

Boord: Okay, I think we're ready to begin. I'd like to welcome everybody to the NIOSH/NIST/SBCCOM Public Meeting on the standards concepts for development of the full facepiece air-purifying respirator for CBRN protections. By way of introductions, my name is Les Boord. Rich Metsler (?) was unable to be here today, so I'm sort of filling in for his opening remarks. The... by the way, you know you're in the right room, because on the table outside, we're not the one with all the food on the tables. We're the ones with all the food for the mind, the printed literature. The program that we are going to discuss today is a ... has been a cooperative effort between NIST/SBCCOM, OSHA, NIOSH and NFPA to develop standards for CBRN protections, and specifically over the next day and a half we're going to be looking at the standard developments for the full facepiece air-purifying respirator. The process of developing the standards, we've been working through memorandums of understanding between NIST/SBCCOM, OSHA and NFPA where the collaborative efforts that are required to define the requirements and to develop the standards have been set down. And then in addition to that there are inter-agency agreements with NIST and SBCCOM and NIOSH/NPPTL to actually implement the work for standards development. The initial funding for the program, actually what you would almost consider the seed money for the CBRN standards development for respirators was actually provided by NIST, and this continues to be a source of the funding as well as additional funding sources through CDC and sponsoring the program. The purpose as I said, the purpose of the public meeting is to present the concepts for the full facepiece air-purifying respirator. And to that regard I think everybody has received an

agenda in the packet of information that was one of the foods for thought out at the front. And I think if you look at the agenda you can see it's a pretty extensive range of topics that we have to cover over the next day and a half. A lot of it is obviously slanted towards the technical side. Before we actually begin the presentations, I'd just like to review a few of the, let's say administrative details or administrative aspects of how we want to conduct the meeting. The front table in the hall, there is a sign-in sheet, so everybody, I think, has signed in their name and organizations, and we will maintain that for both days of the meeting. So for today we will have a log in sheet and also for tomorrow. The entire meeting will be audio recorded, so all the discussions and questions and so forth will be recorded and transcribed following the meeting. The transcription of the meeting will then be placed on the website so everybody will have access to it to follow the discussions in the course of the meeting. The presentations that will take place over the next day and a half will follow the agenda. What we'd like to do is try to stick to the time slots as identified on the agenda. And I think if you glance over it you'll see it is a pretty aggressive agenda. We have a lot of topics to cover. So we'd like to begin the sessions according to the time slot that's identified and stick with that. We will try to keep the presentations in a form such that we can have a question and answer period following the presentations. And then I think at the end of the second day, tomorrow afternoon, we would probably have, we should have additional time for questions and answers that we may not be able to cover due to the time constraints. We do welcome the open dialogue and the open exchange of ideas and concepts. What we would ask that anyone who has a

comment or a question, we would request that you go to the microphone in the middle of the room and identify who you are, your organization you're with, prior to stating the comment. That way we'll be sure to have it all in the transcript that's ultimately produced. The transcript, as well as any of the information, the concept papers, the presentations that are to be presented here will be available in the docket on our website. And any additional questions or any comments or information, they can be addressed specifically to the docket address that's illustrated there. With that I'd like to turn in over to Phil who will give us a few introductory comments.

Mattson: Good afternoon. I'm Phil Mattson and I'm a SETA (?) contractor working in support of the Office of Law Enforcement Standards and NIST, the National Institute of Standards and Technology. What we are going to do is provide you a short overview of OLES and how we got involved in the process, and a little bit of background and history. You're going to be hearing the word "standards" a lot over the next couple of days. And at a time when our country is scrambling to prepare itself against any number of potential threats, it seems that standards may be hardly a priority. But they are for us and for everybody in the room or else you wouldn't be here. Well let me start by answering a question that's asked a lot. What does a National Institute of Standards and Technology even have an office related law enforcement? After all, NIST is part of the Department of Commerce and not the Department of Justice. So what exactly does the Office of Law Enforcement Standards do? For the answer we have to jump back to 1967. In the 1960s, you may or may not remember, we were not all good days and sunshine.

The United States was in a grip of political and social transition. The rate of serious and violent crime was skyrocketing and the public sense of security and its confidence in law enforcement was plummeting. A presidential commission studied the problem and reported that law enforcement officers at all levels were inadequately equipped to protect themselves and the public. Not just because they didn't have enough money, although that's always true, but also because they had no source of reliable information about the equipment they needed to buy. When a County Sheriff in New Mexico, a State Police Superintendent in Tennessee, or even the Chief of Police in New York City needed to buy any kind of equipment for their personnel, they're on their own. There was no consumer products magazine for law enforcement. In fact, there were no performance standards or guidelines for anything used in the field. The only information available for making even the most critical buying decisions was a manufacturer sales brochures, of course we know those are always accurate, and whatever you can hear from the grapevine. Federal, state and local agencies were spending money by the truckload on equipment that came with no assurance that it would perform as advertised, and often it didn't. Congress directed the Department of Justice to fix that mess, and DOJ's research for the National Institute of Justice came to NIST. And why? Because before they can recommend a 52,000 law enforcement and public safety agency in this country, what equipment they should buy, you have to evaluate that equipment. And the only way to do that fairly and accurately is to establish uniform standards and test the equipment to determine whether or not it meets those standards. NIST had already been doing that kind of work for

70 years, helping government and industry develop standards for manufacturing procurement and federal regulations. And NIST knew how to tackle the technical challenges involved in a project like that. Let's see, I guess we are getting a little bit ahead of our self here. That's okay, just keep it right there. In 1971, through an agreement between the Department of Commerce and the Department of Justice, all this was born, and NIJ and OLES have been partners ever since. Now OLES is really a matrix management organization. This picture was taken on a particularly good day for the group. And it's a group of project managers, each with a specific areas of expertise. We help NIJ and its partners identify the standards that are needed most. We design projects to meet those needs. And then with the exception of projects involving ballistics and body armor, we farm the work out, and we go out to the very best investigators and labs in the country to do the actual bench work, which is an example of us being partnered with NIOSH and SBCCOM in this endeavor. Over the years, OLES has evolved six core program areas, each dedicated to specific area of technology. All they have, together we've developed more than 250 standards, test protocols, technical reports and user guides for our clients and sponsors for all types of equipment. Our joint mission is straightforward. We identify standards for the criminal justice and public safety community needs most. And by the criminal justice and public safety communities, I mean law enforcement agencies, prisons, fire service, HazMat and those related agencies. We designed standards or facilitate others to develop the standards to meet those priorities. We create test methods and procedures for evaluating equipment according to those standards. Our mission is to... okay

where are we at, okay we one ... we develop critical equipment and compliant testing programs and use the qualified independent laboratories to evaluate items that manufacturers submit to us. Next. And we also publish technical reports and user guides that give equipment manufacturers the information they need to understand the standards, and like consumer reports, give end users the information they need to make smart buying decisions. And we have been doing this now for about 30 years, and we've had a tremendous impact. In particular, OLES has developed a standard for body armor that the police wear, and approximately, since that standard has been in place, approximately 2,500 police officers lives have been saved through the use of compliant body armor. And we don't do this by our self. So we are partnered with a number of organizations who serve as investigators and consultants on specific programs and through several laboratories right at NIST; also university and private laboratories, government military organization, manufacturers, US and foreign law enforcement agencies. Scientific and technical working groups and recognized experts around the world, these partners have keyed our success and their hard work is behind most of what we've accomplished. And they are also the reason that OLES has been able to continually expand our mission into new areas and take on new responsibilities, such as after September 11. As you all know, this work has been in progress long before that. We are going to shift gears here a little bit and talk about standards. Voluntary standards movement in this country began in the private sector over 100 years ago and quickly became the framework in which America built its industrial base and modern infrastructure. In the late 1800s, companies within

certain industries got together and created their own standards committees. These committees developed procedures for specifying product characteristics, setting safety and performance criteria in determining if products conform to these criteria. Individual manufacturers were free to follow the standards or not. But if they didn't, they soon discovered that their products were ignored in the marketplace and came under close scrutiny of regulators. Ever since the system has worked so well, the United States has never felt the need for a centralized government-run standard system. Okay. I think we've ... yeah, you can back up one here. Did we miss my ... yeah, I see here, so instead of doing that, we are going to develop the IRS. Okay. That doesn't mean that anybody can just come up with standard and have a generally accepted standard test to meet certain standards. Okay, next slide. Like industry, the Federal Government depends on standards, and they're written in the procurement contracts to ensure that the tax payers get their money's worth from the suppliers. And, of course, their volume of compulsory standards related everything from environmental to worker safety. Since before World War II and up until the mid 90s, the number of government and especially DOD standards, not to pick on my DOD friends here, was multiplying exponentially. In the mid 1990s, somebody realized that a lot of government standards and specifications weren't all that different from voluntary consensus already on the books. In fact, a good percentage were practically identical, so this led the idea that Uncle Sam could save lots of redundant effort in tax payer money and get out of the standards writing business. And that's the essence of the National Technology Transfer and Advancement Act, the NTTAA.

Very specifically the NTTAA states that in developing regulations procurement guidelines, federal agencies will adopt existing voluntary consensus standards whenever possible. They will also participate in the standards development process by sending their own scientific and technical folks to represent the government's interest before various private standards organizations, and that's one reason OLES serves on so many standards committees. As you can imagine the NTTAA has deeply affected the work that OLES does. In particular, it spared us from having develop every standard from scratch. Now every one of our programs starts with reviewing the literature, seeing what standards already exist from other organizations, considering which ones we can modify and adopt to the needs of the criminal justice and public safety community. And we want to focus on minimum performance standards. Each one defines essential performance criteria for a type of equipment and sets thresholds that the equipment must meet to satisfy the needs of the people who will actually use it. The performance standards are different from other types of standards, such as design standards. Design standards tell the manufacturers exactly how to make the mouse trap, whereas performance standards simply state how well the mouse trap has to work. The manufacturers are free to come up with their own approaches and designs. Our work on technology for first responders is being done largely through our participation with the IAB, the Inter Agency Board for equipment standardization interoperability, which many of you are familiar with and many of you are members of. The IAB was created in 1998 by the Department of Justice and the Department of Defense to help state and local law enforcement and public safety

organizations equipment themselves to protect their personnel and minimize the impact on the public in the event of a terrorist incident. IAB's core mission initially was to develop and maintain a standardized equipment list or SEL. SEL includes hundreds of items considered essential for responding to CBRNE attacks, that is attacks involving chemical, biological, radiological, nuclear or high yield explosive agents. Items range from detection communications and personal protection equipment to decontamination gear, medical supplies and pharmaceuticals. The list is updated and published annually through the IAB. The SEL was a good start, but it was just a list. Very early on in the process, the IAB realized that some of the equipment available in the market simply wasn't good enough, and this was a serious problem. It's very much like the situation back in 1967 where there was plenty of equipment out there, but no one really knows which items, if any, will perform as needed when the time comes. Part of that also is because we didn't truly understand the threat at the time and what the equipment really needed to do. The IAB created its own standards coordination committee, which currently is chaired by the NFPA, the National Fire Protection Association, and NIOSH, National Institute for the Occupational Safety and Health. OLES has had a seat on the committee for almost three years. In 2000 we were appointed the committee's executive agent, making us the arbiter for CBRNE standards nationwide. The coordinator of multi-agency efforts develops standards and the organization responsible for implementing and administering those standards. And we were chosen for this role because we've been in this game for a long time and understand how to develop standards and test methods,

and also because of our long history in being able to bring together the best qualified individuals and organizations attacked all this technical challenge. And, again, that's why we are gathered here today. Speaking of technical challenges, the technical challenges in this process are enormous. Prior to a few... several months ago now the only existing CBRNE equipment standards were hybrids of industrial standards for hazardous materials equipment and military standards for battlefield equipment. Yet as we know, the CBRNE agents terrorists are likely to use are far different from the industrial HazMats, and the situations where civilians CBRNE equipment will be used are dramatically different from those of the battlefield. In addition, the existing standards were developed and tested using traditional laboratories techniques and technologies, which are inadequate to ensure safety and reliability against the kinds of threat that we're talking about. Again, a few months ago, we only had a general idea what the threat was, the types of pathogens, toxins, the concentrations of agents the terrorists may use and the first responders will encounter. To that point, CBRNE hazards had not been systematically been identified and measured, and there were and in fact still are, wide gaps in our ability to do so. And so you can see in many of the critical areas of CBRNE research and development, we're starting literally from scratch. The IAB had to pick a starting point, and the top priority it picked for standards development was for personal protective equipment. In the summer of 1999, the standards coordination committee members of the NFPA, NIOSH and OLES were joined by representatives from our long time partner, the National Institute of Justice, Office of Defense and Preparedness, and OSHA, the TISWIG, and the

SBCCOM. This group establishes its first objective to develop standards for CBRNE respiratory devices. The participants signed a memorandum of understanding, and NIJ apportioned sufficient funds to begin work and OLES was appointed the project manager. And just to emphasize, this project is funded by the National Institute of Justice, both for the respiratory equipment, and also on Thursday, we're going to be talking about PPE; that's also funded by NIJ. Based on its expertise and establishing industrial respiratory standards, NIOSH was given the lead technical role in the program. And SBCCOM, which is DOD's National Center for Research and Development Chemical and Biological Defense, was contracted to support NIOSH's efforts. In the past two years since PPE's standards development team has formed, we've racked up a number of achievements - identifying specific hazards and exposures that CBRNE equipment must protect against. This is a crucial base line for all of our efforts and that's still an ongoing research project. Developing a computer based tool for accessing hazards posed by specific types of CBRNE attacks, the model can program models of three different incidents outside and interior incidents using a variety of agents. We've identified and analyzed a number of standards from around the world, and I think today that some 340 standards contain elements that are appropriate to the work that we are doing. And then this led to the completion of the first CBRNE respiratory certification standard for self-contained breathing apparatus that was implemented in January of this year. Testing is currently ongoing. Additionally, we published a series of equipment guides, and those will be coming out on the CD Rom here shortly, providing the user information on the

most crucial types of CBRNE equipment, personal protection, detection, decontamination and communications. These user guides are in a format that makes it easy for first responders to compare the characteristics of each piece of equipment on the market today, or we thought it was; we're getting some feedback now that maybe perhaps it's not as understandable as some of them would like, but we can't please everybody, I guess. Next. In the next year and the following years, we're expanding in the program. The focus right now has been for chem bio, PPE, expanding that to cover chem bio detection, decontamination, and then radiological, nuclear and explosive type threats also. Thanks. Now I hope you see why we're so passionate about standards. Standards play an enormous role in the world of criminal justice and public safety. And in many cases, they're the difference between life and death. That why at OLES when people ask us for the definition of a standard, we give them this one. And next. And that concludes my presentation. If there is any questions? Thank you.

(Applause)

M: What we'd like to do to initiate the presentations and the discussions is give a sort of an overview of the CBRN/APR development program, the process that we're using, and talk a little bit about the milestones. So what we'd like to do is give that overall presentation so that when the follow on presentations that focus more on the detailed technical areas, I think it will fit better into the overall puzzle and you'll have a better feeling for what the concept totally is. And to begin with, go ahead Mike ... to begin with I'd sort of like to go back to a few things that Phil was talking about in the standards development process. You know, you have to

ask and say well why do you need to develop respirator standards? And pretty much you can bring it down to three possibilities, and that is the first that just nothing exists. The second consideration would be if you have new technologies, actually the second and third are centered around new technologies, if you have new technologies that enter into the area of hazard generation, and I think we can all appreciate that it doesn't take a whole lot to create a new hazard. Just the creativity of a terrorist can produce wonders in generating hazards. But new technology obviously also goes into equipment designs and products that evolve with changing technology. So standards that address respiratory protection need to be in tune with the new technologies, both from a hazard point of view and from a design performance point of view. And the respirator standards that we are looking at for terrorism really it would fall into the situation where all three of the criteria fit. As Phil mentioned, no standards... no respirator standards specifically for terroristic type events are currently existing. And certainly we know that new technologies are applicable in both hazards and in respirator design. So the bottom line is that the military standards or the existing NIOSH standards don't totally fit the bill for a CBRN standard for terrorist events. And when you look at the real reasons there, you really get into the purpose between military standards and NIOSH standards. NIOSH standards are principally for certification of product to ensure that performance requirements, quality assurance requirements are present in any product and are maintained in a product. Military standards on the other hand are geared more to a procurement type cycle to identify design performance requirements for a different purpose. The user groups are typically

different between a NIOSH standard and a military standard. Typically for the products that are certified under 42CFR, we're looking at general worker population type user groups. For the military standards, obviously it's a much narrower segment of the population; we're looking at military personnel. So they are quite, quite different. And you can carry the same type of logic through the hazard analysis. Okay, the hazards that we're dealing with, respirators that are certified for 42CFR are basically for industrial workplace settings. So we're talking about hazards that are sometimes very toxic and very difficult to deal with but, nevertheless, in most cases we do know what they are and we can control and have appropriated administrative processes in place. Military standards are designed specifically, or designed around battlefield scenarios. So it's a different type of a hazard, principally chemically warfare agents, as well as toxic industrials, but it's a different scenario. The terrorist event is totally unknown. We don't know what they can do, and they have the full range of both industrial hazards as well as general warfare hazards. So there are quite a few differences between existing NIOSH standards and military standards that create the void that really creates the opportunity to produce CBRN standards for respirators for terrorist events. In developing the standards, the CBRN standards, we've pretty much identified a program that we'd like to follow in identifying the requirements and actually coming up with the final product. And that process is basically the seven steps that we've identified there, and we'll just walk down through those. The hazard analysis, I think, is pretty obvious. Okay, before we can really do anything to define a standard for any type of breathing protection product, we

need to understand what the hazards are that we need to deal with. And really there is two components to the hazard analysis. We need to know, first of all, what we're dealing with and then we need to know and have some idea of what the quantity of the hazard is. The next step, or the next area of work is what I call protectability. And the protect ability actually has, I think, two components to it also and in our standards work really reflects that. And the first component is we know the hazard, we know what it is, we know how much it is, but we then need to apply the appropriate technology to provide the breathing protection against that hazard. So the protectability really needs to identify the technologies required to either barrier out the hazard or to process the hazard out of the breathing zone. The second part of the protectability though is once we do that and once we know what technologies are required to provide the protection, the question is well to what level do you need to do that, and what is a safe level to produce in the breathing zone of the respirator? So the protectability has the two aspects that we need to be looking at. Along with the hazard analysis and the protectability evaluations, we also go through a process of evaluating, identifying human factors and environmental factors concerns. And I think probably everybody in the room is pretty familiar with what we mean when we refer to human factors. Okay, we're talking communications, speech intelligibility, field of vision, ability to see through the respirator. Human factors concerns such as those. Environmental factors are different types of environmental conditions that the equipment may be exposed to during its use cycle. So during the standards development process, we're doing work on the hazard analysis, the protectability, the human factors,

and environmental factors analysis and investigations, and we do our work and become smarter in those areas, and eventually we come to the point where we can define a concept. And the concept basically starts to envision what the final product might be, and the final product, both from the point of view of the standard, the document, but as well as what type of product may be coming out the door through a certification process. So the concept, we like to put it down on paper and use it as sort of an evolving and a working document, but then follows the progress through the continued hazard analysis, the protectability investigations, the human factors analysis, and environmental factors analysis. So all these work their way into the concept paper and as the process matures in each of those areas, they're factored into the concept paper or the concept definition. So the concept is really the evolution of the standard. Once we have that and once we have the concept defined, we need to really be translating that into detailed requirements, specifically how we will define a requirement to achieve the objective that we've identified. So the requirements process, actually defining and identifying what the specific detailed technical requirements are, and then attendant to that, certainly we need to be developing test procedures. And the test procedures obviously need to be based from a certification point of view, because we need to make sure that we have a consistent method of performing tests and evaluating product against the requirement. So identifying the requirements really coincides with defining detailed test procedures for validating and proving the existence of the requirement in the product. Obviously, once we know the test procedure and define the test procedure, then we do need to validate that it can

repeatably do what we want it to do and establish the ability of the product to perform to the requirement. Then in addition to these steps, we also have the provisions to evaluate and to investigate any special quality assurance provisions that may pertain to the particular type of product that we're looking at, and in this case, the CBRN respirator. So the quality assurance provisions of the standard also need to be addressed. The other thing that we tried to do is as we progressed through the process of developing the standard, evaluating the various steps, defining and refining the requirements, and developing the test procedures, we certainly try to do it in an open environment,, and to encourage the information exchanged between the various stakeholders and user communities that will actually touch the standard and the products that the standard regulates. So we do try to have the open forum. Obviously, this public meeting is one step in that direction, okay, but in addition to the public meeting, we have numerous situations where we have meetings with various stakeholder groups, NFPA, IACP, and so forth. We have open discussions with different manufacturing organizations and manufacturers specifically. And in addition to all that, the concept that we've identified and the evolution of that concept is maintained on our website. So the concept for the CBRN/APR respirator is posted on the website, as well as the success of revisions and development of that concept. With all that in mind, one of the first things you need to do, and we probably spent what may seem like a disproportionate amount of time early in the program, is to develop the goal. But I think to do that is very worthwhile, because you can't really get to where you want to be unless you know the road that you're going to

take, okay. And if you don't know where you want to go, any road will get you there. So I think it was very important for us to take the time to really define what the goal for the program is for the air-purifying respirator standard. And, basically, the statement right there, pretty much, that is the goal. And to summarize it, it is to develop a NIOSH standard for a full facepiece air-purifying respirator for chemical, biological, radiological, nuclear and terrorist inhalation hazards. And we want to do that using a minimum number of filters, as the product and its intended, for first responder community. So that became the goal that really started to drive the product in the development effort for the CBRN/APR standard. And with that goal in mind, again, conceptionally, you can pretty much put down on paper what the types of products may come out of that standard. So very early in the game, we sort of developed this little tabulation that basically says that to maintain the goal, or to achieve the goal for our minimum number of filters, we wanted to try to keep it to perhaps four, and four that would fit a category based on duration, plus the level of protection that was being afforded by the product. So in this little illustration here, we have short duration considerations, long duration considerations, then the hazard protections being broken down into the toxic industrial materials including the chem bios with CO and without CO protection. So right along with our goal, we sort of envision perhaps a standard that could resolve in a respirator standard that would produce that type of product; basically four products, duration, duration dependant and hazard protection dependant. Now to do that, in being consistent with our steps in processes in developing the standard, the very first step was to identify the

hazards. And what we've done there for the CBRN/APR standard is basically we consulted with three different sources, and these were basically NIOSH... existing NIOSH standards, European standards, and existing military standards that talk about the types of threats for terrorist activities. Using those three sources, we've basically identified 12 primary hazards. Now these 12 hazards can further be categorized and broken down into groups that basically provide additional protections for up to approximately 110 chemical type hazards, plus biologicals and radiological hazards as well. And by categorizing the hazards, I think we'll certainly touch on that a little later in the program, but we're looking at basically breaking them into organic vapors, acid gases and so forth. It's also interesting to note and to be aware that the list that we've identified does include military considerations for threat levels of hazard also. Now with the hazards identified, we needed to look at what we could envision as the utilization or the usage of the product that's covered by the standard. And for this we basically identified two different use criteria or use conditions. And basically these are the warm zone and the crisis provision. The warm zone is in line with traditional use for this type of product which is basically used in areas of concentration less than IDLH exposures. It's well characterized, we know what we are dealing with, and the environment is known. That's the primary use for the CBRNA/APR respirators, so the warm zone use. But in addition to that, we envisioned the ability to provide what we are classifying as a crisis protection. And a crisis protection is, conceptually, to provide additional protections for contingency type situations, unplanned, unforeseen scenarios that could exist at a terrorist event.

