NIOSH/NPPTL Public Meeting to Discuss CBRN and Quality Assurance

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TRANSCRIPT LEGEND

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P R O C E E D I N G S

UNKNOWN SPEAKER: If everyone . . .I guess everyone is seated so sorry for the 5-minute delay, but we had a little technical difficulties. What we'd like to do is start the, start the meeting and to kick it off Rich Metzler is going to give a few opening remarks.

RICHARD METZLER: Good morning and welcome. It's a glorious day in western Pennsylvania. For those of you who are familiar with the area know this is about the third day of sunshine we had this year. Again, welcome ladies and gentlemen and partners for improving occupational safety and health. I am very pleased to see you here today and to welcome you.

I'd like to point out that there is a very diverse group with us this morning: representatives from the manufacturing community, the ISEA, private laboratories who perform tests of personal protective equipment, instrument manufacturers, universities, and in particular I'd like to thank the emergency responder groups, the IFF, the IFC, the NABSCA, the U.S. capitol police, HAZMAT response teams. It's important that your participation stay at a high level so that we can implement the best of standards to protect emergency responders. The program that's hosting this meeting today is NIOSH's National Personal Protective Technology Lab. We had our genesis just a couple of years ago prior to 9/11 with a

guidance and a mandate from Congress asking that we focus our attention on state-of-the-art personal protective technologies for all workers but with a special emphasis and encouraging us to work on those special needs of emergency responder communities to terrorist events. The programs relating to self-contained breathing apparatus for CBRN response, full facepiece gas masks, the escape hood program are all part of our special emphasis program. Before I begin additional comments on where we had been and where we are going, I have special announcement to make today. Recently we were able to select our permanent management team and I'd like to announce that Les Boord who has almost 30 years experience in occupational safety and health protective technology business and was a senior vice-president with a major manufacturer is the Deputy Director for the National Lab. Roland Berry Ann sitting in the back here; Roland you want to stand up and let everyone see you; Roland is selected as the Respirator Branch Chief. Ron Shaffer right over here in the corner joins us from Naval Research Lab and General Electric, Ron is a Ph.D. analytical chemist who brings an expertise on CBRN standards or sensor technologies. He will be leading our research program in personal protective equipment.

I see a lot of familiar faces and partners in the audience here. Many of you have been with us since the early 1999

when we were trying to eek out enough budget to hold our first workshop jointly with DoD and OSHA in Morgantown. This was our first real introduction into chemical warfare agents and protection needs of emergency responders against terrorist threats. We held that meeting in March of '99. It had 131 attendees and 15 inches of snow outside at that meeting. There's a book in the back of the room that described for us as a first resource, the protection needs for emergency responders. Our early efforts were aimed at identifying the protection needs for the responder community and building crucial partnerships. And our laboratory, by the way, is founded on the philosophy that quality partnerships enhance safety and health and we do these partnerships through bringing funds in from critical partners and also putting funds out to critical partners to help us do our work. And during that process, we were able to learn that the critical first needs of the emergency responder community was self-contained breathing apparatus and full facepiece gas masks.

Again, I remember sitting in Chicago with Chief John Ebersol and he asked me the question will self-contained breathing apparatus protect fire fighters from chemical warfare agent threats. I didn't know how to answer that question. He kind of put me on the spot. You know SCBA are not products used by the military so that they weren't

certified and constructed to protect against chemical warfare agent threats and NIOSH had no experience in the area. A lack of response lead John to say you should not put your head on a pillow and go to sleep at night until you have an appropriate standard to protect these emergency responders. And it seemed like it's something we might have been able to do in 3 months, but in fact it took a couple of years to develop the appropriate standards for self-contained breathing apparatus. These standard development activities are not the only activities that we as a new lab had been participating in. We sponsored a meeting in New York City following 9/11, that was in December, where we brought in actual responders from the Pentagon, the Oklahoma City disaster, and the World Trade Center disaster and learned from the emergency responder what they're protective technologies needs were, how well did the equipment perform at that scene, and what they're shortcomings and gaps in technologies were.

We're also doing a study with RAN where they're interviewing hundreds of emergency responders in all walks of life from that community to address what they're personal protective technology needs are. And that really does expand it to HAZMAT workers, emergency medical workers, fire fighters, police officers, the full gamete of emergency responders. We're also developing and will have done by the end of this

fiscal year critical PPE guidelines for emergency responder protective technologies during structural collapses.

This is not done alone and there are many partners we have to thank. We did have many official partnerships established. The National Institute for Standards Technology has worked with us all along the way and in fact they along with the Department of Justice really did provide the early funding to initiate our programs and they continued funding in part our work even through today. The SBCCOM, I'd like to think of them as blood brothers . . . we're talking about in the way of the standards for SCBA and gas masks could not have been done without SBCCOM. We are one. OSHA, it's participation with us in providing us with advice and council and also assuring that the standards that we develop can in fact be implemented and enforced in the workplace. The NFPA, as a private sector group, brings its body of standards in use with our own new standards to ensure that we have a full range of adequate protection. Not listed here are all of the user groups, the fire chiefs, the fire fighters, the police, the IAB, many organizations who have participated in every meeting providing us with insights of what their needs are.

Today's meeting is going to discuss two important areas. The first is the CBRN standards for air-purifying and self-contained escape respirators. While the press and national

television media have not been putting a great deal of focus on respiratory protection of late with one exception 20/20 had a program last week in the shortfalls of gas masks protection for first responders. The heat seems to be somewhat off in this area but in fact with the introduction of these standards we anticipate there will be a greater awareness and a greater interest again in the coming weeks. There's also been a major problem associated with the fact that there are so many products that can be purchased from a website where there has been no standards used for designing and developing equipment to provide adequate performance and many, many misrepresentations of the equipment's capabilities.

The second part of this afternoon will address the quality assurance module. A module in our terminology means a set of standards for improving quality assurance in this case. This is a module that we had to set aside while we responded to 9/11 and the CBRN standards, but several things have happened that make the timing in introducing the concepts for these upgraded standards the right time now, that is, ISO9000 recently came out with an upgrade and we see that as a very improved set of quality standards. The respirator branch is the cornerstone of a new national lab and it will and does receive adequate funding from this new laboratory. We have new experienced quality assurance staff who were trained,

educated, and have experience in the quality assurance business and we have experience with using qualified labs in the sense that SBCCOM labs have been qualified to our standards and actually using their standards and ours together. And also we have an experience using private sector quality auditors to supplement our own staff. All these things collectively have given us a broader perspective to redefine the concepts in the new quality standard.

And the last you'll hear from me is just a quick summary of what we have done in the way of the CBRN standards. The SCBA standards were implemented in December 2001. There are 3 manufacturers who hold approval on more than 12 models. Additional applications are in-house as we are speaking and nearing completion. The gas mask program was implemented in March of 2003. There are five applications currently in-house. Four of them passed the preliminary screening test with sarin and mustard test, the system test that's done by SBCCOM for us and we intend to finalize the escape APR standards by this October. We're optimistic that we'll be able to even beat that date. And we've added to our agenda, not only the APR part of it, but the self-contained portion of the standards were integrated into the program. Next year we will introduce the standards for power to air-purifying respirators with other standards such as combination respirators, air

supplied, air purifying built into single products to come in later years.

I would encourage you to continue your high level of active participation at this meeting today, to get your comments into the docket office as it would be our intent to finalize these standards within the next 60 to 90 days. It's a target that we think we could meet and are looking forward to finalizing these standards.

And with that, I'd like to introduce the Deputy Director for the National Personal Protective Technology Lab, Les Boord.

LES BOORD: Thank you. Perhaps first we ought to introduce the CBRN team which I'm sure everybody's by now familiar with because they're seated up here at the table. The first is John Szalajda, Frank Palya, everybody knows Rich, Mike Monahan, and a new member of the team is Mike Bergman who joined us several months ago and has been actively engaged in the process. Throughout the audience, there are several others who contributed significantly to the effort: Eddie Sinkule, in the back and I'm sure there are others: Roland Berry Ann. So I think everybody is pretty well known.

On the screen we have the agenda for today. I'm not going to walk through each element of the agenda. I think everybody can pretty much do that, but as Rich mentioned, the

focus and the primary objective of the meeting today is to cover two major topics and two major project activities that are being conducted within the laboratory. The first one is the escape respirator standard and secondly is the QA module. Hopefully the sun's shining today for the first time or for the second time or whatever it is for this year is a good omen because we have a lot of information to cover and a lot of technical details. Then tomorrow is equally an active day for manufacturers and applicants to attend a workshop on the certification process. So we have 2 pretty active days of activities that I think will have an impact on the laboratory and particularly on the respirator branch. So the agenda is as illustrated. We are pretty intense with topics today going into the afternoon until 4 o'clock.

The major focus of the discussions today on the escape respirator is going to focus on really five different areas. We don't want to go back and rehash a lot of the information that we've discussed previously in the April meeting that is in the concept paper. What we'd really like to focus on is the areas of work since the last meeting and plus some ancillary things, but those areas really come down to the five topics. One is breathing gas control which is the CO2/O2 concentrations. The second we want to talk about the description of the categories: the general, the specific, and the high.

We want to spend some time on the LRPL. We've done quite a bit of work on the LRPL and that will be a topic of discussion today. Then we want to talk a little bit about the live agent testing and what has been done in the area of live agent testing since our last meeting in April. And then finally, an area of the standard development that we spent some time on in the last . . . since the last meeting is the testing sequence so I think the sequence in which all the requirements will be evaluated, the number of respirators, and so forth. So those are the areas that we really want to discuss in detail.

Also the surveys that you have in your information packet that you received from the meeting, one of the comments that we received from the meeting in April was that a lot of the background information that we presented is kind of redundant because we talk about it at each meeting and we do have a large percentage of the attendees to attend multiple meetings. So what we're going to do is we're going to abbreviate those discussions so we can really focus on the technical content.

Another area that we're going to do a little differently this afternoon in the afternoon session is that we've taken the opportunity to prepare all the comments that we've received during the course of the meetings through the dockets and sort of itemize them, tabulate them by topic area and we'd like to walk through those so you can sort of see how we man-

age and what we are doing to manage the comments and the information that we get from the interchange and the interactive part of the discussions that we do have.

And then finally to round out the day, we have the discussions on the QA module which I think is also a refreshing step in the program. I think most of the people in the audience are familiar with the previous activities on the QA module which we're all very good actions and activities. There was a lot of work done in that program and basically we're renewing that effort and would like to get everybody up to speed at where it is and where it is going.

Just some of the logistics before we get into the discussions, I believe that everybody has used the sign-in sheets at the registration. So if you haven't though, make sure you do sign in so that we have an accurate list of the attendees. The meeting is being recorded so you should be aware of that and it is transcribed then for the docket. One of the activities this afternoon when we talk about the comments that we've collected on the previous meetings, that's where some of those come from, from the previous recordings and transcription. The presentations that we do today will follow the agenda. The agenda is kind of broad without the specific technical requirements, but those discussions will follow the areas that I mentioned just a little while ago. Following each discus-

sion we will have a question and answer period. Okay, so that you have the opportunity to ask any questions or provide comment or provide input relative to the topic that's been discussed. To do that, we would like the individual person to go to the center of the room to the microphone and then announce their name, their organization, who they represent, and then to make the comment into the microphone. Then finally we have the information relative to the docket. Okay so we actually have two docket numbers illustrated there: one for the escape respirator of the CBRN escape respirator and secondly for the QA module. So I think that information is also provided and available in your packet along with the other contact information.

So with that, we'll move into the overview discussion for the CBRN escape respirator and while we're not going to go back and rehash a lot of the background, I think it's very important that everybody understands the goal which we're trying to achieve. So I don't think we can have a meeting without stating what the goal for the project is and that is basically to develop an escape-only respirator to be used for CBRN chemical, biological, radiological, nuclear inhalation hazards in the event or the incident of a terrorist event and it's intended for the general working population.

The escape respirator does represent what I consider to be a very complex problem involving hazard analysis. To really identify escape respirators and escape respiratory protection, there needs to be some forethought behind what the intentions are. Okay, what you intend to use it for, where you're escaping from what you're escaping from where. Okay, what's you're . . . perhaps what the threat level is for the area, where the respirator would be deployed, whether it's in areas where high concentrations could be considered or whether it's in a low-threat area or you may have lower concentrations to be concerned about. All these factors I think need to be part of an assessment to determine what type of an escape respirator is ideal for the situation, but then there's also a wide variation of what those hazards and threats may be. As we well know from previous efforts in our standards development and in our APR. We have, our gas mask APR, we have the hazards of chemical warfare environment. We have biological hazards. We have toxic industrial material hazards. So we have a wide variety of hazards that can be the threat and I think also that the . . . an awareness is to the hazards that are applicable to the particular area need to be a consideration.

In addition to all that, we have multiple escape activities that can be taking place. So when we look at escape from

terrorism events, it is indeed a complex problem. We have a wide variety of hazards. Threat analysis can be site specific. As we said before, the hazards and the threats for one metropolitan area may be significantly different then they are from another depending on the industrial activities in an area or just the general proximity to perhaps military installations and so forth. So hazard/threat analysis can be site specific.

