploys it as like a tactical bag or something, he doesn't realize he's removed the packaging that allowed that respirator to pass environmental conditioning.

FRANK PALYA: Well, I believe what our intent was, and even with the air-purifying respirator, was that the canister was not to be deployed until actual use. So I guess that could be conveyed into the user's instructions.

PAUL DUNCAN: Actually I can think of some situations where an actual facepiece might be delivered to the end user, where it had actually undergone environmental conditioning in like a conforming plastic package, and the user might take that facepiece out of that package and deploy it into a tactical bag not realizing that packaging is what protected that facepiece from the environmental condition.

FRANK PALYA: Got you. Again, I would think that if somebody would convey that in the user's instructions. If there's some way specifically that you know how to do that.

PAUL DUNCAN: Maybe you'd address on packaging it was tested that way, that the packaging goes to the end user advising him that it has to be stored in this packaging, very clearly called out in the user instructions.

FRANK PALYA: So that would deal with the labeling perhaps in some form. Thank you.

MIKE SAVARIN: Mike Savarin, ICS Labs. I was just looking at this, and the main thing that grabbed me was the drop impact test. I think it's not really the best benefit to drop it in a nicely protected package, because that isn't really what happens. The other thing is that of much more concern is the fact that transportation across the mail handling system, not just in the U. S., but any mail handling system, is actualy really aggressive. If you ever watched anything happening, people are tossing bags and boxes all the time with product in it. I certainly, for example, on the drop test would like to see a multiple drop, multiple access test. I think that's much more realistic, and on the naked product, not just in this nice comfort packaging. Because in reality these things are dropped. Someone puts a PAPR on, put it's around their waist, "oh, damn, there it goes." That's another

three feet. While they're using it, they surround them, bang, straight away it hits something else. I would prefer to see something that actually looks at the product unprotected and looks at multiple - maybe shorter duration. I'm not sure about this - the equivalent of 12,000 miles. I think I have some of the concerns that the previous gentleman mentioned as well. But to be looking at more the effect of multiple access testing.

FRANK PALYA: Thank you.

JAY PARKER: Jay Parker with the Bullard Company. When I think about rough handling on cartridges or canisters, the first thing that I think of is leaking carbon out of the canister. I don't see any specific test here to evaluate that, so therefore NIOSH may want to consider having a test for that where you would pass air through the cartridge perhaps and pass that air from the cartridge into an absolute filter where you could measure maybe the carbon that leaked out. The military used to have a test like that. Thank you.

FRANK PALYA: Yeah. We were basically, Jay, was that after we would subject it to the rough handling, the vibration, the drop, and the environmental conditioning, that it would be subjected to the regular gas life testing or the filtration testing. So we felt that if the canisters were durable enough to pass the gas life testing that they would be

durable enough to undergo the drop testing. Thank you.

JONATHAN SZALAJDA: I think for the purposes of time we'll complete the LRPL prior to the lunch break, and then following lunch we'll cover the chemical warfare agent testing and the other presentations that are involved with our part of the discussion today. The next presenter is going to be Mike Bergman who is with our respirator branch, and he's going to be addressing the requirements for the respirator fit testing.

MICHAEL BERGMAN: Thank you, John. And I'd like to start off by acknowledging our partners here, the U. S. Army, RADC, my colleagues here on the team, and I'd also like to say it's very nice to see some familiar faces from NIOSH Morgantown that I haven't seen in a while.

The LRPL is a fit-factor corn oil test. And this is a special test requirement for CBRN respirators. The purpose is to establish benchmark level of protection under laboratory conditions. And it's not intended as an indication of protection in actual response.

The challenge aerosol criteria is 20 to 40 milligrams per cubic meter corn oil aerosol at .4 to .6 micrometer mass median aerodynamic diameter.

The pass/fail criteria we are proposing in LRPL 10,000 for 95 percent of the test trials. That comes from U. S. Army operational criteria. And we would like to test it with the

PAPR blower operating. This is a big point that I would like to solicit comments here on the applicability of the RPL level and also for testing it with lower operating and not operating.

We propose that we will use the 11 standard NIOSH exercises.

The anthropometric parameters that are considered are the ones that are only applicable that are based on the design of the PAPR. Neck circumference if the PAPR is or has a tight fitting neck dam. Head circumference if it has a tight fitting neck dam that we would consider for the large criteria. And face length and face width only if the model has a face mask.

The development of the subject panel came out of the need for development of the subject panel for the CBRN escape hood. And for doing that we reviewed population distributions of head, neck, face length and width sizes. And again the criteria that are considered are the ones that are applicable for the design of the model.

Face length and width criteria is adopted from the Los Alamos panel, the 1974 study of selection of the panel for respirator test panels. This is the same criteria that is used for the CBRN SCBA and the APR that is for face length and width. For head circumference and neck circumference we

looked at the latest NIOSH study by Dr. Zhuang and to NIOSH.

Survey data was conducted for the panels of updating respirator fitness panels and for international standards. And subjects were recruited from industries nationwide, manufacturing, construction, healthcare, and law enforcement and firefighting. I'd like to say a review of the data of September of 2001, the protocol was peer reviewed by a NIOSH peer group, which also included external members. November 2001 protocol received HSRB approval. January 2002 we had a federal register notice that was published for 60 days for public comment on the protocol. In May 2002 the protocol was reviewed and approved by OMB. And from January 2003 through September 2003 the data collection proceeded and is now completed. The data is being analyzed and reviewed for the appropriate public publication format.

So just to recap on the anthropometrics, the face length and width criteria is the same as it's adopted from the Los Alamos panel. The head circumference and neck circumference criteria is adapted from NIOSH population study data. The total subjects in the NIOSH survey was 3,997. Of those, 2,243 had complete measurements for face width, face length, head circumference, and neck circumference. And so we prepared the data on 2,243 subjects to the 1980 Army data study that we had previously considered for the LRPL matrix.

The differences between the distribution of head circumference - I'm sorry, this is neck circumference between the NIOSH population and the Army population is that NIOSH population on a percentile basis have larger neck sizes than the Army population. The previously studied Army population high and low of the range for neck circumference, 292 millimeters, which was the fifth percentile female of the Army population. And then the high range value was 413 millimeters, which is the 95th percentile male neck circumference. So in comparing this analogist looking only at the neck circumference populations of the NIOSH study population, what we did is we looked at the NIOSH population as a whole. The blue line in the middle encompasses both the male and female. And so we have the fifth percentile of the NIOSH population here at 306, and the upper 95th percentile as 451. So comparing the Army data to the NIOSH population data the low range limit has changed from 11½ inches neck circumference to 12 inches neck circumference, and the high end has changed from 16.3 inches to 17.8 inches.

This slide shows the rationale for the actual neck circumference ranges of the PAPR and how they overlap. We see 378 millimeters is the 50th percentile. And what we did is extended the upper limit of the small range to 378 and the lower limit of the large range also to 378. The reason for

doing that is in filling the LRPL matrix it's easier, for instance, if the PAPR has both a tightfitting neck dam and a tightfitting mask, it will be easier to have the same subject fit both the neck circumference criteria and the face circumference criteria by having larger ranges.

For the head circumference criteria if it is applicable it is a tightfitting PAPR, tightfitting neck dam and hood, it would be - would have to meet the criteria for the large head circumference. And you see the current approach with the NIOSH population data is the lower limit 50 percentile, 570 upper boundary, 95th percentile 603, and these upper lower limits are not much of a difference from the previously proposed Army data ranges.

So in summary, this is the population or the subject matrix. We need to update these ranges that are circled here. They didn't make it into this edition of the PAPR. But what's important to remember here is that face length and width circumference is the same. It's based on the panel, which is the same for the CBRN, SCBA, and the APR. And the head circumference and neck circumference criteria will only be considered if it is a tightfitting neck dam PAPR, as well as the face length and width measurements will only be considered if the unit has a facemask.

And so I'll attempt to answer your questions and also

solicit your comments. Thank you very much then.