This may be something like a secondary device, or entrapped areas of hazard, or even bringing in contamination on victims that are removed from the hot zone. So basically we see two usage conditions. Also in the crisis provision, we're looking and thought that we needed to address, a high physiological load. Okay, so crisis provision would allow protection or provide some degree of protection for the unforeseen, unplanned event, but also to accommodate high physiological demand which could be certainly experienced in this type of a situation. So to round it out though, we have the two usage conditions. We have the warm use as well as the crisis provision. Warm use is less than IDLH. Crisis provision is taking us to the unforeseen or the unplanned event, the unplanned scenario, at a higher level of demand, a higher flow rate. So taking the use concepts, combining it with the considerations for toxic materials, CO protection, no CO protection, long duration, short duration and crisis provision, we come up with the tabulation that's illustrated there. So basically we could envision four products that may be covered by the standard. Again, the variables being the toxic materials that are protected against with or without carbon monoxide protection, long duration, short duration, both in areas what we would call the warm zone, less than IDLH characterized, we know what we're dealing with. But then within each of these areas we would also have a provision for the crisis type of a protection. And crisis protection would really come down to the higher physiological demand, and the likelihood or the event that you may encounter an unexpected exposure to the hazard that you're dealing with. As noted here in the concept definition, we are working with the concept. So the times and the durations that are illustrated there

are really for, primarily for illustration purposes, but it also shows, it starts to show if you follow the evolution of the concept, it starts to show the maturity and the thinking and the development of the standard. The crisis provision that we're projecting here would be a five-minute type crisis in each of those conditions, so crisis again being high physiological load. Another area that we've identified and are addressing in the development of the standard is topic of interchangeability. When you think about interchangeability, this obviously is a concern or an issue that's been experienced that the recent events with the World Trade Center, the Pentagon, and Oklahoma City, so it's being identified as a real concern for first responders for these types of events. And the context that is being done is under the terminology of interoperability. So when you look at interoperability and interchangeability and you start to focus on that topic, interoperability could really and conceptually apply to a whole bunch of different possibilities. You could actually envision a situation where you were talking about interoperability being the possibility to exchange and component on a respirator if it's a replacement part. But we think, and in the approach that we've taken, is that the CBRN/APR respirator will be a systems approach. The respirator is a system, so it has a facepiece and the attendant filter or canister. When we talk about interchangeability on that system, we're talking about the possibility to perhaps interchange the filter, the consumable part. So in our definition of the concept for interchangeability, we focus on just the filter, the filter to mask connection. So the evolution or the development of our CBRN standard does have a provision for addressing the interchangeable or the consumable components to the respirator

system. And those consumable components, again, being the filters or the canisters. The current concept for the respirator envisions addressing the topic of interchangeability or the requirement for interchangeability is an optional type of requirement. So the standard will have a provision that identifies the interchangeability requirements and actually defines what needs to be considered to achieve interchangeability. We'll talk a little bit more about this in the technical discussions that follow. But I would like to say that in the process of defining the interchangeability and the approach to interchangeability, we did spend a considerable amount of time looking at different ways to achieve the interchangeable use of the consumable components. And one of the things that we tried to be very sensitive of in developing standards, and Phil touched a little bit on this earlier, is that we like the standards to be performance related. So we like to see our standards define performance level type requirements that the products need to meet. One of the, I think pitfalls, that you fall into when you start to talk about interchangeability, is it wants to drag you in another direction, it wants to drag you to the point where you need to be more design specific. So the standards development team did spend a considerable amount of time looking at creative alternatives or creative options for trying to achieve the interchangeability requirement. The bottom line or the end result was that we really came to the conclusion that the best way to do that was to try to pattern what we do after existing requirements defined in the European norms. So what we do envision is the interchangeability in our CBRN/APR standard will be a... it will be a provision for the standard, it will be an optional provision for the manufacturer to

request that capability, and it will be patterned after the European norm, and we'll talk a little bit more about that at one of the later discussions. So, just to sort of sum it up a little bit, under the development of our standard, we're really looking at three things I think that require and certainly get a lot of attention and focus. And these three issues are related to the ultimate use and how the system or the respirator will be used by the first responder community. And these basically are the warm zone consideration, the warm zone use, the crisis use tied to contingency situations, secondary devices, entrapped hazard or even importing hazard into the warm zone, and then also the interchangeability, the requirement or the provision for providing interchangeability of consumable components. These areas and these usage conditions we are factoring in to our concept, our definition of the respirator, and we are working with our partners, with OSHA, to actually develop the guidelines and the user criteria that would be attendant to these requirements. Hold it there. Go back. So with that in mind, our concept evolution is actually taking us to the point where we can envision the final standard or a standard that has three components or three tiers to it, which is also consistent with the SCBA standard that was developed last year. And basically the three tiers or the three areas are 42CFR part 84 applicable sections, so that's the existing NIOSH requirements, the appropriate sections that will apply to CBRN/APR. The second tier or the second element of the requirements structure is what we're calling requirements that are derived from other standards and specifications. So these are requirements where we have an existing base or an existing standard that we can draw on. And then thirdly, the special CBRN

requirements that will apply to this respirator. If you look at those a little closer, the first tier, the 42CFR part 84 requirements, would be pretty much summarized by the next two slides. This first one are the basically the general sections, the sub parts A, B, D, E, F and G, and ... go to the next one. And then in section I we would envision these requirements as being part of the CBRN/APR standard. Then the next tier of requirements are those that are defined and imported or developed from other existing standards and specifications. And these are summarized with a listing that's on the screen now, and basically these can pretty much be primarily focused on the human factors and the environmental factor areas or requirements for the respirator. So if you go down the list you have the field of view for the facepiece visor, which would be... is patterned pretty much after the European 136 standard. Lens abrasion, communications, also patterned, or not also, but patterned after NFPA 1981, not 100%, and the discussions on these I think will illustrate the differences, not 100% the same as the referenced NFPA requirements, but very similar. Then we go into the environmental requirements, the hot conditioning, cold conditioning, human conditioning, vibration and drop, and these are really the guidelines on these requirements, and implementing these requirements are derived from the military standards, Mil Standard A10F and I believe A10E works its way into there also. The interchangeability feature, again as I mentioned a few minutes ago, we're going to pattern and try to borrow what we can from EN136 and EN148, but I think it goes a little bit further than that and we'll discuss that. And then the bottom two requirements there are the breathing resistance and the CO2 requirements, and

these are patterned after existing 42CFR Part 84 requirements. And then in the third tier of requirements we have the special CBRN/APR requirements which come down to the gas life testing against the hazards that we had identified. The systems penetration permeation type testing for chemical warfare agents, and then the laboratory respiratory protection level testing for the facepiece fit characteristics. It's a busy slide, but if you take the evolution of the standard and the definition of all the requirements that we're going to talk about over the next day and a half, you can actually come up with a test matrix that itemizes the... identifies the various tests... the sequence that the test would be performed in and the numbers of respirators that may be required to do those tests and to evaluate them. This matrix will also be discussed later in the program. This is just to show you that there is an overall flow and arrangement to the requirements that are being defined for the respirator. The program milestones that we've identified for the standards development for the air-purifying respirator and other respirators is illustrated in the next couple slides. And here we can see that for our gas mask, the APR/CBRN respirator, the focal point of this meeting, we had the milestones illustrated there 1 through 6, which basically started with a definition of a concept back in April, a testing program and our public meeting being the second major milestone in the program. The testing program has been in process and the public meeting, obviously we're sitting here... by the end of June and then what we anticipate and what we plan is to have a more final or a final draft of the standard, and I call it near final, by the August 15 timeframe for continued review of the standard, and we're shooting for a release in October of this year and

implementation by the end of the year. Similarly, we've identified major milestones for the next two classes of CBRN respirator standards that we would be dealing with, and these are for the escape set as illustrated there. And the one thing that I would point out here is we have identified a public meeting milestone for the escape sets to be in October, and what we are actually envisioning is this may be moved up to end of August, the first of September timeframe at close in proximity to completion of the final draft of this standard so we could anticipate a public meeting where we're talking about the final draft of the gas mask standard as well as the concept and initial ideas for the escape set. And then I think the next class that we look at is the PAPR and that actually goes through mid June when we anticipate having a release of the standard.

(END OF TAPE 1, SIDE A)

M: ... the other classes of respirators actually go beyond those timeframes so ... Now I think it's important to point out a re-emphasize that the work that we have been doing, the steps that we go through, the hazard analysis, the protectability analysis, human factors and so forth all work their way into the concept paper. The original concept paper was developed in mid April and as the thought processes and work matures on the standard and the definition of the requirements, they do factor and work their way into the concept paper. The concept paper is posted on our website so you have a ready access to what the concept is. What we've been doing is revising the concept paper on what I call sort of a control basis, so we're revising it twice a month, middle of the month and the end of the month, so that it's just not a random bunch of different

concepts that are floating around. So basically each concept paper will have a revision date to it associated with that current level of the development. So far I think we do have the April 30, the May 31, and the June 15 additions or revision levels to that concept paper available in the information packets in front of the room. So I think our plan is to continue to do that so that as the requirements do become more mature and more finalized, they will find their way into the concept paper. But I will also caution you though it can go both ways. Obviously, so the concept paper is a sort of a living document and I would encourage you to stay in tune with the revisions to it. So the balance of the discussions today and tomorrow, we would like to focus on the hazard analysis. We want to talk about our efforts and our programs for the simulant programs and the efforts that we're doing to identify simulant agents for testing respirator products. We'd like to spend some time talking about our testing. While the milestones we had illustrated there was to do a testing program by the end of June, and we have done considerable amount of what we call survey or bench testing, we'd like to share that with you because it's very appropriate to some of the definition of the requirements. We'll talk a little bit about the systems testing and the details of what that testing is and share with you the current thoughts and the current thinking of what that requirement will be and what it looks like. We'll also have presentations on both the human factors and the environmental factors requirements. The human factors requirements looking at field of view, fogging, communications, and so forth, so we will talk in detail about those requirements, what the requirement is and how we envision establishing it, as well as the

environmental exposures and the relationships to the Mil Standard A10. Then we will spend a little further time talking about the interchangeability in our concept for defining the requirements to achieve that provision. And then as a final overview on the technical side, we will go over the test matrix which was illustrated a few minutes ago. So with that I'd like to, I think we're at the point where we can take ... do we? Do we? (pause) Hazard (...inaudible...) (pause) Okay. Why don't we do that. The break will be... we're going to move on to the hazard presentation... to start that and then we'll break probably mid way through that for the regular agenda break. And also I don't want to short circuit any questions and answers. The concept that we've discussed, the evolution of the concept, the information in detail is provided in the concept papers. We will be having presentations focusing on those areas, so we can... I think it's probably more appropriate to have the question and answers following each of those appropriate sections. So that's the game plan that we'd like to follow for the balance of the presentations. (pause) So I will turn it over to (pause)

Szalajda: Alright, my name is Jon Szalajda. I'm part of the NIOSH/NPPL team that's working on the standards development. What we are going to do at this point is to give you a little introduction into our hazard analysis and also discuss the test representative of the substances that we're considering as part of the standard. Once we've completed that part of the presentation, we'll take our break. And then Jim Genovese from SBCCOM will go into the discussion of the modeling that's being used to support the hazard analysis. I think one of the key points that we wanted to make was that we're trying to take efforts underway to categorize

potential respirator hazards in the families with the purpose of minimizing the number of tests that would have to be done as part of any certification program. (pause) Hum? Okay. Excuse us for a second, please. Yeah I guess. Can we back that up? (pause) There we go. It always happens, you know, it's like at home, whenever you get up to ... (laughter) Alright, that but uhm ... anyway what we're attempting to do is we've looked at a variety of lists that were published under various sources, whether they were available in common literature or classified sources within the Federal Government. And what we've done is part of the, as some of you are familiar with, as part of the effort that was conducted for the SCBA standard. We conducted a vulnerability assessment which took a look and identified a list of top respiratory inhalation hazards that we felt that we had to provide respiratory protection for. And to that end what we have done is gone ahead and identified these agents and taken a step back and look and try to classify the agents in terms of their physical properties and break them down into families to identify a test representative agent. And to that end, in a few minutes, Mike Monahan is going to review the work that we've done at NIOSH to break those substances down into those particular families. As part of that we've also done a certain amount of benchmark testing, which we're going to get into discussions tomorrow, first thing in the morning, as part of the presentations which will include the approach that was taken to identify to challenge as well as the breakthroughs that would be evaluated as part of the certification process. John Dower will discuss some of the biological and radiological hazards that are being addressed in terms of the standard, and then we'll wrap that up with a

discuss of the modeling that Jim Genovese from SBCCOM is conducting to support the standard development. And with that we'll let Mike get into the test representative agents.

Monahan: I'm Mike Monahan. I'm from the standards development team. Good one. Hit it once. Okay. What we try to do, we try to put together a bunch of independent experts to NIOSH/SBCCOM and actually Gary Nelson was on the team. Since these are basically media (?) or absorbent-based categories, we thought that the widest representation on our committee would help. So what we did, we've come up with a number of different categories and first one is acid gases, which is probably one of the more complicated ones because of the types of carbons that are available to be used. Depending on the type of carbon, the action against different agent, different chemical agents can be different, so this is why we're saying instead of one test representative agent, we're listing a number of them; Sulfur Dioxide, Hydrogen cyanide, cyanogens chloride, Phosphine, and Hydrogen cyanide. We feel that it's necessary, like I said, because of the number of types of carbons and other absorbent medias (?) that are out there. And the next one. Base gases, Ammonia is going to be our test representative agent. It's rather a small group in this particular category and it's pretty well defined. Next. Hydrocarbons... test representative agent is more than likely going to be Cyclohexane. This is more in line with the rest of the world. Everybody's going away from Carbon Tetrachloride. I think we have enough good evidence to make Cyclohexane our test representative agent. Okay, the next ... there is a group in our list of Hydrides and we are going to use Phosphine as that group test

representative agent. And the next one is Isocyanates (?). We are still studying this group. It's probably going to be broken up into, some of them are going to be classed as Hydrocarbons because they're just readily absorbed on carbon and their vapor pressures are very low. Other ones are probably going to have it be in the stand alone category, but there is a lot more information that has to be gathered on this particular family. Next... Carbon Monoxide (pause) there is actually, we have three chemicals in this family, Carbon Monoxide, Ironpentacarbonyl (?) and Nickelcarbonyl (?). We're still working on this, There is another one and we still have one going to work in and what it looks like is for Ironcarbonyl(?), when you expose it to a carbon cartridge, it deposits the iron onto the carbon and the Carbon monoxide comes through, so you have to... it's going to have to be a two step operation to pull these type of gases out. Next. Nitrogen oxide is going to be a category which is... we had suggested that they use the Nitrogen dioxide for a test representative agent. Based on some of the ongoing work, this may not be the right gas, we may end up with Nitrogen Oxide as a test representative agent, but there is more work going on in this area and as soon as we get the information, we'll put it out there for everybody to see. Okay? Next. There is... in the group of chemicals that we looked at for the NIOSH list of threats, there are a number of different chemicals that act as particulates, and these were just used DOP as a test representative agent. Also, in this particular group, we'll address the biologicals and the nuclear and the radiological agents, since we are going to consider them as particles. Formaldehyde is in a group by itself, I think it has to be addressed and any type of cartridge or canister that we would put forward. Also on the list

there is a number of ... (pause) there is a number of unknowns on our list that we have no idea right now where to categorize them. There very, very... some are, these chemicals have been listed as threats and we're trying to categorize them into some logical group, but there is a lot more work that we're doing on this area here. And then there is (pause) they are going to be some chemicals that will not be absorbed on carbon or any type of media (?), and these are going to have to be used with SCBAs. And these are our categories that we are putting forward for our testing agents. Okay, next. Due to the time constraints, we decided we were going to do a first step because of the amount of work necessary to address all the chemicals in this particular list that we had, plus the list of biologicals and radiological and nuclear agents that were out there. So what we try to do is come up with something that we can do on an intermediate basis. And what I came up with was trying to look at what tests were being run now by both NIOSH, the European sector and through the military. And also NIOSH is working on a... the toxicologists are working on a hazards list and it's not been completely formalized yet so there is not much sense in us coming up with something that's going to be permanent that will not address all the chemicals that are going to be put forward on this new list. It can be anywhere from 200 to close to 400 depending on whose looking at the list. So it's something that's out there and it's being address. Okay? Next. Before our test representative on this first step, the test representative agents, good Terry, we're going to use Ammonia as a test representative agent. I've looked at... it appears on both the NIOSH and the European standard and it's pretty well defined. We will get into the actual

challenge concentrations and breakpoints tomorrow when we talk. The benchmark testing we did... we started out... I took a... since we hadn't had our hazards analysis done, we'd looked at intermediate step to start with of, most of these gases are tested around a 5,000 PPM level. And we took... on our benchmark testing, which I'll talk about tomorrow, we took a number of different cartridges and tried them out to see how that looked for these different types of gases. And I'll get into more of that tomorrow. Some of the other gases are as follows: Carbon Monoxide is on our list, but we're not really testing it right now. It will have to be tested later. Carbon Tetrachloride is what was one of the test representative samples like I talked before. We did test it and we also did test... that's good, Terry, the Cyclohexane. Cyanogen Chloride is a military... is used by the military. It's used for a test agent for determining the quality of the military absorbents. It's quite a challenge for a lot of carbons. Cyclohexane is another organic vapor challenge gas. It's used throughout Europe and plus Japan and I think Canada right now. Formaldehyde on our list, which we already talked about it. And Hydrogen Cyanide is actually on three standards that I looked at. Hydrogen Sulfide is another gas, acid gas which is tested regularly by European and NIOSH. It does present challenges... different carbons and I think it's a good agent to use. The Nitrogen dioxide... I've already mentioned that we're investigating this one further. We did do a lot of testing with this and we looked at it strictly as Nitrogen dioxide in Nitrogen dioxide ought which is probably not the right way to do it. You'll have to look at both Nitrogen dioxide and Nitrogen oxide. Phosgene is another gas, acid gas, that the military uses for evaluation of

military canisters and we thought it was good one to use for this particular area. That's about it I think. Oh, there is one more. There is the particulates. There is Sulfur dioxide is used by NIOSH and the European standard and DOP is a particulate challenge. We didn't do any particulate testing so far. We're going to be doing more of that later in our verification testing. Okay, using these gases, using the chemical agents, the 151 on the NIOSH CWA TIC list, we felt that we could cover with the test agents that we just went through, 108 different agents plus the particulate biologicals which there are 13 of and 16 nuclear and radiological agents. In the organic vapor family, what we're keying on here is the vapor pressure of the gases. And we feel that anything that has a vapor pressure less than Carbon tetrachloride or Cyclohexane would be absorbed readily on carbon. And using that same scenario, your war gases, Sarin and Sulfur Mustard or Distilled Mustard would also be absorbed quite readily on carbon. The acid gas family, the organics are 61 different chemicals. We have a list that we'll show you in a little bit. There is 27 acid gases that we feel that we could readily protect a person with. And there is three base gases with the test representative agent of Ammonia, and four Hydrides with using Phosphine as a test representative agent. The Nitrogen oxide family is up in question right now. There is six in that list. As I said before, the test representative agent may change on that one. And Formaldehyde... there is just the one and there is three chemicals on the Carbon monoxide family list, using Carbon monoxide as the test challenge agent. In the particulate family, Jon missed it I guess, and we talked about it originally. The particulates as of right now, we are going to require a mechanical P100 filter for

our initial concept, and we feel that this will take care of the chemical particulates and the biological and radiological. Jon is going to talk more about these particulates in a minute. The next slide, please. This is a list of the organic family and acid gas family of chemicals that we feel that we can absorb using the test representative agents. It's pretty extensive. You'll be able to look at this once we get it on the website. Want to go on? I think it's pretty self-explanatory. The particulate family, again, there is a number, CS&CN are kind of... they are actually a mix of organic vapor and particulates. We put them under the organics, but any carbon filter with a P100 filter will take out CS&CN and we feel that it grants a good bit of protection there. Okay, Jon, do you want to talk about the biologicals?

Jon: A little bit of voice shift. I found that my bass normally, it carries quite well. Folks, as you can see, from the particulate family you are going to see that from the threats analysis, one of the things that we identified was that for some of the chemicals, because of their crystalline nature, they don't behave so much as gas or a vapor, but the way you would naturally find them in a threat scenario would be as a particulate matter. So to re-address particulates and then we're going to deal, not only with the other particulates that you're going to associate with any potential event, but specifically, we did some investigations to identify those biological and radiologic agents that were a primary concern for US domestic terrorism. I'm a qualify that up front because that model doesn't necessarily hold, but may hold worldwide. Terry, next slide, please. We spoke with the experts on the biologic issue from the US Army's Medical Institute for Infectious Diseases

and from our experts at CDC who have been working on the issue of biological terrorism for several years now. The agents that you see listed there, the organisms that you see are those that are suspected to be primarily or potential used as biological weapons and those are those that present an inhalation hazard. There are other, as you can readily recognize with biologicals, there is a multiple routes of entry. There is breaks or cuts in the skin, inhalation, as well as mucus membrane protections. And the issues of concern with the biologicals are primarily their aerodynamic particle size, their infectious dose, the routes of infection, facial leakage, and actually whether we have the testers available in the field that you can actually detect, identify and quantify what biological agent of concern that you're actually dealing with. But the focus here is that as Mike has already said, our approach is that, as far as the biological organism is concerned, you can generic treat it just like another particle in the air. And from that standpoint, we're recommending the most protective particulate filter that's available, and that is a P100 using current technology. The only international standard as a new standard is the P4 standard in Europe and Australia is a particulate filter that it takes one order of magnitude higher protection and that is a 99.997% efficient filter. Next slide please, Terry. We further spoke with the experts on the radiologic particulate. Again, US Amrid (?) and this time with the Department of Energy... I can tell you that there are other radiologic agents of concern, some 2,500 radiologic materials have actually been identified by the Department of Energy. But these 16 are the 16 that are considered highest probable threats right now. And the realities are from Tritium (?) to

Americium (?)... all radiological agents are Alpha, Beta, Gamma, X-Ray Neutron, or High Speed Electron, High Speed Proton, or some other particle capable of producing ions in the human body. The half lives for these radionuclides (?) arrange from six hours for a Technetium (?) to 1.4×10^6 years to the 10^{10} th, or about 1.4... 140 trillion years for Thorium. Thirteen of the 18 have greater than ten year half lives and will result in enduring hazards in the environment. And for example, fallout... the potential of fallout from Chernobyl was measured around the world, so if we have a nuclear event, it's not just a US issue; it's an international issue. External radiation from external sources, respirators cannot protect against all external radiation. So if part of the user's guidance for this will be, although the respirator will protect against the particulate, you have to be concerned about the ionizing radiation. So anyone that is working that environment will need detectors to continually monitor their total dose, and our focus here is going to be protection from the inhalation hazard. And, next slide please, Terry. With regard to radiological respiratory protection, I'm going to give you some current references. The Department of Energy recommends a full face respiratory protection for entrance into radiologic contaminated area. Actually that instruction set goes on to say that it would have a HEPA mechanical filter plus such other absorbents necessary to deal with other hazards. The respiratory threat can be eliminated by employing high efficiency particulate air filters or P100 filters, that quote's from the Domestic Preparedness Technician HazMat Course that was provided by the US Army to the 120 largest cities in the United States. For the uninformed, and most of you I know are

informed, the HEPA or high efficiency particulate air filter is the filter NIOSH currently approves for PAPRs. And the P100 filter is the current high efficiency particulate air filter that we approve for negative pressure for facial piece respirators. The US Army specifies an M40 (?) full faced gas mask with a two element canister containing a HEPA filtration, an ASVM TATA (?) Cooperite (?) carbon filtration media. That US Army specification is for a P100 mechanical filter only. So the summary of these approaches is that whether it's a biological particulate or a radiological particulate, a particle is a particle... is the fundamental principle. And for those of us that are familiar with the filter efficiency curves for P100 filters, you understand that the most penetrated particle size is around a 0.3 to 0.4 micron particle. Well it turns out that these biologicals and radiologics span the whole spectrum, but the take home message is, whether it's smaller than 0.3, 0.4 or larger, the efficiency of filtration gets better in both direction, but you have to have the full facepiece respiratory protection in order to get the protection, not only from inhalation, but from your eye, nose and oral mucus membranes. And the second piece of the take home message is that the face seal is an incredibly important piece of this respiratory protection, because even if the filter is very effective if the user doesn't have the proper face seal as part of his package, he's going to have a lesser level of protection. And for some of the organisms and for some of the radiologic particulate, an effective level of protection is going to be vital to their long-term health. Mike, I'll turn it back over to you.