Escape strategies also can vary. Escape strategies are exit immediately or progress to designated areas. These factors, these threats, and the escape strategies they do have an impact on what the respirator is expected to be able to do. And as such, I think by virtue of that fact they have an impact on the standard that we ultimately develop for an escape respirator because if we have an escape scenario that has specific requirements. I think our standard that we ultimately end up with needs to be capable of being able to certify that, that respirator. For this reason, we segment the strategy for escape respirators into three categories which most of you're familiar with: the high category, the specific category, and we've renamed the bottom category there. I should have done these or mentioned these in reverse order, but the bottom category we're calling it a general category. When you look at the rough classifications of those

categories, we will start at the bottom here. With the general category, we're talking about multi-hazard protections with chemical warfare agent capability. We move up to the specific. We're now talking about that same general category with multi-hazard protection, CWA capability but then the ability to perhaps look at a specific threat from our list of 10 test agents. So it's sort of the blanket from the general applied to the specific with the opportunity to focus or concentration on specific hazards. And then obviously the high category for oxygen-deficient environments or where you truly have a unknown situation. If you take those categories and then sort of designate them into the hazard description and respirator performance, then I think everybody's familiar with this tabulation if you've followed the concept development for the escape respirator. But basically in going from the bottom up again in the general category, we're looking at an air-purifying type of an escape respirator. The same for the specific category and the finally in that high category where we have the oxygen deficiency potential that's where we really are looking for self-contained. And that's the reason for expanding the scope of the escape respirator concept to include both the air-purifying type respirators as well as the self-contained.

Which gets us to the concept paper, again, most of you are familiar with the concept paper and the process that we've been using to develop the standard which basically is the concept paper. We first introduced the escape respirator concept paper last August where we identified the framework for the standard, a little bit about the categories and the general ideas of what types of requirements should be included. That has evolved through several iterations to the point where we have the June 15th edition of the concept paper which is going to form the basis for the meeting today. That concept paper is organized into two parts. The first part obviously addresses the air-purifying escape respirators and the second is the self-contained escape respirators.

And rather than walk through the requirements in each of those sections or each of those parts of the standard, I'll just enumerate what the sections are and as the discussions progress today, we will focus a little deeper into some of these areas. But basically for part 1, we have the statement of the goal which we reviewed today. We have the description of the hazards categories. We have or section 3 addresses the respirator use, escape only. Section 4 addresses the gas-life testing, the 10 test representative agents, how they are applied to the general and the specific categories. Section 5 addresses the environmental conditioning, the environmental

extremes that the respirator is going to be exposed to. Section 6 identifies performance requirements and here we're looking at like field of view and fogging and general performance areas. Section 7 addresses design requirements which for the escape respirator are not that extensive. Basically, it's a hood-type escape respirator and I think that's a good sign that the design-specific requirements are not very extensive which means that the standard and the evolution of the standard is very much oriented towards a performance requirement. Finally, not finally, but section 8 addresses the applicable sections of 42CFR specifies the appropriate sections there. Section 9 is service and maintenance. Section 10 is training. These areas require, as you review the June 15th document, need to be some work done in these areas, some additional effort spent and focusing on those requirements, and finally, cautions, limitations, and quality assurance requirements. So that's the layout for part 1 - air purifying.

The part 2 of the concept paper addresses the self-contained escape respirator and there we have basically five sections. The first section is a general description of the standard and the description of it. Section 2 identifies the requirements and what we do here is we identify a three-tier requirement for the self-contained unit and those three tiers

are covered by Sections 3, 4, and 5 which basically are the first requirement is that it have a normal 42CFR approval as an escape self-contained escape respirator. The second tier of the requirement is section 4 which is what we're calling the enhanced escape respirator requirements. These are the, this is the area of the concept where we introduce the environmental conditioning requirements for fogging, for field of view, and requirements that are enhanced beyond the normal requirements of 42CFR you have very applicable to escape respirators and escape respirators for CBRN requirements. And then finally section 5 is where we identify what the specific CBRN requirements are and those really come down to two primary requirements. The first one being the laboratory respirator protection level testing which will be a focus of the discussions today and then the chemical warfare live agent testing requirements for the escape respirator are also covered in section 5. And the content of each of these sections is identified in the June 15th edition of the concept paper and will be the topics of discussion today. And with that, I'll turn it over to Mr. Szalajda.

JONATHAN SZALAJDA: Good morning. As Les has mentioned, we're going to cover a couple things in little less detail and other areas, but we felt that there had been a few changes in regard to the gas-life test requirements and we wanted to make

sure that you were aware of those changes as well as the things that we've been consistent with the chemical warfare agent testing for the air-purifying respirators. Just a little bit of background, I think a lot of people have seen this chart in other forms before, but basically we performed a comprehensive review of various toxic industrial material data list as part of the standards development program and consulted with several different Government agencies in an effort to try to identify potential materials that could be identified as respirable hazards to individuals and then identify protection necessary for providing respiratory protection. But as going through this review, we established, the emphasis was to establish a list of toxic industrial materials and chemical warfare agents that proposed or that presented a respirable hazard to the individual and along with that we came up with a list of . . . it varies from time to time but it . . . we came up with a list of 170 potential respirable hazards that would need to be addressed as part of providing protection for the user. In an effort to try to reduce the number of tests that are needed for certification, we took a look at the different materials and categorized them into agent families with the intent of identifying a test representative agent to be conducted as part of the certification test for each of the identified families and the way that

455 we broke the classification down was to work through identify-
456 ing the absorbents required to remove the hazard from the
457 breathing zone of the respirator wearer.
458 Where we ultimately ended up and initially this was
459 promoted as part of the gas mask standard, but the protections
460 that we are providing or providing the gas mask standard as
461 well as in the air-purifying escape respirator will protect
462 against 139 potential respirable hazards. We ultimately ended
463 up using vapor pressure as the single best indicator of the
464 ability to bond the challenge agent against the carbon used in
465 the filter. I think of note here and as far as the particu-
466 late family list includes a list of biological agents as well
467 as radiological and nuclear agents that we've published in
468 other forms. The complete list, the complete list of all
469 these chemicals are available and on our website. If you go
470 back to the initial June 2002 meeting, the list of chemicals
471 is available on that site.
472 In terms of the actual gas-life testing requirements,
473 there are a couple of factors that applicants should be aware
474 of. One is the identifying the test duration for the equip-
475 ment and the application that we've identified rating
476 intervals or duration intervals in 15-minute increments and
477 this will be specified by the applicant, the manufacturer, and
478 we will conduct the tests in accordance with the breakthrough

or at the test challenges and the breakthroughs that we've identified to determine the capability of the item to meet that requirement. In terms of the actual test itself, we'll be conducting two tests: one at a lower humidity and one at a higher humidity at relatively room temperature with a 64-liter per minute flow rate and this is consistent with NIOSH's has historically done with the industrial respirator testing program. And also as a result of information that we've received to the docket, there appears to be a need or a concern over the capacity of these systems or any respirator system at a higher flow rate so we've included a panic demand requirement as part of the gas-life testing where we will expect the respirator to provide a minimum service life of 5 minutes when we test at a 100 liters per minute.

In defining the test challenges for the respirator that we ultimately ended up with a multiples of at least three times the ideal H (phonetically) in determining the test challenges. The breakthroughs that you see in the second column are either set at one-half the permissible exposure limit or at the American Industrial Hygiene Association's Emergency Response Planning Guidelines and what these guidelines are are the maximum concentration and air that individuals can be exposed to for up to 1 hour without experiencing or developing irreversible health effects. Really the

intent in trying to set these, the challenge and breakthrough up was to maintain a balance, a proper balance of requirements for the filter to ensure that we can cover a broad range of potential respirable hazards but yet still provide the adequate protection to the user to the worker to be able to exit from the site of an emergency where he would have to wear one of these devices. As Les had mentioned, I think the area which is new from the last time we were together in April was with regard to identifying specific requirements in response to some of the information and comments that we received through the docket and also from stakeholders that we felt it was important to delineate the requirements for the specific category that there was a need to provide some structure to identifying the test challenge requirements for the system where we ultimately ended up is that we took a look at air purifying, the gas mask standard and the test challenges for the air-purifying escape respirator are based on the requirements on the gas mask standard. The only difference is in the breakthrough values that were set and the breakthroughs are consistent with what we set up in a specific category and the one point I did want to try and make clear in determining the specific category is that we felt based on the feedback we received and the discussions that we've had internally with the project team, we need to provide the general protection,

the across-the-board protection to the worker to the wearer of the respirator in addressing all of the CBRN hazards that were identified as part of the program and where we feel it's advantageous with the specific category is that it gives the leeway for the manufacturer for the applicant to go ahead and identify certain chemicals that they may want to enhance to provide additional protections whether it be ammonia or formaldehyde or cyclohexane or a combination of where we can enhance or manufacturer can enhance those certain test representative agents to provide an additional capability and that can be tailored towards a specific user community or a specific user need.

We covered the benchmark testing. A lot of the benchmark testing that we conducted in the April meeting and in summary at least with the testing that was conducted, the benchmarking of existing products performed fairly well. In terms of where we saw shortfalls were in the areas of ammonia and nitrogen dioxide and in part of addressing the ammonia concern we looked at the, in setting up the original test matrix for the benchmark testing, we used the initial concepts that we had promoted for the test challenges and the test breakthroughs which were more restrictive or more intense than what we currently have specified. There may be some better performance in with the commercially available products, but we

haven't re-evaluated them at the existing breakthrough concentrations. With the nitrogen dioxide, we were originally sampling for NO and NO2 as is done with the gas mask standard, but we consulted with toxicologists within NIOSH to try and make a determination whether or not the amount of NO that would come through the filter media would present a hazard to the wearer then we were able to make a determination that the amount of NO that would come through the filter during the timeframe that the device would be worn would not be presenting a respirable hazard so we were only sampling for NO2 in that test and that may make a difference in the ultimate results. And again, this information, we do not have the charts for the April meeting up on the website yet. We'll probably have them up at the same time that we get the charts up for today's presentations on the site and the benchmark data will be available through the website.

To move to another topic in brief, we discussed the chemical warfare agent testing requirements at the April meeting for the air-purifying escape respirator. Those requirements have not changed. These are consistent with what was previously presented as well as what's currently being done for the gas mask standard. And likewise this is still a requirement for the sulfur mustard test. And with that, I'll

open up if there are any questions specific to the gas-life requirements for the chemical warfare agent requirements.

WILLIAM NEWCOMB: Bill Newcomb, North Safety Products, is it the intention that these escape respirators could be approved for specifics at a different time than general, for instance, a 15-minute general, a 30-minute specific or vice versa?

JONATHAN SZALAJDA: I think . . . I'm not sure I understand your question. All the general requirements have to be met for the, that the manufacturer specific either 15, 30, or whatever identified rating period and that's what will test to. If you wanted to provide an enhanced capacity for the general respirator, we would expect you to submit . . . if you pick ammonia, you want to provide enhanced ammonia protection that we would test at those specified concentrations for the manufacturers, the applicants identified duration.

WILLIAM NEWCOMB: The question really . . . if you look at the concentrations the contaminants, if you had a 30-minute general, you would probably have a 15-minute specific on each of the specifics.

JONATHAN SZALAJDA: Okay now I think I understand your question now. We would probably have to evaluate that in terms of the actual requirement if you wanted to specify that you wanted to a joint approval as a general and a specific

application and then we would need to do the gas-life testing for the specific requirement.

WILLIAM NEWCOMB: I just think it would be confusing to the users.

JONATHAN SZALAJDA: Okay, that's a good point.

UNKNOWN: If I understand your question, you're talking about the duration of use versus the general category and the specific category so you may want to increase a specific category but you're saying would that change the timeframe if you had enough capability in the cartridge to say 30 minutes for a specific application and 15 minutes for a general. I also think it would be very confusing to have different timeframes on the cartridge and we will have a discussion about it and invite your comments for the docket, but it does seem like as though each application should be for a standardized timeframe. Users are not going to be standing around thinking how long they have protection for one agent versus the next one. They won't know it's there, but we would like your comments for the docket and we will debate that in house. Thanks.

MIKE KAY: Good morning. Mike Kay, Ocenco Incorporated. 42CFR allows for multiple durations below 15 minutes above 60 minutes. Why break these down into 15-minute increments? What's the rationale for that?

JONATHAN SZALAJDA: Part of our evaluation, we looked at that comment earlier. We really didn't see that for this type of device not really knowing where the escape respirator could be used for a larger building, a multi-story building in a large complex in terms of the person escaping from a potential event having a specific time requirement to get from one spot to another. We didn't really see it being advantageous to have a 3-, 5-, 8-minute interval for the (inaudible) capacity of the respirator and given the potential . . . one of the potential applications for use and not knowing exactly where the systems were going to be or going to be used or be placed that having that extra capacity we felt was important.