JACK SAWICKI: Jack Sawicki, Global Secure Holdings. Could you go back to that slide number three with the size requirements? Thank you. I'm still a little bit confused if you're requiring three sizes, of if by that chart you would allow someone to have two size system provided they fit those ranges.

MICHAEL BERGMAN: That's a good point. A one-size-fits-all is an option. Two size is an option. A three size is an option. Or if it should be more than that, that's also a consideration. This is just to say if it has a tightfitting neck dam, in a three size configuration the small size would have to meet that small range, and so on for the others. I'm very interested in if anybody has any data they would like to submit on the feasibility of the LRPL of 10,000, and also solicit comments on testing the PAPR with blower on as opposed to off.

GORAN BERNDTSSON: Goran Berndtsson. (Unintelligible.) When it comes to the corn oil testing, I would suggest you consider to include a background test for the respirator prior to, because some respirators if they're using bearings, et cetera, in them, will distribute some (unintelligible) particulates. (Unintelligible) potential leakage. So a background test would be a good way to go.

MICHAEL BERGMAN: That's a good point. Thank you.

JAY PARKER: Jay Parker with Bullard. That also reminds me that filter penetration itself could be a factor. So if the filter is penetrating too many particles, right away you won't be able to meet the requirement of 10,000. And I'm not sure of the relationship of the P-100 media test to that. So in other words it may be possible for a filter to pass the P-100 test and not have - or at that point still have enough particle penetration at .4 to .6 micrometer that you're actually looking at particulate penetration during this test and not face seal leakage. And I know that I struggled with that in my own internal testing at Bullard. So I just thought I'd point that out. Thank you.

JONATHAN SZALAJDA: Thank you, Mike. And thank you, Jay, on your last comment. That has been one, I guess one consideration as part of the protocol as working with the Army especially when we were looking at the development of the SCBA standard and testing the facepiece using a filter to keep out the media. And if we choose to go forward with some more type tests we'll look at the same protocols and carry those over into this device.

I think what we're going to do since it's almost noon and we're only one presentation behind, we'll try to make that up after lunch. So we'll break now.

(Lunch break from 12:00 to 1:00 p.m.)

JONATHAN SZALAJDA: Again, at this point we're going to wrap up with the one element that we didn't address this morning, which was the chemical warfare agent testing. And basically what we're doing, at least for this presentation, is I'm going to give a little bit of a perspective on the requirements or at least as far as how the test challenge requirements and breakthorugh requirements were identified. I think we're missing part of the screen. At least to clarify what's up there. It says sarin and mustard challenge vapor concentrations are based upon the CBRN APR standard.

And the way we wanted to approach the subject here was to address how we derived the concentration and breakthrough challenges. And Ray Lins from RDECOM, the Edgewood Biological Chemical Center, who was did test agent for doing the chemical warfare agent testing, is going to talk a little bit about the protocols that they've established, their equipment, and some of their perspective on PAPR evaluations that they have done in the past.

I think as I had mentioned this morning when I did my preamble on our process for developing a standard, we looked at - initially we looked at conducting the hazard assessment and the vulnerability assessment based on 28 different scenarios or venues for deploying the chemical warfare agents

and use those venues that come up with what we felt was the most likely event that a responder would have to deal with. And this led to the development of the test criteria that we established for the SCBA as a - what we envisioned to be a likely scenario that the responders could see.

In looking at the air purifying types of respirators, again working within the realm of less than IDLH type considerations, but in concentrations where you're still going to need protection, we identified requirements or challenge concentrations for both sarin and mustard that we used for the APR for the gasmask requirements.

A little bit more of a challenge for us at the time was to select a breakthrough test limit as far as what the criteria would be for these systems that they would need to be - in order to provide acceptable protection to the user. The criteria, the health criteria that we used to define this level represents a non-incapacitating health impact. What we're looking for, no respiratory dysfunction or irreversible effects to the user wearing a respirator in this environment. And we looked at varying values that could be considered as part of the breakthrough.

One of these included the worker IDLH. And this was a topic that was debated among the scientists in addressing values because the only IDLH values that had been generated

for the chemical warfare agents have been done by the Army. They don't have any other federal agency type endorsement like OSHA or NIOSH or Mine Safety and Health, EPA. So we felt that even though that the IDLH's were conservative in nature that the Army established, they were only for 30 minute exposures, and we had difficulty in seeing how we could translate those values into breakthrough criteria for the respirators.

Another option that was considered were acute exposure guideline levels or AEGL's. And these were established by a national advisor committee for the Environmental Protection Agency and the National Research Council. And what the AEGL's represent are emergency threshold limits for the general population, which include susceptible portions of the population, the elderly, children, people of that nature. And part of these guidelines were developed as part of an emergency planning and decision-making type process.

With the AEGL committee, they were done - or the AEGL values were developed through a rigorous scientific process with consensus building and review and discussion and a public process but within the federal government scientists but also other scientists in the general public as well. And if you've been tracking this type of thing in the literature that you all have seen over last couple of years that CDC working in conjunction with other federal agencies has provided different

discussions on the topic in the federal register and opened it up for public comment. But with the AEGL's, the AEGL's are broken down into levels based on the severity of the toxic hazard. And they're represented by levels one, two and three. And each of these levels represent the most conservative effort of a concentration by which the specified effect might be seen in the general population.

And I think when you look at the difference between the levels when you evaluate criteria between level one and level two, the effects that a person would see would be mild and transient that they should disappear in time after the exposure. And also that there wouldn't be long-term incapacitation associated with exposure in between those two levels. When you look at between levels two and three, the severity of the health effects that someone is exposed to these agents would see would increase that you could develop some incapacitation effects, like a delayed ability to function normally, inability to escape for a particular scenario. And also as the concentration increase, the long-term health effects could increase. But once you get above the AEGL 3 then you're dealing in a scenario where you're starting to deal with fatalities associated with the exposure to the agents.

Another aspect that we looked at in terms of the modeling

or the terms of identifying the breakthrough criteria was looking at modified AEGL values. And there were certain uncertainty factors that were considered to be applied to the range of AEGL values that were determined for different agents. But I guess there were some concerns that at least in trying to apply modified AEGL's to these populations that it put some uncertainty or additional uncertainty and additional factors on the use of the AEGL values and whether or not the emergency responders, the people that we were gearing the standards toward, would fall into that population that would use the modified values.

So where we finally ended up was that we felt that AEGL level ones shouldn't be considered as an exposure level for the respirator valuation since that's a level where no protection is required for the general public during an emergency situation. That by setting the - by using the AEGL 2 values as setting our breakthrough concentrations that by setting those criteria below the AEGL 2 value that we would provide adequate protection for the responder in dealing with those types of scenarios.

And again, I think the key thing to keep in mind here is that the certification of respirators and how we set this up is that in addressing the use of the AEGL 2's that the certification criteria is below those values. And again we're

talking about that range between level one and level two where health effects are reversible and there are no long-term health effects as a result of the exposure.

Another thing that was attractive to us in terms of the developing of the requirement was that there was significant safety factors associated with using the AEGL 2 values as compared to the IDLH values. And I think they were too intense for GB and HD respectively over a 30 minute period of time, so we felt there was an added degree of safety for the responders using those values as the breakthrough criteria.

Another aspect that was considered along with the use of the AEGL's is that, and we hope that the exposure to chemical warfare agents is a once in a lifetime type of an exposure for the individuals, and using the AEGL's it looks at concentrations over several different time intervals which could be corrected for toxic response and exposure to the various chemicals.

When we look at the testing criteria, what we've done with the respirators is basically the overall dosage that the respirator would see on the AEGL 2 one hour limit that has been set. And again, I think the thing to keep in mind is when we're looking at the chemical warfare agents that we're dealing and the potential dosage that an individual may see, and when you're looking at over a six or eight hour time

period, we're basing that breakthrough criteria on a much more conservative basis by using the one hour AEGL 2 value.

