(Tape 1, Side A)

Rich Metzler: We'd like to start in a moment. Good afternoon. Welcome to Canonsburg, PA. Where? Canonsburg, PA. Hi. I'm Rich Metzler, Director of the National Personal Protective Technology Lab and I would like to welcome you to our public meeting to discuss our standards development efforts for full facepiece air purifying gas masks for CBRN protection. I did want to tell you something about Canonsburg, though. We are famous for a couple of things and you may want to get out in the evening and shop around the town, but Canonsburg is famous for an international singer, Perry Como, you may remember that name, Perry Como was a barber in Canonsburg, Pennsylvania and went on to become an international star and we have a statue of Perry in front of the municipal building about two miles from here. You may have heard of the national singer, Bobby Vinton. We have an alley named after Bobby Vinton down in Canonsburg, and we have a candy store that if you want to take candy home to your better half there is a block-long candy store called Sarris (?) Candies about two miles from here. It really is worth seeing if you're in the neighborhood. And you are. (pause) How do I change the slides? Point to Terry. Point to Terry? Oh, hi Terry (laughter). All right. Modern technology. You have an agenda in your handout material and the only thing that I would add to that at this time is that throughout the agenda there will be sessions of presentations explaining the standard and our rationale and then a break period where we will have an opportunity for you to go to a microphone and have a dialogue with a panel of experts from NIOSH. It's not specifically in

your schedule but that will occur throughout the scheduled periods that you see. Terry? (pause) I've already said I'm Rich Metzler, let's move forward. Before we begin I want to acknowledge our partners that we have worked on for a number of years now in, first, setting the stage in doing work in 1998 and having a conference in Morgantown, West Virginia to understand who the players were and what the hazards and training needs and equipment needs were, and from that timeframe, NIOSH has worked closely with NIST, who has funded our initial activities which since then have been complemented by CDC funds; SBCCOM, who have partnered with us in developing the standard and conducting tests; OSHA who has a memorandum of understanding with us and we collaborate in terms of enforcement impacts on the standards that we're creating with NFPA as we have incorporated standards from the NFPA program. The presentations today are going to be in three different areas. The first will be a description of our standard with an explanation of our rationale. Along that line there will be poster presentations or videotapes tomorrow. The set up over in this corner of the room describes the, a poster setting of environmental and human factors tests, and we'll have individuals at the posters to entertain your questions and go through the posters with you, and in the back of the room is a videotape of the SMARTMAN test. We will have folks at those displays during breaks. Also, we'll be discussing an update on our simulant research that we are conducting with SBCCOM so that manufacturers have an opportunity to use simulant agent for permeation tests. And, last, tomorrow before we close, tomorrow

afternoon, we will go through our initial concepts on escape respirator standards. A few administrative details on the meeting: Logistics – there is a sign in sheet. If you did not sign in please do so, so we can establish a mailing list to keep you informed of our activities. There is, the meeting is being recorded so if you do go to a microphone to ask a question or to give a presentation, please identify who you are, your organization when you go to microphone. There will be a transcribed record of comments on the NIOSH docket, and there will be question and answer periods through different times throughout today and tomorrow. Also on your schedule will be a number of guest speakers who have asked to present information: Dr. Jonathan Kaufman from NAVAIR; Mr. Sam Pitts from CBIRF. Today and tomorrow will be Bill Haskell from SBCCOM and Goran Berndtsson from the SEA Company. This information on how to contact the docket is an individual handout. We want to make sure that everyone is aware that you can provide information to our docket. You can contact the docket at that location, those telephone numbers and provide information to the docket as well as retrieve information from the docket. At this time, I would like to turn the program over to Mr. Les Boord. Les joined us approximately a year ago from the private sector. He was a managing president, executive officer for Draeger, National Draeger in Pittsburgh. We're very fortunate to have him with his experience on respiratory protection as well as certification activities, and Les has assumed leadership role for developing the standards in the CBRN area of activity. Les.

Les Boord: Hello. I think what I'd like to do to start off is basically just introduce the team, what's commonly referred to as our CBRN Standards Development Team. Can everybody hear okay? And basically, that's the group sitting at the table here who are in the front lines of doing the work that we're tasked with to develop the standards. Now there's a lot of other people that are involved, because we certainly like to benefit from everybody's experience and awareness, but the front line is pretty much manned by this group: John Szalajda, Frank Palya, John Dyer, Mike Monahan, and Terry Cloonan. So throughout the course of the next day and a half the discussions that take place will be pretty interactive with various members from the team as well as the participants from the audience. (pause) A lot of what you hear and see during the next day and a half is going to be repetitive as you've already seen, because a lot of the information you've already heard and it will be reiterated again, but there are some new areas, and I think for some new attendees there will be new information. What I thought would be good would be if we sort of encapsulate, give an overview of our CBRN program, standards, respirator standards development program in real basic terms, three areas: where we've been, where we are, and where we're going. And really, when you look at where we've been, we got to go back to some of the things that Rich just pointed out and the CBRN Standards Development effort really started and one of the real cornerstones to the foundation there is the workshop that was held in Morgantown in 1999. At that workshop, I'm sure a lot of you attended it, but the significance behind the workshop was that we had experts from

within the industry, okay, scientific experts, people from the user community, manufacturers, and government, all represented in one forum where the issue of CBRN concerns for personal protective equipment was the focal point. Coming out of that meeting I think there were several main issues that have been identified that needed to be addressed to carry the program forward. And I think we really need to be thankful that the organizers of that workshop had the foresight to do that two years before we had our catastrophic events last fall. But the things that were carried forward from the workshop were the identification of needs to develop guidelines and training scenarios for people who would be using personal protective equipment in a potential terrorist event. Another issue was the need to have a NIOSH, and specifically a NIOSH certification program, for respiratory protection products. A high priority was considered for self-contained breathing apparatus, air purifying respirators and powered air purifying respirators. And then still a third element coming out of the workshop was the continued need for research in the area of PPE and how it is used and applied in the terrorist theater or the terrorist environment and PPE and detection equipment. So a lot of the real groundwork to initiate the program was sort of born at that meeting. But following that, then NIOSH and NPPTL developed working agreements and memorandum of understanding with the various government agencies and user organizations and manufacturer groups that Rich mentioned a little bit earlier through our MOUs and our IAAs. And those have been very crucial to the development effort. As I said at the beginning, while the CBRN team is

the front line, we certainly have been drawing on the experience of all the people that we can benefit from their knowledge and awareness in developing standards. Whoever thought respirators could be so complex, but they really are. And we do need that broad base of experience and expertise. So the MOUs and the inter-agency agreements have been crucial in the development effort. Then we finally started to see some results coming out of the program last December with the introduction of our CBRN standard for self-contained breathing apparatus. The standard was released in December of 2001 with the initial applications for certification received in January, and certification testing beginning shortly after that, with initial certification issued in May of this year. And, currently, continuing certification evaluation and testing is in process for self-contained breathing apparatus. So we've already seen improvement in that area, and results in the area of CBRN standards. But where are we now? Well, obviously the SCBA standard is in place. Certification tests and evaluations are being implemented. We're here today to discuss the development efforts for a full facepiece air purifying respirator that has been in the development process for the last six or seven months, actually since January of this year, February of this year. So full facepiece air purifying respirator has been developed and matured along to the point where it's in a near final configuration. And then we've also initiated the work to identify and develop requirements for a standard for escape purposes. I'm sure that the continuation of that work and the development of the escape respirator standard is going to be quite interesting. It's probably the most visible and

probably has the most prior activity of any of the standards that we've looked at as far as a product is concerned. So where we are now: SCBA certifications, full facepiece air purifying respirators, and escape respirators in the early concept stages. But where are we going? (pause) If you look at the tentative timeline that we've laid out for our standards development effort, and I need to preface this by saying anybody who works through project times and program plans knows that these types of plans are under continuous scrutiny and continuous massaging and management, but the program plans and timelines that we've identified for the various classes of respirators are as illustrated in the slide. The gas mask or full facepiece air purifying respirator is the standard that we're here to talk about today, and our timeline calls for a near final version of that standard in the Fall of this year, October/November, and final implementation and certification beginning early next year, so March 2003. The next set, standard or the next respirator class that we identified to work on was the escape set. And we can see that it is identified in the timeline and our objective with the escape set is to try to bring that development effort along to the point where in the March 2003 timeframe we are talking about a mature version of a standard for escape respirators. Immediately following and probably overlapping a little bit with the escape respirators will be the powered air purifying respirators. In 2003, those will be the primary focus from a purely development point of view. Implementation will also include the air purifying respirator, but development efforts will be focused on escape and powered air purifying. When we go beyond that, we

look at the combination open circuit self-contained breathing apparatus in combination with an air purifying respirator and the closed circuit SCBA for CBRN applications to be addressed in the 2004 timeframe. Beyond that, we look at the escape, self-contained escape sets and the supplied air respirators and the requirements that they may entail for CBRN applications. I think that as we continue to work and develop the standards, we obviously will be factoring in information and priorities can change from day to day, but one of the big areas I think that will probably come under scrutiny is the self-contained escape sets. (pause) So with that type of a timeline and a game plan of where we've been and where we are and where we're going, a natural question is, "How are we doing that, what is the process that we use to develop our standards?" and a lot of you have heard this explanation before and it's still the same explanation, so I'll go through it. But basically, our standards development program really evolves and develops around eight different areas. The first one is the definition and the focus on the hazards. When we look at the hazards we need to be concerned about what hazards we need to deal with, so obviously identification of what those possible terrorist threats are or hazards to be encountered need to be identified. But the second part of that equation is to try to figure, well, how much of it do we need to contend with? And, for different classes of respirators, we have different levels of hazards I think that need to be addressed. So the hazard analysis is really one of the leading areas that needs to be developed and addressed in preparing a standard. The secondary is the area of protection technology. And

when you think about protection technology we're talking about, again, two avenues. The first one is the type of breathing protection or respiratory protection technology required to provide the desired protection. Open circuit self-contained breathing apparatus certainly have their own technology as compared to an air purifying respirator. So the type of technology and even the technology within those classes for the different respirators I think becomes important and we need to be able to match those technologies and the respirator performance technologies with the hazards that we need to deal with. But the second part of it is how well do we need to do that? How well do we need to provide that protection and here we really look at the concept of breakthrough. If we're in a hazardous area then what is the acceptable level of breakthrough that can penetrate or leak or permeate into the system, into the respiratory system and still be safe for the emergency responder or the worker who's using the respirator? So, protection technology, we look at the two avenues: the technology for respiration, for the respirator; and the level of protection required. Then in addition to all that, we need to be aware, and cognizant of, and familiar with the human factors and environmental considerations. With a respirator everybody knows that the human factors are an important element because it's a device that's worn on the body. It's the interface that a person uses to protect them from the ambient, from the hazards. They have to be carried, so the human elements concerning how something is best carried, comfort, and so forth, need to be addressed in identifying a standard for respiratory protection. Environmental factors. Not

all respirators throughout their life hang on a wall. Respirators can be carried around in automobiles, in the trunk of an automobile, on a fire truck; can be stored in an office desk; can be in a laboratory. So the environmental conditions that the respirator sees can be pretty extreme, so when we develop our standard, we need to be aware of how that system, how that respiratory system is actually going to be deployed throughout its life. Where's it going to go and how's it going to get there? (pause) So, we do our hazard work, we do our protection technology work, our human factors, our environmental factors and we start to focus on a concept for our standard. And the concept in its early stages can be pretty vague, but it starts to identify what the thinking is and the way we think that the standard needs to address the hazards, the protection, and some of the human factors and environmental considerations. If you take a look at our escape respirator concept paper, you can see that it's in its early stages because we just basically started to identify what our approach is to addressing the wide range of hazards that are possible as well as considerations that need to be addressed for human factors in environmental conditions. But it's an evolving process. So the concept is defined and the concept continues to evolve as we do more research and more work, more development work, talk to more people, and provide more clarity to the topic at hand. So the concept continues to evolve to the point that we actually start to identify the standard and the respirator in terms of requirements. What are the requirements that really will govern what that respirator is? Identify the performance that the respirator needs to meet. As we

develop those requirements, then obviously we need to establish a means, a mechanism, a way to verify that the respirator will actually comply with them. So we develop the test procedures and we actually go through the process of performing the test. We actually push the buttons and put them on the tables and run the gas lifes and so forth so that we actually know that, yes, this is the requirement and indeed we can perform that requirement that way to validate that the performance level is in that respirator. So we develop the test procedures and validate the process for performing the test. Then in addition to that, as everybody, I'm sure is, aware of, the quality assurance aspects become important. Because if we've really identified a good standard and we've built good requirements to design that respirator, then we need to have some insurance or some assurance, that when it's produced a year from now that it is still maintaining the level of performance to meet the requirements that were identified so the quality assurance provisions become important to the standard development as well. And in the CBRN area, there are peculiar quality assurance provisions that need to be addressed for the respirator. And then, finally, the process that we've just described is done in a pretty much open review. And I think this is where we really benefit in creating a good standard, because we really do try to listen and to benefit from the experiences of everybody involved in the program. Everybody involved in the program and interested in the program. So we really try to create an environment and the buzzwords that I use are, we try to do it in a glass house. So that anybody who is interested in following the development can do that. We posted the

concept papers on our website so they have easy access to anybody who wants to follow and maintain awareness of the standards development effort. So we do that process in an open environment. (pause) So those are the eight areas that we typically look at in developing the standard, but then in addition to all that, you really need to have some degree of program management to make sure that we are, indeed, moving ahead and accomplishing the things that we want to do and in a reasonable timeframe. So obviously the program management for CBRN respirator development involves identification of our major milestones, and our timelines. Okay? And then moving the project and managing the project to ensure that we are staying on or near on track. (pause) Another really important element ties into the open review process and that is the stakeholder meetings and discussion we have with various groups and people who are in the audience and others who've not been able to attend. But again the stakeholder meetings and discussions are valuable and do create a better product for us. (pause) And throughout the whole process when we look at defining requirements, okay, I'm sure everybody who's been involved in some standard-setting process or requirements identification process recognized that with most products, and respirators are no exception, you typically have two types of requirements. Your requirements come from two areas: they're either performance-based or they're design-based. Naturally, the preferred method and the preferred way to develop and build a standard is around performance issues, performance criteria. Okay. Then, it becomes a good yardstick to measure the respirator. It creates freedom of design and it