Monahan: So far in our hazard analysis, I need the next slide, hazard analysis, we've been

talking mostly about the cartridges. As far as the systems-based test, we are going to continue with the paradigm we started with the SCVAs in that we're going to use penetration permeation challenges of the complete system. These are based on the most creditable event indoor scenarios and are... the units would be challenged against GB at 2,000 milligrams per cubic meter and distilled Sulfur Mustard as a vapor challenge of about 300 milligrams per cubic meter plus a droplet challenge of approximate equal to 10 gram per cubic meter. Now our test scenarios for this particular area are going to be based on use scenarios. And I put together a... it's a more less a stylized challenge what we feel that we might, that these tests are going to look like. Essentially what it is it's going to be a ramp up to 2,000 and then, which you would, then... we are going to call it our critical event or critical exposure in the crisis area. You would immediately leave that area, so you'd get a drop in concentration almost immediately. And what we're doing is carrying the test out for the six hours just to make sure that we don't have any penetration or permeation through this system while, that would be used over one day. Okay. Terry Cloonan is going to talk more about this later on when he talks about the testing. That's about it for us for today. Okay? Thank you.

M: Does anybody have any questions at this time on this information? I think we are probably in a good position to take a break, especially since they just brought the refreshments in. So why don't we reconvene at 3:00 and we'll move on with the hazard... (...inaudible...)

(break)

M: We're getting pretty close to a quorum, so we can probably go ahead and get

started again. I had a couple of administrative notes that I wanted to pass along and hopefully nobody will miss this in the transition. Tomorrow morning instead of starting, originally we had anticipated starting at 9:00, what we would like to do is move that up a half an hour and begin at 8:30 to try to accommodate some people's travel plans in the afternoon. Hopefully that won't present a problem. (laughter) Hopefully that won't present a problem for anybody to get up that early, but we figure a lot of you are captive here in town anyway and the locals will have to deal with the traffic a little bit earlier. That was the first item, so please keep in mind, we're starting at 8:30 tomorrow, not 9:00. Second item, to get along with the topic of making presentations at... we would like to invite... if you're not on the agenda but you want to make a contribution in terms of making a presentation here at this forum, all we would like you to do is either to see me or see one of the two ladies, either Adrienne or Christine that are in the back to get your name included on the agenda and we'll accommodate you during the presentation period tomorrow afternoon. That's the second item. The third item is what we'd like to do today, we're going to finish up the hazard analysis and also address the work that NIOSH has been doing with SBCCOM and other parties on simulants. In order to facilitate the presentations that are going to happen after NIOSH is done with... NIOSH and SBCCOM are done with their discussions, we would like to take about a ten minute break following the simulant presentation, and if Larry Brey or Janice Bradley have any information that they wanted to make available through the CD, we'd like to accommodate that at that time during that break. So just the recap, because this is my old Army training, I told you

something once already and I'll reinforce it, but you know, first thing is as far as we're going to start at, what time tomorrow?

Audience: 8:30

M: Thank you. (chuckle) The second thing is that if you would like to make a presentation and you're not on the agenda, either please see me or please see one of the ladies in the back and we'll accommodate your request. And then the third is that following the simulant presentation, we'll have just a brief ten minute break. I guess at that point we'll go ahead and conclude the discussion of the work that we've been doing on the hazard analysis. And I think one of the things that we really wanted to reinforce as part of this analysis, is that this is an ongoing process that, you know, back last year that we had took a step forward with conducting a vulnerability assessment, identification of potential hazards, and developing a test program for the SCBA/CBRN standard. And where we are now is in the next evolutionary step of that process that where we've moved on to a new class of respirator, but in turn we're still using the same principles and the same methodology that we approach the SCBA process with. And to that end, you know, as we continue moving along with the respirator develop... or this development of standards for the variety of respirators, we're just going to continue to build upon the initial foundation from the vulnerability assessment and the modeling that has been done and will continue to be done as we move forward with the standards development process. So to that end, I'd like to introduce Jim Genovese. He is our lead contact with SBCCOM in conducting the hazards assessment and modeling and he's going to kind of review for you right

now what he is doing as well as with his contractor to conduct modeling and support of the APR standard development. So, Jim.

Genovese: Good afternoon. One thing, just a little administrative comments from me, personally, I've been here since 1:00 and I haven't heard any questions from the audience. As an instructor off and on for over 24 years teaching 5th grade girls, 9th grade and 12th grade females, nursing students, medical technologists, and teaching across the country hazards materials to those civilian and military, one of the things that, certainly a teacher likes to hear is questions. And what I am going to be presenting you today on hazards modeling really has to do with counting molecules and particles and how that chemistry is really driving the challenge criteria that we're going to use for these APR, so I would like to at least hear from some of the students in the audience some questions about anything that I might present that poses you some concern. I remember when I was at St. Paul School for Girls, I heard some of my students out front... saying to me, or saying to themselves before they entered class, they said, "You know, if Mr. Genovese says it loud or he says it twice or he says that it's important and he writes it on the board, it'll be on the test." And I didn't realize that I was giving away the test every time that I was acting up here at the podium or in the classroom, but if you pick up any of those nuances during my presentation, don't be afraid to write it down because I may ask you a test question later on. Okay. Hazard analysis of the toxic industrial chemicals. This a real challenge. This is different than our... basically our chocolate and vanilla Mustard agent and Sarin analysis for the chemical warfare agents. There is a wide range of chemical hazards that we're

looking at here. As you heard from my NIOSH colleagues, There is hundreds of these hazards out there, and then to ask this simple sorption media-like carbon to be able to sorp all of these different chemistries, we're asking for a lot, and in some cases, I'm going to show you some numbers here that are pretty shocking... pretty high. And I'm concerned that, number one I think we need to go this route, we need to improve on the APR capabilities, but the same time we need to make sure that, you know, we're covering our homework and doing it well. Okay, Terry. Okay, so we're going to look at the objectives. I'll comment a little bit on warm zone strategy that Art Stemfley (?) and really nobody's ever done that before, but what actually happens in the warm zone. We kind of already know what happens in the hot zone; it's the place where you go when you don't know anything. But in the warm zone, well you might know something and in that warm zone scenario you certainly may find APRs there. And how do we characterize the hazards in that warm zone? Well that's a real challenge for my colleague from Optometric, Inc., Mr. Art Stemfley (?). He's a world class physicist and a former chemical division chief and SBCCOM and he and I are working feverishly to figure what really happens in the warm zone. We'll look at some of the assessment technology, some of the estimations we're making on this modeling. What we need from you all as users and builders of this technology and then wind up with just some discussions and conclusions. Terry. So, we'll do basically an overview of assessments looking... I'm just going to re-visit the chemistries since I am a chemist. I want to present the problem from a chemical perspective from a chemical guy whose worked 20 years at the Army, but it's also

been a chemical instructor, there is a lot of interesting chemistry going on here that I think we need to be concerned about. Hot zone modeling which we've done with our chemical warfare agents and how we'll use that as a basis to develop what we're going to do in the warm zone. And then I'll show you some typical vapor concentration time profiles that allow us then to determine what are those challenged concentrations that we're going to use to challenge our air-purifying respirators. Terry. The finding the vulnerability, that's that little blue splotch in the middle, is actually a Venn diagram of four critical areas that we need to look at when we're looking at vulnerability. It's not a simply problem. It's not straightforward. It's actually quite difficult. And so this challenge that NIST and OLES and SBCCOM and NIOSH are attempting to do, give us a little bit of grace here because this is not easy. No one's done this really before, especially with what we're trying to take on, and I think our application to this new environment where bad guys are coming on our own soil and using these hazards against us, I think we need to do better and I'm not sure that we can rely on our old OSHA regulations under traditional HazMat to get us through the night. And so that's why I'm presenting sort of our logic to how we are doing this hazard analysis. First of all as challenge concentration I get into some specifics on what that is, but what are the drivers for the amount or the concentration of material actually reaches at casualty. Deliver methods, we're going to be looking at what we did for the CWAs, the chemical warfare agents, spills, explosives and sprayers. We're also adding, because of the acquisition capability of a terrorist for some of these tics, we're going to look at compressed gas cylinders as well. On the bottom there

you see toxicology. A lot of interesting things I think we need to talk about from toxin. I think one thing, even though this form is addressing APRs, I think we'd better be looking at humans as systems and be considering multiple routes of entry, both what the guy is wearing from an inhalation perspective, but also what is he wearing as far as an ensemble to protect his skin exposure. Protectability, what is that gear? What is that combination of gear that he's wearing? Is it what, and what deployment operation is acceptable to wear what gear? I think we need to really look at that just to get to that small vulnerability box. And guess what? See that small blue box? Whatever that is, all of our threats have to fit within the box. That's how it works. So if your vulnerability box isn't big enough and your threats don't fit in there, then we haven't done our homework for developing this whole system. Okay, Terry. Alright, toxicology, very simply you'll get a quick lesson in toxicology. What is it? Water is a chemical, so is Hydrogen cyanide, but one's more toxic than the other, but there is an LD50 for water. So what are we dealing with? How bad is the hazard? How fast does it react? How much is out there in the environment during or after an incident, the concentration? We call that C for those guys that actually do what we call CT calculations. How long are you exposed? Or if I hold my breath and I'm in a toxic environment where inhalation is the biggest driver, I'll hold my breath while I'm precluding that route of entry, but how long can I hold my breath before I actually do have an inhalation hazard? And then what routes of entry are the drivers? Obviously we're thinking inhalation here, but we'd better be thinking about percutaneous as well as inhalation because remember we're all a system. We have multiple routes of

entry in our body that we use to function and live daily and we need to consider that. Terry. Here's some relative inhalation toxicities. Look at the range here. It's kind of interesting. You've got VX down there. There is even, you know... so you're down there in almost the single digits and you go four orders of magnitude, 10,000 times increase in toxicities to get up there around... Carbon monoxides up there at the high end. That's a pretty tall order. Ten thousand times the toxicity, and this is what we're trying to work with. It's a challenge. The chemicals that you see in there have all kinds of different properties. Some are more reactive than others. Some slip by charcoal better than others. Some actually get on charcoal and make other things. So it's not an easy challenge, and what Les had mentioned to you his concept about how we're approaching this and Mike Monahan on how we're dealing with these chemistries, I agree with them wholeheartedly. It's not an easy process. Terry. Just to give you some ideas on it, here's the CWAs, go back and review. It's always good to review. I was in teaching school. It was excellent. You know, these kids, two months ago you taught them this and they absolutely look at you like they're clueless after two months and don't remember anything that you've taught them. So I'm going to go back and review CWAs with you. Sarin which is our big threat agent there molecular weight, but look at the vapor pressure and volatility, now I like to think... I like the volatility, see I like big numbers. Art's definitely put these in grams per cubic meter, which is that's an equilibrium saturation condition at a specific temperature. I think it's at 20 degrees C there. Usually that would be expressed at 16,000 milligrams per cubic meter, but we can go with that. But look

at the gambit there as you go down to GD and soman (?) 3.9, Sulfur Mustard you can see not very volatile. You've got to coax it with a little bit of surface environment, a little bit of heat and let it sit around in a confined space and even to get the reasonable vapor concentrations. And then you got CK. And CK its volatility, that's a compound. That compound does not want to be a liquid. It's a vapor. It wants to be a vapor. With that kind of volatility, and so when you put that compound in inside environments, you've got problems because it wants to self distribute and then you have a closed box scenario like this conference hall here which is just going to make matters worse. These have changed since my colleagues presented. This is an old list that they had provided me a couple, actually about a couple months ago, but some of the compounds are still the same here. This is part of the list that my NIOSH colleagues presented and, you know, no real surprises here except you do have some toxicological bad actors, some things that do strange things on charcoal, and some problems where the charcoal really doesn't like these things, the just sort of, they either slip by the charcoal or you have some special thing in order to get them to sorb. So, There is some real thinking that we need to do to figure out how we're going to use this primary list to protect our personnel. Terry. And then we get into the physical properties here, and I'm going to show you some Ammonia curves later, but look at that. That's actually 6,200 which would be 6 million, 2 hundred milligrams per cubic meter. That thing doesn't want to... it's obviously a gas, very chaotic in a room like this where it's going to move wherever it feels like it wants to move. If you got it in a multi-story building, you can get it to go wherever you want it to go. And I just

want to point out some interesting thing here just for sake of chemistry. Maybe a little chemistry test here. What you're seeing here is significant volatilities and I think that's a real, real problem here with these toxic industrial chemicals. Chemicals that have significant volatilities... unless there is a reactive component on that chemical, it'll usually try to meander past the charcoal. But if it has a reactive component like the acid gases or the base gases, sometimes they get through. But Ammonia certainly is an exception to that rule. So I just wanted to give you a flavor for kind of where our problems are. Terry. Okay, now again, the same thing. Look at the volatility with your Hydrogen cyanide, basically a million there, a million milligrams per cubic meter. And I just want to show you this one, just to bring out a point here. Just more of a chemical point than anything else. Look at Phosphine, 57 million milligrams per cubic meter. Go back to the first chart before. Phosphine is basically what we call isovalent (?) with Ammonia. It's one element down below it on the periodic table. Ammonia's only got 6 million, 2 hundred milligram per cubic meter, where Phosphine go to the next one, where Phosphine's got 57 million. Now just a question for all you chemists in the audience, why does that occur? That doesn't make any sense. Phosphine has a higher molecular weight. Why is it 10 times the volatility? And if anybody knows the answer, it's actually a two-part answer, you can see me after the presentation. But this problem on volatility and reactivity of these materials is going to be important to us, as well as delivery methods. Spills, probably not many spills, although some of these materials are liquids, but they're probably not going to be liquids for long. Spray devices are certainly possible. Explosives are also possible,

and as well as pressurized cylinders that Art and I have sort of done a quick market survey, and it's easy to do that here in the United States, because they just come out and give you all the information. There is lots of pressurized cylinders that a bad guy can carry in to a venue and use the cylinders just as they were intended and disseminate these toxic industrial chemicals without a problem. Terry. And this challenged concentration. This is the multi component thing that makes challenged concentration. What actually gets into your lungs or into your systemic system, remember there is a route of entry through the skin, that's the slower process, your skin's usually pretty protective. But that inhalation route of entry, I'll make the same statement... the same statement I make to my students across the country when I teach HazMat... the main route of entry for all toxic materials that are biological or chemical in nature is through the inhalation route of entry. I'm saying 95% is my guess right now and I'm pretty confident with that. So if you protect that inhalation route of entry, your going well on your way to protecting the hazards that could enter the system. Okay, so the venue characteristics, closed box scenarios, compartmentalized rooms, multi-story environments, subways, dome stadiums all are going to have different characteristics and where are the lungs? Where are the casualties, the location of those casualties? If you're in a dome stadium and you disseminate... you're on top of the dome stadium, I think you did one of these with Keana Reeves one time where he was on top of the stadium. But if you were to drop Hydrogen cyanide from the top of the dome, it would never to the bottom of the dome at the ice rink because of its vapor density, and so all the lungs are at the bottom of the zone, so

if you don't look at the venue, look at your chemical and look at the characteristics of your chemical, you could be... as a terrorist you could be making some big mistakes in wasting a lot of time. So also we need to look at the amount and type of hazard as well. Alright, so challenged concentration is pretty complicated. Remember, you have to overlay the hazard over top of the people who are ingesting or breathing or somehow inhaling that hazard, and it's that game, that challenge that they receive when they're exposed, that's what driving your casualty rate. Terry. And the venues, the venues we've used were from our chemical warfare agent venues. We're going to have a couple more eventually doing some things that are really related to this type of dissemination environments. But right now we're starting off with these large meeting room, auditorium and theatre all the way up to some big things like airport concourses and...

(END OF TAPE 1, SIDE B)

Genovese: ... the introductions that Art and I are making with this that are, I think, of importance. The mass that's delivered... the volume that's delivered is a function of the container size and type. Not anything, not a no brainer, but just remember so the bad guy's coming in, if he comes in with two other accomplices, you only come in with so much of the hazards, so you can use that as part of your scenario and a certain physical volume can be basically put in there unless you really got an excellent plan and some smart terrorists. The rate of mass release is dependent on the method of dissemination. Absolutely important. The slope at which the material enters the room, the faster it gets out and generates, the highest concentration it can, before it reaches what we call dissemination equilibrium, the better your mass release and your device is going to be. Compressed gas discharge relies on a lot of things. It's dependant on the material itself. How fast does it come out of the container. Does it go through "Joel (?) Thompson expansion and cooling." Compressed gases are also subjective to pressure, temperature changes, valve sizes, and I'll show you some examples of that in just a little bit. Terry? Some more things, they usually follow what we call, and this is where Art Stemfley (?) is the stand out in this. He's got, he has enough choke flow equations that would choke this room. It's five or six from anything from 1912 all the way up to 1950. But these are equations when you're opening up cylinders. You open up a 2,000 PSI cylinder of Chlorine, you let the thing go without even a regulator and after a while you don't have 2,000 PSI pushing out the Chlorine, you actually have a gradual reduction. Well Art actually can do the physics calculations using this equation to tell you what that's drop off rate and what's the flow that's occurring through the dissemination of that compressed gas cylinder. Ventilation kinetics drastically influences the vapor concentrations of these toxic industrial chemicals. There are all kinds of things going on here. You have convective currents in this room. You have HVAC system, just people move

around. All types of things. If it has a high vapor density, low vapor density, high volatility, and even chemical reactivity, all these will have affects on what actually happens. And right now we're trying to simplify our calculations here. We might go back and do heavy gas, we might do on the outside with things like a 90 ton tanker car of Chlorine on the outside, and do some heavy gas or what we call Phen 3 (?) analysis, but for right now we're simplifying our analysis and just using basically transport and diffusion and evaporation without looking at the heavy gas affect. Terry? Indoor scenarios, they're complex as I mentioned. There is all kinds of buildings. There's all kinds of rooms in the buildings. There's different ventilation characters. Do you have the windows open? Do you have them open or closed or the doors open or closed? Do you have elevator shafts? Do you have long stairwells? Is the AC on or off? Do you have a pressurized stairwell in some of the more modern buildings? Where is the source? Where is its location? Is it a continuous source? Is it not a continuous source? And then you could also, which we've done in our model that Art and I have worked on, we can actually recommend some remediation techniques to help in dilution and just distribution of those hazards. Terry? And here's an eye chart, but all this is, you can look at this later when we, is it already published, John? Yes or no, it will be. Okay. Just different scenarios with the identification scenario, the intent or the size of the scenario, and then the total volume, which means includes the HVAC and how many rooms you're involved with, and then the number of air exchanges per hour and outside air integrations. We actually use those detailed calculations in our modeling. Terry? And here's more of the same. And what you do after you do a range of these things is what we call power metric approach where you look at a whole bunch of everything. And you start seeing some things that really look like bad actors. And those bad actors are the ones that we really then start looking at when we start doing data analysis and summary so that we can give you some

numbers that when you would ever experience these kind of hazards in an environmental real operational scenario that we feel that our numbers are pretty close. Terry? Here are some of the ones that we're adding some gas cylinders and bottles with different sizes and different dissemination methods to... which we didn't do on our CWAs, but definitely are specific as we did a market survey with Matheson (?) and Fischer (?) and a whole bunch of other chemical providers and there's a whole gambit of different stuff that you could buy just with a credit card. It's amazing. So tics are really going to be a challenge to us. Just one comment I want to make. When I briefed the National Command Authority before Operation Top Off, I was asked to talk about toxic industrial chemicals, and these were with three and four stars there in that briefing. And I told them don't make the same mistake that we made in 1915 with the Battle of Empery (?) where the Germans used 6,000 Chlorine tanks and they just opened up the Chlorine tanks, waited for the wind to be right and just dropped that high vapor density Chlorine down on the British and French troops. I still believe that. Now we have 90 ton tanker cars of Chlorine. I did an assessment for the FBI before the 96 Olympics. I told them I says there are rail cars going past Fulton County Stadium and new Olympic stadium as we speak, 90 ton tanker cars of Chlorine with an eight inch breaching charge, I can provide a continuous source for 30 minutes and we'll knock out both stadiums for that period of time. And the FBI rerouted their HAZMATs during those Olympic ceremonies. So these tics are not anything to take lightly. They are of concern, certainly to me. Terry. This is Art's description of ventilation connects. We look at two things when we model. We look at the initial, there is two things that happen when you have a chemical event. First of all you have to have chemicals, you have to have a target, you have to have an event that distributes the hazard. That first part here, we call this our dissemination sphere. And depending on, well if you have a spill, this sphere is kind of localized if you

have a spray or an explosive. It can become, you know, a little more expansive. You know, for instance, a small bursar charge might give you a 30 meter dissemination zone. But what we're doing in that is that we have a variety of these things that we've been collecting them over the years a data base on different source terms and different scenarios, so that its the event, the initial distribution event drives the bugs in the gas. After that, mother nature takes over, whether it's inside or outside, so all your other conditions after the initial dissemination, and this is important, nobody in the old days, we never did this. We used to do chemical modeling and still do this. Bob Morrison is back there laughing. He remembers. We would just take a container, we'd blow it, we just... soon it became instantaneously disseminated, oh yeah, it could be two gallons of GB and all of a sudden, boy, it was just out there. And then we let the wind act on it. That's not exactly what happens and with different scenarios and different devices you're going to see these hazards give you different initial sores terms (?). so we need to get a handle on that, and that's what Art and I are doing with our different scenario development. But then you can use, if you are on an inside scenario, different ventilation characteristics, convective systems, collective protection systems if you actually happen to have them in place. You can look at the effects using HVAC and air exchanges on the outside, as well as even for you fire fighters and HazMat guys in the audience, you can even dilute or distribute the hazard with certain carefully used positive pressure ventilation techniques. So I think our model's pretty robust in that we can look at the hazard, tell where the molecules are going, and then even make some recommendations on what you can do to kind of dilute and redistribute those molecules. Let's say if you have to do an extraction (...inaudible...) with personnel that are unprotected. Maybe you want to do a dilution to help that out. Terry? Here's a typical one that we did for a chemical warfare agent. This is a pretty good device. See what I'm saying here.

See that concentration. In 10 minutes, look at that high, steep slope. That's a good device. If a terrorist had that kind of a device, he's doing good. Especially on the inside. Now, somebody... the terrorist looks... somebody opens the window and looks what happens... or a door. And you start seeing decay immediately. And if you use... somebody comes... oh, we got that right, look at that... it's about the time for, you know, at least the second engine to arrive, and with the proper use of PPV we can really significantly drop off that challenge concentration, let's say that we got to do an extraction with a lot of people that are unprotected. Okay, Terry. Here's some runs we did for Ammonia. This is a .25 inch opening. That's without the regulator on that. It's just you open up the nozzle and you let it out, and what's... called choke flow conditions. In a meeting room, this is a small room. I just want to show you the numbers. If you open that up, don't do this, cause this is not good. Cause if that... if 200 milligrams for cubic meter is the IDLH, what am I getting here? Look, let's do the math here. Roughly in that 10 minute interval, I'm getting 500,000 CT, that's doesn't sound good. All right. So, it's these kind of numbers where you probably don't want to go in there with APRs. You definitely want to follow OSHA regulations and be in SCBA, but you want to me... if you happen to get stuck in there, you can get out. And I think that's what the concept that we've presented is... more of a, if I make a mistake and I'm in the wrong place at the wrong time, I still can get out. But these are different scenarios. By the way, let me just show you these numbers here. 1K is 150 pounds. What's that one there say? Yeah, that's 50 pounds and this is 18 pounds. And, you know, these down here are probably doable, but that's just showing you what happens with just Ammonia. Terry. And then here's an Ammonia gas cylinder and here's what we did here... was change the orifice size of the nozzle and you see different, you know, you see different concentration time per... with that. So it's this kind of calculation where we are doing the, to 12

or whatever, that we finally come up with, so that we look at the agent's specific characteristics, we look at the venue characteristics and device characteristics and role it all together and say, "Wow, this is probably what this APR might experience in the warm zone, and also what it might experience if for some reason it accidentally gets stuck in the hot zone." Okay. Protective... next one. Okay. Respiratory uses. These are just my own assumptions and Art's as well... escape hood respirator, atmosphere greater than IDLH, you know, it's just... you're there and you shouldn't be there and you can get out, and we've already talked about the duration... short duration, but high protection for that. Self contained breathing apparatus, obviously, for hot zones this would probably... this is certainly in level A, level B type scenarios where you have an unknown and you're concentration is well above IDLH and actually your air bottle's probably going to be the limited factor. And, the APRs is what we are addressing now, and we're assuming less than IDLH. I'm thinking, just a gut feeling, on some of the scenarios that Art and I are playing around with the warm zone, that are not less than IDLH were probably near PEL in many cases and only in certain situations, where, let's say, you are doing a tech decon where a guy has been sliming around in it in level A, where if you happen to be in the gear where you would start getting approaching IDLH, but in most cases I think we would be good to go in the warm zone for technical decon corridor operation. And, fairly longer protection duration, the only thing you need to watch, though, with APRs is moisture loading. You know, in those enviro decon carters (?) you got high humidity concentrations, you also have high aerosol concentration, your particular filters, you're going to collect those, and you're going to be sorbing off moisture vapor... we need to be thinking about what effects that has on the sorption life of the carbon. Okay. Some of the operations you are using common sense for perimeter security decon, as I mentioned, maybe for EMS support, and certainly

at the hospitals are looking at that as some assists to emergency room operations as well. Okay. And in conclusion... some... this assessment, this vulnerability assessment, looks at these four. It is not easy. It takes... it's a lot of legwork to do this. As you can see, I just showed you two of those Ammonia scenarios. We've got to do a lot more of those and you have to plug in all the specifics for each of those. And we are not necessarily intending to do exactly what the terrorist is going to do, but we are presenting some generic options that he might use. The toxicities of the TICs and the CWAs that I mentioned before, we got a large difference there. Now, here's the game plan, you may make up cause you have a more volatile material, you can distribute that toxic industrial chemical quicker, but you have less toxicity, so you see, so, there might be somewhat of a tradeoff there. Let me make a comment there. I notice Genovese getting on his high horse here on TICs and CWAs, my concern about TICs is I can get, as those concentration curves showed you, I can get concentrations that are high. Not even approaching saturation, but high. And I'm wondering, are those concentrations to a point where they dilute the air that you are breathing so that your oxygen content is reduced. I'm concerned about that. I don't know the answers yet. And, also the fact that with these APRs, if you don't have the right ensemble with them as well, you have another route of entry. I mean, if you do have high concentrations that percutaneous route of entry from a systemic calculation perspective could add up to trouble. Okay, challenge levels... are venue specific and you see the different once that we are looking at, and we do a lot of these so that hopefully that we build our vulnerability box big enough that all of our... that we think that the threats might be all of them, those threats fit with in that vulnerability box. And then the test standard is dependent on respirator uses, and my argument is stay in the warm zone. Okay. Any comments or questions for Jim on hazard modeling analysis or anything I have talked about. Yes ma'am.