And also a concern that we wanted to identify as part of the exposures was to include peak excursions as part of our evaluation. And we used the 10 minute AEGL value as far as peak excursions that you may see during the test. And we captured that as part of the pass/fail criteria that we only allow three or no more than - you're only allowed three peaks, peak excursions during the test, or three consecutive peak excursions during the testing. If you would see that, then that's cause for failure of the evaluation. But we felt this added a degree of safety to the evaluation criteria that in the event of if something happened to the respirator during operation or some sort of effect to the respirator where there may have been some excursions where an agent had penetrated through the system through one of the components that the individual could still be protected.

Where we ultimately ended up for the gasmask, the vapor challenge again was based on evaluations that we conducted with the Army and looking at the potential concentrations that could be seen and in a warm zone type of environment. And we had calculated the challenge at 210 milligrams per cubic meter as the challenge concentration. The breakthroughs for the APR were set assuming interoperability or accommodating the

interoperability characteristics between the canister and the facepiece, that we set the breakthrough criteria at half of the 10 minute AEGL 2 value. And so there's an additional degree of protection there.

With the sarin, the test of the agent has generated and challenged against the respirator up front over the first 30 minutes. And at that point the agent concentration ends and we continue to monitor over seven and a half hours to determine if there's any breakthrough of the agent to the respirator.

With the mustard challenge it's a combination of a liquid and a vapor challenge. The liquid challenge is based upon the components that are associated with the respirator and the pattern that's been developed and it's been included as part of our standard test procedures that we developed for how the liquid is applied to the respirator. And in general one thing to keep in mind is that we intend on challenging the interface areas of the components of the respirator and the interface between the visor and the face plank, potentially the interface between where the filter would attach to the face plank. And also along with that, we look at any component, you know, if you have a system of hose that connects the filter to the facepiece that we'll challenge the hose with the liquid to determine penetration and permeation effects. And

with this test, as a result of our working with the Army, that we the provide the vapor challenge or we identify that vapor challenge up front, and then during the last two hours of the testing we apply liquid to the system and continue to monitor for penetration permeation effects to the respirator.

And with that I wanted to introduce Ray Lins from the Edgewood Biological and Chemical Center. Ray has many, many years of experience in working with respirators and in testing with chemical warfare agents. And just as a little side, I kind of like to think of him as the father of the Smartman. It was back in my former life when I worked for SBCCOM in the mid-'90s, the concept of using the Smartman really began to evolve. And I think Ray was very instrumental in proving out the concept and using it as a valuable tool for evaluating respirators. With that, Ray.

RAY LINS: As John said, I'm Ray Lins from SBCCOM, RDECOM now. We are accredited for ISO-17025 by the American Association for Accredited Laboratories. We're certified to test masks, SCBA's, negative pressure respirators, for NIOSH. And we also are certified for doing ASPM 739 testing, as well as many other things we're certified for, but these are the ones that are important to us here.

Swatch testing for the 739 for looking at materials, I have six cups in three different systems for looking at

materials using mini cams for detection. One set of swatches for vapor or liquid. Another set of Dawson cups, which is a larger swatch, about a five inch swatch to look for semipermeable material for vapor to go through it. Then smaller technology, you know, fruit flies, which have been around for years. And that's part of the military standard to test swatches for the fruit flies. A 170 tester to test for HD, VX, luycite, using an indicated vapor.

To date we've actually tested quite a few more than a thousand Smartman tests. We've tested escape masks, APR's, air-purifying respirators, powered air-purifying respirators, SCBA's, and self-contains. We've done many of those for NIOSH, many of them for Domestic Preparedness. And quite a few of those results for Domestic Preparedness are on the Internet, so you can look at the results of them.

That's actually a Smartman head form. As John said, we've had that for six or seven years now in cooperation with SBCCOM and ILC we developed this. This is an M-40 mask on it. It's inside of a box. The next slide will show it's inside of a hood. When we test the SCBA's or the PAPR's all the equipment will be inside this hood as well. And all of it will be exposed to liquid and vapor.

That's one plumbed and setting inside of a hood. It's kind of a spaghetti all around it as far as the hoses and

everything. It is hooked to a breather pump inside the head form. In the nose cup area we're monitoring for what comes through the mask, penetration into the mask. Inside of the chamber we're monitoring the concentration, both of them full time.

A breather pump made by JACO. It's a military standard breathing pump. It does - produces sinus leeway, and this is what we've been using for NIOSH testing. It does have limitations as far as the top end of 1.1 liter hydro volume is about the top end of end of it. We have a variable speed control on it so it can vary the strokes per minute. We do have a commercial version, much smaller and much cheaper, but it doesn't last quite as long. With this one we test the 40 liters a minute per NIOSH. With the other pumps we can test the higher flow. We use those up to 120 liters a minute on escape masks, military masks and everything, what the performance is.

This is the typical output of our system as far as the two mini cams looking at the breakthrough concentration. On the top is milligrams per meter cubed versus time. No particular mask or anything, just a chart that we've done on some escape respirators in the past. The bottom chart is a cumulative CT. So these two numbers on the left-hand side there, that's where the breakthrough criteria which Jon

spelled out would be looked at.

HD, duplicates of the of the same thing. We're looking at monitoring the whole time, full time inside the hood. These are inside the mask and just take the top one and accumulate it to come up with the cumulative CT. Concentration is monitored full time inside the hood as we do the vapor challenge, and all the liquids in there were monitored as well. This is just a typical challenge profile showing the ramp up to 2,000 milligrams per liter cubed. It takes about three and a half minutes for us to fill the chamber up to 2,000 milligrams per liter cubed, and about five minutes to come back down. And then we can hold it with pollution air for as long as we need.

Presently I have five Smartman medium systems in operation. A medium Smartman system for CK. A medium leak test system which we use for leak testing systems. All of the masks and everything are leak tested before we ever put them into agent system. We'll test them in the clean system to make sure that they're not leaking. There's no sense in testing with leaks. Once they pass that, then we'll put them into the system.

As was mentioned this morning, when the PAPR's - one of the problems with some of the PAPR's, we do see bearing will give off a little bit of a background, so we will see that

during a leak test. It doesn't have an effect on the agent test, but we will see it on the leak test. Two small leak test systems. One we have in the lab, the other one more or less travels all around with us. We don't have it here this time. The last one we did have it at. And one small agent test system.

In November we'll be setting up two additional medium Smartman test systems, and in December two medium Smartman test systems with the automated breathing simulator. Questions?

JONATHAN SZALAJDA: We have two additional topics we wanted to cover today, things that have been of interest to the community over the last several months with regard to supporting activities that we're conducting to enhance our ability to developing standards. One is an update on progress that we're making with the chemical warfare agents simulate project that we're doing in conjunction with the scientists at the native R&D Center in Massachusetts that is part of the RDE Command. And the other activity that we're going to want to give you an update on is a flow study that Mr. David Caretti of RDECOM is conducting for us to address some of the issues that have been raised over the last several months regarding flow rates. Following Dave's presentation I have some summation parts to go over. And we have one attendee

presentation for this afternoon, and then we'll have an open comment period. So that with Frank Palya will give you an update on the Simulant Project.

FRANK PALYA: Thank you, John. As John has mentioned, I'm the project coordinator for the Chemical Warfare Agent Simulant Project. And the principal investigator was Dr. Rivin of both Army Research Development and Engineering Command, formerly SBCCOM, and he works out of NADIC. Unfortunately he was unable to attend this meeting.

I mentioned chemical warfare agent simulant and I want to make it clear that we're specifically looking at simulants that replicate the actual permeation effects of the live chemical warfare agent, namely HD, a sulphur mustard, NGB, sarin. So we're not looking at simulants of for a training nature or anything other thing. But we were looking for the actual effects of permeation through materials, varying materials used and PDE.

I'd like to go over some background here. At the April 2001 NIOSH public meeting held in Edgewood, Maryland, when it was announced that NIOSH was going to perform official NIOSH certification with actual chemical warfare agent, respirator and other PPE manufacturers requested that NIOSH identify simulants so they could perform search and development and do some pretesting on the respirators before submitting them to

NIOSH. The reason they requested this was that the actual chemical warfare agents weren't readily available. The chemical warfare agents themselves are very toxic. Having surety labs do this testing is very expensive. And also they just wanted to see how well their respirators and PPE would perform against chemical warfare agents without going through all the expense. The same concern for the simulant development was conveyed in the ISEA, that's the International Safety Equipment Association, January 22, 2002, letter to NIOSH.