MIKE KAY: Well if it's a CBRN event or a non-CBRN event, the user doesn't know that they would purchase an apparatus of any duration. Again, why would a CBRN event require a 15-minute escape when a non-CBRN event may . . . you could have a 10-minute, 5-minute, you could have a greater than 60-minute respirator. You seem to draw a distinction between a CBRN and a non-CBRN event.

JONATHAN SZALAJDA: These respirators are designed in response to an event of terrorism. Now the intent is to provide protection for the workers in a terrorism event where a CBRN which could be a tech/bio/rad/nuke type of device could be used. I think if you were looking at taking the device and

having it approved for another application, an industrial-type application, our existing NIOSH requirements in place to take those devices for specific hazards and provide protection in relation to where an event has been categorized but we're dealing in developing of the CBRN standard. We're dealing with unknown, uncontrolled, unquantified types of events where we're trying to develop a and provide a balance of capacity in what the respirator can provide.

LARS RONNER: Lars Ronner from Sundstrom Safety, why is not any requirement for carbon monoxide for specific category?

JONATHAN SZALAJDA: Oh thank you, that is a good point. We, um, it didn't, it wasn't captured on the chart. There will be a requirement for carbon monoxide identified. I think it's identified in the concept paper, but that will be an option for the manufacturer to do to submit a piece of equipment that provides carbon monoxide protection. That will be included as part of the specific category.

BODO HEINS: Bodo Heins from Draeger, in your introduction you showed that for the high category it has to be in a self-contained breathing apparatus and for specific and general air-purifying, what's that mean that we cannot get approved and unit oxygen supply for specific?

JONATHAN SZALAJDA: Well for the self-contained unit which we'll be addressing in greater detail this afternoon,

you know you're dealing with a supplied area, some sort of oxygen source type system. There are no gas-life requirements associated with that. There's no filter with those types of systems. What we're looking at in terms of the higher concentrations are dealing and identifying the requirements are dealing with the potential of credible events that we identified as part of the SCBA program as with the initial modeling that we did in conjunction with the Army and identifying the tests that would be required for the system to resist the chemical warfare agent penetration and permeation and provide adequate protection for a person in a high concentration type environment.

WILLIAM NEWCOMB: Bill Newcomb, North Safety Products, when we're talking about carbon monoxide as an option, carbon monoxide is usually associated with a product combustion. Yet the flammability requirements are not optional. Well I don't think that an escape respirator should be made out of a flammable material. I'm wondering if the requirement that's in there for flammability is a little stringent for the application. Not talking about is something that's specifically designed for escape from a fire.

JONATHAN SZALAJDA: Thank you for bringing that point up too with the carbon monoxide requirement there'd also be a requirement if you choose to provide protection for carbon

694 monoxide, there's also a flammability requirement associated
695 with that and for the flammability requirement we are using an
696 existing EN standard. I believe it's EN136 to conduct that
697 test. If there are alternate types of tests that we feel we
698 should consider, we would welcome you know to bring those to
699 our attention.

700 **KAREN NELSON:** Karen Nelson, Safety Matters Agent for the
701 Phoenix Protective Hood, I wanted one question. Should the
702 concept for the CBRN escape respirator standard contain any
703 suggestions regarding weight and dimensions of this escape
704 hood. Also, the 3,500 ppm carbon monoxide requirement, I'm,
705 why did they find concentrations so high in something that
706 could be like a 15-minute escape respirator. It takes, I mean
707 that's, it just seems high to me. I've been in a lot of test
708 chambers. It took us a long time to get it up to 1,200 ppm in
709 a small room contained when we were monitoring it so I can't
710 imagine if you were leaving an area where there was a carbon
711 monoxide, a fire say that you would encounter concentrations
712 that high.

713 **JONATHAN SZALAJDA:** Okay, thank you. I guess like with
714 all the other requirements, we try to base the carbon monoxide
715 challenge and the breakthroughs based on either a multiple of
716 the ideal H (phonetically) or the permissible exposure level
717 for the breakthrough or the Industrial Hygiene Association's

718 Emergency Response Planning Guidelines and we've tried to use
719 those numbers consistently throughout the identification of
720 the requirements for the testing and if we feel there are
721 other values that are appropriate, we welcome your comments on
722 that as well. I missed your first question.

723 **KAREN NELSON:** Regarding suggestions regarding size and
724 dimension. I'm assuming that an escape respirator even
725 though, of course you want CBRN capabilities that this would
726 be something that we can use in a much more likely event that
727 any civilian anywhere in the country would encounter a fire,
728 an ammonia spill, or industrial accident.

729 **JONATHAN SZALAJDA:** Oh, okay I guess just for the docket
730 in case anybody missed it. The comment is related to the size
731 and weight of the units and it has been one of the considera-
732 tions that we've been in considering or one of the topics that
733 we've been considering as part of the evaluation of the stan-
734 dard and you know while we feel we're getting closer to having
735 the goal, we haven't fully sat down and discussed size and
736 weight considerations and we'll make a determination between
737 now and the next release of the concept paper with that
738 requirement.

739 **WILLIAM NEWCOMB:** Bill Newcomb again, I was looking at
740 the June 15th draft where it indicates all specific and general
741 hoods would be subjected to the flammability test whereas the

previous draft limited to those with carbon monoxide. So I'm a little confused with your answer to me.

JONATHAN SZALAJDA: Okay, the intent is if you have the carbon monoxide requirement, then we would do the flammability test for the air-purifying respirator.

WILLIAM NEWCOMB: Thank you. One of the, there is an EN standard for hoods, flammability as well that I wanted to point out. I'd also like to address the last commenter that the weight and size are market driven. If the product fits the panel that NIOSH is requiring it to fit, then it should let the market drive things like weight. Those are design constraints and not performance requirements. Thank you.

JONATHAN SZALAJDA: Okay Rich?

RICHARD METZLER: Rich Metzler, NIOSH, I do want to respond to the size issue. Size is more important and some of it does need to be in the form of the standard and you did mention testing or passing the fit test. In our benchmark testing, we found that some of the respirators that we tested and we tested only three of what we thought were the best among those on the market from three reputable companies and what we found out was size does matter. Some of the neck dams do choke individuals. Some of the size of the hoods do not allow for the internal nose cup to properly be seated on a face. Size matters and it will end up in our standard.

JAY PARKER: Jay Parker with the Bullard Company just to amplify what Bill was saying. I also think we should use the EN standard for hoods for flammability which I did mention back in the April meeting. It's EN 270. Also on the service life testing, you know that can be affected by breathing back through the filter or cartridge. Is there a requirement to have inhalation and exhalation valves on these units because some of them may have integral type?

JONATHAN SZALAJDA: Yeah, there's a breathing resistance requirement in the concept paper for both inhalation and exhalation.

JAY PARKER: But that doesn't mean . . .

JONATHAN SZALAJDA: That doesn't require a valve, right

JAY PARKER: So there could be a unit that doesn't have exhalation or inhalation valve?

JONATHAN SZALAJDA: Right. Having a valve isn't required.

JAY PARKER: Thank you.

LARS RONNER: Lars Ronner, Sundstrom Safety, again. Talking about the flammability tests, the European standard 136 contains two flammability tests. One test with a single burner with at 800 °C; six-burner test at 950 °C. The only reason for the six-burner test is that the fact the full-face mask are used together with an SCBA breathing apparatus.

Could you explain the reason to have a six-burner at 800 °C which do not exist in the European standards?

JONATHAN SZALAJDA: Yeah, I guess the one thing that I don't know if it came out in the concept paper, we were looking at doing a single-burner test not a six-burner.

LARS RONNER: You're talking about a single burner?

JONATHAN SZALAJDA: Yes.

LARS RONNER: Thanks.

JONATHAN SZALAJDA: I'm glad I got the ball rolling this morning.

GÖRAN BERNDTSSON: Göran Berndtsson from SEA, (inaudible) sizes, couldn't sizes be dealt with through the test panel so it doesn't have to be sizes saying it has to be this size or this size? It is spread over a test panel which means you take away the size restrictions.

LES BOORD: If I could, I think the issue on sizing and so forth perhaps gets into our next discussion. So maybe we could sort of defer that a little bit.

UNKNOWN SPEAKER: I want to make a comment on the inhalation and exhalation valve. While the concept paper itself doesn't specify the need for either of the two valves, it is very much performance driven which will become obvious when we start talking about the breathing gas control. Okay,

I mean it is, the factors are breathing gas control and then obviously resistance.

BODO HEINS: Bodo Heins from Draeger, when I read the new draft and came to the part 2, I got the impression that the hood connector for the respirators only required for the height category. Is it right or I guess a hood required for the whole escape?

JONATHAN SZALAJDA: Yeah, there's a hood required for each class of respirator, but the air-purifying is self contained.

LES BOORD: The next area that we want to talk about is the LRPL, laboratory respiratory protection level, requirement and Mike Bergman is going to present to you some of the details of the work that has been done in this area since our last meeting in April, but before we get into those details, I'd like to just go over a few things relative to the requirement. In my estimation and I think I probably mentioned this at the April meeting. I think that the LRPL is probably the most difficult part of the escape respirator standard and the reason is that we're talking about defining and applying anthropometrics data from anthropometrics that really has not been brought together in a requirement criteria previously. So we're looking about identifying the anthropometrics that are critical and of important to ensuring that you have a hood

that is properly fits, properly fits the test subject. So we're talking about the parameters, the anthropometric parameters of certainly head size, neck size, circumference of the neck, but in addition we find a lot of variation in the escape respirators. Some of them have inner masks, so the inner mask needs to be considered which means you need to somehow factor in the face length and face width which we're all familiar with from our previous work with the Los Alamos panel and full facepiece respirator fit testing, but the difficulty is that on a hood, you have all these things at one time. You can have an inner mask, so face length/face width are important, but you have a hood so that the neck circumference is important, but by the same token, the hood needs to go over the head. So you have this inner play of all these different variables and dimensions that come into the equation here for trying to determine how we can properly evaluate hoods and sizes of hoods. So I think it's very complex. Some of the information that you're going to see today will sort of identify to you the logic and the thought process that we've applied to come to the concept that's identified in the June 15th addition of the panel. One of the key things that we found in our testing in our breathing gas testing, the two kind of merge here, okay is as Rich mentioned, we found a lot of human interface issues, let's say, associated with using

hood-type escape respirators and those issues those human interface issues are indeed and can be and appear to be size dependent. So we have the aspects of tightness on the neck, fitting over the head, fitting a nose cup to the facepiece, and how that's done effectively. Our directions and our concepts are in the June 15th concept paper where we identify a test panel. The test panel does I think for the first time actually try to take, it does take a step to identify criteria for small, medium, and large and also a tool or mechanism for relating the parameters (face length, face width to neck circumference) and how we are proposing to approach that and evaluating hoods. So with that, I'd like Mike to come to the microphone and Mike's going to walk through some of the analysis that he's done that's been used to construct the concept the way it's identified in the June 15th paper.

MIKE BERGMAN: Thank you and I'd like to start out by thanking our partners at SBCCOM for their help and their consultation on this concept and also like to thank the panel members here and others in NIOSH who have helped with this concept.

The purpose of the LRPL is to establish a bench-mark for performance in the laboratory for protection. It's not intended as an indication of protection for an actual escape scenario. The challenge we're up against here is that the

884 data on actually fitting hoods and response to anthropometric
885 parameters is limited and again we're trying to bring together
886 all of these anthropometric parameters (head circumference,
887 neck circumference, face length and width). We still require
888 a review of the data on the distribution of population in
889 response with these parameters. The (inaudible) the challenge
890 aerosol criteria remains the same. It's a 20 to 40 milligram
891 per cubic meter corn oil aerosol challenge with a .4 to
892 .6 micrometer mesh median aerodynamic diameter. We believe
893 that the option for multiple hood sizes is important for the
894 user to select the best fitting hood and we've seen that the
895 problems with the human interface if the neck seal is too
896 tight, it's uncomfortable. Also the inability to fit the head
897 through the neck seal and we want to ensure that if the unit
898 has an inner nose cup that it fits properly and also if
899 there's an interior head harness, it's important that it fits
900 correctly to ensure that there's a proper fitting of a nose
901 cup or interface cup seal. And the one-size-fits-all option
902 is also available.

903 The anthropometric parameters that are considered in this
904 concept are the neck circumference, head circumference, face
905 length and as an addition now the face width. There are two
906 LRPL values: the breathing zone LRPL which will remain at
907 2,000 and now the addition of the under-the-hood LRPL which is

simple location under the hood but outside of the breathing zone and I'll get to the rationale for that. We believe that the 2,000 LRPL and the breathing zone is consistent with the current hood technology and I have some data from SBCCOM that will show that it's possible.

What you see here is a chart of six hoods labeled A through F. This is LRPL testing from SBCCOM. What's important here is the past percent at 2,000 which is a cell in the first row. That indicates the percentage of trials for each hood that is at least 2,000. It could be 2,000 or greater. What you see here from these 6 hoods there is only 1 that had a past percent of 2,000 that is greater than 95% although there are 4 hoods that are in the low 80s and approaching 95% so we see that it is possible.