M: Can you come to the microphone please?

(...inaudible...)

F: I just had a question...

M: Excuse me, if you tell us your name and your organization as part of the record.

Jones: I'm Mary Jones and I work with Allegheny County Health Department, and I was personally curious about dispensing a chemical with crop dusting. And I thought with your wide experience, you might, you know, extrapolate from the information you gave us to how it would appear... the types of problems on an application with a crop duster.

Genovese: We have, Art and I have done crop dusting before. Some of it is sensitive. Although we are going to do a couple here. Hopefully we can get out enough information to satisfy your question, ma'am. One thing that I can tell you is that... let me give you some numbers. C130... let's say if the bad guy were able to get a hold of C130, you can put 5,000 gallons in a C130 and they already have systems that spray that amount out. For a typical crop duster, it flies low to the ground, you know, some of those guys fly 10, 12 feet, 15 feet off the deck, cause they want to make sure that they get the crops that they are disseminating the fill capacities for some of those sprayers is around 500 gallons, so that's a significant amount. So if you're doing a fairly small area, not a whole city, you could do a reasonable job from a toxicity perspective with that dissemination system, but you got to get low. Doing it up at high levels usually doesn't work for some of these chemicals. Did that help or answer your question? Okay. I think for right now, it's about all... we'll try... we'll attempt a... one of the scenarios that we're going to do for TICs on the outside was the ruptured Chlorine tanker. The crop duster, we could... see if we could work that in somehow. I think that's a good point. It keeps coming up in the news. Any other questions or comments? Okay. Thanks.
(applause)

(pause)

Payla: Good afternoon. My name is Frank Payla, and I would like to introduce a colleague on the simulant project, Dr. Rivin of the US Army, Solder Biological Chemical Command, who has been working with simulants for years at the Natick laboratories. Next please. We are going to present the project that NIOSH and SBCCOM are now engaged to identify simulant compounds for the respirator manufacturer community to be able to use in the development of new products. I would like to emphasize that actual chemical warfare agents will be used during testing for NIOSH certification of respirators. This project is to provide respirator manufacturers with information so they can select simulants to perform development work and for their pretesting of respirators before submitting them to NIOSH. We will discuss the background, purpose and objective, category one which is absorption simulants onto charcoals, category two, permeation simulants through barrier materials and also, we'll discuss the details of the permeation studies that we are proposing. Also the potential benefits that may resolve from this study. Next please. Thank you. For some background, at the April 2001 NIOSH public meeting that was held in Edgewood, Maryland... when it was announced that NIOSH was going to perform certification with actual chemical warfare agents, respirator manufacturers and other personal equipment manufacturers requested that NIOSH identify simulants so they can perform research, development and pre-testing on their products. The manufacturers requested this because number one, actual chemical warfare agents are not available to them. Number two, chemical warfare agents are extremely toxic. Number three, having SBCCOM or other surety (?) laboratories pretest their products is very expensive. Plus the respirator manufacturers wanted some indication on how well their products would perform before submitting for NIOSH certification. The same concern for simulant development was conveyed

in the January 22, 2002, ISCA letter to NIOSH. From that time, we've been doing some research and we identified that there are a great number of reports out there that address simulants, but a lot of the data was insufficient. In other words, you can't really draw a correlation from the data that we've seen. A lot of times the tests were not held under the same conditions, so it was very difficult to put a sound reliability coefficient or correlations coefficient between the simulants and for the chemical warfare agent. In general, in the past, what the military... what they did, was go ahead and performed a lot of their chemical warfare agent testing with actual agent. There was no need for them to go and do a lot of testing with simulants because they had access to the live agents. There are two categories of simulants that we will be addressing: number one would be the absorption of simulants on activated charcoal; number two the permeation of simulants through barrier materials. For the permeation category, a correlation coefficient of a given simulant to a chemical warfare agent may be different for different barrier materials. In other words, the correlation coefficients are material dependent, so that makes it very difficult because there is just a whole array of materials, a whole array of simulants to different agents. Next please. NIOSH and SBCCOM reviewed some databases that contained reports that pertained to simulants vs. (?) barrier materials vs. (?) chemical warfare agents. So in other words, we were looking at reports that if they went ahead and they tested a certain material, at a certain thickness, with a certain agent, under the same test condition, and then with that same material from that same lot be tested with simulants. And we were trying to identify these reports so we could draw some correlation coefficient, and there's very limited amounts of reports out there available. From this, the solder or SBCCOM Agent Simulant Knowledge Advisory Office developed a matrix dated February 20, 2002. This indicates eight unclassified reports. It indicates the simulants used and the materials tested. Now this is about the closest thing we got

to it, but from that data on those reports, it's still inconclusive. We can't really identify a correlation coefficient from those. This matrix, by the way, is on the tables outside the room here, if you guys here...if the stakeholders are interesting in obtaining it. Also the reports identified in this matrix will be provided upon request by NIOSH to any of the stakeholders. As you could see, there is a list of simulants. There are 10 chemical compounds that were used as chemical warfare agent simulants on the permeation testing of barrier materials. Next please. For category one, the purpose is to identify chemical compounds that simulates the absorption of Sarin, nerve agent, and Sulfur Mustard, blister agent on activated carbon. The objective is to identify through research chemical compounds that can be used as an absorption simulant and to identify pertinent reports that are available to the public. Next slide. For category two the purpose is to identify through research and testing, chemical compounds that simulate the permeation... the penetration and permeation effects of GB and HD through barrier materials. The objective is to identify the simulants in laboratory procedures that can be used by manufacturers for estimated GB and HD permeation through barrier materials used to manufacture respirators. Next slide please. Dr. Rivin will present the details of the simulant permeation study at this time. Dr. Rivin?

Rivin: This project is being carried out by SBCCOM in two locations. The agent work that will be part of this is at Edgewood and most of the simulant work will be at Natick. Now, the objective is to be able to predict or at least estimate the agent resistance of a materials by doing a simulant test. Now the simulants that we are looking at, one of the criteria that we are setting is, not only must it be correlating well with the agent, but it should be a chemical that is easily handled and is not particularly toxic. Another aspect here is the question of the test itself. And what we are trying to do is develop a test which will be relatively simple to do, that will give reproducible results and that could be used by the manufacturers themselves

if they chose. Now we are going to try to select two simulants for each of two agents. And we are going to then look at the simulant permeation properties using this new test, which I will go into briefly, and we're going to do this on three materials, initially. And these materials will be selected from those materials that are used in the PPE. After doing... developing... let's see, designing the apparatus, the test, in doing this agent permeation, we're also going to be doing... I'm sorry, simulant permeation... we'll also be doing agent permeation in order to get this correlation. This will be supplemented by tests of the solubility. And I'll mention a little more about that later, about why we want to do that. And finally this will be produced as a NIOSH guidance document with all of the test results and the description. So, what we do, we will try to be as transparent as possible about this. Next slide please. Now, I mentioned that we want to make this test simple, and we want to make it reproducible. In order to do this, you have to have a method of putting on a very controlled amount of your challenge materials. There are a lot of methods that have been used in literature... drop implantation, there is vapor, there are combinations of these... the most extreme and the most reproducible is a fully flooded surface. In other words, you put sufficient of the liquid agent or simulant on that surface, so that the surface is completely or the material is completely saturated. And in this cell (?) the specimen which is about a one inch diameter specimen, is held between the top, which is screwed down on the specimen and beneath it is a sweep (?)... just a pure gas sweep (?). And the sample after insertion, you screw this down and the top part becomes a liquid well. You can then add the liquid and saturate that surface and you are continually sweeping (?) through the bottom-line and into a real-time detector. And this type of method will give you the highest permeation as opposed to vapor concentrations or to partial absorption that you get with drops. At the same time it gives you a very reproducible result. The basic test will be developed using

simulants and then it will be checked with the agent and with additional simulant studies. Now this is part of an overall system, which is on the next... the idea is... to keep this both... to control those parameters which are most important and those parameters are the gas flow... I've already mentioned that the surface will be fully flooded. The detector is one that should be able to determine the materials of interest and there are a number of relatively simple detectors that could be used. We are not talking about fruit flies or indicator paper, things like that, we are talking about our detectors such as photo ionization or flame ionization detectors. And, the whole system is quite small. As you noticed that cell has a total... cylindrical cell and total diameter of around two inches. Now permeation is determined by a number of factors and the next... all right, basically, there are three key components to a permeation value. The diffusion coefficient which is the rates that the molecule moves through the medium. The solubility, which is the amount of material that actually gets into the medium and the thickness which I have as L . So if we know the thickness, we measure the permeation, we also are measure solubility and therefore one can determine the diffusion coefficient. You don't need the solubility and diffusion coefficient to be able to determine that a materials is going to be agent resistant. But we need it because we want to understand. We want to make sure that we are picking simulants that are going to mirror the properties of the agents. And to do this we want to make sure the solubility and the diffusion coefficient are in keeping with what we want. Because you can control the permeation... let's say you want to have a very low permeation, you can do this by having a very low diffusion coefficient or a very low solubility or a very thick material. You are limited on how thick you are going to make the material, so it's going to be one of these two other factors. Now, those factors are determined by basic properties of the material and the challenge molecule. And for the diffusion coefficient, molecular size is probably

the most important. This is followed by concentration and temperature. So the larger the molecule, the slower it will diffuse through a particular medium. The simulants are going to be of a different size than the agents. And, however the relationship between the simulant and the agent should scale as we are showing here. The solubility is more complicated, because the solubility has to do with the interaction between the diffusing molecule and the matrix that it is diffusing through and it's different for each molecule that you use. So that if you want to mirror an agent with a simulant you have to be sure that you are getting at least similar chemical interactions. And this is going to be difficult but there is enough information available in the literature, enough work that has been done, so we think we have a reasonably good shot at getting both of these. Once one has these individual components, eventually it should be able to predict the permeation from some basic physical parameters of the membrane that you are looking at, material, and the diffusant. But that's the not the first objective of this work now. The first objective is to be able to select the simulants, show they correlate with the agents, and come up with a relatively simple test that could be used in a variety of ways and that it will be reproducible. We are working on a pretty tight time scale and we are hoping to have this in keeping with NIOSH's goals. So I think at this point I will turn it back to Frank, unless there are any questions right now that anyone has.

(...inaudible...)

Murphy: Robert Murphy, US Marine Corp, Chem Bio Instant (?) Response Force. Sir the detector that you have on the material that you are utilizing. To what levels do you have the photo ionization detector detect the chemical coming through. Is it at a IDLH level, is it a LD50 level... at what levels are you picking up the...

Rivin: It will be different for the different chemicals. But you can, with a photo ionization detector you can get down to parts per million, and because this is a

flooded surface, you know, you are getting the maximum permeation, and by controlling the flow rate that you use, you can get quite high concentrations so that we have a lot of flexibility in terms of changing temperature or changing flow rates so that we can keep within the range of whatever (?) the detector.

Murphy: Right. And I think you can also... you can understand, as a user, it is very important to me that I know at what level this is going to come through... it's going to permeate through the material that I am utilizing, cause obviously, I want to know the breakthrough time at a level in which I know if I am using this concentration and this type of work or this type of atmosphere, I need to be able to tell my workers, okay, we've got this amount of time because of this, the information that you are providing. We need to get out of this equipment, get out of this gear, change (...inaudible...), get through decon. So I think it's important to understand or to know, and I think you do, that we understand the breakthrough times at the certain level that it comes, right, so we can catch it? Am I thinking the same way that you are presenting this?

Rivin: Well, what you're... the point you are raising is an important point. It is not the main objective at this stage.

Murphy: Okay.

Rivin: What we are trying now is simply to be able to show that a particular material is relatively resistant to agent and it's worth using that material and going ahead. We are going to be doing work along the lines of what you are mentioning also. I didn't go into that, but as part of this study, we want to get some idea of the concentration dependence, and what you are referring to is really looking at what happens at lower concentrations. Because you are not likely to be in a situation where your surface is fully flooded. So we will be getting some information along that. But the main objective is to look at this at the most severe conditions, to be able to get the correlations that people know this material is safe to use. They are

not going to know from this first work exactly what the break time will be at a lower concentration, but you can be sure it's going to be much longer than the break times we get in this test. But that's just something that has to be done too.

Payla: Thank you Dr. Rivin. Again, this is more directed at the manufacturers so that they can go ahead and do a lot of their development work. Then when they go ahead and submit their products to meet certain standards, so, hopefully if they meet the standards, then that will satisfy your needs to, so. Next slide, please. The potential benefits that we are looking at here, hopefully will provide the data so manufacturers can make a determination on potential pretest simulants to do their development and research work. Also, system manufacturers and their decision on selecting barrier materials based on scientific information, reducing product development costs and times, and expedites availability of new respirators and materials technology for the users. Next please. In summary, we are going to identify through research, chemical compounds that can be used as absorption simulants and to identify pertinent reports that are available to the public. Number two, identify simulants and laboratory procedures that can be used by manufacturers for estimating chemical warfare agents permeation through barrier materials. Number three, write a NIOSH guidance document that describes test procedure, simulants and results of the agents tests. Again, I want to emphasize that NIOSH or SBCCOM will not guarantee the simulants identified in the report... excuse me, I want to emphasize that NIOSH or SBCCOM will not guarantee the simulants identified in the project will work on all materials and their correlation coefficients to chemical warfare agents. Therefore, passage of the manufacturers pretest with simulants, does not guarantee passage of official NIOSH certification testing. If anyone has... would assist NIOSH or SBCCOM by providing additional information or reports or test data with simulants, we would certainly appreciate that. This concludes our presentation, and at this time I

will address any questions. Thank you.

Denny: Frank Denny, I'm with Veterans Affairs. I'm not sure who to ask the question to, but since there was discussion about breakthrough times with regard to concentration, I was curious as to whether anybody is dealing with humidity and physical exertion as a factor in these breakthrough times.

M: Are you referring to the breakthrough times on...

Denny: On the cartridges on air purifying respirators.

(END OF TAPE 2, SIDE A)

Payla: Because we are looking at different levels of humidity.

Denny: How much of an impact might that have? Are you going to look at that? (pause)

Monahan: We are going to address... this is Mike Monahan. We are going to address humidity levels and some of the stress factors tomorrow. We are... essentially the humidity levels we are going to look at 85% RH and 25% RH which is the... both ends of the spectrum. Okay? Does that satisfy you?

Newcomb: Bill Newcomb, North Safety Products. Speaking for the manufacturers that are in the room, one of the things that we were really looking for is to use simulate and (...inaudible...) NIOSH testing as well as other... as preconditioning testing, the test at SBCCOM are expensive and are meaningless if you fail because you don't get the respirator back, you can't see what's going on and so forth. What we really need is simulants that can be used across the board. If they are truly simulants they can be used for certification testing as well. Thank you.

M: Thank you. We will take that into consideration.

M: Any other comments at this time. All right. We'd like to take a 10 minute break and then we'll wrap up with two presentations from the audience.

(break)

M: ... and NIOSH, you know, invites everybody that has an opinion on the subject matter to have an opportunity to speak in the forum and present their views on the

subject matter. And that extent (?) today, we are honored to have two presentations from stakeholders and interested parties. The first presentation... the first presentation is going to be by Dr. Larry Brey. He is with the 3M Corporation and their Occupational and Safety and Health Division in St. Paul, Minnesota. His presentation is going to deal with some of the work that they have been doing internally with simulants. Our second and final presenter today is going to be Ms. Janice Bradley with the ISEA organization and then we will have a couple of concluding remarks before we adjourn for the day. So with that, Dr. Brey?

Brey: Thank you. I would like to say I greatly enjoyed the last presentation because it's exactly the sort of thing that I find interesting and some of the same sort of work that we've been doing internally at 3M, looking at simulants, or at least one simulant for one of the chemical agents. In the background, Sulfur Mustard is one of the penetrating chemical agents through polymers. And, as a manufacturer, we need a screening method for selecting potential materials of construction for personal protective equipment to select the best candidates for this expensive and time consuming agent testing, which is expensive and time consuming. Now we are not looking for the perfect simulant. We are not looking to predict breakthrough times. We just want some way of ordering candidate materials as to whether or not it is reasonable to spend the time and money to have them tested against actual agent. We also want to be able to test the final finished respirator or protective equipment device on a mannequin or a head form against some sort of simulant to see if there are any failure mechanisms that we haven't seen... any leak pads for example that are susceptible to rapid permeation through the final item. Here's a graph showing the molecular structures of Sulfur Mustard in the upper left hand corner and some of the simulants which have been talked about for use as simulants to Sulfur Mustard. Chemically, the most reasonable thing to a chemist would be half-Mustard, which differs from Mustard... the only thing that

it lacks is one of the Chlorine atoms in the two group in the two position of the second Chlorine Ethyl Group. However, that molecule has some of the bite still of its cousin, Mustard. And it smells very bad to boot. So, we would look... we'd like to have something that's a little less toxic and less unpleasant to work with. Now, another molecule that has been mentioned or thought about is 15 Dycloral Pentane. It has about the same, superficially chain linked as Mustard. It has two Chlorines on the end of the molecule, however, it is a much more volatile molecule than is Mustard as was mentioned earlier the vapor of Mustard at room temperature is about .07 millimeters; whereas the vapor pressure of 15 Dycloral Pentane at room temperature is closer to .7 millimeters. It's almost seven times more volatile. That is the equilibrium concentration above a pool of the liquid simulant would be seven times greater for 15 Dycloral Pentane than it would be for actual Mustard. That has some consequences in some of the tests that I'll show later. Methyl Solisolit (?) has also been indicated as a possible simulant. We haven't done any work with that, but it's low in toxicity and might... and highly polar... it might warrant further considerations. We are certainly not wedded to 15 Dycloral Pentane if another better simulant comes along. Certainly, there's no problem with considering that. That would be taken up very enthusiastically. But 15 Dycloral Pentane is fairly low in toxicity as well and it's easily detected at low concentrations with fairly simple equipment. So... here's a permeation cell that was devised by one of the workers in our lab, Rugru (?) Pateoff (?). It's constructed from commercially available modular high vacuum piping flanges and clamps. All this is off the shelf type item. And one very slick thing about it is that clamp that holds together the two halves of the permeation cell. It's not your wing nut sort of thing, it's a spring loaded clamp which compresses those "O" rings down when the engaged position so that the "O" rings aren't really exposed to simulant. Okay. You see there are two possible configurations differing from

each other just by turning the apparatus by 180 degrees. On the configuration on the left, we can put liquid drops of the simulant on the surface of the polymer film or polymer material, and enclose the cell, pass pure Nitrogen through the sweep (?) chamber at the bottom and analyze the affluent (?) for the concentration of the simulant as a function of time, using a gas chromatograph with a gas sampling valve. And the other configuration, flip the 180 degrees, we can put a pool, or a liquid content of the simulant in the bottom half of the chamber and allow the equilibrium vapor concentration to be established above that pool of liquid to challenge a polymer film with the saturation concentration, which for 15 Dycloral Pentane is about 1,000 parts per million. Remember, for Mustard that equilibrium concentration is more like 150 parts per million. People who work in industrial respirators talk about parts per million and not in milligrams per cubic meters.