But anyhow, after that we started the project and we were doing some initial literature searches. Then we found out that there were reports out there that looked at the permeation effects of chemical warfare agents and simulants, but there just wasn't enough data there to make any strong correlation between the two. What data there were out there that tested both with chemical warfare agents and simulants, they were tested under different lab conditions, different thicknesses, so you really couldn't have used that data with any confidence. Plus the military when they were doing their testing, when they tested the military equipment, they just went ahead and used live agents. So they really didn't have that much use for the simulants. So in June '02 the Chemical Warfare Agent simulant project really began.

Since that time I'd like to go over some of the accomplishments. We developed an inexpensive permeation system with a new cell design for testing both hard and soft barrier materials up to one centimeter in thickness. And this technique is called the flooded cell technique. When we first came up with this we were looking at, of our goals, we were looking at a low cost, rapid simulant screening method for determining agent barrier performance of the materials.

This flooded cell technique for testing liquid permeations through nonporous barrier materials was incorporated into the NIOSH test method. Basically what this test method is, is an interim test method at this point. It's not to be used for certification. So this test method that I'm referring to is just something - it's a guide for the PPE and respirator manufacturers to use at their convenience for an aid to go ahead there and use with the simulants so they could make a determination of how well their barrier materials would perform against actual live agent.

This slide illustrates some of the components of this test method that we're going to be releasing soon. So it's pretty basic. It's just nitrogen and air going through a flow controller and then through a permeation cell and then it detects what agent permeated through the materials. And then there's an acquisition board and a computer and then the trap.

This next slide here is more of a detailed design of the permeation cell itself. Here's the air speed through the bottom here, and then the specimen, then this is the Teflon gasket, okay, and the agent is applied to it, it's in a flooded form, just totally covering the surface of the specimen. And after a while it'll detect what agent permeates through.

This is the real life photo of it and the components. And this is the configuration of how it's assembled. This right here is a cap. The agent is actually poured or applied here, and this cap is put over top of it to minimize evaporation.

Next what we did was we did come up with four simulants, the DCH, CEPS is mostly associated with simulated sulphur mustard HD, and then DEMP and DIMP is associated with the GB simulant. And I put nominal here for the reason that in some polymers that these simulants can be used for both chemical warfare agents.

When we were developing these simulants, we selected the three materials. We selected butyl rubber, EPDM, and the silicone rubber. And the reason why we did that was to go ahead there and try to get a broad range of varying materials, broad range and chemical agent performance resistance. In other words, the silicone pretty much breaks through

relatively fast, the EPDM has an agent resistance midway, and the butyl has a very good base of permeation resistance. So we normalized it by looking at different thicknesses. The reason why we did that was we tried to keep everything on the same scale, and so one wouldn't break extremely fast and the other would just continue on running. So that's how we tried to normalize everything.

And then after we got all this information we developed an interim NIOSH test method to be made available to the stakeholders. This test method describes equipment, procedures, the data, balance techniques. It also will include the mechanical drawings for the permeation cell. This interim test method will be made available on the NIOSH Web site or through NIOSH in December of '03. That is our goal to try to get it up there. Eventually then we'll have a - this test method will be published in the future as an official NIOSH number document. But again, this is an aid for the manufacturers to use.

The results of phase one of the chemical warfare agent project were very favorable and revealed areas that needed further investigation. So we went ahead there and decided to go with the phase two. If you notice there's a NIST symbol here, and the reason for that is that NIST had an interest in it as well, and they funded the phase two portion of this

project. The phase two primary goals is to improve the estimated reliability of the flooded cell technique by using additional simulants with other barrier materials, determine the quantitative relationship between the flooded cell technique and the traditional loading. Basically the traditional loading is primarily what we're testing now when we're doing the agent permeation test. So it would be good idea to see how the material would perform with the flooded cell versus how it would actually perform during certification. So that would more like a correlation right here. Determined a chemical warfare agent and simulant sorption and desorption of representative barrier materials. This would be useful information in addressing a lot of the decon issues. Identify critical properties of permeants and barrier materials that control permeation. The next would be to develop capability of barrier permeation based on available chemical and physical properties of the material and of the barrier polymers and the permeating molecule. So if we looked at different types of physical features or characteristics of the barrier materials and you could identify those critical properties of the material that affect the permeation, I think that would assist in selecting the materials immediately. And then the next step would go ahead there and continue on with additional testing with the actual agent - not agent, excuse

me, with simulants, then eventually the agent, if need be.

So the potential benefits is to assist the manufacturers in the selection of the barrier materials based on scientific information that we obtained and to reduce the product development time and cost, expedite new respirators and material technology for the users, determine quantitative relationships between the flooded cell technique and the traditional test loading, and determine the chemical warfare agent simulant sorption and desorption of barrier materials, and again, to identify critical properties of the permeant - of the barrier materials.

Eventually we'd like to try to set up some sort of matrix to go ahead there and identify the properties of the material and some of the other features of the permeating molecule, so that once we get this database it'll be easy just go ahead there and access it and get an idea just by the properties how the material would perform.

So in summary, we developed a rapid, relatively low cost laboratory procedure that can be used to estimate the chemical warfare agent and permeation through barrier materials. Identified four simulants, two for HD, two for sulphur mustard. Wrote an interim NIOSH test method that describes the equipment, procedures, data analysis techniques. Again, the goal is to have it available in December of 2003. Then we

initiated phase two of the Chemical Warfare Agent Project. And another thing is thing is that I wanted to emphasize is that NIOSH or RDEC does not guarantee that when you test your barrier materials with your simulants in your own laboratory, and if it passes, and then if it goes to a NIOSH certification and fails the actual certification, that we're not going to guarantee that if it passes for you that it's going to pass for us during the certification process. And also, the test method that we felt was not a certification test, it's just a name.

That concludes this presentation. At this time I'll answer any of your questions. Thank you.

JONATHAN SZALAJDA: The last presentation we have on our agenda is an update on the flow study with Mr. Dave Caretti for ECBC.

DAVID CARETTI: Thanks, John. So everybody in the audience is now sighing because that's all we want to hear is another flow rate presentation at a NIOSH public meeting. I am not here to settle this issue, so keep that in mind.

A few months back NIOSH had approached myself and some others and said, I think we need to - they said, we think that we need to do some study to really try to get a grasp on what are realistic flow rates of individuals doing different types of work, what would be anticipated in the workplace,

what do we need to do to understand so that we can get a comfortable feeling that the flow rates being proposed for these standards are adequate for whatever testing, filter testing, system testing, whatever may be. In that regard we put together a test plan and have gone forward with some of that. And I just want to share with you some of the work that's been done to date and what we're trying to go forward with at this time.

The main objectives in laying out this test plan were we really wanted to try to define ventilatory parameters. Ventilatory is actually the respiratory physiologist's word for ventilation of air. Respiration occurs at the cellular level in our minds. So I use respiration and ventilation interchangeably. But based on real world work rates, somebody doing their job and where they're required to wear a respirator over how many hours of work that they do.

We are looking at trying to understand what occurs when the respirator is not worn and when any type of respirator is worn, whether it be an APR, an SCBA, or a PAPR. We all know that wearing a respirator impacts ventilation, and we're just trying to gauge this is the potential for a non-respirator situation or a non-resistance breathing situation, and this is what you may expect with respirator type whatever.

And part of this also leads into another test or study

that will be initiated very soon through ECBC. We're going to take some of the flow rate information that we are able to gather and apply it to some filter testing at these different flow rates. So instead of just looking at a 64 liter minute or 85 liter minute or 100 liter per minute flow rate, if we find data to suggest that there is a regular occurrence of high flow rates, we're going to go in and test a wide variety of filters with different aerosol challenges to those particular flow rates.