The rationale for the under-the-hood LRPL is we want to protect users from an impairment of the vision due to exposure. It is based on a percutaneous ECT50, an effective dose for GB and with that effective dose it is possible to have a slight reduction in vision, eye injury, and the pupils reacting weakly to light.

Further discussion on that, it is based on the percutaneous limits for GB. The LCT50 of 10,000 which is the median lethal dosage and the ECT50 of 1,200 CT which where a user could experience mild visual effects and so we come up with a

15 by dividing the outside CT of 10,000 which is the challenge CT by 1,200 CT and we arrive at approximately 15. We multiply that by a safety factor and arrive at 150. The rationale for the size ranges come from a published study in the Department of Defense Military Handbook. The author is Gordon and it is a 1988 Anthropometric Survey of U.S. Army Personnel. The ranges from that set of data covered the 5^{th} percentile through the 95^{th} percentiles for both men and women. That is for head circumference and neck circumference. For size in the face length and width, that's adopted from the Los Alamos panel which is also the criteria that we have for the CBRN, SCBA, and air-purifying standards that are currently passed.

This is from the Gordon study of military personnel and what I have here is a chart with the 5^{th}, 50^{th}, and 95^{th} percentiles for men and women with their neck circumference and head circumference. This is a graph of the percentiles of neck circumference and what we see here is an overlap of the ranges for the medium size hood of neck circumference range for the women and the men. For the head circumference, we are currently only looking at the large head size which is from the 50^{th} through the 95^{th} percentile of men which also covers the top of the population for the women. This is the subject matrix that we have arrived at the columns, small, medium, and large. If, for example, it's a three-size model, the small

size would have to meet all the criteria for the small column, the medium size for the medium column, and the large for the large column. If it's a one-size-fits-all model, it would have to meet separately the criteria for the small and the medium and the large. For selecting the panel, it's possible that, for example, cell A for the small that is face length and face width, if you select subjects for that cell and those subjects also meet the criteria for the neck circumference for the small cell C, you can use those subjects simultaneously tested for the criteria of that cell. And again, for the head circumference, currently we're not looking at the criteria for the small and the medium sizes. There's a change in this slide from what's printed in the handout of the concept and that is in cell H, the large circumference, the change is now 568 millimeters. It was 569 and the reason for changing that is to include from the 50^{th} percentile man head circumference at 568.

Here's an example of the requirements for simultaneously including subjects. If it's a large hood, for example, and there are no overlapping parameters for those subjects, you would have a total for the large size 31 subjects. That's 11 subjects from the face length and width cell, 10 from the head circumference cell, and another 10 from the neck circumference cell. If you select your 11 subjects for the

face length and width cell and if 10 of those subjects also meet their requirements for head circumference, they can be tested simultaneously with those same subjects, but if they do not meet the requirements for cell I for neck circumference, you would have to recruit 10 more subjects for that cell.

And we now have a slide here. It's a chart of the minimum and maximum subject requirements, subjects required for testing. If it's a, for example, three-size unit (small, medium, or large), then you would have to find subjects for those cells. If it's a one-size-fits-all unit, then you'd have a minimum and maximum subject number as well. That's all and we will welcome your comments and questions.

WILLIAM NEWCOMB: Bill Newcomb, North Safety, how does NIOSH intend to address the subjective things like the fact that the neck seal is choking someone?

LES BOORD: Good question, what we intend to do is introduce a practical performance requirement that will be part of the evaluation of the respirators and the issues that we'll talk about a little bit later that became significantly important in our testing will be used to evaluate and establish those practical performance evaluations.

WILLIAM NEWCOMB: Thank you.

GÖRAN BERNDTSSON: Göran Berndtsson from SEA, did I understand you right? We're talking about three sizes only? Is that what we're talking about here?

LES BOORD: We have the ability with the anthropometric panel that we've identified. We segmented it into three sizes, correct.

GÖRAN BERNDTSSON: We, as you know, we're working a lot on this particular part in the eye system*, but then, of course, you have the same problem in the United States as we have in the world. We will have a big mixture of Asian and other types of ethnic groups and they could have big heads and small noses so big heads and small faces and this is a . . . I would assume that you would like to have three sizes on the hood and the neck. That where you have three sizes on the inner masks so you can go up to six and nine sizes.

LES BOORD: Well there are three . . . You have that capability within the panel that we've identified because you do have the face width and face length considered but then you also have the uniquely or you have the neck diameter as well as the head circumference to consider into the equation as well. The problem and the problem that we see is that we're talking in some cases it's like apples and oranges. You don't know the relationship between this and this so our approach is that you do see and you do expect that there will be overlap

between those, but we don't expect it 100% of the time. And in those cases, then you need . . . according to the concept that we've identified, you need to uniquely look at those parameters that don't overlap.

GÖRAN BERNDTSSON: Just for your information, we got hold of a publication that was done by the U.K. government who has actually a very comprehensive face sizes, neck sizes, head sizes on the very broad population taken out from the number of surveys around the world. May be we should have a look at that.

LES BOORD: Yes, we would certainly be interested in looking at that anthropometric data. Thank you.

RICH STEIN: Rich Stein from QPS, I have a question about the protection factor of 2,000. For example, you showed that six hoods had been tested and that one barely made the 95^{th} percentile level. Has anyone done any testing on repeat of those hoods because there was wide variation and person-to-person protection factor testing? One of the things that I'm concerned about at 2,000 is that's about as high a number as I've ever seen on any product anywhere. The military which has five sizes and a very limited sized population has a 1,667 and one of the things from a practical matter is that you could pass the test today. Let's say you had 20 subjects and you tested that same 20 subjects 6 months later on a QA audit

and one of them fails which is not unusual because they can either pass or fail it at 2,000 on any given day and now you've got units in the field and what do you do about that?

LES BOORD: So, well . . .

RICH STEIN: Let me just continue, Les, a second. One of the things that you showed here is why you've had a PF requirement of 150 in the hood and you showed you wanted a certain margin of safety what at 10,000 CT, etc. Have you got a slide equivalent to that showing where you found and what was the rationale for the 2,000?

LES BOORD: First of all the 2,000 is the same level of protection that we've identified or the same level of performance that we've identified in the full facepiece gas mask analysis and that analysis does have a rationale that produces the 2,000 number, okay, and it's based on a number of different variables and I can get that information for you, but secondly, I wanted to comment on the data that was illustrated relative to the testing that's been performed and the level of protection the 2,000 performance level for the ABC whatever it was, 6 different respirators. The thing that you need to keep in mind there is that those respirators were not necessarily designed, at least not to my knowledge, designed against a specific-size criteria. What we've done in our concept is defined requirements for what those size criteria would be.

The fact that that one indicated a greater than 2,000, 95.7, I think, greater than 2,000 was a design that was covering the range, okay. I think when you focus on size, if your seal is indeed achieved by the neck dam. I think when you focus on size, the design capability is there to achieve the numbers.

MARY TOWNSEND: I'm Mary Townsend. I'm adjunct at the University of Pittsburgh and I have a comment related to this man's comment about the general population and that is did you inquire whether the National Center for Health Statistics in Haines, the National Health and Nutrition Examination Survey that was conducted across the entire U.S. population, sampled heavily Caucasian, Hispanic, African-American, did they do this kind? They measured lots of things. I know lung function I'm especially familiar with, but did they measure head size and things like that. It was just in the late, early nineties I think.

LES BOORD: To answer your question, I cannot answer it specifically relative to the cite of reference that you made, but I can answer in general that we did research potential sources for the anthropometric data because we were very keen on trying to find what the variables were and really what we wanted to try to do was connect them. We wanted to try to find out perhaps what those relationships were and we have been unable to do that to our satisfaction at this point.

MARY TOWNSEND: I'll check and see whether any . . .

LES BOORD: That would be great.

MARY TOWNSEND: I forgot about that too.

LES BOORD: And anybody, we would certainly welcome any anthropometric information that is available to make that known to us. Any other questions?

So you can see my opening remarks. They say that the LRPL is I think one of the most difficult and challenging aspects of the escape respirator standard because, just because of these variables and the lack of scientific information, technical information, connecting and establishing those relationships. We have done, as you've seen, quite a bit of work to analyze existing data and try to form it into an approach to define a requirement. We are obviously breaking new ground in defining the panel and in defining the way the panel will be applied to testing a performance requirement.

GÖRAN BERNDTSSON: Göran Berndtsson from SEA again, last question, are you going to adjust the sizes in the heads of smart man to accommodate these different neck sizes and so forth.

LES BOORD: Good question, but the smart man, you need to keep in mind that the smart man testing requirement is focused on a different performance. When we do the smart man testing,

we're not looking at the seal of the respirator or the inner face between the respirator and the mannequin. We're looking at the performance of the respirator and the functioning of the materials in that chemical warfare environment.

GÖRAN BERNDTSSON: That's true, but it's relied on the inner mask sealing on the face. If you have a bit of leakage on the inner mask on the smart man, you will create a negative pressure inside the hood and if you don't have a good tight seal around your neck, you will have leakage into the hood then. That's not because it doesn't work too well, yes, but it always doesn't work on the smart man.

LES BOORD: And that is as well a good comment, but the smart . . . and to perhaps take it another step, I think the smart man is available in multiple sizes. There are small, medium, and large smart man for that type of situation. That I need to defer to our SBCCOM partners including the net. Yes.

UNKNOWN ZONG: This is (inaudible) Zong from NIOSH also. I just want to let everyone here know that our project is going well. We have measure almost like 4,000 worker rates so far by (inaudible) height and weight and lately we also had another dimension to measure the neck size. Also as soon as I let them know that, we need to consider that dimension, but we do have the head circumferences and the other things that I

mentioned so our data correction is expected to finish by the end of the month and then we'll look at the data, analyze the data so by that time if we see, yes, a significant differences we'll revise the panel and we'll incorporate that into the new standard.

LES BOORD: Thank you Dr. (inaudible). I forgot to mention that we have been working with Dr. Z in establishing the parameters that we talked about today. Just one other thing I would like to, two things that I would like to cover. One I'd like to backtrack a little bit, back to the comment of size and practical performance. I think you can see the direction that we're going. Okay, we do see that the sizing of the respirator and the human interface is an important criteria and we need to be able to address that, but secondly I would like to talk about the size and weight in terms of perhaps the package and the envelope and that's where I think that . . . So I think that we have two different topics on size and weight and I think the size and weight can't fall into the design requirement as opposed to a performance requirement, okay, of the package and I think in my opening remarks as I mentioned, the design requirements that we have identified thus far are kind of minor or kind of minimal not minor but minimal and I think that's probably good because that indicates we're achieving the performance that we want or

the operation we want through performance requirements. With that, we're going to . . . we're running a little bit behind, but we're going to take a 15-minute break.

Okay, if we're ready to resume . . . Continuing on with the requirements and the areas of the requirements that we've looked at since the April meeting gets us to the topic of breathing gas control and to start this discussion what I'd like to say is that the definition that's in the June 15th concept paper is actually a little confusing because it's the blend of two previous, two previous contests and it wasn't quite, it didn't come out quite the way we wanted it to in the June 15th edition. So what I want to do at the beginning here is identify what that requirement is and then I want to talk to you a little bit about how we get to the point to identify that requirement and then we'll take some questions.

But basically the concept for breathing gas control and we're talking about carbon dioxide and oxygen in the breathing zone for the respirator. The concept requirement is that for carbon dioxide to maximum average inhaled concentration of 2½%. The 2½% is actually a 42 CFR, Part 84 requirement identified for self-contained breathing apparatus so that is the maximum and actually it's a sliding scale. If you're familiar with 42 CFR, it depends on the duration of the device. I think for less than 30 minutes it's 2½%. For 30 minutes to

60 minutes, I believe it's 2% and then it continuously changes with the duration of the unit. That is the requirement that we are invoking for or attempting to use for CO2 so the maximum is 2½%. The oxygen the minimum inhaled oxygen concentration is 19½% and again that's identified in 42 CFR, Part 84. The way we intend on establishing conformance with that requirement is through human subject testing. Okay, so to establish and evaluate CO2 and O2 breathing gas performance, we will test it using human subjects. The criteria will be is that we will have two different weight categories that we look at: first one greater than or equal to 80 kilograms and then less than or equal to 60 kilograms. And the test subjects will wear the respirator for the duration, rate of duration of the unit and we'll have three levels of activities: standing, walking at 2.5 miles per hour on a treadmill, and walking at 3.5 miles per hour on the treadmill. That's the requirement the way it will be editorially revised in the next edition of the concept.