The next slide. This is just a picture of the apparatus showing the flame ionization detector with a gas sampling valve. And you can see to the far left hand corner of the picture the actual little permeation cell device. Stainless steel tubing connects the permeation device to the gas chromatograph sampling valve. Next slide. Now if you do one of these permeation experiments, what do you expect to see. As Dr. Rivin pointed out, the little droplet model is not a very theoretical easy case to treat. A much more easily theoretically case to treat is the vapor concentration which is the saturation. And, if you do that, this, for example, is the permeation rate observed for a piece of saran wrap from the grocery store... half a mil thick, it's a copolymer of Poly Vanilladean (?) Chloride, so it's pretty good barrier polymer. You see, there's no penetration for some time, then all of a sudden, the simulant starts to penetrate and eventually the concentration of the simulant in the affluent (?) reaches a steady state of concentration, a steady state value. And the equation there describes that steady state. P is the permeability coefficient. It's the product of the kinetic term and the thermodynamic term, the solubility term that

Dr. Rivin talked about in the earlier talk. P is the product of those two terms. Also, the steady state permeation rate is proportional to the difference in the pressure of the permeant (?) on the two sides of the film. Remember for Mustard, that would be seven times less than for this simulant because the vapor concentration of Mustard above saturated liquid is $1/7^{\text{th}}$ out of the 15 Dycloral Pentane. This is a vapor permeation test. Okay. The area, I should say, of our little permeation device is 9.5 square centimeters, about 10 square centimeters which is similar to some that I believe are used at SBCCOM in terms of area. The sweep (?) flow is 500 millimeters per minute Nitrogen. Next slide. Now a perfect Mustard simulant would have the same value of P , that is the product of the kinetic term and the solubility term as Mustard, but we are not looking for a perfect simulant. I don't even know that there could be such thing. Now you'll see later on in the presentation when I show some data, that the permeation coefficient for the simulant DCP seems larger than the permeation coefficient for Mustard. Still, even if the magnitude of the permeation coefficient is different. You could get useful information from DCP as a simulant if it varied in the same way as the permeation coefficient for Mustard did as a function of the polymer against which... that you are challenging with the simulant. So just because the permeation coefficient is not the same as Mustard, doesn't necessarily mean that you can't get useful information out of using this simulant. Next slide. I should emphasize that polymer samples from a variety of sources were used in this work, and the permeation performance may be strongly effected by the sample in history... the cross-link density for elastomers molecular weight, presence of fillers, plasticizers, etc. and of course, highly important, the thickness in determining how long it takes from breakthrough to occur to a polymer film. So no general judgment about the performance of any polymer type should be drawn from this data later... right now. Next slide. Actually, let look at some Mustard

data first. SBCCOM has a website upon which they have published two reports evaluating different protective gloves against actual Mustard agent, in a liquid challenge, liquid droplet Mustard test and looking at the vapor permeation through the glove materials. Those agents (?) just 10 grams per square meter. Several interesting things about this diagram, one... actually, several types of polymers don't do well against this liquid challenge. For example, Polyvinyl Chloride and the Nitrile type polymers. Now again, I'm not saying that this is characteristic of Nitrile but this is what the SBCCOM results seem to show. Now I should emphasize also these are not the SBCCOM results per se, I have taken the raw data from the SBCCOM website and recalculated that as breakthrough curves instead of cumulative permeation curves. Cumulative permeation is important for the biological effects of the chemical agents, but when you want to look at the material properties, it's more informative, I think, to look at the actual breakthrough curves. So I took the cumulative curves and differentiated them and that's some of the data that's shown on these slides. The raw data is in these reports that are on the website. So you see, Nitrile and PVC showed fairly quick levels of permeation. Neoprene glove was intermediate in performance. And, there were to extremely high quality performers, the Viton (?) glove... Viton (?) being a Fluoro Elastomer and the Butyl glove. And I believe that the cumulative penetration never reached the failing value for either of those two gloves after 24 hours of testing. So they were extremely, extremely good barrier layers... uh, levels... uh, barriers. Also, of interest is the magnitude of the permeation rate. You see at several hundred nanograms of Mustard per minute per square centimeter. And you will see later on the permeation rate for the simulant is going to be much higher than that. Let's see... also of interest... is the fact that this uses a very sensitive detector to determine Mustard breakthrough. It's called a minicam. It uses solid state concentration followed by thermal desorption and analysis using a

flame photometric detector. So it can detect permeation rates perhaps less than one nanogram per minute per square centimeter. Now they had used a flame ionization detector instead of this super sensitive detector, the sensitivity of the flame ionization detector would be approximately 100 nanograms per minute square centimeters. It would look like all four of those polymers behaved the same, because you wouldn't be able to see the cumulated penetration using the detector if it was only as sensitive as a flame ionization detector. So this shows the importance in this type of cumulative permeation work of having an ultra-sensitive detector. We are hopeful that we wouldn't have to use that for the simulant type of work that I'll talk about now. Now, here is some simulant work using 15 Dycloral Pentane. First, notice the magnitude of the Y axis. It's much higher than it was for Mustard, that is partially due to the higher volatility, the higher vapor pressure of the simulant and the (...inaudible...) is going to be reached. You see, some of these materials did not reach the (...inaudible...), but again, you see PVC and Nitrile did fairly poorly on this test against a simulant. You see EPDM rubber did poorly. However, you should mention that some of the best barriers known are blends of EPDM with butyl. So just because EPDM... this particular sample of EPDM did poorly, doesn't mean that a compound of EPDM would not be an excellent barrier. Both Nitrile samples were fairly poor in resistance to the simulant, again, Neoprene and Neoprene natural rubber glove showed a little bit of resistance to permeation by the simulant. The Chloralsulfinated (?) Polyethylene, a Hypalon (?) type of polymer, showed pretty decent resistance, permeation, and also notice the plateau (?) value at which it is starting to go to. It looks like it's an extremely good barrier layer. And then of course the ones for which really hardly any breakthrough was noticed at the end of 24 hours were the Neoprene two layer glove, the Butyl rubber glove, however, there was a slight lifting of the baseline. I had just reached the level of quantitation of

the gas chromatograph flame ionization detector after about 20 hours into that run, and you see there's a tiny bit of upward motion on the Neoprene two layer and the Butyl rubber glove. But I should emphasize again that the flame ionization detector is not sensitive enough to rank these low permeability samples at these chemical agent cumulative breakthrough levels. So, it could be that Neoprene is only half as good as Butyl rubber. It's just impossible to tell from this type of test. But we are not looking for those type of results from a simulant work, at least as a manufacturer. We are looking for ranking of things which clearly won't work or that aren't going to be useful to submit for agent testing. For the actual very good barrier layers, we have to bite the bullet and actually have assurance lab do some testing against live agents to rank extremely high quality barrier layers. Let's see... anything else about that... oh, two extremely good samples were thermoplastic Fluoropolymer, one of ours, (chuckle) and Polyamide, a very thin Polyamide, a three mil Polyamide. (laughter) Quite exceptional performance for that very thin material. Okay, next slide. Now those were liquid permeation tests. Here are some vapor permeation tests using the saturated 15 DCP simulant. Again, you see Polyethylene isn't much... doesn't look like it's going to be very promising as a material of construction. Again, PVC doesn't do well. Again, EPDM rubber doesn't do very well. But interestingly enough, here the Nitrile glove, even a thin four mil Nitrile glove had decent barrier properties against the simulant vapor. And, the 25 mil Nitrile rubber glove actually had extremely good resistance to the simulant vapor. Now I don't know if that would hold true for Mustard or not. Certainly it would be interesting to see. Again, as a vapor barrier, Polyamide at one mil lasted a long, long, long time. Okay, next slide. So in conclusion, there's only limited data that indicates that permeation testing using the simulant 15 Dichloral Pentane may be useful in screening polymers for resistance to permeation by Mustard. This test would be most useful in excluding

candidate materials, not a differentiating between good performers. For one thing the flame ionization detector can't... doesn't really have the sensitivity to get down into the ultra-low levels at which chemical agent breakthrough occurs. And would have to say that results from permeation testing using simulants would need to be confirmed by live agent testing, especially in the case of those very, very high quality barriers. So, any questions? (applause)

M: And our last presenter for today is going to be Ms. Janice Bradley from the ISEA organization.

Bradley: Good afternoon... a most good evening. I think NIOSH put me on last because they thought there wouldn't be anyone left in the room by the time they got on. However, I do think they were confident that I would bring the discussion out of the molecular level, and I will. Thank you for the opportunity to address some issues today. I do want to preface my comments by saying that I have not edited them on the hour since this meeting began. So, as some of these issues have been discussed already today, I have not gone through with a red pen and crossed out some of my remarks, so... some of these might have come up before, but I will not exceed my allotted time. So that's the good news. ISEA supports NIOSH in its attempt to develop a standard for evaluating the effectiveness of respirators for use in atmospheres that may contain CBRN war agents. We recognize that it is imperative that these user needs be address as soon as possible, however, the formal rule making process, which considers input from all stakeholders, is necessary for developing appropriate CBRN equipment standards. As NIOSH did with 42 CFR Part 84 standards for particulate respirators, we encourage you to develop performance based standards for equipment that will protect first responders and resist including design restrictive specifications in the standard. Design criteria inhibits innovation and prevents new technology from being designed and incorporated into products. With regards to the interchangeability

concept that NIOSH has introduced, the interchangeability of consumable filter cartridges and canisters was raised in the RAN report by responders to the World Trade Center, the Pentagon, and Oklahoma City events. It is our opinion that there was an adequate supply of products supplied to these sites, however, due to confusing logistics, inadequate training and enforcement and the lack of fit testing, the supplies were depleted prematurely or never reached the users in need. Respirators are designed as a system, this includes the combined performance of the individual components as well as the quality systems of the individual manufacturers. Focusing on the interface of the filter element to the facepiece will negate this system's approach. A comparison has been made to OSHA allowing for the interchangeability of SCBA cylinders under emergency use conditions. We believe that this is a faulty analogy. There are currently only three principle manufacturers of SCBA cylinders. Their products are made to specific standards from the United States Department of Transportation and the Compressed Gas Association, and operate under consistent pressures. The SCBA transforms that pressure to a breathable rate of airflow. Nothing changes the form, fit or function of the SCBA. In developing respirators, however, manufacturers must take into consideration the weight, size, height, positioning of various components in the development of the system. The performance of the approved system could be negatively impacted by attaching a filter element that is heavy, heavier/larger, shaped or positioned differently, or has a greater breathing resistance than the filter element originally designed in the system. A system cannot be considered interchangeable just because it meets the performance requirements set by NIOSH and has a military type thread or some type of adaptor to accommodate that thread. In addition, the interchangeability of respirator components is a use issue and should also be addressed by OSHA. It is unclear how NIOSH would ensure user protection of interchangeable parts in a certification test. We believe that

interchangeability will decrease the level of protection provided to users because any NIOSH certification test cannot ensure user protection when different parts are used in the field under any conditions. Manufacturers are also concerned about the liability and the confusion that this provision may lead to with the user community. Given the high degree of liability associated with respirator products in the United States, how can companies be held harmless for misuse or in the case of a terrorist agent, be held harmless for providing respirators that are not complete protection. Who will determine the type and the form of cartridge or canister connection? And will this void the approval since NIOSH tests systems? We recommend that NIOSH seek system level approval and not regulate the interchangeability of components. NIOSH should satisfy the rank (?) concerns by supporting the development of emergency logistical support, training, enforcement and fit testing. Regarding potential misuse and decontamination issues, we fear that air purifying respirators that meet the NIOSH requirements for CBRN protection, will be born (?) in atmospheres where the concentration of the agent is unknown or IDLH. Using air purifying respirators for entry into an IDLH atmospheres goes against today's common use practice. Does NIOSH plan to promote these devices as appropriate for use into an IDLH atmosphere or an unknown environment? It is not appropriate to provide product approvals for a liquid agent for an air purifying device. The user should never be in an environment where a liquid exposure is present using an air purifying device. One of the proposed test agent levels is as high as 2,400 times the IDLH, for example, the Phosgene level. This exceeds the capabilities and use recommendations of any air purifying respirator. Only full ensemble protection should be used if potential to liquid agent exists. Because an air purifying respirator should not be used in an atmosphere where there exists the potential for direct exposure to Sarin or Mustard, Section 5A of the proposed test for certification test is not necessary.

Equipment guidance on use selection (?) needs to be an integral part of the new NIOSH standard. Section 3B under respirator use section, provides a weak statement only and gives no real guidance to the user. The table in Section 3 shows a need for crisis units for 20 minute duration. Physiological studies have shown that this is not possible to sustain a 100 liter minute volume for any length of time, and the use in testing that are assumed are not realistic. NIOSH should not rely on manufacturers for decontamination and disposal recommendations. Manufacturers do not have proper expertise in weapons of mass destruction to adequately provide this information or this service. We recommend that NIOSH strongly recommend that air purifying respirators not be used for entrance into IDLH or unknown atmospheres, self contained breathing apparatus along with appropriate protective clothing should be used, and decontamination and disposal should be handled by onsite response and HazMat personnel. Regarding surrogate test agents... because this is the second NIOSH proposed standard for equipment to protect against CBRN challenges, we must again strongly urge NIOSH to focus their effort on developing surrogate test agents. This would allow manufacturers of all PPE to test products in their labs prior to submitting them for approval. It would also significantly reduce the cost and time of approval. This is an urgent need that is necessary for equipment development testing, design, and equipment refinement. Regarding some certification test issues. The current NIOSH and OSHA APF for full face respirators is 50. The Sarin vapor test features a challenge concentration of 2,000 micrograms per cubic meter and a maximum peak excursion of 0.087 milligrams per cubic meter. That equates to a protection factor of 22,989. The allowable permeation penetration ratio during testing should be within the APF of given respirator. The rough handling requirements in Section 6B are far in excess of what is required of a non-military type apparatus. There is nothing in this type of air purifying respirator that can be adversely

effected by any of these tests except perhaps drop and vibration. These tests only add to the cost and duration of the testing without significant benefit to the user. Again, there is no need for permeation test here. The full facepiece fogging test in Section 6B is a new concept that is not easily addressed or eliminated. This seems to be very extensive, expensive and a subjective test, and NIOSH may consider a more routine steam generator light transmission test. NIOSH proposes a visual acuity testing and fogging testing, yet there is no field of vision test in the proposal. We suggest that NIOSH consider using EN136, the European Full Face Standard for Field of Vision Requirements and to evaluate the facepiece using bench tests for definition or fact (?) or power (?) etc. using preconditioning. This would be less subjective than using a vision test on the wearer. ISEA would also like NIOSH to address some of the following questions regarding certification: Does NIOSH have any concerns with organic compounds that have low boiling points, such as lower than 65 degrees C? Why is NIOSH considering the use of both Cyclohexane and Carbon Tetrachloride for organic vapor qualification. I understand you discussed this this morning. Cyclohexane was developed in Europe as a surrogate for Carbon Tetrachloride due to the lack of availability of it. And there is significant documentation on the relationship between Carbon Tetrachloride and Cyclohexane service lives. Also, Chromium containing Carbon is used in military canisters as an infective and pregnating (?) agent for acid gases. However, NIOSH currently bans Chromium-containing Carbons for industrial cartridges. Will this also apply to CBRN cartridges? Some approval issues: Is it proposed that approvals will be released in two phases, the first half step is scheduled to be released in October with the second in early 2003. Given the length of time required for manufacturers to develop a product and gain NIOSH certification, there could be an overlap and possibly a conflict between the two phases. We recommend or ask NIOSH to allow for grandfathering of approvals or

eliminate the phase of approval-approach (?). Addressing cost: And this is based on testing fees associated with the current CBRN/SCBA standard. One air purifying respirator model undergoing 10 or 12 permeation tests, conditioned or not, 13 basic service life tests, a particulate test, plus service lives and five different conditioning, a required man test, including fit test, speech, fogging, etc. puts the estimated approval cost at about \$250,000 per respirator cartridge filter combination. The total costs of running through all the tests is one hundred times the cost of a current industrial full face respirator. If the certification costs are prohibitive, they will serve as a deterrent to manufacturers to develop these much needed products, and for those manufacturers willing to make the huge investment in certification testing, they will be forced to pass on the costs onto the end users. At ISEA, we appreciate the opportunity to present our views to you today. Thank you for your consideration and your time. (applause)

M: Does anybody have any questions for Janis before she steps down? I have one. (laughter) Alex you can come up, I'll go first. On the subject, and I don't know, it's not fair to ask you to give a specific answer right now, but... on the subject of interchangeability and the concept of improving logistics as part of the... any response to, you know, a terrorist incident... I think we saw with the World Trade Center and the Pentagon, and probably, you know, even with this presentation this morning, that chaos is the rule of the day.

Janice: It is.

M: And my question is... is ISEA undertaking any initiatives or have any specific recommendations on how the user community can improve it's logistics in response to the terrorism incident.

Janice: I mean I... obviously... you know... the World Trade Center was the worse case scenario. I think it's fair to say, both in the Oklahoma incident as well as the Pentagon incident, things were a lot better controlled. People were on the ground

quicker, making respirator recommendations, providing appropriate things... the controlled environment was such that it lended less to the chaos. Everyone's heard the same stories that we have heard about the World Trade Center, people throwing away whole respirators at a single time. The whole logistics nightmare of there being five giant depots where things were just being shipped without being... no one had any inventory controls... and I think that you're going to get that in the early times of a disaster of that significance. A lot of manufacturers went up there and started fit testing and are still up there, providing fit testing and end use and selection. It's difficult, though, to take into consideration the amount of users that have never been introduced to these types of products and teach them how to use them correctly. All I can say is the efforts have been started. They started early on at both incidents of the Pentagon and the World Trade Center and are ongoing aggressively today.

Pappas: Alex Pappas, SBCCOM.

Bradley: Hi, how are you Alex?

Pappas: How are you Janis? I had two questions. One question is...

Bradley: Sorry, I only let you ask one.

Pappas: (chuckle) There is an urgent need for first responders, I guess, for law enforcement... is there any law enforcement people here?

Bradley: There were law enforcement at the New York meeting that...

Pappas: What do you recommend that they wear in a chemical response to terrorists?

Bradley: Well it depends where they are. I think law enforcement typically tends to do perimeter control of the area. The problem with hot and warm zone is, you know, we can talk about it, but where is it delineated? I mean, know one really knows without kind of real time monitoring for people to go in an evaluate. Where does that warm zone start that negative pressure devices will work adequately and what are the concentrations. They tend to be a good target group for negative pressure

respirator. I think, and I've heard from the enforcement community, that they don't intend to be first responders. The law enforcement community tends to be perimeter control. They are out there with people that tend to be not protected at all. They want a device that doesn't have the limitations of a battery or a cylinder and they want to be able to be trained, know how to use it, have it be part of their arsenal of tools to protect themselves. And, they need training on how to do that. They just can't become part of this voluntary use community.

Pappas: Well, who... just some... terrorist kind of stuff that Jim went over. What is there is a terrorist in a stadium that has several devices and someone has to go in there and shoot the terrorist basically. Do you expect him to go in there with SCBA and florescent green level A suits.

Bradley: You know I can't answer that question Alex. (laughter)

Pappas: I mean, he's gotta wear...

Bradley: Are you crazy... it's 5:00.

Pappas: He's gotta wear a negative pressure respirator or do you want an alarm where the alarm says that terrorists can see them and...

Bradley: Hopefully he'll wear high visibility apparel that meets the 107 Standard, but... (laughter)

Pappas: And my other question was...

Bradley: That's three!

Pappas: Sorry... CBRN testing is not mandatory testing. You don't have to go out and have your respiratory approved for CBRN approval, so you could still market your items in the workplace and industrial use, you just won't get approvals to use it in a chem./bio event.

Bradley: I know, but I think it's realistic to say, all of these efforts to get product approved to CBRN agents, is not... just an exercise in providing letters on a mask. I think given the certain climate today... I mean, I live outside Washington, D.C. You

know, the pressure is on to have some testing of equipment that has a certain level of reliability given a terrorist event, okay? There's money for it. There is manufacturers willing to devote time and effort into development products, improving products. Certifying products. Training on how to use products. So, you know, you can say that it's voluntary, but, the fact is is that there is a need and manufacturers have been providing this need for many customers and many users for many, many years and intend to step up and meet that need.

Pappas: But how do you... how does a first responder have confidence in your item... your mask or you respirator if you don't go through a series of tests?

Bradley: Well, how industrial users have confidence? Everything isn't tested to Formaldehyde and all... and Chlorine and all these nasty things. There are surrogate agents that are established that represent worst case scenarios... and I'm not saying, and manufacturers don't anticipate, that they'll be... you know, Sodium Chloride will represent all the most penetrating particles. There may be several, several surrogates, many surrogates that may be material specific, but that's better than having just live agent testing available. You can't ask four questions.

M: That's right. Roland?

BerryAnn: This Roland from NIOSH.

Bradley: Be nice... I'm going to find you.

BerryAnn: I will. I'm not here to ask a question. I'm here to answer a couple.

Bradley: Thank you.

BerryAnn: If that's acceptable. (laughter)

Bradley: Pay you later.

BerryAnn: You asked a question about us reversing the policy on Chromium impregnated (?) carbon.

Bradley: Yes.

BerryAnn: It is our understanding that there are other impregnants available that provide the same level or better protection as Hexavalium (?) Chromium, so at this time we are not looking to reverse our policy. We are looking to remain the prohibition (?) on that.

Bradley: Okay.

BerryAnn: On the surrogates, I'd just like to say as the project progresses and we learn more about surrogates, if there is a way to use surrogates in the testing, we will certainly look at that. On the costs we are looking at different mechanisms to help defray the costs the best we can. And that's about as far as I can say on that. What else did you cover? (laughter) I think that's...

Bradley: I covered everything, are you kidding?

BerryAnn: Okay, thank you.

Fatah: Alim Fatah from the National Institute of Standards and Technology, Office of Law Enforcement Standards. And I have two observations, one on the surrogates. We deal... our office primarily services the law enforcement community and we survey them, we got there opinion (...inaudible...) and one of the... we also work with the fire, NFPA (?) and fire folks, and my observation is based on our dealing with them over the last three or four years. The users will never trust to use equipment if it's not specified with an agent. The surrogates can be used for the physical development and for initial testing to cut down on the costs, whatever, but the final test of confidence on the user is basically... "has this been tested on an agent?" If it's not tested on an agent, they will not have the confidence to use it. And that's just an observation.

Bradley: I understand.

Fatah: The second thing is on the... what's the law enforcement? Do they go through the hot zone or warm zone or whatever, you know, it is very difficult to say where they will be but all the terrorist incidents have shown that police officers are there

somewhere... what incident happens. But they are not primarily there to go rescue and go into the hot zone.

Bradley: Right.

Fatah: There mission is to maybe perimeter control, crown control, safety... and to get a chance to get out of the way, you know, go to a... maybe out away from the hot zone. So there need primarily is not level one or SCBA, but they want APR type (...inaudible...) escape mask or APR type of equipment.

Bradley: Right.

Fatah: So, but they need that to be satisfied... again it's the agents.

Bradley: Sure. That's why we are all here.

Fatah: So, that's why it is very important that NIOSH should do those. It should be certified against the agents and whether it's a 15 minute or one hour or whatever time duration. Hopefully, you will have to label the different products so that the user will know which product they would like to use or will suit they... they feel they will face.

Bradley: I understand.

Fatah: So... I wanted to say one other thing, but I forget it right now.

Bradley: I'm sure this is not the only meeting we'll be at.

M: Janis, Al reminded me what the other point was. Thank you. It was a senior moment.

Bradley: I don't have those yet.

M: (laughter) I have enough for both of us.

Bradley: Okay.

M: It was on the entry onto IDLH, and I think Les made it in his presentation earlier and I just want to reinforce the APRs that we are talking about here, we are not talking about changing the paradigm of entry into IDLH with an air purifying respirator, we were talking about entry into a defined below IDLH level, but with

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the uncertainties of a terrorist event, we think it is prudent to have a provision...

(END OF TAPE 2, SIDE B)

(TAPE 1, SIDE A)

M: ... all right. Where we stand right now in the agenda. We are about 30 minutes behind in the schedule, so, I guess the challenge to the presenters at this point for the rest of the morning is to get us back on schedule so we go to lunch at the time we had planned. To that end, we are going to round out the morning with addressing the human factors, the rough handling, the discussion on interchangeability and then a quick overview of the test matrix that was in the concept paper. So, to that end, we will have Terry Cloonan come back up here and he and Dave Caretti will lead the discussion on human factors.

Cloonan: Without further adieu, Mr. Caretti.

Caretti: Thanks, Terry. Good morning. I'm glad the discussions have gotten a little more lively this morning, so I'm going to try to add some fuel to that fire. One thing to keep in mind, though, is if you have a problem with any of this, you blame Terry... if you like anything you give me the credit. What I want to brief are just ideas. Everything is open to discussion, and I've learned a lot in this process, and I've learned a lot more this morning after talking to a couple other colleagues about some of these tests. So, in no way do I claim to be an expert or a legend, even though some have told me that I act like I am a legend in my own mind. We will just try to disprove that rumor right here. The idea behind human factors was for the APR standard for the CBRN. It was an opportunity to rethink the idea... do we need to have some human factors test standards. From the military side of the house, we usually evaluate these human factors and we find them... we think they are very important. From just looking at 42CFR, Part 84, with the NIOSH

(TAPE 3, SIDE A)

M: ... can exit unharmed. So that's the goal.

Genovese: Janis, I just want to say one thing, this is Jim Genovese. And it's just an observation... and I can feel your pain based on some of your comments, cause I've been...

Bradley: I didn't mean for them to be so painful. (laughter)

Genovese: Well, actually...

Bradley: Well, painful for you cause you're listening.

Genovese: They're quite painful actually. For the 12 years I have been in this business, a couple lessons that I've learned... very difficult lessons to learn, were to things. I started out in retaliatory chemical weapons where I was a military guy doing tactical things on the battlefield. And, I thought that was tough at the time, back in the early 80s. Actually, when you look at military operations with chemical and biological, there's... there's a limited finite number of scenarios, especially when we were against the Soviet Union, and so, even though the problem was protracted and difficult, it was still something we could work out. Then, I started working with the HazMat teams and the old conventional HazMat response dealing with predictable maximum, credible events on toxic industrial chemicals across the country and how they deal with it and the products that they use to respond to, that sounded logical. Wherever you have transcended now with terrorist use of chemical, biological, and radiological materials is that... we're not.... And neither one of those Venn diagram circles, we are not in the right military operations anymore (?) and we are no longer in the convention HazMat

response anymore. We are in a new environment where the terrorist has a broad range of hazards, lots of ways to disseminate them, and based on some of the numbers I showed you this afternoon when I was doing mine, some numbers that are pretty alarming, especially when you do them on the inside, and so... I think part of what we are going through here is... a learning process and it's a little painful for all of us. This is new and convention systems that we have both in the military and the HazMat civilian areas have some application, but in other areas, like some of the scenarios I've been looking at, they just don't apply. We are trying to fix that with the standard, at least the first approximately.

Bradley: Clearly... in all seriousness Jim, we are all here because of one of the darkest events in our nation's history occurred this year and, you know, we have all different types of expertise in the room here. People like yourselves have hands-on experience. Manufacturers have been making protective devices for people in a lot of different types of hazardous environments for a lot of years. And they are trying to match that set of talents, expertise, materials... use, selection with what the needs today are... and the fact is that people want a quick and easy lightweight mask with no breathing resistance that will protect them in all environments, like supplies air will, and there isn't such a device. The fact is that it's going to have to be a different type of device. It's going to take some training. It's going to take some investment on the part of employers and users to learn how to use these things right and to know the limitations of them. And that's the fact. And I think that we are all working together to reach that end... at that end point, and very successfully thus far as well.