The approach that we've taken is we do believe that a substantial amount of information does exist in the literature, it's just a matter of trying to gather all that literature, put it into one database or into one report and try to make heads or tails of that. So the first thing we're doing is a literature review. The second thing is there's a lot of data that exists that's never been published in an open literature reports that many of you may even have in your possession where we may be able to combine data into a database and do kind of a post-analysis or meda-analysis (phonetic), if you will, to get a better feel for what's published in the literature really makes sense or maybe it doesn't make sense. So in essence what we're trying to do is find some empiracal data that somebody has a whole database of for certain work rate, certain conditions of respirator wear

or non-respirator wear, put it all in one big database and re-analyze data from multiple studies.

It's very challenging to do that type of work because every study has different population bases, different work rates that were tested, were they tested under a ramping or continuous increase in work rate, a type of an exhaustion test, was testing done under constant work rate. So there's all these variables that play in there.

And the last thing that we really want to do is go and do more human use tests. That's the, of course, the most regulated thing, the most expensive thing to do, and causes the most headaches. But if we identify data gaps, that may be what needs to be done to try to fill in those data gaps to put some of this information not to rest, but at least to try to gather it in so it makes sense to everybody that can take a look at it.

So far we've collected over 100 articles. And you've got to understand that the initial search of this data was anything after 1990, because we all know what the literature says in the '50s, '60s. We were trying to limit our database based on new applied techniques for collecting data at the bottom line, collected online with a computer because you can collect it so much faster, get better resolution of your data. But in the process of trying to find articles, of course we've

come across all the Silverman's reports and all that kind of stuff, and they're in our database and we're well aware of all that information. We're trying to review these articles. There's two of us that have been working on this for about three weeks now. Once we go in all the articles that we had requested, we have articles that span respirator wear, breathing resistance in terms of some kind of resistance was applied to either the inhalation or exhalation side of ventilation, whether that was with a facepiece or mask on of any kind, or if it was just a mouth bit to where a small orifice was applied to create a different airflow resistance. All those kind of papers are being considered.

Occupational studies. We've tried to find any data that shows somebody doing work at their workplace where ventilation or work rate have been recorded or measured or estimated to some reasonable degree of accuracy. And we're also looking at any lab investigations that involve maximal work rates or simulated workplace types of activities. And we've also looked into any speech ventilation and coughing and sneezing flow rates. And the coughing and sneezing kind of goes towards something else that's part of the filter study that we'll be doing as we're looking at some potential impacts of coughing or sneezing when wearing like a half-mask for readout erotization of particles. So that information is also being

investigated.

We've also gathered some data from in-house stuff that I have in my lab and initial contact with a colleague at the University of Maryland at College Park. Those are two current players with raw data. Now, Bruce was standing up before saying that the NPTL - or NFPA, I'm sorry, has reports about high flow rates as sustained information. We've exchanged business cards, because I'm trying to find anybody out there that has that kind of data that's willing to provide for this examination. NIOSH, I've spoken to a couple of folks at NIOSH that have given a few potential sources. I ask all of you in the audience if you have any of that data, please let me know. We would be very interested in including it in this analysis. We've contacted, if you recall, Mr. Pitts, who still calls himself a neanderthal, he doesn't give himself enough credit, with the Marines. They've done some high intensity workload testing and they've got some of that data. So we're gathering that data. We've been a little slow in that process. But that's part of this investigation.

As far as the human use testing goes, all we've really done in-house is we were already going to do some work related to speaking with a respirator on kind of to look into some of the information that Mr. Berndtsson's talked about with speech flow rates, just to get a feel for that information as it

relates to different data collection techniques.

Busy slide. It's really only here to show you some of the articles that we've gathered, and I don't know why it's off to the side, but really it's just a list of a few of the articles that have been reviewed. It talks about the types of tests. Some of them were work sites and some of them were on site done with portable equipment for collecting metabolic data and respiration data, ventilation data. Some of them are simulated tests done on work sites. And some of them were on work sites where it wasn't just free reign, go do your job. It was a matter of, okay, for 15 minutes we want you to do this part of your job. And that's kind of what I'm referring to with the last work site control condition.

With some of the tasks that have been looked at and ventilation rates. It shows ranges of ventilation. Rates reported in the literature for site tasks. And if you look at that, probably the highest values you're going to see are up in the 60 liter per minute values for the shoveling tasks.

Really, that's just kind of what we're looking into at this point. Now, you've got to understand some of the literature we are reviewing we are trying to be very picky about the techniques used to collect the data. We really are, you know, I don't know everyone's understanding, but there are so many different kinds of flowmeters out to record

ventilation. And if somebody's doing a very heavy intensity exercise test where it's 90 percent of their maximum capability and the researcher says we used a Flash number 1 pneumotec, guess what, that's the wrong flowmeter to collect that high of flow rate data. So that's what we're looking into, some of the details of the data that's been collected.

Some of the occupational literature that we've seen with respirators. Two SCBA's. Obviously most of the literature is related to firefighting tasks. And then this one particular article, a whole range of different respirator types done on a work site. Now some of these ventilation values are estimates based on specific relationships established for individual subjects that were collected in the lab at first and then when they went to the field. And what does that mean? When they went in the lab they would set up a relationship of heart rate to ventilation. So when they were in the field and they measured heart rate they could at least estimate the ventilation of that individual based on their heart rate condition, that type of information.

Again though, just looking, taking a quick look again, 60 liters per minute. The highest flow rates reported. Whether these were means or peaks. Right now some of them are just ranges. Again, it's just a sample of the data.

And then again, as I referred to, laboratory test reports

where resistances may or may not be applied, whether they wore a respirator, whether it was just like the last sample here of mesh screens of different resistances, the types of tasks that were involved, some of them were to exhaustiion, some of them that are very high intensity exercise levels, and then again you see the different ranges of ventilation. Just by a quick look at this, obviously laboratory data is giving us high flow rates. But that's probably a direct reflection that most of the laboratory data involves higher work rates.

This is more of the applied - it didn't go forward. There we go. Some of the other literature that we're looking for, not only minute volumes, you know, the amount of air respired a minute or ventilated in a minute, we're also looking at some of the peak inspiratory flow rate literature. It's a limited database. Not a lot of researchers look at actually measured peak flows. They may measure average minute volumes, but not all people collect breath by breath data and look at a wave form of data, that's reported in the literature. Many people may have that information in-house, but they just didn't publish it that way.

Of the couple of the reports we've looked at, we're really just trying to again gauge what are peak inspiratory flow rates that would be anticipated in the field, in the work site, and the graph is just an example. Over the top line is

no resistance, the bottom line is a resistance condition. And that's just to say, well, guess what, work rate increases, but with some kind of breathing resistance the peak flow rates are dampened. I think we know that, but we're just trying to validate that and we're also trying to quantify that information.

As I referred earlier about the data compilation and collection data from other sources, one big data set that we recently gathered and actually formatted for analysis has to be - had to do with data collected by Dr. Coyne from the University of Maryland, College Park. Essentially these are breath by breath values of high intensity exercise. But they also did other intensity work rates. They did low and moderate and very high work rates under steady-state conditions and collected a lot of breath by breath data.

And essentially these are wave forms. These are instantaneous wave forms collected over a certain amount of time once a steady-state exercise or work intensity have been reached. And the list is just a list of the types of variables we can calculate from a wave form. Inspiratory/expiratory times, tidal volumes, minute ventilation, whether it be on inhalation or exhalation, respiration rates, right down the line. We can also look at the breathing waveforms, apply some analysis to those

waveforms, and look at wave shapes and maybe get into the information about what is a good estimate of a peak flow rate based on an average minute volume.

The nice thing about this data again, they did no resistance testing, no resistance to airflow, and then they did testing with different levels of breathing resistance.

This is just a sample of a 10 second graph of the data. It just shows you a waveform. And the table underneath is just really displaying some of those values that we talked about that can be ascertained from analyzing the curves. And in that curve anything below the zero is an inhalation, anything above is exhalation. It's just the nature of using the pneumotec for collecting flow rates.

Our plan is to finish this literature review by the end of this month. So there are quite a few more articles to review. To complete the literature review really means weed out the good from the bad and then go forward so we can go forward and provide flow rates for this high flow filter testing that will be coming onboard probably more towards the middle or end of November. We hope to have a draft report of our literature review out by January. And also in January we're looking to either implement or development some test plans to fill in the data gaps.