Now, how did we get there? In the last meeting in April, we reported on testing that we've done relative to evaluating breathing gas control. The bench-mark testing that we discussed I think to some degree at that meeting was the bench-mark testing involving a metabolic simulator and this testing involved the escape respirators, various escape respirators at

six different work rates as illustrated in the overhead there. We had a low work rate of established at approximately .5 liters per minute oxygen consumption and then varying at half liter increments, oxygen consumption up to the high work rate of 3 liters per minute oxygen consumption. Again, the bench-mark testing was performed on commercially available escape sets. We performed multiple metabolic simulator tests using each respirator and the results of those tests were that we observed carbon dioxide levels that exceeded 4%. That was common. In fact we had levels I think that went as high as perhaps 8%. On the oxygen concentrations, we likewise measured levels of oxygen that were considerably less than 19.5%. I think in some instances it even went down to under 10%. So when we looked at the metabolic simulator data, we obviously had some concerns relative to what the requirements should be and what was the best way to achieve and establish conformance with those requirements. So what we did was we embarked on the second part of that bench-mark testing which is what we called human subject tests. And to do that we performed human subject testing using seven different test subjects: four men, three women and we had the tests performed at the work rates, three work rates: standing, treadmill 2.5, and treadmill at 3.5 miles per hour. The results of this testing were that we saw carbon dioxide levels as high as 5.5% and

that would be a maximum average inhaled carbon dioxide concentration and we saw oxygen concentrations that were down as low as 14.8% minimum average inhaled concentration. Now both of these values obviously exceed what the requirements that we have identified from 42 CFR and that we used for other testing of other respirators so both exceed those requirements. But the question is: what's the physiological consequences?

The next chart that you see is going to be overpowering for you, okay, but there's help. The chart that's on the bulletin board is what this is replicated from and the key values there, basically, this, to break this down a little bit, this shows test results from three different respirators using seven different test subjects at the three levels of work that we discussed. The areas highlighted in the blue are the areas where we experienced and had actual measurements that were reflective of the numbers that I mentioned: 5.5% CO2 and 14% oxygen. So I don't want to go into the chart during this discussion because I can't read it. So I'm sure you can't read it, but it is on the poster illustrated in the corner of the room and I think during the breaks Mike will be available and will be available to answer any questions that you may have relative to that.

Other observations that we had during the bench-mark testing and as I think was already mentioned, we did observe a

number of human factors, human subject interface issues and these were, ranged throughout the comments that are identified here. We had quite a few comments relative to the degree of tightness of the neck seal. Hooded respirators primarily achieved a seal using a elastic neck membrane. Types of comments we had: neck constriction, sensation of strangulation. And in some instances, we had people who just couldn't complete testing because of that. Other instances we had: people that had negative reactions to wearing and breathing through mouth bits and mouth pieces and interfaces between the breathing zone and the mouth and some individuals expelled mouth bits and so forth. In still other test subjects had difficulties donning the respirator, actually being able to physically open the neck seal, the neck dam, and stretch it over the head. So these are the types of requirements that we observed during the testing illustrated on the poster and these will be factored into practical performance evaluations for the escape respirators. So at that point, basically, we've dropped back to the 42 CFR criteria for carbon dioxide as I stated at the beginning. We will set the CO2 requirements at 2.5% maximum and with a sliding scale so if it's a long duration unit, the CO2 will go and follow the tabulation that's identified 42 CFR and the oxygen concentrations at

19.5%. At this point, I think we can open it up for any discussions.

GÖRAN BERNDTSSON: Göran Berndtsson from SEA, I don't know if I misunderstood or was asleep here, but you said you're going to test over 80 kilo and under 60 and you classified that as two classes. What do you for the people between 60 and 80?

LES BOORD: What we've observed in the testing? We actually have, the situation that you have relative to measuring the CO2 and the O2 is the ventilation rate. Okay, and where you have a particular problem is where you have a low ventilation rate so you have a low breathing exchange and the relationship that has with the dead volume of the mask, okay, and typically that low ventilation rate, you're going to experience with a light weight individual, okay, in the standing conditions. So that's why we wanted to capture performance at that level. You have the other end of the extreme where you have a high ventilation rate where you have a large individual who's breathing heavy, okay, who perhaps has a different phenomenon that's occurring relative to CO2 retention in the respirator and displacement of the oxygen. So those, the testing that we have performed actually indicates that those two extremes are the most interesting areas.

GÖRAN BERNDTSSON: But, wouldn't that be three classes then? What I don't understand is over 80, below 60, and then between 60 and 80.

LES BOORD: Yeah, but you only, I think when you capture the performance at those two, at the two ends, then I think the in-between is going to be in line with those worse-case scenarios.

GÖRAN BERNDTSSON: Okay. The other question is that you showed a slide with oxygen uptake and there was five, six, seven classes. Can you put that slide up again please?

LES BOORD: Now those were for the metabolic simulator.

GÖRAN BERNDTSSON: Ah.

LES BOORD: Those were tests that were performed on a machine, machine tests.

GÖRAN BERNDTSSON: Are you going to test those . . .

LES BOORD: No. No. This was part of the, this was part of the bench-mark testing that we did to, in the development process and the process of developing our requirement the first thing we did was look at machine testing using a metabolic simulator operating at these ventilation rates. Now the reality is that if you look at the breathing rates that we've or the work levels that we've established for the requirements standing on a light individual less than 60 kilograms, you're probably going to be in the .5 per minute consumption rate.

GÖRAN BERNDTSSON: Oh, maybe, but the, what we are doing, what we're doing in ISO, you are measuring this, you put body weight and we're using an ISO standard for, which is based on height of the person and starting at 1.7 as the standard ISO person male and 1.6 as an ISO woman I think and from there you can then scale it up and down because the metabolic rate is related back to your body, square meter surface area of your body, and then you can that way very easily don the different liters of oxygen required for doing this workload. So just an advice that may be don't using kilos may be using sizes and refer it back to ISO standard, it would be much easier as times moves on to have the same kind of starting references.

LES BOORD: Thank you.

JAY PARKER: Jay Parker with the Bullard Company, Les I didn't hear a reason why you removed the metabolic simulator testing. Wasn't that in the last draft?

LES BOORD: Yeah.

JAY PARKER: I guess it has been removed?

LES BOORD: Yeah, it has. Actually we're relying on the human subject testing and the reason that we've decided to go that way is when we went through our bench-mark testing, the first phase was machine testing. Second test, second phase was the human subject testing and what we've found was that the low ventilation rates, we really didn't get 100% tracking.

Okay, in other words, human subject testing the values that we were obtaining for CO2 and O2 were not identical with the types of results we were getting on the simulator. So rather than trying to identify a machine requirement, okay, that would be equivalent to the human requirement, our decision was to use the human subject testing. That's the proof. The machine test would be an approximation.

MICHAEL KAY: Mike Kay from Ocenco, getting back to the ABMS and the human subject testing, at the public meeting regarding the SCSR rewrite of 42 CFR, the concept in that was to go to ABMS testing to get away from the inherent problems with human subject testing. Now the pendulum seems to have swung back the other way.

LES BOORD: I think that, first of all, I can't speak on behalf of the SCSR, but I think that with the bench-mark testing that we've observed, that there are appropriate tests at this time that can be done using the simulator and the tests that perhaps aren't quite there yet. We think that there would be additional work required to actually tune and to develop a protocol that would be appropriate to use a machine test for the certification requirement, for this certification requirement.

RICH STEIN: Rich Stein, QPS, Les, let me see if I understand correctly. If we make a submittal, is the first thing

you're going to do is run a bench test to prequalify or you're just going to jump in to human test on this or how are you going to run this?

LES BOORD: Yes, actually there is no machine test, no bench test relative to CO2/O2 that the criteria will be established using the human subject testing.

RICH STEIN: Okay, so you're just going to run into that and put it on a human subject on a unit that comes in?

LES BOORD: Yes and the test sequence will be identified actually in one of the next discussions what the overall test sequence is.

Any questions? Okay with that we'll go to the next topic.

FRANK PALYA: Good morning, my name is Frank Palya from NIOSH and I'm going to discuss the test methods and required quantity of the escape units that are required to complete the NIOSH certification of the CBRN air-purifying escape respirator. This chart is the summarization of the test categories, the quantity of escape units that are required for each of the test categories, and the test sequence within each test category. Each column is a test category and it identifies the test sequence: the top being the very first test and the bottom being the very last test within each of them. As you can see, there's the resistance in breathing gas and human

factors and service life. There's no sequence to the ones right here, but basically it just starts at the top within each column and then goes down.

I want to discuss each one of those columns. First being the resistance and breathing gas, from that we'll initially, a total quantity of 12 is required and 3 will be used for inhalation resistance and 3 will be used for exhalation resistance and now 12 will be used for the breathing gas concentrations. If you take note, the same respirators will be used for all the tests. In other words, there's three respirators that were used in the inhalation/exhalation will also be used in the breathing concentration. The reason for that was we're trying to conserve on the number of respirators required from the manufacturers. Again, as Les previously discussed, there will be 12 required for the breathing testing. Each one of these units which will be the human subject testing will only be used once by the human subjects for personal hygiene reasons.

For the human factors, the total quantity of 3 to 9 is required for this series of testing. This is size dependent. If there's one size, then three are required. If there are three sizes, then nine will be required for this particular series of tests. First it'll be the field of view test conducted. We'll use the STP CBRN 0312 and that is the same

standard test procedure that is used for the gas mask air-purifying gas mask.

The next step would be the fogging and 3 to 9 will be used in that particular test. This is a new STP 0321. It varies from the gas mask fogging test in that you'll enter, you'll don the respirator in ambient conditions and then enter into a hot environment, a hot environment being 90 degrees Fahrenheit at 60% relative humidity and then go through a series of visual acuity tests and then another set of respirators, you'll don in ambient conditions and then you'll enter into cold condition of minus 13 degrees Fahrenheit.

And then the final test in this series is the flame and heat resistance. No human subjects required for this particular one, but it will be in the equipment in accordance with 136-1998.

The next series I want to discuss is the gas service life. Thirty respirators are required for this particular test. Three respirators will be tested against each of the gases, each of the ten gases; however, before they'll be tested for the gas service life, they'll be subject to the hot-temperature storage, the low-temperature storage, humidity, transportation vibration testing, and then the drop test. These tests are pretty similar to the gas mask CBRN gas mask requirement; however, take note at the high-temperature

storage. It'll be at a constant temperature for 5 weeks as opposed to the (inaudible) test required under the CBRN gas mask standard. After they go through all these series of durability testing, then they'll be tested for service life at 100 liters per minute at 50% relative humidity in the challenge.

The next is the service gas life rated at 64 liters per minute; 60 respirators are required for this. Again, they'll be subjected to the same durability testing. The durability testing is the same throughout all these tests categories: same hot temperature, low temperature, humidity, transportation drop. Six gases, six respirator units will be tested for gas. Again there are 10 gases. They'll be 3 at 25% relative humidity and 3 at 80% relative humidity for 10 gases at 64 liters per minute.

For the permeation and penetration testing, six respirators are required. However, initially there will be two respirators that will not be subjected to the durability testing. They are considered pre-qualifiers and they'll be subjected to the initial or one will be tested for GB and one will be tested for HD. Again, these are pre-qualifiers. Two of them will not be subjected to the durability testing. Once they pass their pre-qualifications, the four will go through the high temperature, low temperature, humidity, transporta-

tion, and drop and then they'll be tested and challenged with the two against sarin vapor and two against sulfur mustard HD liquid and vapor. This was at the (inaudible) discussed previously.

For the filter particulate efficiency, 20 respirators are required for this test. Again, they'll be subjected to the durability test and the filter efficiency will be tested, challenged, tested in accordance with the outlined in 42 CFR.

And last is the laboratory/respiratory protection level testing. A quantity of 30 to 65 tests or respirators are required for this particular test. Again, when using human subjects, respirator will only be used once for hygiene purposes. The donning procedure is still being developed and the LRPL test is similar to the STP 0352. This 0352 initially was planned to be a generic test to test all of the, to test all the classes of respirators: the SCBA, the air-purifying respirators, the escapes. However, I think that we're going to have to make some modifications to this because of the donning procedures and different probes so, but all in all, it's very similar to the self-contained breathing apparatus standard test procedure that we currently use now to test LRPL test. And at this time, just any questions? Okay, thank you.

UNKNOWN SPEAKER: I have a question here. On that test protocol, may be I'm not up to date, but the test protocol,

the procedures you're doing in the test chambers, you said there was going to be the same with only some small changes because of the donning. What are we doing in the chamber? They do, I suppose to know that. Are we lifting boxes and all the other stuff that was done or is it (inaudible) an escape. Can you fill me in on that?

FRANK PALYA: Well right now when we go ahead through the procedures, we're reviewing the procedures, this 0352 is on the website, but as we're going to go through and develop the test procedures, we're going to have to go ahead and find out exactly where the probe the respirators, may be from the oral nasal region, may be for the under the hood area, the ocular region. So with the test procedures, you're just going to have to be some slight tweeks* to it. I mean to go ahead there and follow one test procedure by step-by-step process would be very difficult so then we're going to have to break away from that again.

GÖRAN BERNDTSSON: What are the subjects performing in the chamber?

LES BOORD: Yeah, Göran, I, questions relative to the exercises they perform in the LRPL test. Those will not be the full set of exercises that are performed under the gas mask, but they will be a subset of those. Okay, so we don't see all of those as being the applicable exercises that'll be

performed on this test. We haven't actually identified exactly which ones are included and which ones omitted, but it'll be from that list of exercises.

GÖRAN BERNDTSSON: Because I would assume that very large proportion would be to run down stairways and that type of thing when you're escaping and that's very very much different than what we're normally doing for the other testing.