allows new technologies to be introduced to improve the methods by which the requirements can be met, so performance is the preferred way to go. But, what we find is that design requirements are almost inevitable. Particularly when I think you start to look at products and standards and respirators that are designed for perhaps a more well-defined segment of the population. So I think it's inevitable, and it's very difficult to have a standard that is totally void of design requirements and I think we just get to the point where we need to have certain design requirements to ensure the integrity of the product and to account for the user needs. And again, I think the more narrow that segment, the more well-defined the user, the more sensitive we can become to the user needs. (pause) All that said, I think the other underlying principle that we try to maintain and to enforce in the process of developing the standard, is we try to maintain a consistent basis of applying science and technology and experience, real world experience, to identifying the respirator requirements so we try to be logical and consistent in what we do, as I'm sure everybody in the room who has participated in, again standards development, or in any type of program, the consistency is sometimes tough to do. Nevertheless, I think if you look at some of the efforts that have taken place there is a consistent theme and a consistent undercurrent to what has been done. And, again, we look to the engineering, sound engineering principles and scientific principles in defining those requirements. The consequence of this type of approach is that, yeah, you might stretch technology. Okay? If we design good performance requirements, then we not only stretch it, but we encourage the

opportunity to stretch the technology because that way we improve the state of the respirator world. A consequence of stretching technology is that maybe not all existing products will meet the requirements as they're defined, but that's a fact of life. If we create the opportunity to introduce new technology and if we stretch the envelope then maybe not everything out there is going to be at that same level. But with, in all that, with stretching the technology, and an awareness of what the existing area of respirator technologies are, okay, we still need to be operating within state of the art because it doesn't do us a whole lot of good if we have a standard that is five years out in the technology area. So, in our standards development process we need to be going through out benchmark testing, our survey testing, baseline testing, just about any kind of testing you can think of, to ensure that we have a good understanding of what state of the art technology is, so that our product, so that our standard can actually be met by product and actually produce a worker benefit. (pause) Some of the redundancies in the terminology that you will hear, probably more often than you would care to over the next day and a half, will focus on the three tier approval. Our SCBA standard that we released in December actually started that effort. That standard does consist of three tiers of approval requirements, performance requirements, and design requirements. Those three tiers for the SCBA are 42 CFR compliance, compliance with NFPA 1981 standard for open circuit self-contained breathing apparatus, and then as the third leg of the approval, requirements that are designed specifically to address CBRN environments and CBRN requirements. (pause)

And, in doing that, the standard was developed trying to maintain a level of consistency and a logical approach and application of scientific and engineering principles throughout the hazard modeling; safety factor analysis for the various requirements that were established; and again, trying to maintain state of the art technology. (pause) Those of you who are familiar with our air purifying respirator standard and the current state of it will also recognize that it is taking the form of a three tier approval. A little bit different than the SCBA for sure, but nevertheless we bracket the requirements into three different categories. Again, we have the base 42 CFR. So many of the requirements from 42 CFR from a programmatic point of view as well as a respirator point of view are applicable to the air purifying respirator. (pause) Then we have a second group of requirements that is derived from existing requirements. So, we try to be aware of other standards that are used in the field of respirator protection and in technology in general to be aware that if somebody's already done something, then we don't necessarily have to re-invent the wheel. Okay. So, we have a group of standards or a group of requirements in our standard that are based on existing standards, existing norms for respirators and for testing procedures. And then finally we have the third requirement or the third leg, third tier of the approval, or the, of the proposed standard, that would be the new requirements for CBRN applications. And again, the requirements and the challenge for the standard development is to try to maintain that logical, consistent engineering and scientific approach in identifying test challenges and concentrations, that will

provide respiratory protection in a traditional, less than IDLH use for the product; okay, some awareness to the safety factors when we do this; what are the margins of safety that are built into the requirements; and then, lastly, are we really talking within state of the art technology? Okay. Is what we're defining capable of being produced, so that the emergency responder will have a product to use in a short time? (pause) So to look a little bit and to start the discussions relative to our air purifying respirator program, I think it's good and as probably any program manager would tell you, when you start a program or any effort it's good to have a goal and to know what the goal is. That way you can have universal buy-in to it from your team. So, the saying is, that if you don't know where you're going, any road will take you there, so I think it's really important that we know what our goal is for the product. And for our air purifying respirator, you see what the goal of the program was, and that is basically to develop the full facepiece air purifying respirator standard for protection against possible terrorist hazards and threats using a minimum number of filters for emergency responders. So the goal really sets the tone for what that program is. It identified the objectives that we really wanted to try to meet. (pause) In responding to that goal and in developing the program, we had to be aware, we knew who our user was. We know who the recipient of the product that's produced from our standard is. It's the emergency responder community. So we have an opportunity to really hear and listen to what that user is requesting and what their needs are for this product because they're the guys that are going to be using it. And for the air

purifying respirator, we do hear that voice, and that voice is telling us that we have these strong interests. One is for the multi-hazard protection. They wanted to have the ability to have multi-gas and vapor protection from a single filter as opposed to going into an area where they have a trunkful of filters and trying to decide which one is required. Another requirement is that the respirator be used in a non-IDLH environment. So we're talking about traditional use, traditional interpretations of how an air purifying respirator should be used, but at the same time, we recognize that there can be secondary occurrences whenever we're working in a non-IDLH area. There can be hidden hazards. There can be trapped hazards. So we needed to have the ability to do something in the way of contingency protection, so while the user is working ideally in the IDLH area, less than IDLH, we needed to have protections in the standard that would actually exceed those levels. (pause) Another area is the physiological requirement for an increased flow. I think during the course of the discussions today and tomorrow we're going to hear user input and other experts speaking about the physiological demands that may be experienced while using a respirator. And they're real. Okay. Typically, when a person is working at a hard rate, everybody knows the ventilation rate increases. So, one of the things that we needed to be cognizant of and aware, in developing our standard is to take a step in that direction, to actually look at what performance is and what performance is required at a higher ventilation rate. (pause) Another really strong area of user input and really was identified as far back as the workshop in 1999 is that personal

protective equipment and in particular, respirators, need to be tested against live chemical warfare agents. The user is telling us they need to go into these environments and they need to know that the equipment has been tested to some degree against the expected hazards. So, the need for live chemical warfare agent testing is a strong signal and a strong interest coming from the user group. And then finally is the concept of interoperability. Interoperability, as most of you I'm sure are aware, was an issue that was vividly identified in the incidents at the World Trade Center. So our emergency responder community is telling us that this is a real genuine requirement that needs to be addressed. (pause) So we have five strong items, issues, identified by our emergency responders that need to be factored into our air purifying respirator. And again, and this is the transition to hand it over to Jon, we get back to our three tier approach. So the standard that we're developing has really taken the form of the three tiers of approval requirement. Again, its 42 CFR, requirements based on existing standards, and then finally requirements that are designed specifically for these applications. And with that, I'll turn it over to Mr. Szalajda.

Jon Szalajda: While we're finding the next set of slides, during the introduction of our panel there's one name that slipped through the cracks, and for whatever reason he's very good at slipping through the cracks at time, but actually Terry Thornton (?) who's manning our projector right now is a chemist within our organization. We're very fortunate to have him. He has a very broad background and expertise. He started out as an NBC NCO in the Army for

more years than he'd like to acknowledge and he's moved into other aspects of chemistry, both working in the crime lab and working for PRL before NIOSH/NPPTL was lucky enough to bring him on board. (pause) And, as Les said, this is going to be the continuing theme over the next day and a half. One of the things that we'd like to try to accomplish today is to review the status of the standards development in each of these three areas as we go along, and as Rich had mentioned earlier, what we're going to try to do is strategically place some breaks during our presentations to allow the opportunity for you to provide feedback or ask questions or express your opinions on the concepts that we're discussing. (pause) What I'd like to cover, I guess, over the next forty minutes or so addresses some of the special considerations, the special tests that we envisioned as requirements for the CBRN air purifying respirator. (pause) But I think what we need to do is go back and revisit some of the history associated with the CBRN program and how we went about determining the hazards and the selection of the hazards and the analysis of those components as far as what we saw as respiratory threats. The selection of the test challenge agents initially was conducted as a comprehensive review of available technical data and we also consulted with several other government agencies such as the Department of Defense, Department of Justice, Department of Energy, National Institutes of Standards, and I could go on with the alphabet soup, but where we ended up was that we identified various chemical data lists including lists from the EPA, from within Centers for Disease Control. We looked at the National Fire Protection Standard 1994

for the chemicals that were used as test representative challenges in that document. Another one, we went to the Army and looked at the Center for... I know I'll mess this up if I don't look at it, the Health Promotion and Preventative Medicine as a Tech Guide Number 244, we evaluated that. And we also looked into other classified sources available within the government. But basically where we ended up was that this review established a list of toxic industrial chemicals and chemical warfare agents that we viewed as potential candidates for challenge agents. And going on from that, at that point we evaluated these lists in an effort to reduce the number of certification tests necessary for the CBRN standard, and to that end we categorized the potential respiratory hazards into families with representative test agents identified for each family. And this categorization approach was used to relate the test representative agents to the sorbents required to remove the chemicals from the breathing zone of the respirator. And, we broke these respirable chemicals down into classes of organic vapors and hydrocarbons, acid gasses, basic gasses, special families where chemicals like formaldehyde that require a special impregnate on the carbon to remove the contaminant and unknown chemicals, you know, things that required further study, whether they were relatively new or things where there wasn't a lot of physical property data associated with the chemistry, and also with particulates. (pause) And in developing our test representative agents, we selected physical properties of the chemicals as the means of classification. We considered a number of properties including things like molecular weight, boiling point, vapor

pressure, relatively toxicity and polar/non-polar characteristics. And we believe that the vapor pressure was the single best indicator of the ability to be absorbed on activated carbon. And one of the benefits of using this approach was that vapor pressure data for most compounds is either readily available through literature or you can determine it in the laboratory. Along with that, the lower the vapor pressure, the greater the affinity for an organic vapor or hydrocarbon to bond to the activated carbon and the higher the vapor pressure the lesser the affinity to bond to carbon. Part of our effort we also reviewed the current carbon technology used in canisters and cartridges from existing certification standards. This included looking at European standards as well as the NIOSH requirements. We also evaluated the military purchase specification for the ASCN Teta (?) carbon. What we intended on doing and what we did with this data is that we identified the most common parameters from the review of the military specifications and the certification standard into a middle range challenge area. (pause) I'm sorry, Terry, go back up on that point. I wanted at least a little bit of detail about some of the challenge agents that we looked at Cyclohexane as being the representative chemical for organic vapors. One of the reasons for this was that Cyclohexane was accepted as an organic vapor test representative agent by other standard generating organizations like the Europeans and the Japanese. One of the other aspects associated with that is that, and we'll get into some of the data later in the presentation today, that meeting the organic vapor test for Cyclohexane would provide for protection against organic vapors that had

vapor pressures less than Cyclohexane. For as far as the acid gasses goes, we're covering these through the testing of the Cyanogens Chloride, Hydrogen Cyanide, Hydrogen Sulfide, and Sulphur Dioxide. Ammonia represents the base gasses as well as covering some other chemicals. And then we had some special case chemicals which didn't really fall into any specific categories and these included Formaldehyde, Phosgene, Phosphine, and Nitrogen Dioxide. The other aspect along with that when we're addressing particulates as respiral hazards that we evaluated particulate biological agents and particulate radiological and nuclear agents as part of our development process and that we felt that the respiratory hazard posed by radiological and nuclear material results primarily from the dispersion of radioisotope dust particles, not from the radiation itself. The respiratory route of exposure to biological agents may be through the dispersion of either aerosols or droplets and we felt that protection against these particulate matter hazards could be achieved through HEPA materials and the design of the canisters or the cartridges. And we believe that the P100 filter requirements are appropriate to address the filtration considerations for these materials. (pause) So where we stand is that 105 of our chemicals that we identified as part of our initial review can be addressed through the testing of the ten chemicals that I just previously discussed. I think one thing of note, when a lot of people heard about the ITF 25 and the other hazard lists that the Army has been working through in other forms, that nine of our ten chemicals are represented in the ITF 25. We're also addressing, and a lot of this information is available in the

concept paper as far as what the biological agents are that we feel the requirements of the standard will protect against, and this list is based on a list that was generated by the Centers for Disease Control, and that's also available through their website. And we've also provided in the concept paper the list of the radiological and nuclear agents that we believe will be protected, that we'll provide protection as part of the CBRN APR. (pause) This is, you're probably saying, "What's this thing?" (laughter) and sometimes we'd like to know as well. Actually, this is sort of a teaser to keep your interest for later on in the presentation. This is basically information that we shared at the June public meeting and also this chart is available on our website if you go through, there's a link to the public meeting from June, which includes all the presentations that were provided at that time. I think in contrast to the particulate filters that I was just talking about and which are effective no matter what the particulate, the cartridges and canisters used for vapor and gas removal are designed for protection against specific contaminants and to address that, what we did is we tried to determine test challenges by a calculation through comparing the higher of the safety factor multiplier on the permissible, or on the REL on the permissible exposure limit or three times the IDLH. In instances where the values were other than the higher REL or the IDLH will lose, then we used the selection of an alternative value based on test technology limitations or on test values established by OSHA guidance. The challenge concentration, I think the one thing that sticks out in looking at it when you look at Cyclohexane, the logic for picking the Cyclohexane

would fall into line with either using the safety factor on the REL or the safety factor on the IDLH, but 30,000 did not seem to be a representative test requirement so we selected the three times the IDLH value for Cyclohexane. I guess a couple other benefits with Cyclohexane and I think I touched on this earlier, is that we'd also considered use of Carbon Tetrachloride as the organic vapor test representative agent, but there are some issues associated with Carbon Tetrachloride and we felt that in the Cyclohexane, given that its being adopted by other standardizations worldwide provided an acceptable alternative to the use of Carbon Tet. Also, in addressing the breakthrough that we originally, our concept was to set the breakthrough concentrations at 50% of the REL. And at least at this point we've gone through several iterations of benchmark testing associated with the filters and their performance against these agents and different scenarios as part of reviewing that data we'll cover that a little bit later today. (pause) At least at this point we felt that a little more history was required especially when considering how the SCBA standard was done and the approach that we're taking with the APR, but at least in terms of, we felt there's a need, and this is also in response to feedback from the user community that there's a need for systems testing of the APR for penetration and permeation and through that we felt there was a need to evaluate these materials against chemical warfare agents. Again, one of our stakeholder recommendations from a previous public meeting was to consider using the chemical warfare challenge chemicals identified in the NFPA 1991, and we've gone ahead, for those of you who aren't familiar with