We haven't thought through exactly where, when, why, and

how to do all that, but we probably will approach some of the folks at NPPTL and try to use some of the resources available to them to do some of that testing. We hope to - any data that we can gather, raw data that anyone's willing to put forth to play into this research project, we hope to have all that compiled and analyzed by March and come up with some flow rate recommendations or guides, or at least quantify flow rates for respirator types and work rate conditions.

Parallel projects going on in all this is - are some of the international efforts to develop international respirator standards, and we're keeping abreast of the information that's occurring under those activities.

That's all I have. Any questions?

GORAN BERNDTSSON: Goran Berndtsson from SEA. Very good. Finally we're getting good attention (unintelligible). The graph you had up there when you were looking at work rates, was that (unintelligible).

DAVID CARETTI: That was absolute work rate.

GORAN BERNDTSSON: Absolute work rate?

DAVID CARETTI: It was, yes.

GORAN BERNDTSSON: What do you mean by absolute work rate?

DAVID CARETTI: The external work load. That's actually data from Silverman's 1951 paper.

GORAN BERNDTSSON: Thank you.

MIKE SAVARIN: Mike Savarin, ICS again. As far as I can see, Dave, will there be any intention anywhere from all of this to define a protocol under which these measurements will be made so that we can generate some kind of uniformity somewhere? I know the things inherently problematic with this, but something you said - before you reply - something you said kind of fired off something in my mind. There's a need for you, because of the nature of the data, to be technically, you know, selective in what you present going forward as what you determine or the group determines as valuable research data. So I'm saying can we get a protocol out of that?

DAVID CARETTI: That's a good question, Mike. I don't really intend to put into the paper that this is the only accepted way to collect flow data. There are many accepted ways to do it. There are turbine flow meters. There are mesh screen flow meters. There are many types. Really the search or the review of the data is to just feel comfortable that a valid method was chosen to collect the data under whatever work conditions were tested. I probably will list the different types of equipment and methods that were utilized, and it will be listed in the report, but by no means is this to lead to some kind of standard of acceptable - only acceptable way to evaluate flow rates with or without

respirators.

MIKE SAVARIN: I appreciate that that may not be at this time such an intention. But I can see the scenario where we're going to need as a test community to put something together that forms and even platform by which people can test to and say, "Yeah, that's what we're seeing," in a certain situation.

DAVID CARETTI: And I would, not to blow it off, but I would say that once NIOSH has the report and they feel that they want to go forward with something like that, I'm sure we can discuss it at that time.

MIKE SAVARIN: Thank you.

PAUL DUNCAN: Paul Duncan, Scott Health & Safety. Again, I'm also looking forward to this. Just a comment. You may already be considering this. I would encourage a good lead in to this report as far as defining so everybody can clearly understand the difference between minute volumes and peak flow rates and inhalation cycles, because I think there's a lot of confusion generated in these discussions by people not really aware of the physiological significance of some of the different descriptions.

DAVID CARETTI: Yeah. We will include that. If I can make a 500 report, I'll go ahead and do it, if that's the only problem.

GORAN BERNDTSSON: Goran Berndtsson, SEA. You said that some of the data was recorded with no resistance. How can you do that?

DAVID CARETTI: Well, okay, when you get technical. What is the resistance of a pneumotec at certain flow rates? And for the purpose of the paper that will be defined. But by no resistance it was being used in the board term that nothing was imposed against ventilation other than the flowmeter device. And we're talking very small resistances for some of the these devices, less than a centimeter of water. A half a centimeter of water, a tenth of centimeter of water depending on the type of device. And, you know, if you want to get technical, what's the dead volume of the breathing tubes involved and all that type of information?

GORAN BERNDTSSON: I didn't try to make it difficult for you. But there is some resistance, and that resistance would be changing as the flow rate is increasing as well. So I mean it is --

DAVID CARETTI: You are correct.

GORAN BERNDTSSON: When you say no resistance, of course there is some resistance.

DAVID CARETTI: There's always resistance if you're going to measure ventilation, unless you use some kind of respiratory inducted psysomograph (phonetic). There's a term

for you.

MARY TOWNSEND: I'm Mary Townsend. I'm a respiratory epidemiologist. I'm affiliated with the University of Pittsburgh. Before you start thinking - I was referring to your comment about developing standards. The American Thoracic Society, as you know, is very big in sending out specifications and recommending laboratory testing at the LPS Hospital in Salt Lake City of commercially available pneumotecs.

DAVID CARETTI: Yes. They do many reviews of new devices that come out and --

MARY TOWNSEND: The manufacturers send them in and they either say yes or no. But, so this isn't an area that you would like (unintelligible), I don't think.

DAVID CARETTI: No. Thank you very much for reminding of that fact. Thank you. Okay, thank you very much. And everybody route for the Red Sox tonight.

JONATHAN SZALAJDA: I guess though from Dave's perspective, if you're from Baltimore you either - you hate New York and you hate Boston, and it's just a tradeoff of which team you hate more. I think everyone would say that's the Yankees.

What I'd like to do at this point I have summation remarks that I'd like to make at the conclusion of our part of

the meeting today. What I'd like to do is we have one individual, John Morawetz, and I hope I didn't butcher your name too much, John, had requested to make a presentation at this session. And we'd like to have him offer that at this time.

JOHN MORAWETZ: Thanks. It looks like my slides are going to get butchered on the left-hand side, too. I came across the work that NIOSH is doing in this area doing a search and found out the AEGL's were referenced originally in the air-purifying respirator, the escape respirator work that NIOSH is doing. And I stand corrected that the work I referenced earlier that Terry Thornton correctly pointed out. The APR breakthrough times are identical to the PAPR breakthrough times.

I serve on the AEGL committee along with Rick Niemeier from NIOSH and done this work for a number of years. And I was - I'm always intrigued as to where they're going to use AEGL's outside where they're designed to be used. And I think that has to be done with a great deal of caution, and the particulate needs to be explicating stated. Even the escape air-purifying respirator document that as far as I understand is finalized and sent out by NIOSH last week does not include any references to AEGL anymore. However, in that document for both sarin, GB, and sulphur mustard, HD, the breakthrough

concentrations that are being used by NIOSH are the AEGL-2 values. But it's not spelled out what the AEGL-2 health effects will be, and it's not spelled out that these are the AEGL values. And I think that's quite frankly a mistake.

I think that they may be appropriate. I've had a lot of good discussions with Rick Niemeier and the NIOSH staff on this. And because of large uncertainty factors that the AEGL committee use, it may work. But I think that it's very dangerous to go down a road where we're using these values, the non-occupational values, and using them in a very different situation for inside the respirator concentrations, the breakthrough concentrations.

So what are the AEGL's? AEGL's originally date back to the Clean Air Act and mandates for EPA regulations about accidental releases. And in particular the legislative reference is 112R has mandates for risk management plans that companies have to produce. As part of the risk management plans, they have to determine the worst case scenario. And that worst case scenario includes what is the most toxic material, very interesting phrase, and determine the maximum distance from this filter release of everything in the largest container that's all released in 10 minutes that would produce a toxic endpoint, and what is the distance, how far would that toxic endpoint go to. And there are various computer

programs, Aloha and Cameo, that you plug in the numbers, what the volume of the chemical, how much, the wind condition, various values, and a level of concern. And you get an answer that the cloud will go 3.3 miles. Well, to get that level of concern you have to know - have to come up with that numerical number, PPM.

This work was preceded by AIHA, which determined ERPG values. And they - right now the risk management plans in general uses the one hour ERPG values. And the ERPG's actually are only set for the one hour values. The committee is sponsored by the National Academy of Sciences. It's governed by the EPA. The main sound byte here is the last line here, that it's meant for once in a lifetime short-term exposures to the general public. And those are really the two big things. It's once in a lifetime and the general public.