PAUL DUNCAN: Paul Duncan, Scott Health & Safety, question, two questions, for the breathing gas test, do you actually have an STP established for that yet or is that one of the existing STPs or is a new one going to be coming out for that yet?

JOHN SZALAJDA: Yeah, the breathing gas is not an existing STP at this point because this is the first time that test will be used.

PAUL DUNCAN: Okay, when do you expect that to be available?

JOHN SZALAJDA: Actually we're in the timeframe. We'll talk about the timeframes and the schedules actually this afternoon. We're looking in the August timeframe to have that completed.

PAUL DUNCAN: Okay. Just getting to a general comment, a sort of respectful request, it seemed like in the latter stages of developing the APR gas mask standard in the last

draft a lot of design requirements showed up that hadn't really been previously discussed. For instance the gasket material requirement got much more specific than it was in the previous drafts and there's a last minute change in the lens abrasion testing. Lens abrasion testing in particular actually required manufacturers provide flat samples. So here in the last minute the last draft that came out all of a sudden the manufacturers had to go about the trouble creating molds to mold representative thickness samples of their lens and hard copy them and etc. There was a frustration in the fact that appeared that that standard that portion of the standard actually been developed in conjunction with one or more manufacturers and that information wasn't generally available to all the manufacturers. So it appeared actually like an unfair advantage to one or more manufacturers that were involved in that. I was asking if you could in reviewing just the general portion of the standard, where do you anticipate major changes in this? This is a good job of reviewing what has changed since the last standard since the last draft was issued but where do you anticipate the major changes occurring between now and the next review period?

JOHN SZALAJDA: Okay, that's a good question. First of all, I'd like to just backtrack a little bit on the two areas that you mentioned. In both of those, the abrasion, the

development of the abrasion concept as well as the development of the specifications for the gasket were both the result of comments that were generated at the last public meeting that we had for the air-purifying gas mask as well as comments that were submitted to the docket. So both of those were revisions to those requirements that were actually implemented to address comments that were submitted, raised at the meetings, and submitted to the docket. So the answer to the second part of your question, what we envision perhaps the impact of the changes as we go forward that is somewhat dependent on the kind of comments and the interactions that we get through these types of discussions and submittals that are made to the docket.

PAUL DUNCAN: My observation wasn't . . . I could be entirely wrong, but that last version of the material standards almost looked like a manufacturer's, a particular manufacturer's material spec. I pulled out our engineering drawing and plunked down the standard and all of a sudden so one manufacturer had it and everybody's going to have to meet it.

JOHN SZALAJDA: Actually the requirement came from the military specifications for the gasket material that's used in the military masks and that was done. I don't want to go down this far, this path too far because it's related to the gas

mask, but that was done because in the earlier editions of the concept paper and actually into the last public meeting, the design requirements for the gasket were very specific. They were specific in that it said it needed to be EPDM. The comments that were generated at that public meeting and in the docket was that there are other materials that can pass the agent requirements that by specifying EPDM we are being too design restrictive and what we should do in lieu of that is identify what the performance requirements that we needed to achieve as well as the physical properties of the material and that's basically what we did and to get to those requirements we looked to the military specifications for the M40 gas mask. So and then to try to anticipate the changes as we go forward, I think . . . The only thing I could say in a definite response okay at this time is that as we are going through these discussions you see that there are things that we've identified that we need to concentrate on. One is the comment that Göran just mentioned relative to the exercises that will be performed during LRPL. We pretty much know what the parameters and we looked at the parameters and how to do that and so forth, but we haven't focused on what the specific requirements will be. So that would be an area I would look to. Also in the area of the . . . as we get into this afternoon's discussion, you'll see some of the discussions and

perhaps some open areas relative to the way that live agent testing is performed. Okay, so those may be types of areas to look at. So I think from listening to the meeting, you can sort of glean where we think we need to do addition work and we will do that work, but then we're always and we remain responsive to input that we get.

GÖRAN BERNDTSSON: Göran Berndtsson from SEA again, one thing you could have done better on the last one was that actually you had a draft and then it went nearly 6 months and then it was finished and there was no communication via your website for 6 months and that I think how all of us who tries to be ready to go and you can do that better in the future. Make sure that you continue with what you started so well. Update every once a month and we will all be ready when you guys are ready.

JOHN SZALAJDA: Yes, thank you and that is a good comment. We are sensitive to that, but unfortunately some of the situations relative to timing and issuing or let's say posting the requirements and the concepts are not . . . there are hurdles that we need to go through and it's really tough to predict what those hurdles, what their timelines will be.

PAUL DUNCAN: Echoing Göran's comments, along the lines of . . . if something as simple like a monthly update, you know those have to . . . totally revised copy of the draft

which is like a monthly update saying hey we here at NIOSH in developing these standards we're looking at these areas. So at least it gives a flag to the manufacturers like okay hey something that I might be doing in my development work. I may need to rethink this or may change my priorities a little bit and be prepared for a change that may be coming out.

JOHN SZALAJDA: Good point.

PAUL DUNCAN: Because it was quite a long time.

JOHN SZALAJDA: That is a good point, thank you.

UNKNOWN SPEAKER: And to wrap up this morning's for the air-purifying part of the standard, we wanted to at least initially identify some of the costs that we envision that are going to be associated with the application of material for our evaluation. Basically and if you're familiar with the CBRN program, you know that we work with our partner and our NIOSH test agent at SBCCOM to do the chemical warfare testing and the LRPL associated testing. That will be no different for this system. We are currently in process at the NPPTL facility in Bruceton of establishing our own internal capabilities for conducting the environmental conditioning for the respirator systems. We hope to have that in place by this fall. What we're doing is again we're working closely with SBCCOM to replicate the systems that they have established at the Edgewood facility for conducting these tests. And again,

as Frank had mentioned in discussion at the tester base, primarily on the Mil standard, the Mil-STD-810 and you know we're working closely with them to ensure that we get replicable results for the challenging of the respirators. Again, it's a long test cycle, you know, and unfortunately with given the types of tests that are available for us to do the testers, we don't see anyway to circumvent that portion of the process that we are looking at around 70-75 days to conduct the testing. And I think everybody can read the number at the bottom.

How that breaks down, you know again we're looking at the testing but excuse me, button sensitive there, we're looking at doing the testing at the two sites. We have the penetration permeation testing which is done by SBCCOM. Again we are considering as part of the application process to do the qualification testing first with two systems to ensure that they pass the chemical warfare agent testing, the penetration-permeation test prior to going to the expense of conducting the environmental challenging the systems. Again, we would end up ultimately testing six systems: the two qualification units and then the four units following environmental conditioning.

With the LRPL, the numbers are off the actually we're looking at 30 to 65 escape respirators which will be dependent

on the design, the individual design from the applicant as well as the (inaudible) if the manufacturer comes in with one size or multitude of size that will determine the actual number of items that are required for the LRPL. Again, we're looking at these tests will be done by SBCCOM using their facilities and their test subjects.

As far as the particulate testing, we intend on doing that at the facility in Pittsburgh. Frank had mentioned the breakdown and the test that will be conducted as part of that application. A couple of things that I wanted to bring to your attention, things that may go away between now and by the time the standards are released. We had considered doing a particulate test following cyclohexane challenge. This was something that we had looked at as part of the development of the gas mask standard to ensure that we weren't getting particulate penetration following exposure to organic vapors and this was a consideration for the gas mask because of concerns that had been raised over intermittent exposures of the filter to contaminants. In looking at the escape respirator as a one-time only use, there may not be a need to conduct that test and we're in the process of evaluating the necessity for that. Everything else I think is fairly straightforward in terms of the sequence of doing the environmental conditioning and then breaking out to either doing particulate testing

of the service life testing or the bench testing for the human factors types of evaluation. We don't have a similar chart for the afternoon session. We go and discuss the self-contained units but I think you can pretty well identify the things that would be included in this part of the self-contained that we would be looking at . . . there wouldn't be a need for doing the gas testing as well as the particulate testing and that's about a $9,000 savings. So with that I think we're pretty much on scheduled. I wanted to at least open up the floor for any comments from the attendees related to the air-purifying respirator.

WILLIAM NEWCOME: Bill Newcomb, North Safety Products, is it the intention of NIOSH that this is a single-use escape device?

UNKNOWN SPEAKER: Yes.

WILLIAM NEWCOME: Then okay, I don't think it's specific in there any place and there is a requirement for maintenance in the proposed draft so I'm kind of confused as to whether this was the intention or is the intention?

UNKNOWN SPEAKER: What I think part of what we're working and I guess this goes back to the gentlemen from Scott's comment as far as refinements to the standards. Part of what we've seen and getting comments back is a need for training and maintenance care and use of these systems and by main-

tenance, I guess as part of what we're doing in a concept paper is we're going, and when we identify in terms of maintenance requirements we're going to define that characteristic in the concept paper, but primarily we're looking at in terms of maintenance is the long-term care of these systems. Whether or not when a user which were to be, purchase one of these systems, put it in a drawer, put it in a filing cabinet, put it in a central location. Which should they do long term with these systems? Should they inspect these at some sort of relative frequency? After 6 months, should they perhaps consult the manufacturer and go back and have the items evaluated to make sure that they are maintaining the . . . meeting the requirements? These are parameters that we're still trying to come to terms with, but I think in terms of what you'll see in the concept papers that will define what we mean by maintenance.

UNKNOWN SPEAKER: Excuse me, relating to the actual test method that we're working toward, if you had . . . How flexible is this and how . . . For example, if you have 10 escape respirators that qualify to be tested and 8 of them are canisters, okay and one of them or two of them are fabric, completely different structure and makeup and everything else, is it up to the manufacturer to submit what a protocol for what they would think fair and accurate, a fair and accurate

test of this filter material would be since it's so different than the other ones. How does that work?

UNKNOWN SPEAKER: If I understand the question correctly, I think you're talking about different respirators that may utilize common components and how those would actually be evaluated through a testing program?

UNKNOWN SPEAKER: Through different, yes, if there's one set that has a canister and the other set that has fabric or something different and the whole construction is quite different that you want, but the filter material, I mean, you get past the leak test and everything else.

UNKNOWN SPEAKER: I think the answer to the question in a general sense is probably the best we can do at this time is that we do have guidelines that we use in both the CBRN programs that are already in place for the SCBA as well as the gas mask to determine how and what materials need to be tested and those guidelines come down to identifying materials that form a pressure boundary or materials of contact can likely contact the agent as well as materials that actually are used to provide the protection if it's a filter. So there are guidelines that we follow for the current programs and I would anticipate that there would be similar guidelines applicable for the escape.

GÖRAN BERNDTSSON: Göran Berndtsson from SEA, in regards to I think it was Nort's (phonetically) question here. When a respirator runs out of shelf life, could it be sent back to the manufacturer for re-fitted, restored and sent out again. It's never been used. The agent just run out of shelf life.

UNKNOWN SPEAKER: I think that those types of issues, the issues and what I think John was alluding to is a lot of those maintenance issues are, when we talk about maintenance, we're looking at what the manufacturer would recommend needs to be done to that unit as it's sitting in the desk drawer or hanging on the wall or being carried around in the car. If there are procedures unit specific that a manufacturer develops for doing measures such as you mentioned, then I think those need to be technically rationalized and justified through the certification program through the certification process. So I don't see that it's necessarily prohibited but I think there needs to be a technical rationale behind it.

GÖRAN BERNDTSSON: Another question, is it going to be a maximum shelf life allowed from other approval process? In other words, if the manufacturer claims 10 years, is that going to be some kind of testing to validate that or is it . . .

UNKNOWN SPEAKER: The testing that we envisioned is basically the environmental conditioning that we expose the

unit to. The actual recommended shelf life is I think a manufacturer specific or driven type of a specification. Otherwise we would need to specify the packaging.

GÖRAN BERNDTSSON: Isn't that a little bit loose? I mean that a manufacturer come in and say that I recommend 20 years. How do we know that the field tests are going to last after 20 years?

UNKNOWN SPEAKER: That's a good point. We are open for any original thinking there.

KAREN NELSON: Would not the test the filter materials, are they not themselves be of fabric or (inaudible) or whatever's inside the filter? Is that not subject to tests that can determine if it looses integrity after a period of time? I mean, just the materials themselves, would that, isn't that . . .

UNKNOWN SPEAKER: First of all address your name into the microphone.

KAREN NELSON: I'm forgetting, Karen Nelson, Safety Matters.

UNKNOWN SPEAKER: Okay, then to answer your question. I think that that, again, that perhaps becomes design specific. Okay, and the way the various materials that are used, the materials of construction are used and how those are packaged,

contained, or sealed from the environment, I think is a design specific type of a situation.

KAREN NELSON: Right, but my, as far as the question, would it not, if you're looking at this, at these materials as you test or as far as the construction of the item, is it not, I mean aren't there engineers who can tell you that like certain grades of rubber will loose integrity after and become brittle after so many years, so you couldn't claim a 20-year shelf life on that and just extrapolate that to the other materials.