the 1994 standard, there's a... the NFPA identified nine chemicals which include four chemical warfare agents as part of that standard. We considered the characteristics associated with the requirements that were identified in the NFPA standard and we made a determination that for our evaluation that Sarin which is GB, and Sulphur Mustard which is HD would be appropriate test representative agents for the penetration and permeation tests. GB, I guess, is representative of our nerve agents because it's the most volatile of the traditional chemical warfare agents. It also has a low molecular weight and the molecular configuration of the material is such that it penetrates more readily through material than the other nerve agents. Part of our considerations as well was whether or not we should have a liquid and a vapor challenge for GB. But we felt that doing a GB test wouldn't, a liquid GB test wouldn't be practical because of the volatility of the compound, that it would evaporate very quickly and it would be difficult to maintain the liquid challenge on the respirator. HD was selected because of its permeation characteristics. It's a linear molecule and is expected to permeate through faster than the nerve agents. We're also, with the HD test, we're using a combination of a liquid vapor challenge where liquid droplets of HD are placed on selected areas of the respirator and as the vapor challenge of HD is introduced in the test chamber, the liquid tests the permeation but also indicates if the integrity of the materials is able to withstand the persistent chemical effects of HD. And then the addition of the vapor challenge of HD as well tests the permeation of the materials. And one of the things that we're going to address tomorrow for

those of you who aren't familiar with how the testing is done, is that we'll have a sub-panel demonstration in the back corner that Ray Linz (?) who up here in the front row—raise your hand, Ray—runs the lab at the SBCCOM where, they are NIOSH's test agent for conducting this test. He and Terry Cloonan who have worked extensively with the SCBA program in setting up the test facility to run the SCBA certification program, have put together a video to demonstrate what they're capabilities are and how the test is conducted. (pause) So, now that we agreed on, as part of our initial work, we agreed on what the test agents were going to be, the next step was to determine what the test concentrations associated with those chemicals should be. And what we did was that we developed in conjunction with SBCCOM, we developed plausible incident scenarios that considered multiple venues in things like a small conference room, a room this size, an arena, airport concourses, as well as dissemination devices, you know, how a terrorist could deploy a chemical warfare agent. We identified those part of the development of the incident scenarios is that the magnitude of these hazards was really dependent on the dissemination method, the quantity of the material that was going to be disseminated, the incident site, the conditions... the environmental conditions associated with the different scenarios. It wasn't a very clear and cut decision as far as how the hazards could be quantified. We saw that each scenario was unique and demonstrated a wide variation in the concentration profiles that could be identified. So, what we did as part of that evaluation is that we considered things like worst case scenarios, saturate... you know

where the environment was saturated, concentrations that the Defense Department uses for testing military masks, as well as concentrations that were used by the Army in conducting domestic preparedness evaluations. (pause) I think one of the things that, at least in evaluating those aspects, you know selecting worst case option for a test standard is an extreme approach. You know the saturation vapor pressure of a volatile liquid represents the highest concentration of molecules that can be sustained and these conditions can rarely be generated by normal dissemination methods. So we felt that saturation vapor pressure for a chemical warfare agent would be an unrealistically high challenge level. Similarly, generating consistently high concentration levels below saturation are challenge for both deployment and evaluation characteristics. So we thought, okay we'll look at the other aspects of the set of data that we had to look at. And then we looked at the next step was to look at the defense department military mask concentrations as part of the domestic preparedness program and we felt, at least in doing the evaluation at the military mask concentrations were not appropriate because their operational scenario that the masks were designed to were indicative of outdoor operations, which are both environmentally challenging for the deployment of the chemical warfare agent as well as resulting in lower exposure to the individual. And then we looked at the domestic preparedness concentration standards and after review that these concentration values were essentially arbitrarily set and really aren't indicative of what could be a credible event. So where we ended up working with SBCCOM we developed,

or SBCCOM developed a model called INDVAP (?) which enabled us to model various scenarios for determining the concentrations associated with potential chemical CW incident, along with that, these scenarios, what we called at the time,

(End Tape 1, Side A)

(Tape 1, Side B)

Jon Szalajda: ...and along with that we looked at the concentration profiles associated with each of the scenarios and with the assumption that the first 30 minutes of the environment are probably where the concentrations are the highest and they drop off because of environmental weathering or ventilation or other factors and where we ended up with, make the long story short, with the SCBA values that we determined that our most credible events for GB was... indicated 2000 milligrams per meter cubed vapor challenge as well as a 300 milligram meters cubed vapor challenge for Sulphur Mustard. (pause) So what does that mean in context of air purifying respirators? Well, that's an excellent question. And we've been working on what that aspect has to do with determining the concentration associated for certification challenge to a respirator that could be developed. And some of the factors in looking, you know in trying to do a comparison with the SCBA that, the life, the use time of the SCBA is fairly well regulated, that given the size and the capacity of the bottle. You know, with the APR, we've gotten different views on how long an APR could be used. Preferred shift is, could be six hours, a shift could be eight hours, 12 hours, but we settled on the selection of 12 hours as probably

the longest shift that a responder would be operating in a potentially hazardous environment. (pause) The other aspect that we were trying to come to grasps with, in addition to setting the concentrations is what's an appropriate breakthrough associated with the chemicals and what we've done is we've looked to requirements that were set by the Army which are called eagle values for the selection of a breakthrough. The eagle value that was chosen for the SCBA was considered or is what is known as a 10 minute eagle. But we felt that maybe the direct application of this eagle wasn't appropriate for the APR. (pause) So, given the uncertainty in not being able to directly use the modeling that was conducted in support of the SCBA not really being able to use either the domestic preparedness guidance or the military mask concentrations that were developed as part of their standard, we decided to calculate the potential challenge that could be used. In determining the systems test challenge concentration, we went back to assuming a single shift operation and an eagle value, assuming that the single shift was 12 hours and using the eagle value that we used for the SCBA as a conservative number. The acceptable, and I guess we'll cover the discussion of the eagles a little bit later in our presentation, but the eagles were developed by the EPA for single or twice in a lifetime exposure of the general population. And the most conservative exposure limits available may be selected for the breakthrough concentration for purposes of establishing the gas life. So what we did was, in trying to, go ahead, let's go to the next one Terry... in trying to determine a concentration for GB, we tried to determine a dosage based on the

eagle value as well as in combination with the shift and the introduction of a safety factor associated with the use of the APR and the calculation indicated that 210 milligrams per meter cubed could be a challenge concentration used. (pause) And then similarly for HD, we used the same computation. However, and our logic kind of failed here, was that the calculated challenge scenarios using these conditions approached the saturation conditions for Sulphur Mustard, and it's definitely beyond the use we felt for the, the capability and the use scenario for an APR. So therefore, what we did was we went back and looked at the most credible event and used that concentration as a potential test challenge. (pause) And part of, Terry could we jump back for one minute please? And part of considering the use of the APR in one shift we felt that we would challenge the respirator initially for a 30 minute interval and then run the test for 12 hours to observe the performance of the respirator against the penetration and permeation effects over that period with the 30 minutes of exposure to vapor and then watch the decay of the agent over the timeframe. (pause) And along with that we're using the liquid challenges that we had earlier identified with the SCBA and they would be applied in that range that the lesser amount is associated with if you were to subject a respirator and a filter against a challenge as you started adding accessories whether if you went with a chest mounted or a belt mounted system where you would have a hose and perhaps a canister carrier, a filter carrier, then an additional amount of liquid agent would be applied. (pause) This is a... this gets into a rather busy chart, but one of the things that we were looking at in terms of trying to

identify the breakthrough as far as what could be a representative value based on the capacity of the respirator and one of the things that we wanted to consider in light of the design of the respirator for interoperability was to look at a worst case scenario where if we had two systems that had received CBRN approval and assuming that manufacturer A had a perfect, assuming that one manufacturer had a perfect facepiece and a less than perfect filter, but it still met the requirement that all the penetration was done through the filter element and the other manufacturer had a less than perfect facepiece where all the permeation came through the facepiece and nothing came through the filter. What would happen, what would be the scenario if, in an interoperability or in a situation where the emergency authority had made a determination that interoperability could be pursued, and if we had those two systems, what would be the worst exposure that the respirator could wear. (pause) And I'm very proud of this picture, because I'm not very good at computer graphics, but I tried to generate this to depict that scenario, you know, assuming that you would get the maximum peak breakthrough from one or the other component and so what we did simply when you go back to the equation is that, the next one Terry. Other way. (pause) We assumed that the breakthrough value from using the eagle value that we had determined for the SCBA program, by assuming that you can get penetration through either component, to safe side it for the wearer we cut that value in half and then set the peaks associated with half of the values that were set for the SCBA. (pause) And these numbers you'll find are in the concept papers as well.

(pause) I think for either case when looking at the scenario that the cumulative CT, including the peak values, can't be exceeded over the 12 hour test period. Additionally, the way the standard is set up that three consecutive test failures or peaks at the values indicated would also constitute a failure as part of the testing. (pause) The last area that I wanted to cover, at least initially, and then we'll open it up for, this is I know a lot of information for people to digest, but in keeping with the format, what we're going to try to do is break up the discussion into a couple areas and then we'll open it up for questions at this point and then discuss the benchmark testing and then we'll open it up for review after the benchmark testing is conducted, er has been reviewed. But one of the things that our team felt was, that there's really a need for a test to determine or for a laboratory respirator protection level performance test, we felt that what we did was we merged the best characteristics of what the military does as part of their mask program as well as the procedures that NIOSH has incorporated in conducting evaluations within our facilities. The some of the reasons for doing LRPLs include that the test... with the face seal the respirator is really a key to the protection of the individual while wearing the system, with the SCBA the system was over pressurized to the extent that if you did not have a perfect seal to the individuals face with, by having this supplied air, it provided enhanced capability or enhanced protection for the wearer. In the APR, the seal is a line of defense against the challenge agent. (pause) I think along with that in the selection of the 2000 values is associated with the safety factors that we've been trying to address as part of the

determination of the challenges in the standard. I think most of you are familiar with the traditional NIOSH APF of 50 is determined based on an aerosol challenge of 500. In applying a safety factor to that, we felt that 2000, a safety factor 4 is consistent with other safety factors that we're applying elsewhere throughout the development of the standard. I think one of the interesting aspects associated with that APF is that one of the comments that we received in the June public meeting when we were considering an LRPL measured protection of 1000 was that, "Is that high enough? Perhaps it should be higher." And in looking at some of the other standards in particular, I guess the European standards have a higher, use a higher protection factor value, measured protection factor value in some applications, as well as the capabilities of masks that the military has developed over the past several years that we've seen that those types of systems can meet this type of challenge. (pause) So at that point, what I'd like to do is to facilitate a discussion with our panel if you have any questions related to the information that you've just seen. And what we'd like to do at this time is at least open it up for questions on this data and then, if we're close to 2:30, I guess after the questions we'll take a short break and resume with the benchmark studies that we've conducted. So, if you have any questions there's a microphone over on that side of the room as well as here in the center. If you remember the ground rules, if you can just identify yourself and your organization and ask your question we'll try to address it at this time.

Jack Zuicki: Zuicki from GM at Versar (?). We've been doing some emergency response to anthrax contaminated areas over the last year that required long mission durations up to 12 hours, some of them in rather extreme conditions... the desert, the former Soviet Union, and other places like that, as well as buildings. One of the things we've noticed in using APRs, first of all the requirement from CDC that PAPRs be the standard rather than a negative flow or whatever you want to call how to distinguish the characteristic, when you calculate the protection factor of the non-powered versus a powered APR, again that's looking forward to what you're going to be doing in next year's thing, but the statement you just made about the fit being the critical factor, could you comment on how that logic would work through as you might develop from the non-powered to the powered system?

M (speaker): Don't everybody jump up at once (laughter).

Jon Szaladja (?): I guess I don't fully understand the question.

Jack Zuicki: Let me try to be more specific, I guess. For whatever reason, the CDC came down and said, "Don't use a gas mask, use a PAPR for anthrax response." It's unclear to me how they made that decision based on a protection factor really being the same for both systems and based almost entirely on the fit of the mask, in my opinion, when you're establishing your rationale for what a protection factor should be, one of the comments I made previously was, you should allow the manufacturer to advertise and you should make a determination of the actual protection factor that a mask provides on a minimum based on what users actually are measured. It seems like you're

going to a standard of it should be a certain value based on a sort of an overall permeation test. I'm trying to see how you're sort of matching the permeation test characteristics to the defined or the AP, or the assigned protection factor, you know, so what's your logic in terms of how that would be related, I guess?

Rich Metzler: I think the approach can best be explained just by referring back to Jon's discussion in that we are trying to maintain that, some sense of logic and consistency in how we apply the various safety factors that are appropriate to making those calculations, and taking it a step further, we haven't looked at what that next class of respirator may be or how it may be addressed at this point.

Jack Zuicki: But is there a way, I guess I'm asking, in your calculations to provide the manufacturers with an incentive to make a higher protection factor if that would gain them something in other area and also let them advertise in some manner that they have a higher protection factor as a desirable characteristic for the users?

Rich Metzler: Yeah, I'm familiar with the comment and was familiar with the concept to move in that direction. One of the competing things that we may have there is we want to try at the same time to keep the actual use and deployment and implementation of things as simple as possible. So rather than have some sort of a rating based on mask fit characteristics, obviously we opted in lieu of, a of, you know of setting a standard, setting a definite requirement for it.

Jack Zuicki: And so you're still targeting 50 in terms of a fit factor, but when you test it with the agent you're...

Rich Metzler: Yeah.

Jack Zuicki: Still looking for the higher...

Rich Metzler: Yeah, that's right.

Jack Zuicki: Number?

Rich Metzler: And one of the driving forces there is that we do, and we identified a little earlier, that one of the requirements is that while we recognized that the intended use for the respirator is in an IDLH/less than IDLH environment, we do want to provide, we do want to have built-in contingency protection capability. The, if you would, the safety factor or the multiplier that we've pretty much identified for that contingency-type protector is a factor of three or four. So even as far as establishing the test concentrations, the challenge concentrations for the toxic materials, we've applied that same type of safety factor consideration.