Berndtsson: Goran Berndtsson from the SEA. You probably get one of nails here, because as manufacturers we have tried to ignore what is required to make respirators work for people. We want to make them cheap and nasty (?) so that we could sell a lot of them. It is our responsibility now to make respirators who can be worn and used by people, and of course the gap between existing respirators in the industry (...inaudible...) will actually work for people who has to be at them all the time at (...inaudible...) and there is some manufacturers who doesn't like... I am a manufacturer. I am talking as a manufacturer here. But we have to start shouldering our responsibilities for making masks and system who works.

Bradley: I'm not gonna... I'm certain not up here and I'm going to admit that I represent manufacturers that make cheap, inexpensive devices that are ineffective. I'm not going to do it.

Dower: Comment and this is John Dower with NIOSH. And I'm not speaking so much from my NIOSH position, but from my co-chairmanship on the Standards Coordination Committee of the IAB, and within that realm we have caucused a lot of fire chiefs, some of them are here, and policemen. And the information that the IAB is working off of, is that it's probably a 50/50 percentage between whether a fire fighter is going to be the first responder to a site or a policeman is going to be the first responder to the site. And a lot of that depends upon who's closest when dispatch gets the call and who arrives on scene first. So, for some law enforcement, some police, case in point, is the Capitol Police... they will automatically be the first responder because fire will not respond until the Capitol Police have cleared the scene to follow them on the scene. So, they have a

concern about initial site assessment. As well as subsequent perimeter security and control. So, my encouragement... my question then to IOCA (?) that... and NIOSH shares the same question, is how do we provide a proper level of protection for whoever that first responder is who goes in to make that initial site assessment. And I think it's an improper premise to ever assume that the police well not be one of those individuals.

Bradley: No, but if the Capital Police function in more non-traditional roles than other law enforcement agencies, that's a fact. By the virtue of who they are.

Dower: That's true but you can take the same thing at the World Trade Center.

Bradley: But, you know you can take...

Dower: The fire wasn't the first on the scene.

Bradley: I realize that.

Dower: The police were.

Bradley: But... I mean... it's incumbent on manufacturer NIOSH to say... what are the limitations of which device and which is appropriate for them to use.

Dower: Agreed.

Bradley: Otherwise, we're going to have... you know, instead of downed fire fighters, we're going to have downed policemen because they are wearing the wrong device. And I'm not...

Dower: Yeah, I found blue canaries a potentially offensive concept.

Bradley: Yeah, and so, I think we all want to do the right thing. And I think we will... as we move forward.

Dower: I agree. I know we will work together. Thank you.

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M: Anybody else at this point? Janice, thank you for being a lightening rod.

Bradley: Thank you. (applause)

M: Well, we'll try to do a little better on the time tomorrow. Just a couple of reminders... one we are starting at what time?

Audience: 8:30.

M: Thank you. (chuckling) The second thing is I encourage you all to read, if you get a chance this evening, to read the concept paper from June the 15th. That was available in the back. I think you're going to see a lot of the information that's contained in the concept paper presented tomorrow. And again, if you would like to participate as a presenter, please see me... and you are not already on the agenda, please see me in the morning and we'll get you added to the agenda at the end of the day...

(break for evening)

M: All right. Well, thank you very much for coming back today. (chuckling) We're going to get started here. At least as far as the agenda, what we plan on... we plan on covering these topics this morning and this afternoon we will primarily focus presentations from attendees here at the meeting. What we're... what we'd like, again, is to encourage your participation. And, if you are currently not on the agenda for this afternoon and you would like to make a presentation, please let me know and we will work you into the agenda for this afternoon. And again, along with that, if you are a presenter, if you have electronic media that you'd like to either CD or disk for your presentation and you'd like to use our equipment, please see me at a break or at lunchtime so we can get the information loaded on

to the computer. And, I had one administrative note... from before we left yesterday, there was a pocket computer, I guess it's a calendar and what not... it was up... it was left up here in this front area. It's a Sharp ZRX3500X, so if it belongs to anybody, please come up and see me to claim it. But it was up in this general area in the front of the room. (pause) And where we'd like to begin this morning, is give you a synopsis of some of the work that we've done to date on benchmark studies and the concepts that we're currently evaluating and the methodology for how we got there for determining the gas life test concentrations and the potential breakthroughs. And again, you know, this is based on the information that we've accumulated today, you know, I think as we continue with our benchmarking and the evaluation modeling that is being done for us by SBCCOM, you know, that you may see that as we go through the process of updating our concept paper over the summer that there will be some variability... there's some potential for variability. And, the test concentrations, so, you know, please keep that in mind as we go through the presentation. But at least for initially wanted to give you a snapshot of where we are right now and the data that we've accumulated in support of developing the standard. So with that, the two presenters that are going to cover the benchmarking are Mr. Les Boord and Mike Monahan.

Boord: Good morning. What we'd like to do is start off the discussion and the presentation with an explanation of the draft test challenge concentrations that are being proposed and presented in the concept paper. So we'll walk through the logic that gets to those values. And then what we want to do is take those and

basically compare them with the data... the benchmark data that... test data that's been ongoing for the last couple of months, to sort of set the pace and to see how the proposed or the draft test challenges stack up against the benchmark testing. The guidelines that we used in establishing the test challenge concentrations, really had several components to it. In the first, in the overwrite criteria was pretty much recognizing that we are working principally in a warm zone environment, so we are looking at the traditional uses for air purifying respirators in concentrations less than IDLH. But at the same time we wanted to ensure that we had in the protections, additional protections for those secondary situations in the crisis provision that we've talked in the standard. So with that in mind we have used the calculation in an analysis that basically is looking at... first of all two components. One is to establish the test of possible concentration based on the assigned protection factor for full facepiece. So to do that we've basically taken for each of the hazards that we have identified in the concept. We've taken the relv (?) numbers and these are in PPM, so we have taken the rail (?) numbers multiplied by the assigned protection factor and then assigned a safety factor of two on top of that to come up with the first column of challenges. Then what we did was we said, "Well, let's those and let's make sure that they are at least some multiple of the IDLHs for these hazards." So the next set of calculations, basically does that. It takes the IDLH and multiplies it by three and comes up with this list of values. Then what we did was we took the greater of those two. So we took the greater of the rail (?) times the APF times the safety factor or three times the IDLH and basically that is this representation here for the test concentration, the

initial estimate or calculation of it. For the breakthrough values, we basically went back to the rail (?) and are looking at 50% of the rail (?) for the breakthrough. (pause) I'm sorry. Okay. So then taking that a little bit further, what we did was we looked at the initial calculated test challenge concentrations and we tried to balance that with testing expertise, testing capabilities, testing technology, to make sure that we weren't talking about numbers that were not achievable in a consistent basis for testing purposes. So we did, in fact, make a couple of changes to the initial test calculation based on that time of analysis. And basically that is this column highlighted in yellow. Okay, so these became the test concentrations that are being proposed... are in the concept paper. If we made changes to this based on test evaluations and testing capabilities, we tried to maintain the same ratio that we had between our calculated test concentration and the calculated breakthrough. So there are some differences between the yellow and white as you go down the list and that's basically the reasoning behind it. So, these... the data that's identified in the yellow and is also identified as the test concentrations and breakthrough concentrations in the concept paper. Now, by way of comparison and for comparison purposes, just to sort of set the stage for the discussion that Mike's going to go into discussing the benchmark testing, the benchmark testing that we did is identified over here in the survey columns. So the test concentrations that we used are identified here, compared to the proposed challenge concentrations. Within the survey tests there are some additional tests, and I'm sure Mike will talk about those, where we actually ran at different concentrations than we have identified here, so the benchmark testing does go a little bit beyond what's

identified on this particular tabulation. So again what we have here are the draft test concentrations and breakthroughs compared to the survey test data, benchmark test data, test concentrations and breakthrough values.

Monahan: Thanks, Les. Okay in the... with the benchmark testing program that we did. We started this a long time before we had our concentrations and that set. So that's the reason why they are in some cases much, much higher than what we are proposing. Okay, what I did is... we're not... I wanted to look at what's on the market now and how does it compare with what we are trying to do. So what we did is... I went out and purchased quote "responder" type cartridges that are being advertised. And I had... I put a couple restrictions in that I wanted the 40 millimeter thread on it and I wanted them to have P3 or P100 filters on them. And, we ended up with five different cartridges... let me go through them. I'm basically a carbon guy, so everything I do is based on what's inside. And, so... the first one is an ASZMT cartridge, it's rather small. It has a 178 millimeter fill. And the second one is one I had put together. I wanted to look and see what the old Wetleright (?) carbon with the chrome six in... how it would perform with these gases to see if there was some advantage to using them. Okay. Then the next two are commercial cartridges, first responder type. One head (?) is a... just a single impregnated (?) in it and the other one has two impregnants (?) in and the last one is a rather large European cartridge. It has a 355 milliliter fill. And it is a... I believe it is a layered bed in the carbon. I'm not sure, but there's more than one type of carbon in this bed. Okay, next. For conditions, we had set the flow, air flow at 64 liters a minute, and at 25 degrees C. Now for the humidity conditions,

what we did is, we based these on how we felt these were going to be used.

Which is a little different from initial use. We are anticipating that these cartridges would be put on the mask immediately before you go into a situation. You don't let them sit on the mask in the back of a car, or whatever, you want until you are ready to use them, open the package up, put the cartridge on, then use it. Okay? And we took the two extremes of 25 and 80 percent RH to do the testing. Next. We've more or less gone over these gases already. I don't think there's anything unusual there. The next one please? What I... I'm going to present my results in two different ways. Basically... versus... one was the challenges gases versus the cartridges that I tested. And then I'll show you what it looks like all the chemicals versus each cartridge to give you an idea of how the coverage looks. Okay, first one. Okay for Ammonia... our initial testing was done at 2,000 PPM and as you can see there's a larger... there's quite effect... the more carbon you get, the better off you are going to be. Now there's a big difference between the AZZMT cartridge and the European cartridge on the far side. Our testing was done at 2,000. What we were looking for originally was to get the cartridges to pass the 15 minutes that we were forecasting we were going to put in as a standard. That's what this line is here. And as you can see, some of the cartridges do fairly well with it and others don't do well at all. This cartridge on the end, I believe would have some sort of an Ammonia impregnated carbon in there. We're not too sure what it is, but it's obviously been beefed up to take care of that. Okay. And with the proposed standard... this is going to be one of the chemicals that's probably

going to be the toughest to meet for the new standard in that it's going to be 2500 PPM versus the 2,000 we tested at.

M: What are these... (...inaudible...)

Monahan: Up is better. In other words you have service time here... and... this is the 25% RH and the 80 percent RH testing. Okay?

M: (away from the mike) Just a reminder, if you have questions, please come up to the microphone. We'd like to (...inaudible...) can hold your questions (...inaudible...) yesterday. If you can hold your questions until the end and then get up there and to the mike.

M: (...inaudible...)

Monahan: All right. Okay with the new draft standard we are also going to look for an end point concentration which is half of what is normally tested at right now. This will be one of the challenges for the manufacturers to... when they build their canister... Ammonia is going to be one of the challenges to get the coverages for. Go ahead. Carbon tetrachloride. We tested it at 5,000, the new standard is at 3,000. So basically this says that most of the cartridges will pass this test with no problems. Okay. Next. Cyanogen chloride is a tough (...inaudible...) to absorb on carbon but these cartridges do a relatively good job of taking care of the problem. Also, our challenge was much, much higher than proposed standard. So this is going to be... make it easier for the manufacturers to come up with a good number. And the end point concentration of this... we're trying to keep... it's basically... it's the same thing as they are testing for now. And it should be easily attainable on an analytical basis. Okay. Cyclohexane... we tested it at 5,000, like

the carbon tet and again it shows that there shouldn't be much of a problem meeting the 3,000 PPM break... or challenge in the 10 PPM break. Okay, next. Formaldehyde... basically all these are doing fairly well against formaldehyde at 1,000 PPM. This test was adjusted in the standard we were proposing in that to generate formaldehyde in the laboratory, 1,000 is about the limit of the capability of getting that into a gaseous form. So that's why we have left it at 1,000. And basically you can see most of them have been tailored to meet the formaldehyde challenge. Hydrogen cyanide... we tested at 5,000; the new standard is going to be 940 PPM. Basically with this test, I don't see a big problem of meeting the challenge of the new standard. Okay, next. Hydrogen sulfide again is a... there doesn't seem to be much of a problem in trying to get these to pass. The challenge is... the new challenge is a fifth or a 20 percent or actually 80 percent lower and it's at 1,000 PPM. So this is another one that's going to be relatively easy to pass. Next. Nitrogen dioxide. This test was run at 2500 PPM and we analyze for nitrogen dioxide on the back end of the test... the breakthrough. As I spoke before, we are doing further studies in looking at the NO coming through this cartridge and we'll see what happens with this. But the challenge here is also much, much lower. We are looking at 2500 versus 200 which will make things somewhat easier to do. Phosgene again we were challenged with quite a bit more than our actual standard's gonna be and most... we shouldn't have any... there shouldn't be much of a problem meeting this particular test gas in our standard. Okay. Next. Phosphine, we haven't done a lot of testing with this. We had problems, we ran out of it. And we weren't able to get resupplied in time to finish the testing we

were doing. But basically what we are seeing here is... the carbon, the cartridge that we did test had a good capacity for the Phosphine. It's a tough one to run the laboratory. You have to dilute it with Nitrogen if you using the pure form of it because when it contacts air it explodes. You have some laboratory problems with it. But when you hand over... dilute it first with nitrogen to get it down to the concentrations you need, you shouldn't have a problem with it. Sulfur dioxide. We ran it at 2,000, the new standard is 1,500 which should be relatively easy to get this one to pass too. I can't foresee any problems with this test. You want to go to next slide? This is what... we had originally we had started out with tests running at 5,000. As you can see it comes through rather quickly at 5,000 PPM. Next. This is a comparison of Cyclohexane to Carbon tet, the service lives were running with the different cartridges. Basically you have the Cyclohexane at 25% RH and the Carbon tet at 25% RH and the Cyclohexane 80 and Carbon tet at 80. There's relatively little difference in these tests, and I think this more or less supports what the other data is out there when they put the European standard together, it shows that... Cyclohexane is a good... substitute for Carbon tetrachloride. Okay, next. Okay, go ahead. These are the cartridges when you would look at all the different gases, just to give you an overall view of what our testing looked like. This particular cartridge was rather small and it had low capacities for a lot of the chemicals, in fact most of them. And ... let's keep going. As the bed depth increases, and of course these are different challenges, this looks like it's better than the first cartridge but there is a lot more volume here. And I think if you were to even out the volumes you'd end up with

comparable numbers and maybe slightly less. Okay. This is one of the commercial products and as you can see for the most part, it passes most of the tests as it is sitting there... the Ammonia test... it's probably going to pass to with the new standard and everything else it (?) should be pretty good on. Okay. This one too... same thing. It has a little more... the SO₂ is right on the line, but these can be adjusted, I think. The manufacturers can adjust these numbers and get what they need out of them. But it shows that there is products out there that do a fairly good job of what we are proposing. Okay. This is that European cartridge. It does have chrome six on it and it is very large. It is hiding way up (?) but it's... pretty cumbersome. I don't know if it's... you get to the point where it's going to cause problems on the mask when you move it around on your face, but it does have a lot of capacity. And, that's about it. Oh, here. The... what I did was... I wanted to see... when our... we talked about crisis conditions and what this shows is that as your breathing rate goes up so does the resistance. And when you talk about 100 liters per minute you are almost up at the 70 maximum we talked about at 85% flow... not percent, liters per minute. But, this could be used, if you wanted to, like, split the cartridges up and look at pressure drop that way. But thought it was pretty... gives you some interesting data. That's about all. Any questions? Andy?

Capon: From Avon (...inaudible...) What was the humidity of the air flow? It was as received the cartridges...

Monahan: 80% and 25% they were both tested.

Capon: And you just took them out of the bags... as received... didn't leave them around...

Monahan: No.

Capon: Straight out the bags.

Monahan: That's our... what do you want to call... paradigm of use. In other words, we don't want them used or taken out of the package and let it set around like you do with an industrial cartridge. These are made to be... what we are looking at is something to be used in a situation and then gotten rid of on the same day.

Capon: Okay... so... I understand. Thank you very much.

Monahan: Okay. Anybody else? Okay.

M: Can you go over to the mike and...?

Samputza (?): Mike Samputza (?) United States Marine Corp Chem Bio Incident Response Force. Can we get a copy of this data?

Monahan: This data will all be put on our website?

Samputza (?): For the Marine Corp... could we get the filters that were tested... could you identify those for us by their commercial name, for us, off line perhaps.

Monahan: Roland? Are you in the audience? (laughter) I don't know. I mean... I would give you it, but... I don't know what the NIOSH policy is so...

M: I will have to check on that and see what the procedures are... I'm not sure. I'm not sure what the availability of that is...

Monahan: I... frankly I don't think we should give it out. That's, you know, we did this...

M: We'll have to check with the attorneys...

Samputza (?): Even if I swore an oath not to pass it on to anyone else? (laughter)

Monahan: We'll see. I don't want to get myself into trouble on this.

M: (...inaudible...) so the data is very important, the form that you receive it in... meaning the filter cartridge in the origin... that will be solved within 30 to 60 days.

M: I don't understand sir.

M: There's some contracting vehicles at work that provide... that will provide you... there are couple of contracting vehicles that are being computed right now that will provide DOD and the federal government filters with these types of substances and resistances and capabilities and flow rates.

Samputza (?): I was specifically interested in...

M: I understand.

Samputza (?): ...manufacturers...

M: Yeah. Westmont (?) from Aegis North America. We are the US arm of the Swedish team that builds both the decontamination trailers and our suits are back on the booth back that. I only brought Bridgette and Samantha with me today. That's our infant and children's suits. The adult suits are sort of old hat and I didn't have room for them in the car so... but what I am trying to say that the solution will be available at large capacity and under contract almost by the time you get your bags unpacked.

Monahan: Sam?

M: We'll talk offline, Mike.

Monahan: Also, we will eventually... we are planning to do studies at the actual concentrations too. I don't know if it will be with the same cartridges or not, but

we'll have to make that decision soon. We will actually... there's more tests coming... to fill in some other blank spots in our data.

Samputza (?): Just the data will be helpful to us.

Monahan: We'll get you all the data you need.

Samputza (?): Right. Thank you.

Monahan: Anybody else? Okay, thank you.

(pause)

Cloonan: Come on up, Alex.

M: Mr. Caretti, please.

Cloonan: You don't want to get up here yet. You want to stay behind Mr. Wayne Davis?
(chucking)

M: I'm going to get a prop.

Cloonan: You gonna get a prop? All right, man. We also have Mr. Jeff Peterson who's the Certification Leading Specialist out of Morgantown with us here today and he'll provide us with some background on... wants to get into some nitty gritty details. But we'll go ahead and get going here. Good morning! In case you don't know me, I'm Terry Cloonan. I'm a Lead Physical Scientist out of the NPPTL. I have responsibility for the CBRN/SCBA testing program from a policy perspective which we just successfully completed a transition to the Certification Team. Thank you for attending, and of course, this is your public forum. Before I get into the next two 30 minutes sessions of slides, allow me to open up with a few significant quotes that I observed from yesterday. See if you can guess who these guys are... number 1, "We have wide gaps in our ability to characterize the

threat.” Once again, “We have wide gaps in our ability to characterize the threat.”

Leading presenter. Second quote, “GB and HD would be absorbed quite readily on carbon.” I say again, “GB and HD would be absorbed quite readily on carbon.”

Third quote, “Look at humans as a system.” “Look at humans as a system.” Now that’s not revolutionary. That’s just a standard (?) concept. But you’ll see that common trend throughout this entire presentation. “Look at humans as a system.”

Both from a cutaneous and from an inhalation perspective. “In relation to crop dusters, we’ve done it... some of it is sensitive.” “In relation to crop dusters, we’ve done it... some of it is sensitive.” Now, I’m doing all this for a reason.

“Tests at SBCCOM are costly and meaningless.” (laughter) “Their surrogates are true...” correction... “If surrogates are truly simulants, they can be tested for certification also.” We can present about a three day long conference on that topic along, but I would just bring to your attention that a first time that a responder goes down from a device that has not been live agent tested, that will be when the liability comes into play. Granted we have a mix of manufacturers and end users in the audience, but that one statement yesterday, was enough to set the tone for the entire day, the next day and the next day. But, I’m not here to talk policy, I’m here to talk technical perspectives. And, John I can’t limit these to three or four... I got three more to go. “Focusing on a 40 millimeter interface will negate the system’s approach.” “Focusing on a 40 millimeter interface will negate the system’s approach.” Now this is a system. The respirator device is a system, even though we at NIOSH in (?) the respirator branch focus on the respirator purely and that’s essentially what you see in this public forum here. The whole total

concept is the total system... skin protection, inhalation protection... Jim Genovese talked about 95% of the hazards that are presented from the threat today... if you can stop it from being inhaled, you can protect yourself. That other 5%, hey, you got a percutaneous hazard or you've got a persistent (?) agent and I will go into the detail about persistent (?) agents and HD, etc. But the bottom-line here is if you can stop it on inhalation perspective, you pretty much can escape from the hazard, hopefully. We're going to show that to you and that's one of the main reasons why we do systems testing. "No change to the APR paradigm. Prudent to have a provision to allow us to convert to escape." And we all know who that classic gentleman is. He is very prominent in policymaking, but there is "No change to the APR paradigm. It is very prudent to have a provision to allow us to convert to escape." Now what that is referring to is... traditionally there might have been a mind set that the negative pressure product was going to provide you with an all encompassing form of protection. Did we say it was going to eliminate the SCBA? No. Did we say it was going to eliminate the SAR? No. We will utilize use and limitation concepts per the current NIOSH protocol. We will not deviate from them. We weren't (?) sure that the use and limitations support the use of a negative pressure product, but do we have the responsibility to tell a responder that, hey, if you get exposed to a high concentration that is lethal to you, that this device will not save you. We cannot do that to the responder. So we have to incorporate a crisis provision. "The user will never trust equipment that is not live agent tested." I say again, "The user will never trust equipment that is not live agent tested." Now some of you may know you from a

previous opportunity where I chose to excel (laughter)... I was very, very adamant about live agent testing. Very adamant. And, we also had a comment from a previous presenter yesterday, who discussed the fact that, you know, typically in the old days when the law enforcement community was exposed to sales periodicals and how in 1967 they didn't have all the technology that we have today... and the brochures came around and you couldn't trust those brochures? Well, one of my main prerogatives was to ensure that if you were going to present this product into this marketplace, one of the most qualifying criteria is live agent testing. And then when NIOSH approvals come along, that's when you say, this is NIOSH approved and you can do it on a domestic perspective. So why are we really here? Why are we really here? Now, I'm not here to be confrontational. But I am here to bring you to a sense... to bring you to a perspective and an opportunity to share in a public forum, because one of Rich Metzler's primary directives to us before we started this was to share information... was for feedback. Because what you present here is gonna... is what's gonna guide us in the future. We are fast tracking a policy, not in your interests, in the interest of national security. Let me just bring that to your perspective. Bring all this back in a perspective. We are doing this on a fast track for national security. That is our main focus here. NIOSH, as you typically know, can take an exceptionally long time in taking a product to marketplace in terms of promulgation, etc. We are enhancing the current responders kit bag. We are giving you a product that's going to allow you to have the confidence that it has been exposed to known agent concentrations and it's going to perform to this parameter. That's the main

reason we are here... for you the responder. We want to prevent mass panic and mass casualties. We are not talking about an industrial setting, where there's a known contaminate, there's a known... you know, toxicological level, we are talking about the age of terrorism where things are unknown, where factors come up upon you on surprise... where the terrorist takes the opportunity to use that surprise to his advantage. So it is very important that we get this right. The combined speaker presentation you are about to participate in is draft information. It is open for discussion as I stated. But as you know, please hold your questions until the end of the 30 minute period. At this time I'd like to publicly extend a special thanks to the teams at Edgewood, Morgantown, West Virginia, Pittsburgh, PA for a job extremely well done on initiation of a CBRN/SCBA program and extended thanks to the teams at Dugway, Utah for anticipated well done jobs in support of the interagency agreement between NIOSH and SBCCOM. John Dower, Doug Riffel (?), Ray Lanz (?) and Alex Pappas, thank you. A combined presentation approach is the best way to present this information. That way you hear from the sources, you can provide feedback, again I stress your feedback is crucial in the continuing (?) process. NIOSH and SBCCOM teams will be discussing air purifying respirator systems testing and human factors testing under chemical, biological, radiological/dirty... everybody understand that? The difference between radiological and nuclear? If you are watching the media, you are very conscious about the dirty concept. You realize that the Bureau was very adamant in presenting the position about preventing the utilization of a potential "dirty" device, now just bear in mind what you read in the media is not everything

that really happens. You can thank God there is no media here. (laughter) Under CBRN or C-Burn test conditions, specifically GB Sarin (?) which is a non-persistent nerve agent, HD Mustard, which is a persistent blister agent, and Corn Oil (?) Aerosol Particulate. We are lucky today to have an SBCCOM living legend with us in the forum. Mr. Lee Campbell. (applause) Lee Campbell has extensive experience in live agent testing and just recently we were able to enhance Lee's knowledge through SCBA performance and share in that. So we have a very viable relationship with SBCCOM and it is something that we will not jeopardize for any means. Following Lee will be the SBCCOM Mass fit (?) Test Facility Principal Investigator, Mr. Alex Pappas. Alex will discuss the laboratory respiratory protection level, the LRPL test. Following Alex will be Mr. David Caretti, SBCCOM Research Physiologist. He's not at the panel... he refused to come up here right now. (laughter) All these gentlemen are from the Edgewood area of Aberdeen Proven Ground and it's a pleasure to work with them. As Mike Monahan discussed, systems testing provides quantifiable pass/fail repeatable data on a performance of a given respirator against laboratory concentrations of GB vapor, HD liquid, HD vapor and Mazola Corn Oil Particulate. Of the three types of systems testing, these last two types are systems testing that are proposed, but they are essentially a carry over from the CBRN/SCBA concept, all right. And that essentially is the chemical warfare agents systems testing which is our first presentation and then the LRLPL/doning using Corn Oil Aerosol systems testing. We will spend roughly 15 minutes on each one of these, and then we will follow that with human factors and Mr.