UNKNOWN SPEAKER: To answer your question, I think there are engineering guidelines and so forth for the design process to do that type of work.

RICHARD METZLER: Rich Metzler from NIOSH, we have an experience with self-contained self-rescuers in the mining industry where there are substantial reliability problems with regard to the age of the unit and the use underground and the ability to inspect and know when to remove the products from service. While we invite your comments on the shelf-life issue, I can tell you if it comes down to a policy matter, there will be a limited shelf life of a short duration that's reasonable from an engineering perspective, but that age would be at the lower end not the 20-year end that I hear everyone talking about.

GÖRAN BERNDTSSON: Göran Berndtsson from SEA again, this is really important. We really need to settle some kind of guidelines or some policies here because the difference between (inaudible) to the end user is going to be very much dependent on the shelf life and the price charged for this. So we can't leave this. We have to make sure that this doesn't get left open and no open ended (inaudible). We need to have a discussion or a dialogue to solve this unsolved question.

UNKNOWN SPEAKER: Thank you. Just one other thing, I just want to remind everybody as far as we'll have individuals available to discuss the charts if you like to review the information that we've accumulated related to the breathing gas and the bench mark testing that we will have personnel available during lunch and the breaks to talk about that. I think at this point we'll go ahead and take our hour for lunch and I don't know exactly what time it is, but I'm guessing that it's 12 o'clock so if you can be back at 1, we'll resume with the self-contained portion.

UNKNOWN SPEAKER: Okay as far as what we're going to cover this afternoon, we're going to spend about an hour addressing the self-contained escape requirements. We'll have an open period for comments to close out the discussion on the escape respirators immediately following the self-contained

discussion of the escape respirator requirements and then we'll conclude with the QA module and wrap up at the end of the day.

I think to reset the stage you know this morning we talked about part one of the standard. We addressed what we're conceptualizing for the air-purifying escape respirator and part way through the project of doing the air-purifying respirator, we had thought originally, the original plan that we had in terms of the sequence for developing the respirator standards we had considered doing the escape, the self-contained escape standard later in the cycle but you know we felt there was enough commonality between the requirements that it made sense from a programmatic stand point to go ahead and address the self-contained aspect at this time and so part two of the concept paper was born. And I think in looking at any time with the self-contained unit. You know we like to take advantage of the lessons learned and the modeling and the other work that we've done in developing the concept. Then in looking at, there's a lot of similarity between the self-contained families of respirators and to that end, we went back and looked at the SCBA, the self-contained breathing apparatus, standard. The first CBRN requirement that we developed and in that we had three tiers of requirements and it make sense for the self-contained escape respirator to use

the same type of model and in that we're looking at compliance with the requirements of 42 CFR enhanced performance requirements that we feel are necessary to harden the unit for this type of application as well as unique CBRN APR requirements.

Again as I said, the first tier is the compliance with the requirements that have been delineated in the 42 CFR, Part 84 that have been established for a few years at least for the community that's familiar with these types of pieces of equipment that these requirements are the same. The second are things that we felt needed to be considered for the potential user population for people who may not have the familiarity of respirator usage. When you look at a self-contained self-rescuer type devices, there's certain parts of respiratory protection program that the mining industry takes into account for how the equipment is used. The worker, your conventional worker, may not have that same opportunity so we identified these requirements as considerations for the second tier of the escape respirator and we'll get into that a little bit over the next few minutes. The third tier is the requirements for the CBRN in particular the chemical warfare agent testing and the LRPL and we're going to discuss those in some detail. And with that, we're going to cover first is the chemical warfare agent requirements and Les Boord, Mike Bergman, and Ray Lins from SBCCOM will be leading that

discussion. Actually Les is so good he doesn't need the charts.

LES BOORD: To start the discussion on the agent testing for the self-contained escape respirators, I'd like to just back track a little bit to refresh what we had presented and what we discussed in the April meeting. And basically, at that point in time, we, in the April meeting, talked about bench-mark testing for escape respirators and the self-contained units in the form of testing that we did on hoods. And basically when we look at the agent test requirements, we're looking at a self-contained unit so we're talking about high protections which really throws us into the levels of testing and challenge that we've identified for an SCBA which means sarin. We're looking at 2,000 milligrams per cubic meter and mustard, 300 milligrams per cubic meter. In the April meeting, we reported the results of bench-mark testing using hoods at those exposure levels and basically the result of that was that we were able to come to the conclusion that hood technology even at those levels of agent exposure was I think in line with the requirements so we didn't envision that would be a problem. So that bench-mark testing proved the hood capacity or capability. Since that time, what we've been doing is taking it a step further and we wanted to look at the, two things primarily. The first one is the challenge

concentration: the 2,000 and the 300 and basically profiles for actually administering that type of a test on an escape respirator. So some of the discussion that Mike gets into is going to discuss different profiles for doing that test, but then the second thing is that we actually wanted to gain some experience and we'll share that with you relative to bench-mark testing existing escape units, self-contained escape units against the hazard levels that we've identified and the profiles that Mike's going to talk about in his discussion. And so with that, what I'd like to do is have Mike Bergman talk about the agent, the live-agent testing profiles again associated with the smart man testing and then following Mike, Ray Lins will share with us some experiences of the bench-mark testing on self-contained units. And before I go on any further, I would like to point out which I fell to do earlier is that we do have a smart man test set up at the back of the room which I think probably everybody has seen already but that is back there for your observation and questions to the technicians available to demonstrate that.

MIKE BERGMAN: The concentration challenges for sarin and mustard have stayed the same. They are the same as the SCBA/CBRN standard. For sarin gas, the paper challenge concentration is 2,000 milligrams per cubic meter and that's going to be an important number. That concentration is going

to tell us something about the time that we need to expose the unit in the chamber and I have a graph on that that I'll show you. If it's a 15-minute or longer rated unit, 15 minutes will be the time that the agent is generated for the exposure. The total test time will be twice the rated service time of the unit. For mustard gas, the challenge concentration is 300 milligrams per cubic meter. Again if it's a 15-minute or longer rated unit, it'll be exposed with a generated agent for 15 minutes and then it will remain in the chamber for a total time of twice the service time. The profiles come out of the fact that for GB it's not possible in 15 minutes to have a 10,000 CT and that will show that we need to vary the concentration for that. For HD it is possible within that 15 minutes to have a 4,500 CT and that will be a constant exposure at 300 milligrams per cubic meter. For GB, this is stage one of the agent. This is, the time is at the bottom of 15 minutes and what we are doing here, the goal is to achieve 10,000 CT as a total exposure. We are increasing the concentration up to 2,000 which is the maximum and then a decrease of the concentration. And then here, this is the total surface of, excuse me, the total testing time for a 60-minute rated unit. That is the first 15 minutes, the agent is generated and then stage two there's no agent that is generated. For HD, we have a constant exposure at 300 milligrams per

cubic meter for the first 15 minutes and then it will remain in the chamber for a total time of twice the rated surface time of the unit stage two. And now I'd like to take any questions about that and then we're going to have Ray Lins come up for further comment.

GÖRAN BERNDTSSON: Göran Berndtsson from SEA, what's the logic of leaving it in the chamber twice the duration time than it is in SCBA? I mean it is when you're out of air, you're out of air so?

LES BOORD: Yeah, but I think we all know that the service time on a self-contained unit is a function of the use rate.

GÖRAN BERNDTSSON: That's true.

LES BOORD: So even under 42 CFR, we have testing that establishes the rate of duration, 15, 30, whatever it is, but we also have testing, sedentary testing that's performed on the unit that goes well beyond the rate of duration of the apparatus. So the idea is to see what those affects are beyond the rate of duration.

GÖRAN BERNDTSSON: Yes I can understand that, but when it comes to escape, it is very likely that the duration would be shorter than the rate because you're probably use much more than your testing.

LES BOORD: I think that depends on the escape mode, the mechanism for escape because I think one escape strategy is certainly as you mentioned. Put on the escape respirator and go as quickly as you can to a identified area, a fresh air area, but it also may be to put it on and go to another area and perhaps wait. So there are different escape strategies and scenarios that I think need, that are realistic and need to be addressed as well.

RAYMOND LINS: I'm Ray Lins from Aberdeen Proving Ground, Protective Equipment Team. We are accredited by ISO 17025 by A2LA and we're a certified testing laboratory for NIOSH for CBRN. It's kind of a timeline and you saw it this morning. In May we started on the (inaudible) testing of escape respirators. Recently we started testing the self-contained escape respirators to develop the standard test procedure and the goal is to start certification in October.

In addition to the smart man testing that we do, we have swatch testing which we do and you just saw the swatch cup sitting in the back. It's important to look at the materials before you ever build the hoods. Escape respirators and know if they're going to last or not so we do have the system to do that. Three sets of six swatch systems, we use mini-cams for the agent detection. (inaudible) cups we use. That's a larger swatch for a semi-permeable material. A cheaper test,

fruit fly test on swatches, we do those and then we can put a hundred of those in at a time so it's pretty inexpensive that way. And we're also a certified testing for NFPA swatch testing and we were certified by A2LA for that.

I have a couple of charts to show you on some testing that we did. The first one was a hooded unit which used lithium hydroxide as an passive scrubber. That was mounted on a smart man head form. We only take one sample. One time we talked about different samples inside the hood and inside the breathing area. Since this just had a no nose cup or anything, we just took the samples inside the hood.

This is an off-the-shelf item. Very short duration unit and worked out fairly well. Another test of the identical unit, both of these tests were with GB. HD, this kind of shows it. It probably needs some work on materials but it did perform for the first few minutes. Just a duplicate of the second test of the same thing. Another unit we did a self-contained compressed oxygen breathing apparatus contained lithium hydroxide. This one was a little bit different. It didn't use passive. You actually breathed through the lithium hydroxide and we had to modify the smart man tests setup for this. This actually used a mouth bit so we didn't have a smart man head form to put it on. This one did much better, test duration 1 hour and that was the HD. This was also an

off-the-shelf item. After doing leak test on it, we had to kind of modify the hoses and seal them a little bit to make them leak proof. They did leak on a TDA 99 test before we ever put it on. So there was no sense testing it without fixing it first but after we fixed some of the leaks, it performed fairly well. As you saw the concentration profile earlier, that's a typical. That is the concentration profile running this unit up to 2,000. Held it for a couple of minutes then dropped down. The concentration profile that you saw in the HD would also have a ramp up on the front. It doesn't start off at 300. So it would have a ramp up very similar to this compared to what the other one did. Presently we have five smart man agent test systems. One smart man CK system, one medium leak test system, two small leak test systems, one of which you see in the back. In July we'll have a small head form set up for agent test. September we'll have two additional smart man agent test systems setup mediums and then to accommodate the self-contained tests that we're doing, we'll have two additional units set up with automated breathing simulator like the smart man. Questions? Pretty straightforward.

UNKNOWN SPEAKER: Okay the next two requirements we want to talk about is the breathing gas control and the LRPL and these are basically a repeat of what we've discussed this

morning. The requirements are the same and the evaluation methods will be the same as we discussed. So the CO2 is a maximum average inhaled concentration 2 1/2%. Again, it comes from 42 CFR, Part 84 and the paragraphs there are actually referenced here: 101 and 97. And then the oxygen minimum inhaled oxygen concentration is 19½%, paragraph 84-79. The establishment of compliance with a requirement will be through human subject testing. Again, two test subjects greater than 80, less than 60 and the work rate's standing 2½ and 3½ miles per hour and conducted for the duration of the, the rate of duration of the respirator.

And again, the LRPL is the same, same performance requirement that we identified this morning. Okay, so we have the purpose to establish a bench-mark level of protection under laboratory conditions and the 20 to 40 milligrams cubic meter of corn oil .4 to .6 micrometer mass media aerodynamic diameter. Again, factoring in the same panel, neck circumference, head circumference, face length and width, two areas of LRPL values, breathing zone and then secondly under the hood and so it's the same repeat of the APR requirement that we discussed this morning using the same panel with the F metric dimensions and the same application of the panel for small, medium, and large. Any questions?

RICH STEIN: Rich Stein, QPS, on that breathing zone protection factor of 2,000 for the high again it doesn't quite fit in with the other categories which are low or specific which would also have an appropriate breathing zone LRPL probably lower which would make sense or raise this and then you won't have any units that pass?

UNKNOWN SPEAKER: Thank you.