Jack Zuicki: I guess what I'm concerned about is that you may be putting an artificial, um something artificial into the mix there by, if you measure some kind of a protection factor on the SMARTMAN with live agent, which is based on both some kind of a fit to the SMARTMAN head form, which has problems based on a lot of different kinds of masks fitting, it sort of penalizes somebody that might get a 10,000 on a human test and you're balancing...

Rich Metzler: Yeah, maybe, to clarify, this test, the LRPL test is, it is a human test. It's not established on a SMARTMAN.

Jack Zuicki: Then you're taking the number for the permeation, you're going to base that on a SMARTMAN test?

Rich Metzler: Yes, that's correct.

Jon Szaladja (?): Yeah, the penetration permeation test is a systems test, you know, against to evaluate the materials and the respirator against GB and HD...

Jack Zuicki: Right. What I'm wondering is if you're confounding the fit with the permeation in that system as opposed to the high protection factor you might get on a human. You might have something that fits very well on a human, doesn't fit the SMARTMAN so well because it's an unyielding surface.

Jon Szalajda: I think one of the things that Ray and Terry will probably cover tomorrow as part of their presentation are some of the mechanical means I guess that are built into the test protocol, which can be used to ensure that the respirator is seated, I guess for lack of a better term, seated well against the head form, because we're not really trying to evaluate the seal of the respirator and the head form of the SMARTMAN with that test, we're trying to evaluate the penetration and permeation effects of the chemical warfare agents against the respirator, and I think probably, I kind of, one of the comments that I've heard recently is with the, you don't see the forest because you're walking amongst the trees, but with the LRPL, in doing that assessment that we are using the Los Alamos panel as far as ensuring the fit of the respirator to the wearers and with the criteria associated with that depending on the type of respirator you have, whether you have one-size facepiece or multiple sizes, it would depend, we would determine from a test procedure how many respirators you would

have to submit as part of your application in order to fill the panels associated from Los Alamos work, and along with that we recognize that you're going to have people like me who don't fall within the panel that are going to be an outlier or you may not necessarily fit in this, so there is some leeway there with what the acceptable percentage is for the standard.

Roland BerryAnn: Yeah, this is Roland BerryAnn from NIOSH, I just wanted to expound a little bit on what Jon said. On the SMARTMAN test, there's, it's, artificial sealing of the facepiece. We can do that to eliminate that face seal leakage. And the other thing on that is that even with the powered air purifying, our current paradigm would be that it would not be used for IDLH so the potential to increase the APFs for those units would be limited by, would still be a non-IDLH intended use.

Tom Holmquist-Brown: I'm Tom Holmquist-Brown from 3M Company and I have a real specific question regarding the challenge concentrations that were shown on your big blue chart. I was one of the people going through with Jon there. But in terms of using three times IDLH to set the challenge concentrations, it occurred to me that, I'll just show by way of example, and if I missed something just correct me and I'll go away, but if we used Cyanogen Chloride as a TRA, Cyanogen Chloride is also on the list of 105 and so using three times IDLH of CK or Cyanogens Chloride, that connects for me. But what I noted was that for Cyclohexane, while it's a terrific indicator of capacity for nerve agent because the capacity for nerve agent is usually far exceeded with a good Cyclohexane result, I noticed that Cyclohexane is, I'm assuming not

on the list of 105, and if we set our challenge level using the three times IDLH for Cyclohexane, there's a disconnect perhaps between that and the resulting capacity for GB and HD which maybe very, very large, like far in excess of what you've done with your good work on the permeation and I ask this only because I know every cubic centimeter of Carbon is precious and if we can use it someplace else that that's handy, and I'm just wondering if that may result in an inflated service life for GB and HD?

Jon Szalajda: I think that part of the answer, Tom, is that the next presentation we're going to get into some of the benchmark studies associated with that as well as a comparison with, testing that we did comparing organic vapors versus GB, and if that doesn't answer you question then maybe we can bring it back up after we're done with the benchmark.

John Cobes: John Cobes (?), MSA. Question related also to the same slide. I understand how the logic proceeded with the establishment of those concentrations, either by an exposure limit or safety factor with the IDLH. My question was then this, that the concentrations that have been recently listed in all the concept papers, what the majority of those don't seem to follow with any of the concentrations listed on that slide and I was curious as to why that was?

Jon Szalajda: I guess kind of simply, with the concentrations that were on our slide, that's a re-presentation of what we showed at the June meeting, and I think when we go through the benchmark presentation next you'll see, you'll know the progression of our thought as far as, you know, where we started earlier this year through the series of testing and then where we are now. I guess, again, if

after you see the next presentation if you have a question, if you still have the same question you can come back up.

Jay Parker: Yes, Jay Parker with Bullard. Back to that same subject. The slide said the test concentration was 30,000 PPM but I thought I heard you say that we're going to go with 3900, so I just wanted to verify what the right...

Jon Szalajda: Right. It's 3900.

Jay Parker: Okay, so the slide was incorrect?

Jon Szalajda: No, the...

M (speaker): (...inaudible...)

Jon Szalajda: It's three, I'm sorry it's 3,000 and 3,900. It's 3,900 is what we're going to use.

Jay Parker: The slide did show 30,000 though.

M (speaker): Right.

Jon Szalajda: Okay, well I guess at this point we'll take a break and reconvene in 15, 20 minutes.

(BREAK)

Rich Metzler: Okay, if we could get started, I'd like to start off by just going back to the last discussion and re-address a couple of questions that were raised. The first one was the question concerning the test challenges and the concentrations and the multiples of three times IDLH and why the differences in the test challenge concentrations identified in the concept paper versus three times the IDLH threshold. And the reason is we actually had three criteria that we used in developing the toxic industrial materials test challenges. The first criteria was we based it on a calculation based on the rell, assigned protection factor and

the safety factor to determine what would be an equivalent maximum use type concentration. Then we looked at a three times IDLH concentration and we compared those two numbers, and what we wanted to do was we wanted to go with the larger of them. The reason that we wanted to utilize that logic is that one of the user inputs that we've received is that if you're using the respirator in a traditional sense, in an IDLH, less than IDLH environment, you need to have additional protection capacity in that respirator in the event that you encounter a secondary device, a secondary device or an entrapped pocket of hazard, or if there's just some emergency condition that it suddenly exposes you to a greater than IDLH concentration. So, we are calling that a contingency type provision. So that really drove the requirements to look at a multiple of three times IDLH or a maximum use concentration with the safety factor as a guideline in establishing the test concentrations. But, in addition to all that, what we've been doing is through the process of doing our benchmarks and baseline testing, we've also then made adjustments to those numbers based on testing capabilities and test capacities. So when you look at the challenges that are identified in the concept paper they may be different than three times the IDLH, or the maximum use with a safety factor, but that was the basis for really establishing the initial concentrations. The other factor is that using the three times IDLH or maximum use with safety factor concentration, that concentration then versus the identified breakthrough, which was the REL, 50% of the REL, that established a ration between challenge and breakthrough. So whenever we made changes for testing

reasons to a different challenge concentration, it was typically in the higher direction and we maintained the ration between the three times IDLH and the REL so we tried to maintain that ration in establishing the test concentration versus the detected breakthrough concentration. So that's the first thing, and I think you'll see a little bit more of that in the next presentation and some of the data that's reviewed. Also, the question concerning the relevancy of the Cyclohexane versus the Sarin tests, we have done some tests specifically looking at that particular question and we have a couple of data points that we'll show as part of this presentation because we actually did that. We actually tested it, the filter, with Cyclohexane and then followed it with a Sarin test to ensure that we were getting the protections and the ratios that we needed. So with that, what I'd like to do is offer a presentation on the testing that's been done in developing the air purifying respirator standard. And there's really several different series of tests that fall into this category. And to give you a little perspective of how the testing program flowed, the initial tests we have pretty much called our benchmark tests. And what these were tests that were performed right at the beginning of the program. So as soon as we started to identify a list of hazards that we needed to be addressing, then we wanted to try to get a grasp of what was currently available. What filtration, detection capability, state of the art technology for filter designs was measured against those hazards. So we conducted an initial series of benchmark tests using the identified hazards that Jon mentioned at concentrations that were taken from different standards, from NIOSH standards, European standards,

and some military criteria so they were done at relatively high concentration levels. The value in doing that set of tests was it gave us a really good picture for what the capabilities were for off the shelf product to meet the types of test requirements that we were directing our standard towards. So it gave us a good indication of whether we were going down a road that was a safe road to go down, that we could see an endpoint. The second set of tests I call more of a baseline testing, and the baseline testing was done, again, using the same commercial type of filters that we did on our benchmark tests, but they were done in conditions closer to the actual challenge concentrations that we're mentioning in our concept paper. So basically they were a more realistic picture of what we could expect from off the shelf product against our requirements. But it's important to note that the product that was tested and the data that we look at when we get to that point, in fact any of the filter type gas life testing, none of it has been done on filters that have been designed to meet the standard. The tests have been done on filters that were commercially available, filters that we could get and make some strategic decisions on their performance capacity and capability and then actually do the tests. So with that, maybe we can start to go through the benchmark study. So for the first set of testing, which really helped us gauge the possibilities we basically focused on what we called first responder multi-gas canisters. Okay? Just by coincidence all these filters did use a 40 millimeter thread which really has no relevance to the test results, but basically they had that because they were first responder type filters. And they all used the P100 filters, so as far as the media

and the particulate capability they did have P100 or equivalent, since some of the filters were not domestic. This is the illustration that Jon had on the screen a little earlier, and what this does is, this shows how we initially took a cut at a identifying what our test challenges and concentrations should be. And basically, we had an empirical expression where we took the REL, multiplied it by the full facepiece assigned protection factor, and then assigned a safety factor to that to come up with what might be a maximum use type concentration for the hazards that we were looking at. But then we also wanted to do sort of a double check on that, so in order to make sure that when we talk about contingency capability and contingency protections, that we had some multiple of what the IDLH concentration for those hazards is. So, over here we see the representative IDLH and the multiple three times the IDLH then our logic was that we would use the larger of the two numbers so in our test concentrations illustrated here, that's principally what we've done. We've compared the two numbers and used the highest one. For the breakthrough concentrations we set those out to be the REL divided by two, and that's the numbers that are illustrated there. Now the other factor, and this is as I mentioned a couple minutes ago, the other factor that entered into the determination then, was the actual testing information that we learned through the process of doing our baseline tests and benchmark tests that sometimes it wasn't always the best case to use those concentrations and best being from a test point of view. So then we opened the door to make the allowances to make adjustments if they were on the increasing side, but always maintaining

the ratio between the challenge and the original breakthrough which was 50% of the REL. This column here basically illustrates the results of that analysis and the big example there is the Cyclohexane. The Cyclohexane, the maximum, the larger number viewing, doing the two calculations was the 30,000. Yet the three times IDLH was a more realistic number to use as far as testing is concerned. Now the first set of tests we did, the benchmark tests, they were done, they were performed at much higher concentrations so this column here which is labeled "Survey Tests" actually are the test concentrations that were used during our first set of testing to sort of gauge where we were in the technology. And if you compare, you can see, in most cases, the initial tests were done at higher concentrations. This is a little further description of the five different products, filters, that were tested in the first set of tests, the benchmark tests. The five filters, again, were basically readily available so they were product that we could commercially obtain. Another factor involved in the decision in the selection of the filters was the type of carbon and the carbon expert on our team provided the insight into making the determination what representative carbon fills or carbon treatments should be tested. Another significant point is the fill, or the size of the canister which is listed in this column, and then some other parameters relative to the bed design. Primarily the fill is, I think, the big thing to look at as we go through these next slides. The testing, the benchmark testing was all done at 64 liters per minute, temperature 25° C, and humidity conditions, we ran them at two different humidities, 25% and 80% RH. Again, the test

challenges that we wanted to look at during the benchmark tests are the same that we've identified as our test representative agents. Okay, during the course of the program we did focus on Cyclohexane as opposed to Carbon Tetrachloride. This is a chart that illustrates the results of the benchmark tests against each of the hazards, again, tested at the high concentration levels. So, what we're seeing then is basically a product that we obtained off the shelf, tested at what we knew at the time was concentrations, challenges that were greater than what we anticipate the standard would actually be, but it gave us a good indication of what that type of product may perform like in this type of, with these type of hazards. So this particular one is representative of a mask mounted filter that has 178 ml fill volume. Back it up just a moment. The mark here is the 15 minute indicator. So, with each of these we could see that principally we were less than the 15 minutes, which was one of the target service times that we had identified in the early concept for the air purifying respirator. So, with this particular filter, we were getting protections against the hazards, but they were not measuring up to what our minimum criteria was for service time. Okay, this is a second set of tests, again, same hazards, the high concentrations, and again, benchmarked or marked in here with the 15 minutes, and the fill being 248 ml, so it's a little bit larger filter and I'm sure the carbon differences are apparent to, as well. But again, it gave us a good reading that we were getting protections across the boards across the board for the hazards we're targeting. High concentrations, compared to what we were anticipating for our standard. Again, another filter, different type of carbon,

roughly the same fill as the one we just looked at, and again, protection pretty much across the board, and actually meeting and achieving the 15 minute threshold for most of those hazards. Again, same thing, little bit larger filter – 260 ml, again, protections across the board and again, exceeding the 15 minute capacity. And then this is the largest of the filters we mentioned and this is the non-domestic one, 355 mil but we could see that, again, good protections all the way across the board, greater than the minimum target that we had, 15 minutes, and we were getting pretty good representative performance. The results of this type of benchmark testing again told us that we were going down a road where the solutions, I think, could be achieved. We had benchmarked again using filters that were just commercially available and performed the testing and was able to get reasonable results. The illustration here is an illustration depicting what the pressure drop or the resistance through the canister was through the filter and this became important to us when we started to look at the interoperability because when we look at interoperability and the aspect of intermixing masks and filters, then you need to be concerned what you're doing to the overall system performance and breathing resistance is obviously one of those characteristics. So what we wanted to do was we identified our target resistance for the mask, target resistance for the filter and we wanted to gauge where we were falling within that realm. The filter was targeted right at 60 millimeters of water, at 85 liters per minute. And you can see most of the filters were less than that and the one was just slightly above. So again, it added more technical