The three health effects, and I think John Szalajda referred to them earlier, is AEGL-1's, 2's, and 3's. AEGL-1 is a threshold. It's defined as the level, PPM, above which you'll begin to see notable discomfort or irritation. Between AEGL-1's and 2's you get increasing symptoms beginning to occur, but AEGL-2 you begin to get various endpoint, health endpoints, that finally AEGL-2 is then the numerical level which is a threshold above which irreversible or serious long-lasting effects, where they didn't really escape.

Typically some studies have shown human subject studies where a subject said it was intolerable, they left the chamber, severe dizziness, various reasons we've used for that. Which in 2 and 3 you get more serious health effects. And finally level 3 is life threatening or death. And these three endpoints are the same as ERPG endpoints.

Let me ask you to go back for a minute because on AEGL-1 and 2 the numerical values for one of the chemicals used here in the PAPR discussion is sulphur mustard, and in fact the AEGL-1's and 2's are very close together. And the sulphur mustard values recommended by NIOSH are below the AEGL-1 values. And there's no problem there. However, if you look at GB, there's a little bit more than a tenfold, about an elevenfold difference between AEGL-1's and 2's. And NIOSH currently is recommending, as Jon Szalajda said, about half the AEGL-2 values. That still is well above the AEGL-1 values.

Now, there are certainty factors we've plugged in from human studies to what we determine is an AEGL value. But I think that needs to be laid out. It has been in that discussion. I think NIOSH has had it. But it needs to be in print. Because the end result is you're going to have a responder who's going to wear these respirators, may get the symptoms above the AEGL-1 where I think they expect right now

they're going to be safe, they'll have no health effects. And I think that, again, has to be clearly laid out.

We have five time periods we set values for, from 10 minutes to eight hours. That's a complex matrix of 15 numbers that are produced for every chemical, where ERPG only produces three values, AEGL-1, 2, and 3 for one hour.

Again, there are at least two main poles on the AEGL's as compared to most of our work occupational. One is the general population, including many sub-populations that are more susceptible to toxic chemicals than the working population, which is a subgroup of the whole population. That in general will drive our numbers down, and we'll want to set lower levels. At the same time it's not an easy rule of thumb. Because there's a second factor, which is a once in a lifetime exposure, unlike not - obviously eight hour time rate averages, PEL's and REL's and TLB's, ceilings, STEL's, all those short-term occupational values, none of them are meant as far as I know to be once in a lifetime exposure. So you really - that then drives up to perhaps, sometimes we set values that are higher than occupational values. And as much as, and Rick knows it, people will bring up in the discussion, well, we're setting AEGL-1's and look at what the PEL is or the REL. We always say, very different context, you cannot just compare one or the other.

Now, this is really not my slide, but I did add the NIOSH presentation. This is more to say this is where the second slide comes from, which is a previous presentation which is available on the NIOSH, the NPPTL Web site. And I think this is a dangerous conception if we think of this as a straight linear format, where on the right-hand side we have lifetime exposure, micrograms cubic meter; left-hand side a single exposure, micrograms cubic meter, where we assume that on the multiple continuous or the ambient air concentrations are always going to be the lowest and progressively each value will get higher.

It is true that, let's say, eight hours higher than STEL AEGL - I'm sorry, lower than STEL, AEGL-1 is lower than 2, AEGL-2 is lower than 3, and AEGL-3 is lower than the LC50. But not all of them are in the same linear relationship. I know although it does say at the bottom "not to scale," the relationship is not always true.

I didn't know I did this. Excuse me. I copied another graph and look what you get. I think I have to press this again. My apologies. I looked at this, I really did. There we go. This looks like it. Okay.

Rather I see two linear relationships. The top is community values, and there are probably more than this, the bottom is occupational. And in this situation again I'm using

the same format NIOSH used when you get high exposures at the top and lower exposures on the left, lower on the right, the lifetime ensures, that's what we set the values at. On the top it's community, the bottom is occupational. And in this situation the two underlying values, AEGL-1, irritation is higher than the eight hour PEL. And that often happens in even AEGL-1's we set, but not uniformly. It doesn't always work that way. Again, in terms of the AEGL's compared to occupational values, they can be higher because of the intent of the single exposure. They can be lower because of the subpopulations. And the other caveat here is our data is overwhelmingly, and actually the expertise on the committee, single dose studies. We generally exclude multiple dose studies, don't look at them. That's because that's what our mandate is.

And regretfully here's another slide that's going to come on in a minute. There we go. Okay.

Here's the opposite. Wherein this situation the AEGL-1 is lower value than the eight hour time average. And again, it can go either way.

Trends of the application to the work on in general CPR respirator process, which already the step has been taken for the escape ARP's and is being considered for the PAPR's, I think you have to clearly spell everything out. One is the

AEGL's are different from most values, and that has to be clearly stated, along as those statements as to when they're used. Their thresholds, AEGL-2 values are thresholds escape irreversible injury. I have to look at the data again, I haven't looked at it that closely, but the end points for GB are ones that I don't believe are resolved in a day or two days. Some of the nerve conduction loss, some of the myosis carries on for a week. They're defined in AEGL-2's as military casualties that require assistance. These are not symptoms that should be taken lightly.

Now, because of the nature of dealing with CBRN's, terrorism, we may and NIOSH may make the decision to use them. But that decision I think has to be clearly explicitly stated. And lastly you've got to look at the data and rationale.

Again, as I said earlier, for a GB there's a large uncertainty factor. But even with that uncertainty factor we're getting I believe still above the AEGL-1 values for GB. So the question is do we want people to be wearing these PAPR's perhaps with use that's more than just a couple of hours where they're going to get symptoms inside their respirator. And I think that is the presentation. Thank you very much. If there are any questions, I'd be glad to try to answer them.

BILL NEWCOMB: Bill Newcomb from North Safety Products. I think one of the issues that gets sort of lost or clouded when

we talk about breakthrough times, challenge concentrations, and use times, is the fact that test times, test challenges, test breakthrough, are meant to test the respirator components. They're not related to the overall end use of the product. People do not breathe through a canister at a constant rate. They are not always in a - the most highest concentration. And the concentration in the mask is not the concentration we have seen at the end of a test. And you can't equate the two. And I think that it's a common thing to do. We've seen it in all of the sessions that we've had concerning whether it be SCBA, APR, or PAPR, escape hoods. There is a scenario where these products are used and they're safe, and there are also tests that are run on them to quantify the ability of the product to do a certain job. They are not one and the same. Thank you.

JACK SAWICKI: Jack Sawicki, Global Secure Holdings. First I'd like to commend you on that presentation. That's very useful. I think it's a lot of information that's not widely thought of.

As a labor representative and someone who's very thoughtful on this issue, I would like you to maybe address an issue with these standards, the issue of IDLH and what that definition really should be for these chemicals. I wonder if you have any thoughts on that. And I'll throw out just two

things for comment. The IDLH level for tear gas, for example, CS and CN, is very little concentration. The idea is they might impair you, yet the IDLH levels for biological agents, for example, if you look at the philosophy recently used by CDC in it's respirator for healthcare workers, Presaris (phonetic), which is a lethal, non-treatable disease, we have a risk with a protection factor of 10 basically for that application. The question I'm getting to is, you look at this philosophy you had for GB, where should the IDLH levels be set for different types of these toxic materials?

JOHN MORAWETZ: Let me just address the first commentator first, then I'll get to that. Your point is well taken, but I still think we need to clearly lay out the methodology of why we're setting what we're setting. And as much as I stated what I stated about the GB and the sarin, the sulphur mustard levels, on the other hand earlier today we heard the laboratory protection levels discussion. That was a 10,000, I believe, volt production, and that generally would offer a good deal of protection even in these concentrations. But again I think what's clear is have to really state what the variant points are.

In terms of IDLH's, I haven't looked at that quite that closely. And I'm not the one who covers that in my day job of being director of a training center of the staff who teach

respirators. I think I'm much more able to handle that. I don't think I'm prepared to do. But what I do know is that the IDLH values have been under discussion by NIOSH, and NIOSH is well aware that there are a lot of problems with some of the levels and I believe they have contractors looking at different of the derivation of IDLH. It's a difficult concept. And I think they did one clarification recently to say it's not meant to be a concentration you'd be exposed to for 30 minutes. Don't worry about it until it's - just get out after 29 minutes. That was one endpoint. Otherwise, I'm really not prepared to IDLH's. I don't think I should get into it.