Caretti and I will do a technical spar up here for your entertainment, essentially, and do a 15 minute concept per each speaker there. In the CBRN/SCBA letter to manufacturers, NIOSH discusses the use of standard procedure numbers 0 200, 0 201 and of course 0 202. Now if we were gonna have a quiz like Jim did yesterday, we'd say what does all of that mean. Outside on the table out there is the complete document which can answer all those questions. These standard test procedures, or STPs as we call them, address GB HD Corn Oil tests on the SCBA system. They serve as the foundation for this current public meeting on air purifying. We carry over the concentrations from the CBRN/SCBA concept, but we adjust the overall CT values. Now if you have an industrial hygienist background, do you... truly have an appreciation for CT. If you have a military background, you should have an appreciation for CT. Now my background is kind of diverse, I'm kind of like Alex, Lee, Jim, etc., etc... I have a military background, but I transitioned into an industrial hygienist background and now I'm working for an illustrious agency called NPPTL... no, NIOSH... an outstanding agency. Now to supplement all that, what that means is you have to have an understanding about CT because that's concentration over time and that's not something that a normal industrial hygienist has a visibility to. So that's a new challenge for those of you that are not really tracking it. As Les Boord described, a respirator system consists of a full face, tight fitting respirator with a compatible rated dual purpose canister with a built in P100 mechanical filter. I say again, P100 mechanical filter. Now that is subject to debate. But this whole concept is open to discussion. Face mounted or remotely mounted front or back respirator

systems are typical examples, so even though you might think it's a cancer (?) concept here, there may be a hose assembly, there might be a back mounted assembly, might be a chest mounted assembly, etc., etc. Systems can have accessories that are required or optional depending on the manufacturers NIOSH submission application. And we are going to touch on a couple more points on the overall administrative, and please Mr. Merinar, correct me if I'm wrong. The actual application at NIOSH will allow manufactures to specify a required item or accessory item and this identifies the complete respirator system in what we are calling the worst case configuration prior to actual system testing. So it's important for you to know as a manufacturer, that when you come to NIOSH and you say we're going to submit this product for live agent testing, whether it's negative pressure, whether you got a new NFPA approved SCBA down the road, whether you have an escape hood, whether you have a PAPR... we want to know the worst case configuration that you as the manufacturer see this product operating under chemical, biological conditions. How a manufacturer submits a respirator can and will determine how it is tested in a chemical agent systems test. For example, if a butyl shroud is a required item for CBR and APR approval, that shroud is a mandatory part of a live agent system testing and consequently the LRPL testing. Live agent system testing also known as LAT, became a common term in NIOSH since we started actual testing of CBRN/SCBAs on February 27, 2002. In conjunction with over 80 years of live agent chemical warfare testing, the US Army Soldier Biological and Chemical Command has the ability to test and evaluate submitted respirators under defined protocol that serves the ultimate

goal... of granting NIOSH approval to select respirators for use by emergency responders under domestic CBRN conditions. At this time, Lee and I will present the chemical agent systems testing concept and I'd like to turn it over to Lee. Next slide.

Campbell: I just found out today that I was a legend. (laughter)

M: Well, at least you're alive! (laughter) Better than most people are...

Campbell: But I understand that being a legend is the next step before oblivion. (laughter) This first slide has the name SMARTMAN on there. That is an acronym and you'll be hearing a lot about this acronym in the future. It stands for Simulate Agent Resistance Test Mannequin. And that is what we use to test the system, that is the mask, everything that goes with it is mounted on this head form and it is subjected to a challenge concentration of GB vapor or HD liquid and vapor, depending on what the test is supposed to me. We can do other things with it too, but these two, the GB and the HD are the ones that are being used for these programs. This is a list of the components that we use in the test. We use a syringe pump to generate the challenge concentration. This way we can have fine control over the amount of agent that goes into the system. The syringe pump meters out a certain amount into a measured air stream so that we get the amount of agent and the volume of air which will give you a concentration... and this is very well controlled by using a syringe pump. Before we actually do a test, we will put the mask on the head form SMARTMAN and do an aerosol leak test with the TDA 99M Aerosol Leak Tester. The air is supplied by a Miller Nelson Humidity Temperature Flow Unit. We have a breather pump to cause... simulate

breathing in the mask while it is being subjected or challenged by the chemical agent. This breather pump has a sinusoidal breathing pattern and also constant flow functional rate. We have a mixing chamber to mix the agent before we run it into the exposure chamber. We monitor the challenge concentration with a MIRAN Infrared Detector. We use a minicam to detect or monitor the agent that manages to get inside the mask. And we have fans and other things that go along with the test depending on what is required for it. This is a picture of the SMARTMAN without anything on it. It's in an exposure chamber. The front door is open. You can see a peripheral seal which is inflated and this is what will be pressing up against the facepiece of the mask to make sure that there is no leak by the facepiece itself, that's inflated to 3 to 5 pounds pressure to maintain that seal. Next one. This is a SMARTMAN with a mask, the MCU2P (?) with the respirator and the shroud that goes with it. It's kind of a dark picture, but it still indicates... one format that we do testing of the mask in. Next one. This is SMARTMAN with an M40 which is the Army's ARR and it doesn't have a shroud on it. It is just plain on the head form with the peripheral seal making the seal. Next. This shows the setup that we are using. You can see there are two minicams sitting beside the head form and this way we can monitor... the minicams actually samples for a short time and then it analyzes what it is monitoring and the rest of the time... by using two of them we can actually monitor the complete time that the mask is under challenge. Sitting up in the right or the left hand corner is a MIRAN Infrared Indicator. This is the newest version of that. It's called the sapphire. We also use a couple... some of the older types which have a long 10

meter cell (?), but they both do essentially the same thing. We can actually monitor the challenge concentration and we get printouts with charts... we can actually see the profile of the challenge during the test. This is the syringe pump. It's a little dark, but that's the... sitting down there in the front. That's the mixing chamber behind it, the thing wrapped in it with a red heating blanket. But there is a syringe on the pump and it has a long cannula that goes up through a heater coil down into the air stream which goes into the mixing chamber. This is monitored... it's a very well controlled... it has any number of speeds that you can run it and also you can change the size of the syringe. You can also change the flow or the concentration. So it's a very good way to control the challenge concentration.

(END OF TAPE 3, SIDE A)

... air monitoring system, miniature (?). This is one of them. It has a... the main power here in the front is the detector. It's a float the up (?) photometric (?) detector. It's essential a gas chromatograph because it takes a sample on a pre-concentrated tub, then this is de-sorbed into the column and it goes into the detector, which is one reason you can get such a low concentration when you use the particular piece of equipment also why we use two of them to monitor the entire period. This is the TDA-99M Leak Detector. It is manufactured by ATI Incorporated and it... it actually generated an aerosol which we use to monitor the whole... everything about it... we have a wand that we can actually monitor every single part on the mask when it's on the head form. And if there is a lead, we find that first. We do this before we actually challenge with the agent. This is

the breather pump E1R1. It's the standard Army breather pump. Actually that one is a double pump, you can see the two cylinders on the right side. And the control gear box... two of those, one for each pump. And the motor in back which runs it, and we have a separate control for the motor sitting down on the table which we can change the speed of the motor and get any number of different flow breathing rates. All right, now the... a lot of these things that are on the slide here are still in a state of flux and Terry will explain these things to you right now.

Cloonan: (...inaudible...) CBRN/ARP systems test for HD. We will discuss HD and GB in the following five slide format. We will look at 12 overall areas. Method, procedures, test conditions, test time, flow rate and the slide after this will of course address the remaining. It's pretty straightforward adaptation off of NIOSH RCTC CBRN/STP 0 200 and 0 201, all right, this is not the LRPR version, this is the GB 0 200 and 0 201 is HD. Overall this is the goal which has been identified by SBCCOM as far as a resistance permeation penetration statement for this process, but if you recall when we put up the SMARTMAN slide, we emphasis the fact that the use of the SMARTMAN system is a systems test against permeation and penetration. That means a lot because GB acts different, HD acts different. And some of... you know, together, just imagine what they could do. Procedures overall...we are relying on the CAT myth (?) at 139 and Lee has all the details on that because that's an internal operating procedures. But we're going to do is we're going to adopt a portion of that and generate and actual, to be published, CBRN/APR STP, which will be very similar to the current SCBA STP, but there will be slight variations. And the variations are to your front. I want to

address the HD droplet perspective and I want to address the HD vapor perspective. And I want to address them from primarily the crisis provision, and I also want to address them from a drinking tube hydration perspective and the ability to contaminate the canister. Because contrary to popular belief, as any classic decontamination platoon leader knows, HD is highly persistent and when it is used on a target in any location irregardless of weather for most cases, that liquid will be there for some time. Now when you dilute it, it will just move on down the road. Okay. You have to do something that essentially detoxifies HD, so when you make the statement that there's not going to be any liquid contamination in the warm zone, that is incorrect. So consequently there is a need for a droplet test. We take the 25 base figure off of the standard face plank (?) out of the SBCCOM system. That's a standard figure, and you'll see it all the time. But if you compare that to the SCBA, we use 25 there as well. That's our base figure. Now, we add seven on it for the canister at strategic locations. Now, we have a three concept approach toward that. We look at surface area. We look at critical connections. We look at the overall systems approach toward how it would be contaminated from just normal, routine use. Now, so consequently we end up having 32 droplets on a respirator with an attached test canister. Now, if you, the manufacturer or the end user, says, hey, "I would like that to be in a hydration position. I want a drinking device." We would add an additional four droplets on the canteen surface. Now this is all draft so this subject to change. But essentially we are looking at 36 droplets and 32. And the overall vapor exposure, remember now this is a dual test, we have liquid contamination goes first, vapor exposure is

next. And technically we are looking at about a five minute duration for max peak exposure. All right, that may or may not include a 3.6 minute timeframe for ramp up. That might be the slide that Mike showed you about how the curve goes up to a peak and drops. Or it might be the slide that Jim Genovese showed you where it's a ramp and has a small decay duration and then it's a drop off. We have to anticipate what the terrorist is going to do. Can you? Can you anticipate what the terrorist is going to do? We have the aid you in that. That's how we have been tasked by NIST. A steam (?) vapor exposure for defined duration five minutes. Let's just say that's a given. Test conditions... overall liquid droplets are going to be deposited at select locations. If you read the STP this is not going to be anything foreign to you. It's pretty straightforward. If you have a drinking tube assembly that's coming off the respirator, we're going to target it. If you have a drinking canteen that attaches to that and you would like to have it meet CBRN approval, should we test it? It would only make sense that if we have a CBRN approved facepiece that the end user is going to want a CBRN approved canteen. So there's a logic in that. The vapor challenge is at 300 milligrams per meter cubed for a defined duration, is it 30 seconds, etc., etc., time to be determined. All right, five minutes is our plan figure. Now the total liquid, I kind of went of this a little bit, but total liquid concentration is no greater than 0.86 milliliters and Mike you support that with your previous slides on 10 grams. 0.86 milliliters of HD per respirator. Total test time is still six hours. Now that shows our continuity of the test procedure. All right? It's and exposure, plus decay and observation. Now the flow rate... should that flow rate be 85, should it be 65, should it be 40, should it

be 300, should it be our flow rate is representative of what our worker is going to do in a high, tense crisis situation? Maybe, maybe not. But the only reason that we have a 40 liters per minute rate is that because it supports our functionality test. This is a systems test. We just want to have that respirator function. We don't want to test the filter capacity. We rely on the filter capacity to demonstrate to 85 the high breathing rate. We want that respirator face blank (?) and it's adaptability to the canister to be tested, so we are using 40 liters per minute. That's the ideal functional rate. That's got 115 max peak and has a 1.1 liters tidal (?) volume and has 36 respirations per minute. Next slide. Temperature, minicam breakthrough sampling times, max peak excursions, cumulative CTs, the pass/fail criteria, and verification testing. Overall 25 plus or minus 2 degrees centigrade. The minicam breakthrough sampling times will be rated on a three minute per detector on a six minute cycle. Now, if you pay attention, you'll see in the GB area, now everybody knows where everybody is because everybody's looking pretty hard here... that's pretty good. This is a continuous testing cycle. The reason that we want the two minicams is because we need the redundancy. Initially we started this testing program with one minicam. We found out through validation of survey testing that two minicams are actually required and that will be the standard from now on. The maximum peak excursion for HD, as indicated, 060 milligrams per meter cubed. That's the exact same figure from the SCBA standard, however, the CT... and this is draft... is 1080. It's based on vapor exposure to 300 and LCT 50 at 5000 milligrams per meter cubed. Dermal CT values to be determined based on the number of droplets applied, so if you have a canteen device, the CT value

might change. True? John? No? Maybe? Come on John. He knows. CT value is contingent upon a concentration that's presented to the system. So remember CT is concentration over time. All right, that concentration will get no more greater than 0.86 for HD. It will get no more greater than 43 droplets, cause it will mirror the SCBA standard. Pass/fail criteria... three consecutive trials, one respirator per trial. Failure criteria... three consecutive peaks at or above that value. All right, the max peak excursion or if it goes over the max CT. I know, Andy, you're waiting to ask a question. Just hold on a second.

Capon: (...inaudible..)

Cloonan: Yes sir, I stand corrected. Concentration times time. Verification testing, we want to ensure that we prove the test procedures on select respirator protective equipment. Next slide sir. The same qualifying criteria for the APR test against GB. APR systems will resist permeation, penetration and GB vapor when tested on a SMARTMAN under live agent test configurations. Our procedures are a CBRN/APR STP which will incorporate the CAT myth (?) at 139. GB vapor will be at 2000 milligrams per meter cubed for a defined duration of expose. I stress this is vapor only – no liquid. Why is that? GB is a non-persistent nerve agent – Sarin. It has the consistency of water. So is it going to stay on target long? As long as it takes water to evaporate. You can use that as an analogy. So, is there a need for a liquid exposure? Some people say yes, some people say no. But the NIOSH position is, right now, it's a vapor exposure, because that is the ideal technique for dispersal of that type of chemical warfare agent, as Jim demonstrated to you yesterday. Test conditions... 2000 milligrams per meter

cubed for five minutes after an 1800 milligram per meter cubed is reached during a 3.5 minutes ramp up time of ambient vapor. The challenge duration is dependant upon the specs of reasonable event which were clearly identified by Jim Genovese yesterday's draft for discussion. The test time is of course the same, six hours plus a decay observation. The flow rate is no changed in the previous slide. Next slides. Overall temperature variables were the same. The breakthru sampling time is a two minute for each detector at a four minute cycle and is consecutive for 360 minutes. The max peak excursion is somewhat different here. Its 0.087 milligrams per meter cubed. Now why is that important? You have to have three of them to fail the test. If you get one, if you get two... it doesn't fail, but if you get three consecutive max peaks or you fail the overall CT, the product will fail the systems test. Verification testing will prove that the test procedures can effectively work on select respirators that NIOSH selects from the marketplace, or there is an opportunity for products to be submitted in the survey. Next slide sir. So what have we discussed? We had a minor wake up call this morning. We had Mike's outstanding presentation on high speed graphs and the ability to look at filter capacities. I follow that up with, you know, a small systems presentation. We talked about the continuity. The continuity is very important. The ability to transition from a current CBRN/SCBA concept that is being implemented with one actual full fledged approval out in the field which is a milestone from a NIOSH perspective. Two, a CBRN/APR concept which is on a timeline to ensure that the end user, the responder, has a negative pressure product that can perform in less than IDLH conditions but the ability to turn into an

escape device, technically, right? So that allows that responder to get out of a hazard or secondary device explosion or any other type of contamination that may or may not be in or near the warm zone... or a transition from the cold zone to the warm zone. Dual pass/fail criteria. What does that mean? Well, to pass these systems tests for GB and HD. You could fail it if you failed a max CT (?) or you could fail it if you failed a three max peak (?), so there's a dual pass/fail. You have to pass both criteria in order to get a pass on the one systems testing. That's GB and HD only. Now, our CT values are based against the tailored duration, okay, this is a tailored duration of exposure. And, it's to be determined. The five minute concept, that whole concept about negative pressure and duration of exposure is all to be determined, but, you know, when you think about it, what's the probability of you using a negative pressure product for 8 – 12 hours? The fire community traditionally talks about the ability to have a negative pressure product be on them at all times so they don't have to wear and SCBA. And if they are doing crisis decontamination or consequence management, this negative pressure product is going to have to last for 8 – 12 hours. A standard crisis responder, emergency responder, shift is 12 hours, so it's very important that a negative pressure product be able to sustain that duration. Case and point, high carbon capacity. Case and point, P100. Dual purpose. So that ability allows for a tailored duration of exposure, but the CT values are going to be much lower than the SCBA. HD droplet pattern. It's pretty much a given. If you submit a product into the systems testing for live agent testing, you'll be exposed to the standard droplet pattern as will be published. Verification testing, we're talking about a short

amount of time to support the actual publication of this document. So we want to be able to verify the STP procedures in probably the next 60 days. So, we're going to ask for participation from manufacturers to support that, I would think. I'm not in a position to make a policy recommendation on that at all. So with that, that pretty much ends the CBRN/APR GB HD. We are going to move into the second systems test and hold on a second... we have a question that is already being raised... we're not even at the 30 minute timeframe here. Yes Mr. Haskell, state your name for the record please.

Haskell: Is this on?

Cloonan: Yes, sir.

Haskell: Bill Haskell, SBCCOM Natick Labs. At the end of the day yesterday, I believe Janice Bradley, representing ISEA, I think made a statement that they were not advocating the liquid droplet test with HD on respirators? I think that's what she said.

Cloonan: They were not advocating the use of a liquid threat in a warm zone.

Haskell: So what I was wondering is... and it's just a question, maybe it doesn't have to be answered here. Do all the respirator manufacturers have that same stance? Is it unanimous, or is based on the threat scenarios we've seen the last two days, is HD liquid droplet truly a threat that we need to consider for these types of tests?

Cloonan: Is there a manufacturer that would like to address that?

M: (... inaudible...) addressed it yesterday.

Cloonan: Yes sir, go ahead.

Heins: My name is Bodo Heins from Draeger Safety, Germany. I have another question. You collected a lot of high tech test equipment for the SMARTMAN test, but the biggest problem you did not mention. I am for 30 years in the development of respirators and the biggest problem I see here is how to seal the mask on the dummy head. In all my years, I never found a dummy head or a test head on which the masks seal perfect, and you do not have only to seal the outside mask, but also the inner mask because it's a system. And if you only tighten the outside and the inner mask is very untight, you have only have of the protection, which is normally with this mask.

Cloonan: Now in the systems testing that we are proposing, we have allocated the provision to allow engineering measures to ensure that the face blank (?) seal in the actually TDA-99M testing can in fact be eliminated in terms of any type of air, so you're absolutely correct. The face seal is most critical lynchpin in this entire testing process. But when it goes into this concept with the SMARTMAN and the ability to test for gross leaks, we use a TDA-99M Aerosol Test Particulate that tells us, hey, there are no gross leaks. We can proceed at a known standard of exposure from Aerosol Particulate. But in terms of answering your question about the sealing process, we can have Roland BerryAnn address that or John if you want to... or Les if you want to further clarify that, but the bottom-line area is we are prepared to do whatever engineering measures are necessary to initiate a seal on the SMARTMAN. Now on the SCBA, we were not... we didn't have that luxury. With negative pressure we do.

Heins: That's true, but as I said, in all my 31 years I never found a head on which you can seal a mask completely tight. Perhaps you can find it for one mask, but for the second mask it will not fit.

Cloonan: Very good.

Heins: So the sealing of the mask of the head is big problem.

Cloonan: If you have data to support that, please by all means, submit it. We would like to see your data for that. It's very important.

Berndtsson: Goran Berndtsson from SEA. You want to talk first?

M: Yeah, can I...

Cloonan: Sure.

M: I'm sorry. I apologize. I just wanted to respond. In our test protocol for the agent testing where it is mounted on the mannequin we do have a provision in the SCBA and I'm sure that it will be in the air purifying, that artificial means can be used to seal on a mannequin. Because we are not testing facepiece to face seal on that test. It is a systems test to ensure that the respirator will not have permeation and penetration. Okay.

Heins: That you can do with the outside sealing, but to do it at the same time for the inner mask is nearly impossible.

Cloonan: Okay sir. Your statement is the nose cup area, the inner breathing zone area... we need your data sir. Yes sir.

Berndtsson: Goran Berndtsson from SEA. I have to agree with the previous speaker. We have recently done a similar test on using the Sheffield (?) head and we can't in any way reproduce a fit from one to second time to third time on the mechanical head.

It's impossible, and I tried out all the large number of commercial available respirators in the United States as well as military respirators, so that is... the second thing is that you have been emphasizing here is a system testing. Is that correct?

Cloonan: Yes that's correct.

Berndtsson: So if we as the manufacturer would be sending in a system including a hood or a suit for example, that would be system tested according to the standard.

Cloonan: This is the respirator system which is defined by Les as a tight fitting, full face respirator.

Berndtsson: Yeah, but that could be used together with a suit, couldn't it?

Cloonan: Well, it has suit compatibility, but we are not in a position to test the suit yet. And I don't think we are ready to address that from a knowledge perspective.

Berndtsson: So that will be a little bit design restrictive in that case. Isn't that what you are saying?

Cloonan: I do not feel that it would be design restrictive. What it does is it puts the onus back onto the, if you want to put it this way, the manufacturing community with end user input to bridge the gap between the level C configuration of that exposed skin and the respirator and the hood from whatever manufacturer... there needs to be a provision in place, and we were expecting maybe 1994, NFPA 1994 would address that situation. But at is stands right now, the respirator as a system is independent of the suit. For this purposes of this test.

Davis: Let me address that if I could. Wayne Davis of SBCCOM. We have tested suits with respirators before and what we've done is just cut the suit off essentially at

the mid-chest area and sealed it to the mannequin and then we can do the systems test that way.

Berndtsson: Because I think that is important to find a solution. We should get an answer (...inaudible...)

Cloonan: Noted sir. Thank you very much. All right, we...

Parker: I hope there's enough time. Jay Parker with Bullard.

Cloonan: Plenty of time. 10 o'clock, go ahead.