credence to the direction we were going. So with that information, the benchmark testing under our belt, we started another series of tests which I call the baseline tests. Now the baseline tests, again, we're using three of the same filters that we just tested, but they were tested at the concentrations identified in the concept paper and we'll walk through those. So this is the filter, the 178 ml filter, tested against the hazards we identified at the, at or near the challenge concentrations. We can see at 25% RH, the service times we were getting off this filter ranged anywhere from a half minute up to 172 minutes. So, for quite a few of the hazards we were in a zone that is certainly compatible with our filter. The areas where we recognized some work is the Ammonia and the Nitrogen Dioxide, NO2. Another significant piece of data on this particular chart is that one of the requirements that we identified for the respirator to meet our user needs and user requirements was the need for a higher physiological capability from the respirator. Typically, respirator filters are evaluated at flows of 64 liters per minute under the NIOSH scheme. What we have identified as part of our performance requirements is a test at 100 liters per minute. Now it's a test, not to establish the service life or the capacity of the filter, but basically to ensure that you get some minimum time, 5 minutes, when you have 100 liter per minute constant flow, challenging the filter. The data that's illustrated here indicated that on this particular filter we were able to get good representative data at 100 liters per minute on most of the hazards and challenges that we were looking at. The illustration here is for the larger filter, the 355 ml filter, and again, using the same test challenges

concentrations, at 25% RH we see that we had protections ranging from 0.5 up to 167 minutes. And again, NO2, Sulfur Dioxide being the lowest and the Formaldehyde. But again this is a product not designed to meet the requirements, it's a product that was readily available. Again, looking at the 100 liter per minute or the high panic demand, panic situation, again, we were getting times anywhere from 15 minutes, 13 minutes, up to a hundred and two hundred and forty-some minutes. So, again, stressing that filter with each of the hazards at both our testing conditions and at the 100 liters per minute, we were able to see that there was performance there and that technologies would seem to be in line with what we were doing. Then, on the last one, we have the same type of data for the filter with 250 ml fill, and again, the service times we were getting from the filter at 25% RH varied anywhere from 0.5 up to 119 and at 100 liters per minute, again, we were getting indications that the filter would have the capability to meet the requirement that we had identified. So, with that, with the completion of our baseline data, we had confidence that the technology was available to design a product to comply with the hazards, the test challenges and the breakthrough requirements that we have identified, and to comply with our high physiological demand of 100 liters per minute. The illustration that's on the chart now is just a comparison that we made, again, using the five filters that we had tested during our benchmark test but the results of this and these tests were basically to compare and establish the equivalency between Cyclohexane and Carbon Tetrachloride. So, with this data we saw that we were getting good comparison, pretty much across the

board on all the tests, irrespective of the two challenges. Now to address the concern that was mentioned a little bit earlier relative to the capability to have filtering capacity against GB, when we're testing using an OV of Cyclohexane, we ran the test that's illustrated in front of you, and Mike (...inaudible...) why don't you explain the results of this test.

Mike Monahan: What this test was set up to answer was, a lot of the first responders wanted to know the differences between, you know, why don't we test with GB, and how does it compare with this surrogate that we're looking at? And basically what it says is that the Cyclohexane is much more of a challenging test and if you have protection for Cyclohexane, you'll get the protection you get for Sarin or any of the other war gasses. That's about it.

Rich Metzler (?): Terry?

Terry Cloonan (?):One of the other questions that came up from the, that we were asked about was, with the Cyclohexane or Carbon Tetrachloride how does it, how does the service life compare when you look at a breakthrough of 100,000 to 1, which is what the military uses. So what we did was run tests to compare the two. These tests were run with carbon tet, at the time we didn't have the Cyclohexane in the mix, but there isn't much difference, and what I think it shows is, again, that the Cyclohexane, or our surrogate is a much, much more conservative test than what the Cyclohexane is, I'm sorry than the GB. Yes.

M (audience): (...inaudible...) Sorry, just to clarify, are we seeing the Sarin test that you did at a most credible event concentration, and we're getting about 190 minutes?

Terry Cloonan (?): This is the military concentration, this is what the military uses to test their cartridges. It's essentially 4,000 milligrams per cubic meter.

M (audience): Okay.

Terry Cloonan (?): And since we didn't have anything better to challenge it with we figured that —

M (audience): I just, your emcee noted earlier it was 2,000 and so what I'm wondering is if I do, for an organic vapor, just do the quick math and say it's double that for 2,000 milligrams per meter cubed, so it's like, close to 400 minutes. Is that the kind of service life you want for Sarin, is my question. We've got a number for the 3900 Cyclohexane, does that correlate to the kind of service life you want for most credible event, GB. That's my question.

Terry Cloonan (?): A most credible event, I believe, that's a systems test. We're looking at materials there for permeation and penetration of the actual mechanism, you know, the mask itself. As far as a credible event goes, if the mask is working well, the cartridge all that, will give us very, very adequate protection. It's a very conservative number that we've picked for Cyclohexane. We felt that with all the organics out there in the world that this gives us a little bit more safety factor to put in there, okay?

M (Speaker): Actually, the driver for identifying the challenges for the Cyclohexane or the organic vapors, and the other organic vapors toxic industrial materials that are part of the protections that are provided. As a result of that, it turns out that if you have a good filter for OV, you're basically going to get the GB protection you need. I also don't want to confuse the rest of the audience. We're not *not*

testing against GB. What we're doing is we're testing for service life and capacity of the filter using the test agents that have been identified. Cyclohexane is the intended test representative agent for organic vapors which happens to be sufficient for filtration using GB. The GB exposure requirement comes from our SMARTMAN or systems test where we actually expose the entire respirator to a challenge of the chemical warfare agent. So the respirator or the requirements of the standard are actually two-fold. We have the gas capacity, the service life capacity for the filter, but then a systems test where it's actually exposed to GB and to HD. (pause) This is a data, piece of information that we ran, actually pertaining to our high flow 100 liter per minute requirement. We wanted to get some sense of feel for how that test requirement stacked up on a steady flow first basis versus a cyclic or dynamic basis. As you know, the breathing pattern is cyclic sinusoidal curve, perhaps, but typically you're looking at flow rates, ventilation total liters per minute, with peaks occurring during any one inhalation cycle. The test that we're proposing is a constant 100 liter per minute challenge on a filter. So what we wanted to do was just run a comparison test to see if you ran that same test at 100 liter per minute constant flow, versus 100 liter per minute total ventilation, what the comparison was. And this particular set of data was tested at actually two test sets, three sets at low flow, 64 liters per minute steady flow, illustrated here, and 64 liter per minute total ventilation on a cyclic basis, which would produce actually peak flows in the 200 range. So here you're looking at 200 liters per minute versus 200 liters per minute peak,

versus 100 liters per minute constant. And we can see that the steady challenge, actually, on this particular one, stresses it a little bit more than the cyclic flow. Again, this is the same filter but at an 80% RH, and we're seeing pretty much the same trends and same characteristics. Also, for two different filters, the ASCM as well as the impreg—we identified as IMP1. And the interesting one is out on the end here, this is the 100 liter per minute, so for this particular data we have a 100 liter per minute constant flow represented by the chart here by the bar. And here is 100 liter per minute dynamic flow, which actually would produce peak flow results in the range of 300 liters per minute. So again we were seeing that for the Cyclohexane on these filters that we actually stressed it a little bit less using the, or stressing it at 100 liter per minute constant flow was a little more severe or rigid a test. (pause) Okay, the last set of data that I want to show here, it's a little bit busy, and this is the type of data that you can see at the posters anytime during the breaks and with explanation tomorrow. But basically, this particular set of data represents gas life data that was collected on filters that went through the entire battery of environmental conditioning. So what we do as part of the standard is we have the environmental conditions that are identified for the filter. These include a hot exposure, cold exposure, humid, vibration, and drop. So the requirement is that all filters must exhibit their gas life characteristics after being exposed to those environmental conditions. These, this data here is actually illustrating results obtained using the same filters that we had tested earlier on our baseline test through the entire environmental exposure and then gas life

tested it with Cyclohexane and the break times that were observed. Now the interesting thing as you go down, there were several filters that exhibited a decrease in performance, so at some point during the environmental conditionings, something changed in the filter, either it was dented to create a channeling effect or the threads were damaged or something that it leaked, that actually created a condition where it would have been a failure. So we see that on this set of data and then as well on here in two locations. But, other data indicates that it is pretty much in line. Now, it's important to note here, as well, again, we're talking about filters that weren't necessarily designed to meet those conditions, okay, but have been exposed to all those environmental conditionings and then with this test. Do you want to go to the microphone?

M (audience): (...inaudible...)

M (speaker): Okay, talk loud.

M (audience): My question is why did you test for (...inaudible...) out of package. Is it normal that someone would take the filter...

M (speaker): The test requirement is that the filter go through it's environmental conditioning in the configuration that the manufacturer recommends that it be carried around. So if it's in a foil bag then it's in a foil bag in this test. If it's in a

(End of Tape 1, Side B)

(Tape 2, Side A)

Les Boord: Essentially, (...inaudible...) out of the package its just, those are the controls. In other words it was just taken out of the package and tested. I guess it's confusing, but, the rough handling, all the samples were in the original packages when they were tested, but, okay?

M (audience): (...inaudible...)

Les Boord: Yes.

Goran Berndtsson: Goran Berndtsson, of the SEA. Can you explain what's up and down. Was the thread up or the thread down?

Les Boord: I really wonder what's up and down a lot of the times (laughter). Frank?

Frank Palya: Top down is the thread. Bill?

Bill Haskell: Bill Haskell, SBCCOM. On your 64 liter per minute flow you used 25 and 80% relative humidity. When you went to 100, you went to 50. Is there a rationale as to why you threw in a third relative humidity?

Les Boord: Yeah, um, actually the standard actually specifies it that way and the service life testing capacity for the filters are tested at both the 25 and 80% RH, but then at the 100 liter per minute, and I hate to say it, but it was pretty much an arbitrary decision to use a mid-range RH for establishing that test. (pause) Any other questions? We did want to go into a question session now, so any other questions?

Jack Zuicki: Jack Zuicki from GM at Versar. Were these canisters designed for use with PAPRs or for standard, umm...

Les Boord: Gas mask filters.

Jack Zuicki: Gas mask filters.

Les Boord: I think, now I don't know whether any of them have actually been adapted to a PAPR, I'm not sure, but traditionally they were gas mask filters.

Andy Capon: Andy Capon from Avon. Going back to the Sarin versus Cyclohexane, I wonder whether or not we really got to the point where if you get 190 minutes for Sarin is that over-specifying the organic vapor capacity of this filter, and going back to what was said before, that if by getting a Sarin capacity or an organic vapor capacity or an organic vapor capacity which is comparable with your, um, all the other scenarios, then you could leave space in the filter for sorbents that will take out some of the much harder gases like NO2 which by and large are ammonia, not ammonia, SO2 and so is 3,900 right which gives you on those tests about 19 minutes was it? Should that be 2,000 so that the organic vapor capacity goes down giving us more room for other things?

Les Boord: Yeah, that's a good question, and actually, I think the thing to keep in mind is that the primary driver there is the organic vapor protection. So, as part of the multi-gas strategy for this particular filter, and I think Jon identified it earlier in his presentation, there are 61 organic vapors that are covered by the protections afforded by this filter, so in getting to the 3,900 we've basically built that off of our test representative agent and the multiple that we had talked about, so the OV is the primary driver.

Edna Demaderis: Hi, Edna Demaderis (?) Enot (?) Safety Products. For the 100 liter per minute test, there's no time requirements?

Les Boord: The standard time requirements states that it needs to provide 5 minutes of service life at 100 liters per minute at 50% RH.

Edna Demaderis: Okay. Thanks.

Andy Capon: Just to follow up on that. Andy Capon from Avon here again. The Cyclohexane is not one of the ITF 25 or one of the hazardous ones, so therefore is using the same rationale for coming up with the 3,900 correct? Would it be not more sense to use a rationale of one of the ones that was on the list but not necessarily the most toxic, relate that by test to Cyclohexane, and then set your Cyclohexane number accordingly.

Les Boord: Yeah, I recognize the strategy and the philosophy there. I don't know, Mike, do you want to comment on that?

Mike Monahan: Basically we again didn't take it to that level of evaluation. Okay. We looked at the organic vapors. We boiled it down to looking at organic vapors based on the Cyclohexane or Carbon Tetrachloride, using the vapor pressure, I believe is the primary indicator of what other OVs that would draw into the protection, and that became the driving direction. Your points are valid and well-taken, but again the direction that we went was based on the OV and using Cyclohexane as the driver there, test representative agent.

Goran Berndtsson: Goran Berndtsson from the SEA again. You confirmed what earlier the testings had been done in regards to cyclic and steady flow and organic vapors. Have you done anything on ammonia or acid gasses? And if you haven't, will you do that?

Les Boord: Yeah, we intend to perform similar tests and I think that is required for sure.

Mike Kay: Mike Kay, Helsenko (?) Incorporated. Getting back to the rough handling environmental testing here. On the canisters that failed, you said they may have been dented, there may have been some channeling. Was there any observable damage that the user would be able to identify before...

Les Boord: Yes. Actually, two types of visible damage were present. Denting of the canister on the body of the canister, and damage to the external thread, so you could visibly detect those.

Jay Parker: Jay Parker with Bullard. I just wanted to ask a question about the Chromium 6 impregnate that you showed. It's still my understanding that that impregnate is banned by NIOSH and therefore we could not use chromium 6, but is there any other application?

Les Boord: That's correct, okay. The chromium 6 is just, by virtue of that product, was not a domestic product, but I'm also under the advice that the chromium 6 probably did not significantly, make a significant contribution to the type of performance that we were observing. Any other questions? Okay, I think at this point, I think we'd like to turn it over to Jon.