VIJAY AKUMAR: I have a general question. My name is Vijay Akumar with Air Techniques. Probably for the panel in general is the term, a phrase you keep using several times, single lifetime dosage, single lifetime exposure. Excuse me, my native language is not English, but it sounds very morbid that if you didn't have any respirators, all of us would have a single exposure, we all die. I think that's kind of set standard, we should use more common English and not just cliches.

JOHN MORAWETZ: I'll answer that comment on that just in terms of the AEGL work. AEGL work is supposed to be for planners in an emergency response to decide, given we live in

a world that have we have large storage of many toxic chemicals, what if they were released. And for people to make policy decisions based upon some scientific endpoints what would happen. Are people going to get symptoms or are people going to die? And there have been regretfully many a case where we're all aware of there have been releases that people have died. And I think it's helpful to have an estimate as to what that level would be. It may be morbid, it is, but that's the reality of what we all know does happen everyday.

BILL NEWCOMB: Bill Newcomb, North Safety Products. I don't know whether anybody else saw it this week, but I believe that there BL's published on PBA, PB, GAPB, and BX in the Federal Resister by I believe it was OSHA.

JONATHAN SZALAJDA: Thank you, John. I think it's always important that we get different perspectives from the interested parties, and we appreciate you making the time to provide us your perspective.

I guess a couple of things I just wanted to follow up with following on John's discussion, at least with regard to how we're addressing chemical warfare agent effects as part of our respirator standards. We're including cautions and limitations with each of the standards regarding the effects of chemical warfare agents, the fact some of them aren't immediately apparent and are dependent on the duration and the

exposure. We're also within our branch working on developing guidelines associated with the use of these systems. And the concepts like what we just heard are things we're considering in terms of developing those guidelines.

And where we are in terms of our discussion, this is I guess what we consider to be the open comment period. If anyone in attendance of the meeting would like to come up to the microphone and express an opinion at least with regard to what we're doing with the standard and things that you think we should consider, now would be the time to do that.

GORAN BERNDTSSON: I don't need to introduce myself. Goran Berndtsson, SEA. Have you considered particulate filters only now when we are getting (unintelligible) used for a longer period of time? It may be established as be both (unintelligible) biological, et cetera. Would it be possible to have a particulate filter only?

JONATHAN SZALAJDA: We haven't really thought in those terms yet. But that's something we can take under consideration.

MIKE SAVARIN: Mike Savarin, ICS. I'm not entirely sure after this morning's events that the concept of interchangeability of the CBRN, APR devices with the PAPR-1 is the best way to move forward from a performance or technical position. It is, and I'll talk later, nothing I've heard here

today actually convinces me that this is the right way forward. I actually from a technical perspective don't see any problem with developing a separate set of criteria for what is a separate product, in fact, for a separate performance area. I don't know if anyone else has a view on that. It's just my view right now. Thank you.

JONATHAN SZALAJDA: Does anyone else have any comments? Jay?

JAY PARKER: Jay Parker with the Bullard Company. I just wanted to make one additional comment. On the abrasion resistance test, I was somewhat concerned when I see that. As far as I know that's a pretty difficult test to pass. And it originated with full face masks. And my thought on that is that I don't think it's appropriate, or it not be appropriate for hoods. I don't think there's any hood on the market with a lens that's going to meet that requirement right now. And, you know, I think it's going to be difficult. And I don't know that it's necessary. I think a soft hood when it's struck by an object, it doesn't have a rigid structure, so it kind of gives with the blow, and the lens therefore would not be abraded I don't think as much as a full face mask. So I think maybe NIOSH should rethink the abrasion requirements, specifically for hoods, and possibly come up with a different test for hoods versus full face masks. Thank you.

JONATHAN SZALAJDA: Thank you, Jay.

GORAN BERNDTSSON: Goran Berndtsson, SEA. Another consideration, you said in the opening statement that this (unintelligible), directing traffic all the way up to rescue or search. Maybe there is an argument for having a capital level of flow performance, because it is an enormous different work rate between directing traffic and doing search. So instead of putting everything into one particular study, maybe we should point out at least two or three different performance efforts.

JONATHAN SZALAJDA: That's a good point. Thank you.

I guess there are a few things I wanted to provide in summary before we adjourned. I think the one thing that I hope that - and really we value the opinions that you have put forward here today, because obviously this is something that we can't do in a vacuum in terms of developing the standards. And we truly need your involvement with us in the process of standard generation.

I think one of the things that I hope you appreciate from our approach here is that what we're trying to do, and I mentioned this this morning when I talked about the process, was to build as much as possible on existing standards and equipment. And we truly appreciate the magnitude of the resources that the stakeholders have involved with the process

in terms of research and development that's gone into the generation of the canister requirements and the fit testing requirements, as well as the testing for the chemical warfare agents and the toxic industrial chemicals and the environmental considerations, that truly there's been a lot, a lot invested within the community to develop equipment and submit for certification and have available for the responder to use to meet these requirements.

And to that extent we value that resource contribution that the stakeholders have made. And we want to continue to use that as much as possible in bringing this standard forward to fruition. And I think the result of our thought process up to today was to redesign the conventional PAPR to eliminate the airflow from the canister evaluation, going back to standardizing the concept around the concept of using the parameters that have been defined for the CBRN canister.

Having said that, I think we realize there are several issues that we're going to need to address over the next several months in terms of we move forward with the standard development. I think among those are the duration requirements comparing the use of the PAPR versus a negative pressure respirator. The need for universal interoperability of the canisters that responders could be using on a specific site. Also, as far as if we do try to move forward with the concepts

that we currently envision, you know, are there more appropriate flows that we should be considering in terms of the challenge of the canister for evaluation.

Just in closing, I wanted to touch base and remind everyone about the meeting that we have planned for January. One of the things that I failed to mention this morning is in the Federal Register notice that we're going to be putting forward regarding this meeting, we've had some conversations and some discussion with some of the stakeholders regarding our sequence for standards development. Back in the April 2001 meeting we discussed the sequence of standards development that we were going to proceed with the SCBA and the air-purifying respirator, the escape sets, and then the PAPR. And then we also are looking at combination units, self-contained units, and other supplied air system.

What we'd like to do as part of the discussion, and we're looking for your feedback, in terms of if that sequence of standards development that we've identified as a result of the initial public meeting, if that's still appropriate to continue at this time, or if there are other needs within the community where we should be addressing developing one standard ahead of another.

Again, as I had mentioned this morning, is we follow - continuing to follow the same public process with this

standard as we've done with the others. We're looking forward to trying to complete our concepts by the end of the March time frame. And again, as we continue to move along we're going to be continuing our internal discussions within NIOSH on how best to implement this requirement.

And just in closing, I encourage you to submit your input to the docket for formal tracking consideration. If you have any questions, I believe this chart is available in the back at the registration desk. Again, we look forward in working with the community in developing the standard over the next several months. So with that, thank you very much, we're going to adjourn this meeting and then I believe reconvene at 3:00 for discussions on the QA Module. Thank you.

(Meeting adjourned.)

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STATE OF WEST VIRGINIA,

COUNTY OF MONONGALIA, TO-WIT:

I, Carol A. Ashburn, Certified Court Reporter and Notary Public within and for the County and State aforesaid, duly commissioned and qualified, do hereby certify that the foregoing proceeding was taken by me and transcribed to the best of my ability and for the purpose specified in the caption hereof.

I further certify that I am neither attorney or counsel for, not related to or employed by, any of the parties to the action in which this matter is taken, and further that I am not a relative or employee of any attorney or counsel employed by the parties hereto or financially interested in the action.

I do further certify that the transcript within meets the requirements of the Code of the State of West Virginia, 51-7-4, and all rules pertaining thereto as promulgated by the Supreme Court of Appeals.

My Commission expires October 15, 2011.

Given under my hand this the 13th day of November, 2003.

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