Parker: Yes, I just wanted to address the question from the gentleman from Natick about the manufacturers position on testing with liquid droplets. It's not that we are against testing with liquid droplets, I guess all we are asking is for everyone to consider the use of surrogate agents. If it is not possible to use a surrogate agent for testing, then we accept that too. I accept that. I'm here representing Bullard, not ISCA. Anyway, I had a question on the application on the formula for determining the challenge concentration, if there is any justification for that. Three times the IDLH... I was just wondering where that comes from... or the REL times the APF times the safety factor.

Cloonan: Very good question.

Parker: And a...

M: Yeah. I can respond to that. The two calculations were based on the idea to establish the test concentration, they must consider the face seal and the assigned protection factors that are for this class of respirator. So basically that's where we come up with the REL times the APF, the assigned protection factor. Then the safety factor in addition to that was just an engineering practice to assign a safety

factor in some reasonable fashion to that calculation. So that was the first set of numbers. And in most cases, that is the driving number, I think if you examine the tables. But, at the same token, consideration was given just based on IDLH. If we are looking at potential hazards due to the contingency conditions that could be multiples or greater than IDLH, we wanted to make sure we had some multiple consideration or some multiple factor over the IDLH in that calculation. So basically that's how we get there.

Parker: Thank you.

M: If I can, I'll take another liberty. I just wanted to respond to Bodo's comment. Relative to the seal integrity of the inner mask versus the outer mask, you need to keep in mind that on this test, the systems test, we're basically looking at permeation and penetration into the system. The inner mask, the nose cup in the... to establish the effectiveness of that seal, really I think is a secondary importance in this particular test. Because we are looking at the barrier material or the barrier between the agent and the inside of the mask.

Heins: ... excuse me. Leaking into the outside of the mask, that's not immediately mean that it's also going into the inside mask. So it is important that also the inner side... inside mask will be tight. Only then they will have the full protection of the mask, most of the mask, including an inner mask.

M: Yeah, but I think on this test you can't differentiate. If it's in the mask, it's in the mask. Because for these agents and test hazards.

M: That depends on the design of the mask. But, if I may, can I go onto a different question? And this is really to clarify the document I read... I tried to read your

document on... it says 6B rough handling transportability. Is it the fact that you are going to do all of these pre-conditioning tests and right at the end do one system agent test? Or are you going to do 1, 2, 3, 4, 5 system agent tests? It was... I think there was a little bit of confusion last night with the last lady speaker on that. And I was confused myself... whatever time it was this morning trying to read this through... as I read this document, you are going to do a hot diaonal (?), cold diaonal (?), in sequence, then a humidity, then a vibration, then you're doing to drop the filters, then you are going to attach the filters to the mask, then you're going to do a system agent test. Is that the way you see it working?

Cloonan: Andy, I would love to answer that question right now, but I would prefer to defer it after Frank Payla's presentation.

Capon: That's fine.

Cloonan: We'll address the environmental factors, and actually Les will follow that up with an overall test matrix to identify the sequencing, as well as the number of respirators required.

Capon: Okay, as long as that is clarified, cause that was a real confusion on my part. I get confused easily, as people know, but... the other one I'll address to Lee while he's a legend, rather than the next. (laughter) And this is really the concern about the use of live agents and simulants. The point about the test is that you subject your mask to a live agent test, if it fails there is no means of the manufacturer looking at that sample and understanding why it fails because, Lee, quite rightly, will probably chuck it away. But it's in decon solution, if he's... that's why he's still a legend and not in oblivion because he probably does that. Now, if you... if

there's some means by which we could use a simulant in SMARTMAN in development testing, then you could understand the failure mode if there are failures. And that's the concern with just doing live agent testing, instead of say, "Sorry... sorry, Mr. Manufacturer, it fails."

Cloonan: The surrogate program is designed to support the endeavors on an engineering cycle.

Capon: Not in the next three months... I wouldn't of thought.

Cloonan: Well, that's ... you know, it all depends on the timeline, but... Alex did you want to address some of that?

Payla: This is Frank Payla, NIOSH. Our intentions were to look at two fold for the permeation, the barrier materials. Number one would be to find a simulate to just look at the materials themselves to see how they permeate. Another two is within the GODESS (?) document we are going to try to find a simulate that would look for leaks and penetrations in the form of the SMARTMAN. So I believe you are looking at two fold. One for penetration and then the other for permeation. A lot of times you just can't get this magical stimulant to do both, unless you use a live agent, and we know that's out. So we're going to try that, and again, this is just from talking with the experts in the field. I mean, this is a very difficult process and it's the best approach that we are taking. I feel it is. And if you guys have any comments or any suggestions on another approach, please, provide us with the...

Pappas: This is Alex Pappas from SBCCOM. I just want to clarify that. Lee actually gives the contractors an opportunity, once they fail that test, to come in and do an R&D phase to see why that respirator failed on SMARTMAN. So you do get an

opportunity to come in and check your respirator and see why it leaked and why it penetrated... where the agent penetrated. So you do get an opportunity to check it and then fix it and then resubmit it again if you want to.

Cloonan: Okay, we have one more question, and then we've got to move on to... your presentation, as a matter of fact. I would just clarify what Alex just said, real briefly if I may. The opportunity for manufacturers to witness the product after it has been live agent exposed. We do provide a provision for that. If the time is available, Lee works with you or a NIOSH representative with you, but you have to understand the constraints of live agent testing. And one of them is the product has to be under chemical surety (?) control measures. All right. It's contaminated. And so you can't go in there and touch it, willy nilly as you would like. And as much as we want to let you to do that, we can't let you do that. You can visually observe it. You can tell the technician to make adjustments to the product. They can open it up. You can look at it visually it. You can take a diaphragm out, put it in a plastic bag, send it off for... I don't ... localized detection measures... but you know, we have limits with that as well. So the surrogate is going to benefit both the end user, the manufacturer, and the testing agency. Yes sir, your question.

Hasenei: I just had a comment. I'm Ken Hasenei from Maryland State Police. I am an end user. You're very right. We are looking... the first responder community is very much looking for a mask or negative pressure system that could last for 8 – 14 hours. We volunteer with SBCCOM for the law enforcement phase of the testing for personal protective equipment, and we found that 14 hours was about the

maximum time, and ensemble (?) it... an officer could stay out at the scene. And, I think... I want... just compliment you. I think you've got a very good grasp on what the first responder community is looking for. Another comment, when liquid testing or live agent testing. I just finished training about 2000 law enforcement officers in the state of Maryland on this, and I got nailed on all kinds of questions from... was it a stimulant that this mask was tested against? Who did the testing? Was it an independent laboratory? They wanted the answers to all these types of questions, and we fully expect that in a warm zone environment to have incidental contact with live agent and transfer there. So I think it is very important from our perspective and just hearing the comments from training, that they know when they put on a piece of equipment on that it has been tested against a live agent, and the possibility certainly exists there. And they feel comfortable using that equipment should they need to in an incident.

Cloonan: Outstanding. Goran... what are we doing to do man?

Berndtsson: Yeah. (laughter) I think that was clear... this is too important to push ahead at this...

Cloonan: Yes sir, by all means.

Berndtsson: What we are doing here is not testing that the respirator fit a person. You want to do that and the test...

Cloonan: That's right. This is not a fit test. That will be done...

Berndtsson: So in other words you are going to do everything you can to have a positive seal between the mask and the SMARTMAN and it is really this system as such that involved other parts... other respirator systems to be tested.

Tape 3, 6/18/02 & 6/19/02

Cloonan: That's correct.

Berndtsson: If you get the problem and it can be identified there was a leakage who occurred during the breathing (?) hood (?) that is not a failure. Is that correct? If the failure depends on, that the seal to the SMARTMAN was broken was broken due to the breathing rate of the SMARTMAN, that's not a failure.

Cloonan: The mechanical seal of the SMARTMAN should fail, is that the concept that you are introducing here?

Berndtsson: Yeah, because... I mean, the thing we have to be clear here is that we don't fail respirators because we can't fit the SMARTMAN. We're going to fail respirators because the system doesn't stand up to the agent.

Cloonan: That's correct.

Berndtsson: Now. So you understand the differences? We have to be very clear when we are doing this.

Cloonan: Have you had an opportunity... you need to come to an witness some of the testing because you'll get a better... total perspective of this. Before it goes in the hot box, we take exhaustive measures to ensure that the seal meets a known percent of particulate penetration.

Berndtsson: I hear you saying that but...

Cloonan: We utilize the TDA-99M on several instances. Go ahead.

Berndtsson: But there is no respirator is made to fit a metal head.

Cloonan: That's correct. We acknowledge that.

Tape 3, 6/18/02 & 6/19/02

Berndtsson: They are made to fit human heads and there is a take and giving on both the respirator and the flesh on a human to get that seal to be a positive working seal. Ask the gentleman from Germany, we have been donning a lot of testing...

Cloonan: Bear in mind now that this is a systems penetration and permeation test against live agent. The LRPL which Alex is about to discuss. If we can cease the questions now, we need to move on. Alex will pull into the perspective of how the LRPL compliments live agent GB and HD testing. Next slide.

Pappas: Who can follow after Terry, huh? And I thought he was talking about me... about being a living legend. (laughter) I'm Alex Pappas from SBCCOM. I do all the mask fit testing for all the joint services, Army, Navy, Marines, Air Force... we got involved with NIOSH about, what... a couple years ago, trying to write standards... trying to converge that military mask arena with the domestic commercial mask arena. Trying to come together and get some standards that both the Army and NIOSH and the commercial world can live with. This is just some stuff... we talked earlier today about ensembles. Some of the companies and manufacturers here have come and we've actually done suit testing with the respirator, even though the LRPL doesn't involve that. LRPL mission: our mission is to test respirators and suit ensembles to pick out the best ones that we could give to the first respondent to protect his life. Another mission we have is our military mission, and our military mission is to protect the soldier and give a soldier the best respirator or suit that he can have in the field. Some of our customers? We've worked extensively with domestic preparedness program and we have some suit and mask reports out on their website. The M40 Mask Team,

the 45 Mask Team, JSGPM Mask Team, which is Sandy over there... DOJ, which they are here also, TSWG with Tracy Cronin (?) and then we also have a vehicle testing services agreement where we can actually do testing on the site for manufacturers, if they need to mask test it out of NIOSH, we can write up a TSA and we can do a test for you on the side. And then also NIOSH, we started a SCBA testing. Okay, just a little trivia here. Testing accomplished... we have a high turnover. We use 30 soldiers every weekend, privates, 18 – 25 year olds and we can at least get... we can get up to 96 data points per respirator. Current testing, just some of the... again the testing customers. Human use, okay, we'll get into human use. In order to get a statistical significance in your data for the military and the LRPL testing, we at least do 22 different subjects to get our 90% confidence at 90% reliability. We actually do a lot more than that just to be even more comfortable with the data that we receive. We have a joint service standardization agreement with all the armed forces to be the testing house of choice to do the military respirators. Okay. What is an LRPL? Okay. We changed the term a little bit. Everybody is used to PF, protection factor. LRPL, we just changed the term to LRPL so you don't get confused with the military side and some of the other commercial lingo that's out there. Basically it's a concentration of what's outside the mask to what gets into the respirator. Okay. Corn oil testing, we use a corn oil stimulant, Mazola Corn Oil that you buy from Giant, 99.9% corn oil, pure corn oil. We can use it for testing level A suits, level B suits, which are impermeable and also respirators of different classes. We've done escape hoods, PAPRs, SCBAs, all the different classes. Okay. Some of the capabilities

and equipment that are available at the aerosol PF chambers. We have laser photometers. We have state of the art aerosol generation system. Filtration Unit. New ductwork, all stainless, and we also have a control system so we can control our aerosol when it comes into the chamber in certain concentration. And we also have environmental unit even though we are not... we normally run at ambient temperatures for the NIOSH testing, but we can change that if you want high humidity, high temperature, that kind of stuff. Just a little specs on the laser photometers. The rear light scattering, laser photometers made by TSI. They pull 2.2 liters per minute out of your oral nasal capacity. Oral nasal cavity is the most critical cavity. So we would go through your nose cup. Through that secondary sealing surface, and pull a sample out of that area, because that would be the most crucial area where you are actually inhaling the particulates. Self-calibrating and they last forever, basically, 85,000 mean time before failure on the laser. Aerosol generation system, we had aerosol generation system customer made by Dr. Lu (?). He used to be a profession up in TSI at University of Minnesota. This one... one of these generators can keep up the chamber, keep it up to 20 to 40 milligrams per cubic meter in a chamber. There's a... we have little pictures here too. Pictures of the stainless steel; it's all stainless. Part of the plenum system. Filtration unit, okay, we have a fan unit that basically can be controlled up to... from 100 to 2000 CFM. The chamber is always in negative pressure and we do an air exchange 10 times per hour. ECU to some of the specifications on the environmental control unit. The different temperature ranges that we can have in the chamber. One thing we found from doing mass studies with some of the

military stuff, is, when you start sweating and you use some materials... you start seeing slipping. Okay. Some of the materials don't stick as well to the face as some of the other materials. So when you do sweat tests and that kind of stuff, you might have some slipping. Or put a heavy can on your face. Picture of a ECU unit. Just some of you manufacturers might know what respirator this is under that suit. We don't want to give it away, right? And this is for the question at the end of the day, if a SWAT team member is running around in a lime yellow green suit, I would think the terrorist would see him right away. We also do impermeable suit testing and this is the JLIST... it's actually a Lanx (?) suit. It's a commercial available suit and some of the local responders are using some of these suits also.

M: (...inaudible...)

Pappas: Right there, that's a probe that's going through the... we have the ability to test both eye and oral nasal. Terry wanted me to clarify that. We can also see how you are doing in the eye region. Most tight fitting respirators, you probably want to go through the oral nasal cavity and that would give you the worst case scenario. A lot of the secondary nose cup seals, they have valves anyway and you are actually inhaling through the can, up through the eyepieces and then back into your nose cup and then exhaling it out. So really, it doesn't matter what you get in the out... in this range, as long as you check oral nasal because it will see all the leaks. Some of the other stuff that we've tested, TYVEC suits. And this is a level B, so if you are in a level B environment and you're going get liquid on this SCBA. You'll get liquid agent on it. Okay. Now to get into the LRPL testing for APRs.

Okay. Masks will be propped by us. This is all to be open for discussion, but it's better that we probe the respirator so we probe them all the same way, So you don't have to provide us probes. Fitting and donning instructions should be provided to use, sizing instructions... sizing, sizing we are going to do it... we have a suggestion to do it the same way like the Los Almos (?) study, where we pick a panel of people and we run through that panel. APR training, the manufacturer will supply us with either a video and come in and train us some we can train the soldiers. The soldiers will be trained for 15 minutes. They will get a chance to put it on, take it off for 15 minutes, and then there's a 15 minute period where they keep it on. They keep it on for 15 minutes so they get acclimated to the respirator. And then after that we proceed into the corn oil chamber. Now this was something a lot of you manufacturers might have heartburn about... is donning times. This is just a suggestion. The military mask has... is nine second don for seal and then 15 second if you have a hood system, to get the hood system attached. This would mean... your mask would be outside, it would be ready... the can would be on it and basically all you would have to do is put it on your face and get a seal. That would be your eight seconds. Then you would don all your accessory equipment, and that would be your 14 seconds. Okay. Standard, like the SCBA standard, 11 exercises. It's the military standard exercise routine with one extra exercise which is climbing the stairs. Two trials per subject, so if we do the panel for NIOSH, each subject will run twice with that same respirator to verify the result the second time to make sure it wasn't a fluke or something happened to the individual the first time. Okay. This is also the... we are trying to

figure out a criteria for pass and failing a respirator in the... air purifying respirator. It' 95% pass at 1000 LRPL. As you can see, you can see the 40 field requirement is 100% at 1667 on a port-a-count (?) to actually have it fit to your face. And then we also QA... we also note any kind of problems QA with TIRs so you are not in the dark on what happened. And if it was a human error during testing, something that we did, something that the soldier did, like pulling out a sample line before the test was over, then that data will be taken out of the testing and not used for the final analysis. Future capabilities... just some of the future capabilities, a lot of this stuff we've already done, like the flat panel technology. Everything is computer controlled. We also have vapor testing that we're going to get into tomorrow, during the suit testing criteria. And then we also have expand it where we can do two respirators per test day now. So we can do up to 16 people at a time in our chamber. Obstacle course construction, this is some of the military guys or maybe some of the... I guess, the state police might want to do something like that... shooting with it, maybe running on an obstacle course to see how well it performs. And we have some mobile testers that we can attach to them to see if they get seal breaks. Okay. Before we get into questions, I would also like to thank... we have a new engineer on board with our team, Mr. Adam Seiple. And he helped put together that presentation outside, along with Mr. Leroy Stitz, which this presentation couldn't be possible with them. Okay. Any questions?

Berndtsson: Goran Berndtsson from SEA again. The donning time is something which we maybe should think a little bit about. I mean, when it comes to hood, for example, I know we are not talking about hoods now, but a hood... it would certainly be in

an environment which have some kind of contaminant and you need to put on a hood, and that's very important. Can't do that in a fast and rapid time. But when it comes to response to something, you are usually in a clean area, getting prepared to go in as a response. And I think that it is really important that we really make sure that the respirators and whatever accessories goes with the respirator are done property before you go in, then just pushing the time too much here.

Pappas: Sure. Sure. Again, the donning times are open for discussion. That was something we just thought would be... just to show that it could be put on in a practical amount of time... it could be a minute; it could be two minutes. It depends on what the consensus is.

Capon: Andy Capon at Avon. Looking here at your pass/fail rates and thinking around the world whatever pass/fail rates there are, you are suggesting here 95% pass a protection factor of 1000. I compare that with a standard industrial mask in Europe where you have 100% pass at 2000 and our military mask, these more and more look like pseudo military masks, and of course the military masks would be very applicable to this type of application, given the filter requirements which we can talk about. But there your protection factor is 10,000 with a percentage level on that, and I do wonder whether 1,000, so you are giving your first responders half the protection factor of standard industrial workers in Europe is exactly what you want to do.

Pappas: Well the industrial requirement is based on an eight hour, probably, work day at a concentration. And that's one thing you have to keep in mind when you are

looking at some of these pass fail requirements. We are talking about a one time incident exposure usually.

Capon: But we've just heard that we might need it for 14 hours... 14 hours.

Pappas: But he's not going to be in the hot zone, probably for 14 hours, if... my guess or my experience would tell me if he gets exposed, they're going to get out and go through a hot line or if he knows he was exposed and not stay in it for 14 hours.

Capon: Goran just asked, Alex, could you run through the 10 exercises? Have you got the rifle firing in there?

Pappas: Yes. Yes. It's normal breathing, deep breathing, head side to side, head up and down, talking which is recite the rainbow passage, reach for the floor and ceiling, on your hands and knees, turn your head side to side, climbing stairs, facial expressions, and then sight the rifle is one of them also. And there is a couple normal breathings in there.

M: Grimace.

M: (... inaudible...)

Pappas: One minute each. So it's 11 minutes total.

Cloonan; And that's a self-donning exercise.

Pappas: And that's all self-don, so how well your respirator performs might be attributed to how well you provide donning instructions to me or to your subject. So, if you have a nice video where I can put the video on, it's pretty easy to look at and the soldiers can understand it, then that would be to your benefit.

M Jay?

Parker: Yes, Jay Parker with Bullard. A comment on the donning. All I would ask there is that you also pre-loosen the straps in addition to mounting the canister, cause I have found that really speeds up donning.

Pappas: If that's part of your donning instructions, that's what we'll do.

Parker: Okay.

Cloonan; It's all self-donning, Jay. So if you have it in the user instructions, that's how Alex will train the test subjects. They will perform the task. Unlike the MIL Spec requirements were it's expert donning.

Parker: Fair enough. I had a question on the two trials. Can you explain again how you are going to use that? Are you going to use both data points or how is that going to work?

Pappas: We use both data points and we run the subject in... the first time he does his 11 exercises. We get the results. He comes back out. He actually physically takes the respirator off. He has to doff it to considered a second trial. Then he puts it back on and goes back in and we run him again for the 11 exercise routine.

Parker: So if there's 25 subjects, you're actually going to have 50 data points.

Pappas: Yes sir.

Parker: Thank you.

Pfriem: Dale Pfriem, ICS. I see in the discussion document we have lost the non-contributory design restriction on the chamber size. Is that going to stay the same in the final document as far as you see it at this point? Since it's irrelevant?

Pappas: The chamber size as far as what? It's 10 by 20...

Pfriem: In the SCBA document you specified the chamber size, which is irrelevant. Only the concentration is relevant. It's not in this document. Do you intend to keep it that way.

Pappas: It should be... it doesn't matter what kind of volume you test your people in, what it matters is your concentration and particulate size.

Pfriem: I understand that, however, you've put that detail in the SCBA document. Therefore, it's in the document and it's mandatory.

Pappas: Well, I would think you'd want to put that detail also in the APR document.

Pfriem: Why? Why is chamber size relevant?

Pappas: Well, yeah, you're right. Just concentration. You're right. I mean, that was just a spec on what... you don't have to use the same chamber size.

Pfriem: So we can assume that it will be taken out of the SCBA document?

Cloonan: No we cannot. We need to approach this in a more methodical manner. And your question is very well taken. Do you have data which would provide relevancy.

Pfriem: It's simple math.

Cloonan: Yes it is.

Pfriem: Sure I do.

Cloonan: Okay, if you have the data support we'll address it. You are absolutely correct. The SCBR... correction CBRN/SCBA protocol doesn't exactly specify the chamber size. Now, will it be in the CBRN/APR perspective... as it stands, yes, right now, but that is subject to change. Because this is an open discussion... this is a draft protocol.

Pfriem: Well, that's one comment I had. Next comment, you say you don't choose to specify probe location, being that these, we'll say, pre-submittal testing is going to be taken place by manufacturers and other bodies, I would urge you to at least consider specifying where the probe is going to take place so we don't have probe variance.

Pappas: That actually is in our service agreement. They give you the exact location... it's like a ¼ inch and they give you all the dimensions and how far.

Cloonan: Let me understand that correctly. You're asking for an exact location in the oral nasal cavity?

Pfriem: As exact as you can specify, the previous comment was that it was not going to be specified because SBCCOM was going to do that placement and they wanted consistency, which I can understand from there perspective. However, of course, as you guys know, from my perspective, it doesn't cut it.

Pappas: Well, some manufacturers have different design respirators, so it's difficult to put them in the exact same spot within a couple millimeters. I mean you have to have some...

Pfriem: I would believe that the probe should be relevant to the anthropomorphic of the individual, but not the respirator itself, so if we specify that the probe is going to be within a zone... locality... the nasal zone or the oral zone, that that should suffice.

Pappas: Okay.

Pfriem: And thirdly, we've seen a lot of papers recently and a lot of data come out and it's been known for a real long time that the Los Almost facial size matrix is really,

really lacking and it's very difficult to find subjects within those matrix areas. As this is a new standard I would urge you to adopt any of the new protocols are better than what you have there in the Los Almos (?) protocol.

Pappas: I think NIOSH has actually a program now to update that anthropometric study. And maybe John can clarify that.

Dower: All right. This is John Dower from NIOSH. They're... we've done some investigation of alternative anthropometric panels. We've looked at the Air Force panels from 96. We looked at the US Army panel from back in 92. However, those were focused on young military folks and are not at all representative of the universe of the emergency responder populations. Currently we have projects in house at NIOSH to update those anthropometric panels to a modern population that encompasses all industrial workers as well as emergency workers that will allow us to create a better panel, but in the interim we are going to initiate using the Los Almos (?) panel, and at this time, we are having no trouble at SBCCOM appropriately filling the cells that are required within that panel. And, we... our intent is to keep the panel consistent and to keep the methods consistent until such time that we have better validated panels, where we have better validated protection factor testing methods.

Pfriem: I've seen the data preliminary in the preliminary propositions that have come out of the agency and I think they are better, even at this stage, than what you have in the Los Almos (?). But that's my opinion.

Pappas: I think right now, since we're about at the break time, we'll pick up after with the human factors protocols that we are considering. One thing I did want to mention

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before you break for 15 minutes. We've had some questions about the meeting tomorrow on PPE. I believe we have the agenda... is in the back, outside the door, for tomorrow's meeting. If you have any questions, specific questions about the PPE meeting, please see this lady... Elaine Stuart Craig, and she can answer them for you. Thanks. We'll see you in 15 minutes.

(END OF TAPE 3, SIDE B)