Jon Kaufman: Environmental and Human Factors. You can close this one out. He looks good. I think for the interests of, you know, for trying to give adequate time for our attendee presentations I'm going to be a little briefer with the information contained in this section. That doesn't mean, I don't want you to ignore it, but the, I think, all of you an opportunity, I guess, to ask additional questions and perhaps get additional detail in the sub-panel groups tomorrow. But at least what we wanted to do with this iteration is to follow along the

path that we outlined in the concept paper related to the use of existing standards. Following the review of what NIOSH requires as Part 84, our standards development team felt that there was a need for additional minimum requirements to protect responders in an advance environment and basically we felt that these requirements needed to simulate operational and environmental conditions of use. What you see up on the board right now are features that we have adapted as part of the CBRN APR program to address some of these concerns both from the operational standpoint and the environmental considerations of use. And again, to go along with that we want to address other aspects associated with the program. We've spent some time talking about the filter capacities and services lifes associated with the filters or cartridges that would be used with these systems. Earlier we identified the P100 requirement through the use of HEPA or some sort of barrier material it would be, that would meet a P100 requirement to filter particulate matter, and some of the other things that we've addressed as part of our discussion so far that Les has articulated with the service flows, but we also looked to other considerations that we've heard from the user community as far as requirements they would like to see for communications and fogging and things that would facilitate them wearing a respirator in a contaminated environment and I think we all realize that, you know, the respirator is only as good as the ability of the individual to actually, the one to wear the respirator. You know, by incorporating considerations through human factors, evaluations, to try to make the respirator more user friendly and acceptable to

the user. These are some of the, this is just a roll up of some of the different standards that we've considered and have been incorporated into the development of the concept paper so far. I think you'll see the spread is pretty wide, there's a pretty wide base as far as the types of standards we considered both European norms as well as voluntary standards promoted by other organizations like the NFPA, as well as the military standards. And I think one thing that's really important to note with the use of the military standards, not that this respirator is being developed for a military-type environment but the way that the testing requirements are identified in this particular standard, mil standard 810, are such that they can be tailored to the individual requirements, the individual desires of the system. To that extent, mil standard 810 provided us a good avenue to incorporate some of the considerations that we wanted for environmentally challenging the respirators prior to the certification testing. I think based on the receipt of user comments that we've been receiving all along, both from the public meetings that we had in, well I wasn't part of NIOSH in April of 2001, but the April 2001 meeting as well as the things that you told us in the June public meeting here in Pittsburgh, as well as comments that we've received through the docket, we felt it's important to include this series of existing standards as part of the approval process for the APR. Factors that we identified included environmental considerations like heat, cold, humidity, vibration, drop-testing, as well as human factors characteristics such as field of view, fogging, haze, and communications with regard to speech intelligibility so that when the user or a

responder is wearing a respirator that his ability to communicate with his co-workers or with others isn't overly impeded. The requirements that we've identified, as well as the identification of the test procedures we're going to go over. I'm gong to flip through over the next several charts. But the next chart is going to give you a synopsis of the rough handling test that we currently have identified in the concept paper. I think the thing of note to the community is that this chart, prior to the beginning of any certification testing, whether it's the systems test, 42CFR requirements, the service life testing, that the systems would go through this environmental challenge which will last about 34 days. I think the other thing to note, and I didn't want to present this in terms of a chart, but if you go to the APR concept paper, there's a test sequence which delineates the order of the, the sequence of the testing and the order in which the different evaluations will be conducted. And the thing of note is that the pass/fail criteria is determined after the APR has been subjected to this sequence prior to going... you go through the environmental testing prior to conducting any of these evaluations. As far as, these are the different requirements, again I think if you go back through the concept paper, they're further defined at that point, but the breathing resistance is based on the traditional requirements of 42CFR where we're going to be mounting the face piece on a test fixture with air flowing at a continuous rate of 85 liters per minute. Field of view is something that we felt was important based on the comments that we've received through the docket or the user community. One of the considerations here is that we heard from the stakeholders is that

originally we had requirements specified for both the dual lens as well as a single lens type system and it was felt that the requirements that were identified may have been too restrictive so what we did was we adopted, at least at this point in time, we've adopted the requirements for the monocular lens system which can be addressed by either a dual lens system or a single lens system. Abrasion testing, as far as this test that will be testing the specimens not to exhibit a haze greater than 1. Field of view is something that we felt was important based on the comments that we've received through the docket or the user community. One of the considerations here is that we heard from the stakeholders is that originally we had requirements specified for both the dual lens as well as a single lens type system and it was felt that the requirements that were identified may have been too restrictive so what we did was we adopted, at least at this point in time, we've adopted the requirements for the monocular lens system which can be addressed by either a dual lens system or a single lens system. Abrasion testing, as far as this test that will be testing the specimens not to exhibit a haze greater than 14% and this test is based on the requirements that are identified in the NFPA 1981 standard. Carbon Dioxide, where we, there's an existing NIOSH test procedure associated with measuring carbon dioxide. We're going to use a breathing rate of 14.5 respirations per minute with a minute volume of 10.5 liters. This is consistent with the way the testing is conducted. Hydration. Hydration is not a requirement with the APR system; however, one of the, we have received feedback from the user community that hydration could be an

important feature that the user may want to consider in terms of what type of respirators that they purchase. And to that end, we've incorporated a requirement there to evaluate the hydration system if the applicant chooses to submit one with their respirator. One thing of note here on this practical performance test, this was developed in concert with the interoperability requirement. And the thing of note for the applicants for APR certification is that this is a modified LRPL test. We're doing an LRPL test associated as part of the systems evaluation. Along with that we're going to do a modified version where we're going to provide a weighted canister at the maximum weights and dimensions that we've identified in the concept standard and we'll run a limited tariff of masks through the LRPL1 to assure that we still get a good, we still provide adequate protection, we still provide to the measured protection level of 2000, as well as doing a subjective analysis by the wearer whether or not that the sizing constraints associated with the canister present a problem with them conducting the different scenarios that are conducted as part of the LRPL. Human wearer chore(?) trials are going to be associated with the fogging test. We've established a requirement of 70%, and I think this will, one of the concerns that we had and we felt there was a need for fogging, or a fogging requirement, there've been experiences that we've seen with people that wear an APR whether its in a humid type environment where the action of the perspiration of wearing protective clothing along with the respirator causes a build up on the lenses as well as cold weather operation if you have a, say a law enforcement officer who has

that is typically used in the European Norms, EN148. Additional requirements associated with the mechanical connector deal with the gasket that's used to effect the seal between the filter and the respirator and in the standard we actually specify a particular material, a specific material which is EPDM, Ethylene Propylene dimonomer and we specify material characteristics as far as the hardness and the physical dimensions of the gasket and we'll talk about those later, or further in this discussion. Another requirement that is necessary to ensure the integrity of the mask under the interoperable conditions is to put a restriction on the maximum weight that you can suspend or connect to the face in the form of a filter. And again we look to the European Norms for experience and direction on that, and we've adopted the 500 gram maximum weight, which is again derived from EN136. Another requirement or restriction that needs to be addressed again from interoperability is the maximum size. If you put a filter from various sources on a mask you need to have some restriction or some guarantee that it's not going to block the total vision of the mask that it's not a resident filter for. So we identify a maximum physical size for that filter and that size is established by the requirement that the filter needs to be able to pass through a 5 inch diameter. It doesn't have to be a circular configuration, but it needs to pass through an opening 5 inches in diameter. And then finally, we've identified a requirement to provide and to perform a tolerance analysis between the mating components and the mechanical connector. Basically, a tolerance analysis between the thread, the gasket, and the sealing gland that's in the mechanical connector. Again, the

interoperability provision driving the requirements for the mechanical connector is coming from strong user feedback and it applies in the case of the air purifying respirator to the filters, so basically we're talking about filters and masks. Interoperability, if you look at it on a much broader scope, could be interpreted to mean interchangeable or intermixable or interoperable other components: head harnesses, visors, valves, and so forth. For the scope of the air purifying respirator, it's filters. Filters and respirator. And again, to repeat the mechanical connector specifies in the standard, threads in accordance with EN148, the female connector, female portion of that thread on a mask-mounted filter is to be located on the mask with a single connector. The EN148 actually specified more than just the thread. As you can expect, the dimensions, the minimum, major, minor, diameters, pitch diameters for the thread, and the engagements and allowances required to achieve that thread operation are defined, but it takes it a step further and it defines the sealing gland that the gasket fits in at the bottom of the thread. So those requirements are also specified in EN148 which are also important to ensuring that an effective seal is maintained. One of the dilemmas or one of the problems that we foresee in using the EN148 connector is that, while the threads and the sealing gland are defined, and the gasket dimensions are also defined in EN148, we see a real possibility of a leak path created when you start to mix filters from different masks interchangeably. The problem is that the way that the seal is effected between the thread and the gasket is not defined. That seal could be made by a rounded-radiused configuration, or it could be made by a

sharp v-type configuration contacting the gasket, it an be on the ID of the thread, it could be on the OD of the thread, it could be at the root diameter of the thread, it could be in the middle of the surface, so there is no definition as to where or how the actual seal is effected. So what we, the way we see around that is that we need to be very specific on the gasket material. I think the gasket material, specifying the material and the dimensions as well as the hardness of that material will ensure that no matter what the sealing configuration is, that it's always sealing against a constant surface, and that is the EPDM gasket, using a sure hardness of 65. The material EPDM, why was it selected? Actually, it comes from military experience. It's the gasket that's used in the mechanical connector of a similar design on the M40 military mask, so it has a track record and an experience associated with it. The material designation EPDM as well a s the hardness. The other thing is if you do actually perform a tolerance analysis on the allowable dimensions specified in accordance with EN148, the actual contact area that you end up making contact with between the bottom of the male thread and the gasket can vary quite a bit. And for that reason we actually decided and incorporated into the draft concept different dimensions for that gasket. Those dimensions are designed to ensure that you always have a minimum surface area contact between the bottom of the male thread and the gasket. And those gasket dimensions are specified as 25 mm ID maximum and a 37.5 minimum OD. So in addition to the thread configuration and the gasket and dimensional considerations there, we also have designed into the concept paper a

requirement to check the breathing resistance. As Jon mentioned earlier, we have a system requirement for breathing resistance for the respirator system. Then in addition to that we have a requirement for the mask, and that requirement is 10 ml of water at 85 liters per minute. So by testing the total system and the mask resistance characteristics, then the filter should fall into place. So the standard actually specifies requirements for the system and the mask. And in addition to those, the other constraints that are driven by the interoperability are the weight which we've mentioned, 500 grams, adapted from the European Norms EN136; the physical dimensions must pass through a 5 inch diameter; and then as Jon mentioned, the modified LRPL test which is a form of a practical performance test, where the surrogate filter sized to the 5 inch configuration, weighted to 500 grams is tested on the face piece to ensure that it doesn't produce any undue restrictions in use or operation of the mask. Then basically, just to wrap up this section before we go into the questions, the next two illustrations are basically the components of our three tier approval, our three tiers of requirements that are adopted and imported directly from 42CFR. So, what we see is that we have entire sections of Part 84, Sub-parts A, B, D, E, F, and G, and then under the gas mask, Sub-part I, these specific performance requirements which pertain to general overall design considerations, breathing tube and harness configurations and so forth. Exhalation valve leakage performance tests. And then finally, the appropriate sections of Sub-part K which pertain to the P100 filtration. And with that, I think we'll turn it over to any questions.

Bill Haskell: Bill Haskell, SBCCOM Natick. Les, I'm still struggling with the concept of interoperability. When an APR is certified it will be a face plate and a canister and it will be tested as a system and then you'll get a stamp of approval, but does then imply that that canister can be used on any other certified face plate?

Les Boord: Good question. The concept of interoperability and the approval, or the certification concept standard that we're talking about is for a respirator system. So, what NIOSH is treating this very much as a respirator system mask filter resident to that design, so we will approve that as a system. The interoperability concept is an emergency condition that would be established by regulatory authorities for the particular situation that would permit interchange of filters and masks in an emergency situation. So basically, the provision, or the capability is built into the standard, but the regulatory aspect is...

Jay Parker: Jay Parker with Bullard. I have a question about the gasket. I think one of the critical failure modes would be the gasket falling out of the face piece, especially since it's pointing downward so gravity is working against you. Is NIOSH convinced that the EN148 standard prevents that from happening or should there be some additional tests to ensure that the gasket will not fall out of the face piece?

Les Boord: That's also a good question, and we will take it under advisement. I can't say that I specifically have looked at that, but I could certainly see where it would be an issue that needs to be considered. Thank you.

Jack Zuicki: Jack Zuicki, GM at Versar. Is it the intent to not allow a dual cartridge configuration as opposed to a single canister configuration?

Les Boord: On the mask?

Jack Zuicki: On the mask. Right.

Les Boord: Yes.

Jack Zuicki: So you, you're requiring a single canister, basically?

Les Boord: For a mask-mounted configuration, correct.

Jeff Stuart: Jeff Stuart (?), Audio Parenk (?). I have a question about the communications. On your standard you say that you're looking at 60 db for ambient noise. NFPA has now changed that to 70 db. Will you be taking that into consideration?

Les Boord: I think that the, yeah, we were aware of the difference between the NFPA 1981 2002 edition versus 1997, but I think that the, we're talking about two different pieces of equipment. We're talking about a self-contained breathing apparatus versus an air purifying respirator, and I think that the background noise associated at a fire scene is potentially a little more severe than it may be in the warm zone applications of an event like this, so that the intent is to keep the background at 60 dba. But the test parameters and test performance is patterned very much after 1981.

Bob Weber: Bob Weber from 3M. First, I'd like to commend you on all your canister work that you have done, doing all the benchmarking work. That leads me into the fact that I have not seen a lot of benchmark work done with some of these environmental tests, specifically, field of view. In the new concept paper that

you have, you've outlined, you've combined single and dual ocular together and you've put the effective field of view at 70%. Today, out there, there are a lot of dual ocular products that are field-proven, they've been designed for specific missions and tactics and they work. By combining those two together and having an effective field of view 70, what you would be doing is you would be eliminating some of the field proven product. And I guess what I'm suggesting is taking a step back and using the dual ocular products that exist today and looking at them, doing some benchmarking with them and using those field-proven products like the M40, the FM12, S10, and so on, using those as your base line and break out the single and dual like you had before.

Les Boord: Yeah, that's a good comment, and certainly we're receptive to that type of input and information. As I mentioned earlier in our upfront discussion, we need to be constantly aware of what state of the art is, what existing mask technology, what existing filtration technology is, and we need to make sure that we are not, let's say over stepping it or over stressing it, so that type of comment is of prime interest to us.

Paul Newcomb: Les, Paul Newcomb (?) from North Safety. I have a question on the scratch test. This test was developed for the NFPA using criteria of having a gloved, a dirty gloved hand wiping the front of a face piece during a fire situation. It's a very severe test. My question is whether during the hazards assessment part of this whether that was considered or whether it was just picked up because it was a test that was already available? There are a lot of commercial hard coatings available out there that are used on safety spectacles and goggles and

so forth that are very sufficient for what I would consider this purpose and are one tenth the cost of the NFPA coating, and it really wonder why such a hard coating is needed.

Les Boord: Yeah, that's also a good comment, and what our objective was to ensure that we had an abrasion requirement, an abrasion performance statement for the air purifying respirator. To answer a question specifically, no we didn't match the abrasion performance requirements that we're defining with actual expected usage in this particular, in an APR type of a situation. But I think any information that we have that's available like that would certainly be of interest to us.

Capon: Andy Capon from Avon. I was going to talk about the gasket, but I'd like to make another comment on field of view, if I may. The EN136 test head, and I'm sure my Draeger colleague could tell me exactly when it was designed, but I suspect in the 50's, somewhere around the 50's when there were probably one size of mask around. It's a very specific test head with large inter-papillary diameter 67. What the European standard makers are now finding is that as the different sizes of face piece are coming in that even they are contemplating the use of different sizes of test head. There may be one or two European masks around which are specifically designed on that test head to meet that test criteria. But when you're talking about some of the field-proven products, that is not necessarily the case, they were designed very often for military purposes with NATO interoperability in mind, and the test is done on a slightly different head, and I would urge you to look very carefully

from performance, strictly performance based into design specific. The gasket is a good example of that. Okay? In our determination, the gasket is the heart and the essential component that really establishes the interoperability capability. Now, in doing that, we need to have, for lack of a better description, a good base line that ensures that when we start to take filters from non-resident masks and using them interchangeability, that they're sealing against a constant, known configuration. Maybe EPDM, and I agree, EPDM is probably not the only solution. But it is *a* solution. So, we, again, are receptive to any information like that, but again, we have to keep in mind that when we become, when we look at interoperability, the gasket is a key and it forces us to be more and more design-specific. So, again, we will certainly consider the suggestions, and it's a point. But at some point, it does need to be defined.

Doug Durney: Doug Durney (?), ILC Dover. The concept of benchmarking for field of view and some of these other human factors tests have been suggested and I would recommend that that would be very good relative to the field testing. I would also suggest an area of thread compliance that that could be also applicable for checking some of the existing systems that are out there, some of the field-proven systems. Relative to the EN compliance. And I'm speaking of some of the current US military masks and their derivatives.

Les Boord: Thank you. I don't know, is there, specifically, yeah, we've adopted the EN148 because it is a recognized standard that basically addresses this universal connector so to speak, so basically that's the direction we've gone.

Now I understand that there are variations, perhaps in the length of that connector. Now, again, and I will come back to our early discussion and our early presentation. Our goal is to define a standard that provides the necessary protections for the emergency responder. If the length of that thread really doesn't have an impact on what our goal is, then ideas and considerations can be made, but we certainly need to have a universally accepted method of doing it.

Goran Berndtsson: Goran Berndtsson from SEA again. In regard to interchangeability, if we apply for that and we are going to use a simulant of a filter that weighs less than 500 grams, have you seen any filter that weighs 500 grams? Because that is a number that is taken out of the European standard and are we sure we're going to get any mask that meets this requirement. If it weighs 500 grams head harness might not hold the respirators. Have you tested that at any time?

Les Boord: That's actually why we have the mechanical performance, or modified LRPL test, okay, that we actually test it with a surrogate weighted filter to ensure that it does meet...

Goran Berndtsson: 500 grams is a lot of weight. I don't think that... most filters today are between 350 – 400 grams, so 500 grams is maybe pushing it. That's an old number, that's my point. So, in other words, if you have a mask that has a good interchangeability capacity, but only can hold 450, that won't be approved in that case. Or, could it be approval that it holds up to 450 instead of just approved if you meet 500?

Les Boord: Okay, good point, and actually maybe to further that a little bit, what we are in the process of doing, and Bob alluded to it, Andy, we are in the process of going through and performing our baseline verification testing to actually ensure that we can indeed repeatedly perform all the tests that we've identified to substantiate the requirements. The modified LRPL is one of those, so I think, during the course of the next day when you look at some of the posters for the environmental conditioning, also, communications and fogging, you'll see that we have started in the direction of actually doing those tests to verify the requirements and the procedures.

M (speaker): I'm the hook at this point. We wanted to give the, ahh, Sam Pitts from CBIRF and Dr. Kaufman from NAVAIR the opportunity to make their presentations. At this point I just think we need maybe five minutes to make sure we have everything loaded properly on our computer and then we'll reconvene with their presentation, so about five minutes.

Les Boord: Maybe we could take one more question. Andy?

Andy Capon: I'm sorry I didn't see you there. I've got one last question which really stems from Jack's question about mask-mounted filters. You implied that if it was not a mask-mounted filter, a dual filter system was acceptable in your eyes. That being so, if the connector which would take the dual filters is a standard connector, but the connector from the hose to the mask was not a standard connector, an EN148 one, which I think again follows on from what he was saying, the last bit is how have you thought through how you're going to do

the protection factor test in that instance, because the 500 gram rule won't apply?

Les Boord: Yeah, actually, you're correct. The 500 gram rule was applicable to the, to a mask-mounted system, so it's a mask-mounted filter respirator system. So, it would not be applicable in that case. And to answer further your question, to expound on it, the actual intent is that we have the capability for both mask-mounted respirator systems and body-mounted respirator systems, and that has been the concept from the beginning of the development, and the reason that we did that is that we envision that to actually achieve the full protection capabilities, the durations that may be required and the user may need, we needed to be able to be flexible enough to address both mask-mounted and body-mounted configurations. So the intent is that the provision is to do that.

(Pause – possibly break)

M (audience): I've got a nine-month old grandson who can now crawl through the house, makes his way over to the commode and flushes the toilet. And I think we got another engineer in the family (laughter). But we're ready to go with the last part of our program today.

Robert Murphy: Good afternoon everybody, it's good to see everybody back since our time we were together in June and everybody's been safe, and obviously there's been a lot of progress going on since our last meeting in June and I appreciate that, and I especially appreciate NIOSH for allowing us to get up and speak today. It's good to see all their members back, and it's especially good to see John Dower here as well. So with that said, I'm Chief Warrant Officer Robert

Murphy, the Fire and Emergency Services Officer for the Chem/Bio Incident Response Force. Just looking around the room today, the networking has been excellent, you know, seeing all the same familiar faces and whatnot; however, if there is somebody who hasn't been award of our last presentation in June, or seen the minutes from that or whatever, I'm just going to give you a quick history of, you know, what are we doing up here, what is CBIRF doing presenting at these opening remarks and then hopefully try to relate some of the things that we've been doing, too, where we're going with respiratory protection filtration, the APRs and all that type of stuff. Next slide here, please. Really the CBIRF mission statement, and you're going to look at this mission statement and as you read through it, most of you have probably seen this. If you haven't, if you could just take a minute there to read through that. What it boils down to, is we're saving lives. And if you heard me speak the last time we were together, it's very important that we're out there saving the life of the victim first. Number one that's our highest priority, obviously. But secondly, we have got to ensure that our response organizations, our responders going down range are also coming back from down range, doing the job which we are asking them to do: saving their own lives, saving the lives of their own brothers, so to speak, so there's two lives that are very important for us to save. And that's how this kind of ties in together: supporting those first responders when we're out there with those first responders, working for those first responders for the same common goals of saving lives. It's very important that we get the victim and get ourselves out of

there as well, at the same time. So with that said, CBIRF has an opportunity to get involved with a lot of areas as you see in this mission statement, with research, development, acquisition. There's a lot of things because we're able to focus on this issue and these problems day in and day out, 24 hours a day where they're just concentrating on these things, and a lot of things come up in regards to that. As I spoke last time in dealing with the anthrax response in DC, a lot of lessons came out of that that we're applying today. Three of the biggest ones these gentlemen here to my left will be talking about, and that's how it all kind of ties in, between the respiratory protection, how long can you stay down range, and if we are asking our responders to stay down range for a great amount of time, there's certain things that we got to do for those lads. We've got to especially make sure they've got something to drink while their down there, and then guys like myself need to be able to look at the commander and say, "Look, boss, if we're putting them in this hazard, and they're going to be operating during these types of conditions and doing this kind of job, we need to be able to bring them out in a timely enough fashion so we can get them through all the processes so we can get them out of a contaminated environment, which I'm sure you're all greatly familiar with. So that's really where we've been. Where we're going these gentlemen were going to kind of give you an update from where we were in June, coming up with our testing, some of the information that we have available to us now. The biggest thing that you see out of this slide here is not only the saving lives but taking the information, we've got a couple customers we talk about, I

talked about the victims there, but the other customers we have out there is the technology or the tactics of the procedures in which we develop responding to a CBRNE event. That information we get out to our fellow war fighters out in the military. Not just the Marines out in the Fleet and Marine Force doing their thing, but also across the DOD spectrum as well, so that tactics, techniques and, what we're doing here today, technology, that information needs to get out to those military personnel, those war fighters. That technology also has to get out to our national war fighters. Our police, our fire, our rescue, our EMS, that information that we obtained here we also like to get out through the organizations like the Interagency Board, that we're a member of, getting that information out to them, and getting those techniques or that technology out there as well, through boards like this as well. So, we take the saving lives thing very seriously, obviously, but a by-product of that is the research/development/acquisition and getting that information out across the spectrum, both to the military and to our war fighters here in the Nation. That said, I'd like to introduce Mr. Sam Pitts, he's going to be talking about some of the programs we're working on, and update you with any information. Thank you.

Sam Pitts: Good afternoon, ladies and gentlemen. I am Sam Pitts, retired Marine Chief Warrant Officer IV, Nuke Chem Bio Warfare Officer, and I'm assigned to CBIRF in Research, Development, and Acquisition veins. I'd like to, next slide sir, briefly describe our partnerships in developing equipment, basically Marine Corps Systems Command, CBIRF of course, Technical Support

Working Group, Office of Naval Research, and NIOSH, and also here of late, the Civil Support Teams from the Army National Guard. Our purpose is to improve research, development, and acquisition of equipment issues that relate to basically handling weapons of mass destruction mitigation. And, we're focused basically also on delivery of near-term equipment solutions to the operational needs and requirements that we have. Next slide sir. To update you briefly, current projects that may be of interest to some of you in here is our improved filter protocol, our re-hydration while in elevated levels of protective posture, and our heat index calculator. I'll briefly describe them. The reasons why we are doing this are, of course, extended strength and ability and mental acuity down range, and we find that often times maybe civilian firefighters think in terms of an SCBA bottle of about 20 minutes, and don't perhaps consider the real possibility of mass casualties and extended time periods down range, and we think we're making some ground with them on that. Of course, increased operational endurance and improved life saving capability are also requirements for us. Next, sir. First up is our improved filter canister. Basically, this is what we were looking for in an improved filter canister and as an APR. This is, if our wildest fantasy were to come true, this is what we would have in that canister. Next, sir. Re-hydration and PPE. Again, it's very important for our Marines and soldiers down range to be able to re-hydrate, especially if they're going to spend extended time periods down the range. And through the technical support working group, we have quite a few of the manufacturers on board with making a perforation through their

mask face blanks to allow the passage of a re-hydration tube, which we think is a step in the right direction. The bladder that will be used could be any formulation of the bladders that are available, and mounting configurations on the back, under the arm and on the thigh, we're looking at some of the camelback type bladder affairs. Next, sir. Heat index calculator. We have lots of data on MOP Level 4 permeable time periods down range, but we don't have a lot of data on the physiological limits of men going down range in say Level A and Level B under adverse conditions. We envisions something that would give us an axis on one side to input atmospheric conditions, re-hydration, rest periods, and so on and so forth, and then allow us to safe-sidedly determine our maximum time down range before we have physiological damage. Next, sir. Since June, this is an update, a status of these three main projects that we've been working on. Our improved filter requirement. Currently, statements we're working on are under revision by SBCCOM, TISWIG, Office of Naval Research. NIOSH is acting in an advisory status, they're not actually in an approval status of this, they're just helping us out. We patch a lot of stuff through them. They've been engaged with this effort from the get go with us. Recently, we completed a respiration study at our facility down at Stump Neck close to Naval Surface Warfare Center, Indian Head, right across the Mattawoman Creek, actually and we wanted to establish those respiration rates that Marines might display under what we would consider to be heavy operations, maybe moderate operations and light operations. We think we have some parameters for that established.

Of course, our re-hydration, we've looked here recently at some prototypes from the manufacturers within the last couple of weeks and we expect to have some final working prototypes very, very shortly from the TISWIG. And our heat index calculator, we very recently got the final down select from that, and we've not yet had a chance to review that white paper from the manufacturer. And lastly, points of contact that you may want to copy down, and I'm certain that we could leave this with anyone that wants to have a copy of it, but I would like to turn this over to Dr. John Kaufman from NAVAIR Systems Command, who handled the respiration study that we just completed at Stump Neck, and he has some airflow data that may be interesting to everyone here.

(End of Tape 2, Side A)

Sam Pitts: This is an opportunity that is rare and we hold it in very high regard, and I'd like to thank everyone for that. Sir.

Jon Kaufman: Hi, my name is Jonathan Kaufman and as Sam indicated I am from the Naval Air Systems Command. What I'm gong to be reporting on today are very preliminary results from the study that we conducted with CBIRF. I want to emphasize they're preliminary data. We conducted the study about two weeks ago, so things are a little rough and you'll understand why I say that in a little bit. Next slide, please. We involved 48 individuals, 48 Marines from CBIRF as subjects in this study. This slide shows their physical parameters: 22 years of age, normal distribution of height and weight. We used a forestry step test to approximate their oxygen, their maximum oxygen consumption which indicated that they were very fit. We also did preliminary pulmonary function

tests on our subject pool to establish baseline performance. Peak inspiratory flow rate is indicated as PAIFR, forced vital capacity, forced expired volume, and then the ratio of the two. These are all indicative of a healthy population. Next slide, please. The instrumentation that we used in the study to measure volumetric flow rates is indicated here. We used a turbine flow meter manufactured by Interface Associates that is capable of measuring up to 720 liters per minute. The, with all the ancillary parts, we added about 126 grams to the 288 gram filter, C28 filter, here, for a total weight of approximately 414 grams of mass on the mask. In addition, subjects were wearing MOP 4 gear and additional instrumentation shown here, a data logger, an actual flow meter, and a polar heart band. Total additional weight of all that gear was roughly 11 kilograms. In addition, they wore a 50 pound or 22.7 kilogram vest as part of the firefighter agility test. And you'll see that in the next few slides. Next slide. This just shows the experimental design of the study. Subjects had an initial 5 minute rest period which was then followed by 8 different events. These are standardized events in the firefighter agility test. This is the same test, physical ability test that's performed by the Fairfax Fire Department, Fairfax County Fire Department in Virginia. The mean exertion time to complete all 8 events turned out to be roughly 19 minutes and the environmental conditions at the test site was a dry bulk temperature of roughly 20° C, relatively humidity of 65% inside the dressing area, and in the work area it was roughly 22° and 73% relative humidity, roughly equivalent environment. Next slide, please. Okay, what I'm going to do next is walk

through the various events that were performed as part of the agility test. I should point out at this point as Sam indicated, there were really two other tests that were performed. There was a reconnaissance task and a decon task that were performed on a separate day. I won't be presenting that data today, mainly because I haven't finished analyzing it, but this will give you a very good picture of the highest workloads. So, the first event that was completed by subjects was the stair climb. This comprised a 20 second warm up period, walking at a rate of 50 stairs per minute. At the conclusion of the 20 seconds, the rate was ramped up to 60 stairs per minute, and this was continued for up to 3 minutes. Most of the subjects completed that, but many did not. If they did not complete it, they still moved on to the other elements in the task. The second element of the agility test was a hose drag, in which subjects dragged a standard fire hose 75 feet, moved around a drum, and dragged it an additional 25 feet, then kneeling, they pulled in 50 feet of the hose, and then moved onto the next element. The third element in the test was the equipment carry, which comprised taking two saws off of a shelf, walking with them 75 feet, walking around a drum and returning them and placing them back on the shelf. The fourth element was raising a ladder to a perfectly vertical position, making sure that you held onto each rung, and then lowering the ladder; again, ensuring that you hold onto each rung. Now one element that we could not simulate because of the physical dimensions of the facility was that there is a ladder extension as part of this event, but to replace that, we had subjects hoist a full hose reel up roughly 30 feet and then lower it under controlled

conditions, which simulated the ladder extension. Event 5 was simulating a forced entry, and this involved swinging a 10 pound sledgehammer and imparting a total of 700 pounds of force on this target area here, and that really, the time it took really depended on the individuals performing that task. Next, please. The sixth event simulated a search and that involved subjects passing through an 80 foot tunnel with obstructions inside the tunnel. It was dark and the unfortunate thing about this event was missing data primarily was a result of instrumentation being damaged going through the tunnel. Next slide, the seventh event was a mannequin drag, in which a 165 pound mannequin was dragged 35 feet, around a drum and returned to the starting position. The last event was a ceiling breach and pull down, in which subjects had to raise a 60 pound door, three times and then pull down an 80 pound lever five times, and repeat this four times. Next slide. This slide shows a typical airflow pattern that we obtained during the exertion phase. I include this to define the parameters that I'll be reporting on. We defined peak flows as the maximum ventilation rates per breath. The maximum peak flow rate refers to the highest flow rate that we observed during that exertion period, and as you'll see we basically broke down data in 5 minute segments. We also defined a mean peak flow rate in which we just averaged all the peak flow rates and then we calculated a minute ventilation over the five minute period. Next slide, please. Breathing frequency is shown in this slide. As you can see, there were significant differences between ventilation... ahh, breathing frequency in the rest period, represented by the zero to five minute segment,

this is that initial rest period, and then the subsequent five minute exertion period. You'll note there's a two minute gap here, and the reason for that gap is that subjects did not routinely match a specific time period over the 48 people that participated. So what we did was we just blocked out time periods and averaged data over those time periods. Next slide, please. Okay, this slide there is an error and that's indicated here. Basically, the data, the minute ventilations that are indicated should be doubled because these were calculated over the entire five minute period, rather than inhalation period in which the data is actually represented. So the minute ventilations are actually double what's indicated. There was a significant difference between the rest period minute ventilation and the exertion minute ventilations. There were no significant differences between the three exertion periods. The mean minute ventilation for the final five minute exertion period was roughly 78 liters per minute, not the 39 liters per minute indicated here, but what I would like to point out also, is the tendency towards higher flow rates in the population. We had flow rates approaching 100 liters per minute in this subject pool in at least two individuals. Next slide. These are the peak mean flow rates, or the mean peak flow rates, excuse me. Again, the same pattern. Significant difference between rest period and the exertion periods. The mean peak flow rate in the final exertion period was roughly 200 liters per minute and as you can see there were a number of people with mean peak flow rates much higher than that. Maximum peak flow rates, same rest period with significantly different than exertion, and you'll note the tendency in the final rest period for

excursions greater than 350 liters per minute. We had a mean peak flow rate, a mean maximum flow rate of 291 liters per minute. This slide indicates the strongest correlations that we could find with all of the data. Basically, I included this slide to remind me to point out that there were no strong correlations between any of the baseline breathing parameters, the pulmonary function parameters or the VO2max. The strongest correlation that we found was the correlation between mean peak flow rate and maximum peak flow rate. We also measured heart rates with a polar heart rate monitor. Again, the same pattern: rest mean heart rates were significantly lower than the exertion heart rates. I've not had time to correlate heart rate data with breathing parameters as of yet, so that will come. This shows the typical heart rate data. You'll notice that the rest period indicated here is considerably longer than the 5 minute rest period in the breathing data. That's because as subjects were dressed, because of the constraints of dressing them, we had to start the polar bands prior to ventilation measurements. So there was a considerable rest period in the heart rate data. In summary, mean peak flow rates of roughly 196 liters per minute were observed during the final 5 minutes of exertion. Maximum peak flow rates approached 300 liters per minute in the same period. Minute ventilation rose to roughly 78 liters per minute. During this period at a breathing rate of approximately 42 breaths per minute. There were significant differences between breathing rate parameters during the rest period and the exertion period, no surprise, and there were very weak or non-existent correlations between baseline physiological data and that, the

respiration variables measured during the exertions. And, last slide, please. I just wanted to acknowledge publicly, the great support that CBIRF provided, my research team, the subjects were wonderful, couldn't ask for better, and the command represented by Colonel Hamas(?), Lt. Colonel Graham, and Sam Pitts was very supportive of this. I also wanted to specifically thank Karen Coyne and A.J. St. Germaine. They came to the study as observers and they helped out running the study when they really didn't have to. So, thank you very much. (applause).

Bill Haskell: Bill Haskell, SBCCOM. Doctor, what was the spread in the ages of your test subjects, approximately?

Jon Kaufman: Roughly, we had a spread of about 19 to, I believe the oldest subject was 29.

Bill Haskell: 29. Do you think there'd be any trends that you could see based on age versus...

Jon Kaufman: Unfortunately, the vast majority of our subjects were between 19 and 22. We had a few outliers. The 29 year old was an outlier. I would say 80 – 90% of our subjects were within that 19 – 22.

Bill Haskell: We have a physiological database to do modeling of probably about 25,000 military candidates, but what we're hoping someday is to get the resources to populate that with an older workforce that might better represent the emergency responder, and if we can do that, then I think we can do an awful lot to predict performance in these types of environments.

Jon Kaufman: That would be very worthwhile. One of the things that we had hoped to do in the study was to include firefighters as part of our population. Unfortunately,

they were unable to participate. We've asked the Marine Corps to be able to do a follow up study, and if we can get funding that would be one thing that we would like to include in that.

Heinz Ahlers: Heinz Ahlers (?) from NIOSH. My first question would be, were these troops experienced respirator wearers?

Jon Kaufman: Yes.

Heinz Ahlers: They're used to that?

Jon Kaufman: Yes.

Heinz Ahlers: And then my second one is a statement. You're not going to get anyone from NIOSH to volunteer for that test (laughter).

Frank Denny: Frank Denny, Veterans Affairs. Just out of curiosity, are you planning to do any kind of mental agility testing following any of these tests to determine how quick they are, how mentally sharp they are?

Jon Kaufman: That was one of the things we had hoped to do. We were unable to prepare that in time for this study. In a follow up study that would certainly be worthwhile.

Eddie Sinkle: Eddie Sinkle(?) from NIOSH. John, it's a great job, it was a good presentation and it was very interesting. I had a question and a comment. One is, were your flows STPD, or...

Jon Kaufman: These were SPD actually, yes.

Eddie Sinkle: And one thing I would maybe consider doing is maybe separating your smokers from your non-smokers in looking at that data.

Jon Kaufman: We do have that data available to us. The subjects did indicate who was smokers and who were not. We intend to do that.

Bill Haskell (?): I have a question for Mr. Pitts. Sam, can you confirm for me that Chief Warrant Officer IV Murphy is short, meaning he is about to retire in less than a month?

Sam Pitts: That's in fact true. He's transitioning from a manly profession to other things now (laughter).

Bill Haskell (?): Sam, I've had the pleasure of working with Chief Warrant Officer Murphy for the past several years and I just wanted to express to this group, because we happen to be here together today, that Chief Warrant Officer IV Murphy has represented the United States Marine Corps and CBIRF at the highest level of professionalism and has always been extremely clear as to the mission, the goals, and the needs of CBIRF in working against CBRN terrorism incidents. I want to express my thanks and congratulations to Chief Warrant Officer Murphy, and hope that the group here will join with me in congratulating him and wishing him very best in the future (applause).

Sam Murphy: Thank you very much. If there's no more technical questions... 99.9% of the Marine Corps smoked cigarettes when they invaded Mount Iwo Jima and successfully overcame that mountain. So if that's any indication of the smoking/non-smoking question, Marines will endure regardless. (laughter) I just pulled that figure out of my cargo pocket by the way. Couple things I just want to summarize with. The physical agility test. The point I wanted to, I alluded to earlier, a lot of the research development, tactics, techniques and

procedures that CBIRF employs gets out, we share information with the first response community, and that's what the physical agility test actually came from. After the June meeting we started talking about this with some of our colleagues, Jim Schwartz from Arlington County Fire, and that's what he recommended, we do a test that could actually, what we feel, could be utilized immediately to the first response community in regards to that data under the physical agility test, and I believe that's recognized by the I Chiefs, as well as the International Association of Firefighters, correct? So that's one thing that we took right from him and we immediately incorporated. You know it was tough to sell our Colonel that we're doing a civilian physical agility test and that's kind of like non-military. You're not going to see too many Marines for deployed, you know, moving hoses and hitting the pike pole, so we actually, something that Doctor didn't add was that we actually had a shooting competition at the end (laughter) and a little hand to hand combat, just for fun to keep things going with the Marine Corps, keep things in line. And that would help on that mental agility test, seeing if you could hit the 500 yard line. We might incorporate that again. Yes sir?

M (audience): What happened to the Marines that didn't finish the step test at the beginning.

Sam Murphy: I don't know if that's an accurate summary (laughter) Marines normally don't... they finish things... Dr. Kaufman? They went onto the next event I believe. Correct? Yes, they went on to the next event, and publicly over a system like that, I probably cannot deluge the information that the NCOs happen to have of the conversations with those young lads after that

(laughter). So I want to thank Jim Schwartz for bringing us that physical agility test and incorporating that test. And of course, as you also heard, then we incorporated some CBIRF-unique tests, the reconnaissance, what's a reconnaissance Marine when they're going down range, you know, what kind of conditions are they operating under, as well as that decontamination. As well as you know, mass casualty decontamination is very exhaustive, and moving those victims and getting that through, I'm very interested to see the data that comes out from that, doing that decontamination process. Something that I believe the Health and Human Services, National Medical Response Teams, NMRTs, could utilize because that's normally kind of an APR function, that they're doing that decon in. So why is all this important to us? I'm speaking for CBIRF now specifically, and not really the whole emergency response community as a whole. We feel that we can save more lives utilizing an APR, the amount of people we have go down range underneath the right conditions and what we do for a living, we feel that we can get more personnel down range to do the greater good utilizing an APR, that's why we're concentrating so much on this data, constant continual improvement of our resources to do the job that we're asking them to do. That's why we're focusing on the APR specifically. It's a CBIRF-unique kind of thing. Now if that information can cross over for the entire emergency response community, then that's just bigger bang for the buck, and that's outstanding and exciting for us. So for the future, where we're going, we're going to continue on with these processes we've talked about here that Mr. Pitts presented to you. We'll

continue to share that information openly as it becomes available, hopefully get it into the language in which we can all utilize and hopefully all of us together in concert can do the greater good that we can do for our community out there as well. So I thank you for this opportunity. If there's any last questions, and I'm seriously going to miss this body of professionals here in front of me. Yes, I am transitioning. I do, as it reminded me, want to introduce two gentlemen who are going to be representing CBIRF in the future, Lt. Commander Jeff Bessinger(?), Jeff if you could stand up please, Industrial Hygiene Officer will become in IHO a huge wealth of information that came into CBIRF; been here for about a year; and is helping us with our microbiology, the whole biological response aspect and just a wealth of information, and then Chief Warrant Officer Robert Iams, Rob, is taking my place, is my replacement. You'll see these two gentlemen around CBIRF. Rob brings a ton of hazardous material instruction, hazardous material incident response as a disaster planner, disaster preparedness and fire emergency response background as well. So you'll see these two gentlemen representing CBIRF in the future of these organizations. Thank you very much and we'll see you again. (applause)

M (speaker): I just have a couple of brief administrative things before we break for the day. Start time tomorrow is at 8:30. I guess if you're on the agenda to make a presentation, an attendee presentation if you could see me or Terry before the meeting so we could get your presentation loaded onto the system. If anybody else would like to make a presentation as part of the meeting, you're welcome

to do that, just see me and we'll work you into the agenda during the course of the day. We're going to focus on tomorrow morning, we're going to wrap up our activities associated with the APR and the simulant program and have a comment period at the end of our discussions at that point. In the afternoon we're going to focus on the air purifying escape respirator so I guess to facilitate the discussions for tomorrow afternoon, if you didn't get, there's an October 15th version of the concept paper that was available on the tables on the way in. If you didn't have the opportunity to pick one up if Adrian or Christine are still out in the lobby you can get a copy from them, or we'll try to get you a copy if you need one for this evening. What Rich neglected to tell you this morning, in terms of where you're located, I think it's inherently obvious you're in the middle of nowhere (laughter) and the key to life, especially if you wanted to eat somewhere other than the hockey rink where the Penguins practice in Southpoint or the hotel restaurant, is to get to Route 19. Okay, and there's several ways to do that. What I would recommend if you're not familiar with the area is to get back on the Interstate and go south either to the exit for 519 or the exit for Racetrack Road which takes you to the Meadows where the...

(End of Tape 2, Side B)