UNKNOWN SPEAKER: Yeah, I want to discuss the test sequence and required quantity. This presentation's pretty much goes the same way as I did for the air-purifying respirators. Again, I have the charts set up where you have the various test categories: the breathing gas, human factors, penetration/permeation, LRPL. Again, the quantity is on the top here, required quantity for each of the test categories. The testing is at the very first test. It starts at the top and then it works its way down through. First I'm going to discuss the breathing gas. This is just a pretty basic here where 12 units are required for the breathing gas and the human subject testing methods will be used to test for the breathing gas. Again, the respirator will only be used once for personal hygiene reasons. The human factors, a total quantity of 5, between 5 and 11, again, it's size dependent. A 1 size, only 5 will be required. If it's 3 sizes, then 11 will be required. The first test will be the field of view,

then fogging resistance, and then flammability. Again, we'll try to use the same respirators for duplicate tests, multiple tests. The test method, again, field of view is 0312 and for the fogging resistance is the same as the air-purifying escape respirator. The permeation penetration testing, again, total quantity of six is required and same, we're going to have two respirators require two respirators for the prerequisite test which will not go through the durability testing of high temperature, low temperature, humidity, transportation, and drop. They'll be tested in the as-received condition for GB and HD. So, again, they'll be pre-qualifiers. If they pre-qualify, then they'll go through the durability testing and the test methods are indicated as such. And last is the LRPL testing. From Mike Bergman's presentation and we require quantity of between 30 and 65 respirators. Again, it's going to be size dependent. The donning procedures are still being finalized and then the LRPL STP will be used. Again, it's going to be similar to this 0352. Questions?

JAY PARKER: Jay Parker with Bullard, how will duration be tested? I don't see any test for the duration of the unit.

UNKNOWN SPEAKER: Go ahead.

LES BOORD: The first tier of the requirements that it be 42 CFR approved so duration is established under 42 CFR.

RICH STEIN: Rich Stein, QPS, I think there was a suggestion at the last meeting related to the vibration testing wherein you considered separating units and have categories A and B. Have you considered that?

LES BOORD: Yes, actually we did and I think the presentation that follows is going to go through and enumerate some of those types of comments, but on that one specifically, we did look at it and we actually bracketed what we thought those, I think we called them levels, level A, level B and we sort of theorized what they would be and bracket them, but it appeared to us that it was really well two things, making it a complex and complicated type of a requirement, okay, and then secondly, the opportunity for not following whether it's a level A or level B in the field in actual use I think was . . . There was no way to really see that you would adhere to it. In other words, if you had a unit that was designed to just be stored in a drawer, what's the guarantee that it's not going to appear out on a rail vehicle somewhere or a car somewhere being carried. So basically we just came to the conclusion that we decided not to go down that road, but it was considered.

UNKNOWN SPEAKER: In response to your feedback, this is something new and I think as Rich Metzler had said this morning, you know, NIOSH in taking our role in trying to

protect worker and safety and health, we realize the fact that as Rich has stated, that we need to do things in partnership not only you know in partnership with other Federal agencies but you know partnerships with manufacturers, partnerships with the stakeholders, partnerships with people that have a vested interest in the development of these standards for the protection of the worker and I guess this trial at least we're showing this at least as fair as the work that we've done with the escape respirator. You know, we've had an open docket to collect comments that individuals have made that felt that they had a contribution of some meaningful data, meaningful opinions to provide for us to formally consider as part of the development of the standard. And I want to make sure and reinforce the fact that you know with the docket has been open a lot longer than just since October. NIOSH has actually been collecting comments on CBRN since you know 2000 prior to my employment with NIOSH but at least I know for the last several public meetings in discussing this forum that we have invited the comments from the stakeholders to the docket and we welcome those comments and what we wanted to do is spend a few minutes to kind of describe for you what we do with the information. We certainly value the opinions and the data that comes forward through this mechanism. We also value the opinions that you know are voiced here in these meetings or in

one-on-one meetings that manufacturers or other parties may request of being involved with us in developing the standard and I want to encourage you know all of you as a stakeholders in this process that if you feel you have a contribution, position, data, information that would be of value for us to consider in the development of these guidelines prior to us moving too much farther along the path, I would encourage you to make that submittal. What we try to do and what we've done with the information that has been received is to generally categorize the comments either in what's listed up here is how we've done it with the escape respirator. And we've done this all along with the SCBA with the gas mask. As the information has come into the docket, we receive the information, we analyze it, and try to make the determinations where it's applicable, where it may not be applicable, or things that we may require additional research to investigate. What we try to do as part of our internal processes are to address requirements or address information that comes in in a narrative fashion that we might not specifically address a certain topic but if, we will look at the topic of the metabolic simulator in total and look at the types of, type of information that's being submitted for consideration and provide a narrative to address those concerns. And going through a little detail as far as some of things that we've collected on the escape respirator

and I think you've heard in the discussion this morning a lot of these topics have been addressed in terms of our current conceptual thinking right now in terms of the need for the ABMS as part of the requirement. I think based on some of the information that we've seen and analyzed with our different research that we're not considering that part of the requirement for the escape respirator.

Fees obviously is a big topic and whether or not we can see any economies in reducing the number of test items that we subject through the certification process and that is one thing that we still have under consideration whether or not there is some flexibility of changing the number of items that we test. With this type of device, we've seen different concerns regarding beards and glasses and one particular comment was the need for having a good face seal or a good potential seal with the respirator whether it'd be with the nose cup or other concerns have been with use a full facepiece type system that you would need a seal around the face and how that would impact potentially wearing beards or the use of glasses and we see that concern really being addressed as part of the cautions and limitations aspect of the program. Then consideration for whether or not you would want a hooded device or some other type of system. This would really need to be addressed as part of the user's needs analysis for why they would need

to have an escape respirator and how they best wanted to serve the population whether that they wanted to provide you know a hooded type system to accommodate certain things or if they would prefer to go another track with the device that they would select as part of their analysis.

Breathing gas control, again, I think we've heard a lot of discussion about that over the last few hours but where we've ultimately ended up at this point following our review and analysis of the existing bench-mark data is falling back . . . the breathing gas as part of the requirement. Breathing resistance, I guess another topic as far as the, what's currently been specified in the concept paper as being too restrictive enforcing the use of ventilation and exhalation valves, but the one thing that we have considered and based on the population that could potentially be using this device being diverse and various physical conditions that we felt that the 20 millimeters of water was probably appropriate to encompass a wide range of the population.

Communication, this was another issue that we bannered about. We do have a communication requirement for the gas mask. Originally we considered it as an option for the escape respirator, but, you know, from reviewing the docket comments as well as doing some additional conceptual thinking in the application of this device as being an escape respirator that

there probably isn't a need for having a communications requirement, especially in the light of, you know, the potential for using a mouth bit type system.

The chemical warfare agent testing, I think the community as a whole is getting a little, a little more comfortable with regard to how or how this testing is being done. There have been some, I guess, inconsistencies with what we've specified in the concept paper and I think to that and we've tried to resolve those inconsistencies. I think one thing that we can appreciate with the technology, the test technology that SBCCOM has is that they truly have developed a capability of to test a wide spectrum of respirators and I think it's, the trend is that, you know, that capability will continue.

One of the topics that was discussed at the last public meeting was the need for dermal protection and leaning towards the design for having a hooded-type hood requirement for the respirator and we feel that as a very important part of the overall design for the system. I think the concept was pretty, I think pretty well explained this morning with the selection of the two different criteria for sampling in the breathing zone and also sampling underneath the hood. And, again, the overall use of the respirator in conjunction with any other protective clothing would need to be addressed as part of the cautions and limitations associated with the

respirator, you know, granted that, you know, considering using the escape respirator that people will probably maybe dress the way we are today, but in terms of being able to identify for the user community what, what this hood or what this system, the respirator system will and won't protect against.

And, I guess one of the concerns from the last meeting was what specific and low and general and high all meant and I think you know we're trying to define that a little clearer as we move along. I think with the re-definition and I think by the time we get around to identifying the final concept paper that we should have this fairly well defined. Carbon monoxide we've also been discussing and you know that we feel that's important to leave as an added option for the manufacturer to pursue as part of his respirator if he so chooses.

The field of view we initially started out in the concept paper using the requirements that were established with the full facepiece gas mask. Recognizing that, you know, there are intrinsic differences in the design of the system that we've established less restrictive criteria for the use of these hoods versus what had been originally identified.

The fogging requirements, I think Frank had articulated this earlier that there are some deviations with how this test has done as compared to the way the requirement was originally

established for the gas mask and at least at this point we feel those are adequate for providing the required protection.

Flammability testing and wanted to make sure that we didn't ignore Jay with the comment about alternative tests. You know I think this is I guess of interest to the community in particular of using this in conjunction with you know evacuating from a or escaping from a scenario where fire and products of combustion may be involved. You know we have been looking at, you know, the different tests that have been required and we'll make a determination based on what we feel is appropriate for this type of system. Again, as I think Les had mentioned this morning, we are looking at a single burner not a multiple burner test for the requirement.

There's been some general debate regarding the gas life and gas capacity and we did receive several comments regarding what should be established as the test challenges as well as the test breakthroughs. I think, in general, and I can't reiterate, I think reiterate this enough that you know in looking at the filter life is that we're really trying to achieve an overall balance of protection. You know in looking at this system as being an escape device to you know ensure that we're providing enough capacity in the filtration system to allow an individual to escape from an area. I think one of the things that we'll be continue to evaluate with regard to

the gas life and looking at the breakthrough as the potential use of the emergency response planning guidelines and their appropriateness for this type of device. Also as Les had mentioned about the debate on the ratings, looking at level A, level B, you know, we could see this getting into a not just a certification, but also potential use nightmare for trying to sort out, you know, which devices go where and the lack of control in where these items may be used when the user purchase them and where they would potentially place them for use at a later time.

I guess no one has commented on LRPL, but I think, in looking at the 2,000 value, you know, from our perspective, you know we're trying to identify values that are consistent with the protection we feel is necessary. I think, you know, in terms of doing the dual sampling I think is a step forward to helping protect the individual with the respiratory hazard as well as anything that they may encounter in the sensitive areas underneath the hood. You know, 2,000 I guess the, you know, we have some precedence in where that number came from. Obviously it's from a gas mask standard, but I think even with the experience with the military systems even though that the military and the joint service requirements may have a lower value that historically much higher protection values have been seen in testing. And, again, this is something that we

will continue to consider over you know the next several weeks.

Panic demand, you know, again, in trying to be responsive to some of the concerns that had been raised from stakeholders about providing excess capacity in the system for situations where people may be breathing at a higher flow rates that we've incorporated that requirement for both the general and specific category.

One other, we didn't address this specifically as part of this presentation today and I think the manufacturers and other stakeholders that have been tracking the program know that we have a research and development program set up with our partners at SBCCOM for helping the manufacturers conduct pre-certification testing to see how well their materials or high well their systems may perform as part of the overall protection against penetration/permeation, effects of chemical warfare agents. Again, one of the things to note here is that for the R&D program that if there's certification testing to be conducted, certification testing will always have priority over the evaluations of the R&D program. You know, I think that's, I think with the system as SBCCOM continues to expand their capabilities as well as some other activities we may be considering that, you know, trying to ensure that we'll always

have that capacity to be responsive not only to the certification program but also to be responsive to the R&D program.

The R&D, and again, this is a good tool as far the pre-submission data. If you choose to participate in the R&D program, that information can be included as part of the, as part of the application package, but it won't be counted as certification data. I think we addressed this a little bit on the earlier slides as far as the different levels of classification, but again, you know, we felt that, you know, by trying to do too much with levels and with different description that we may be opening ourselves up to a cumbersome process not only for certification but also for user selection and use. I believe this came out of the October meeting that there was an issue raised regarding the population for who the escape respirator should be designed for and the suggestion was or the question was raised whether this system would be designed for the for non-ambulatory escapes or for children and the response at that time was that you know this is designed for the general working population and that still holds for what we're trying to do with the standard.

And, in conclusion, this is where we see the program going over the next couple of months. Based on the oral feedback, we've received from you today as well as the information from the docket and other information that we may receive from

stakeholders, we'll be updating our concept paper within the next week and putting out a June 30th version and I think along with that it's important for you to keep in mind at this time is that we'll be looking for comments on this version of the standard and the information that we've discussed here today by the end of July and what we'll be doing at that time is reviewing, reviewing your comments, reviewing comments from other stakeholders as well as any new information that may be provided to NIOSH through the docket and make any final modifications to the concept paper. From that end, once we've completed that review, we will, we're planning on releasing the statement of standard for the escape respirators in August with the potential for beginning the actual certification program in the October timeframe. The next step in our process is we're going to begin work on the powered air-purifying respirator standards and we are planning on or developing and putting out our initial concept paper for defining the standard in the August timeframe. And I guess just to keep in mind that you know with the concept paper process, it's an iterative process that types of things that you're going to see in August are more of the program goal and the criteria, the overall, the overarching structure as far as the types of requirements we envision for the PAPR. We aren't at this time, the actual definition of specific tests and specific

requirements may not be as well defined as you're seeing now on these current versions of the escape respirator, but, you know, we are going to be moving forward in the development of that standard and to that end, that we envision that somewhere in the October timeframe we'll be conducting our next public meeting to introduce the powered air-purifying respirator standard and begin dialogue on the concepts associated with that. I am aware there are several other conferences going on during October. The fire fighters have the red-man conference in October. NIOSH has a big research agenda conference in October and we will be you know try to be sensitive to the scheduling of that meeting to allow you to make a choice or allow you to be able to participate and not have to make a choice between attending one or attending another. And with that, what I'd like to do is open up the floor for any general comments on the escape respirator and then we had a request is Mr. Bennett still in the audience? Mr. Bennett, okay, but at this point, I'd like to open up for any you know comments regarding the escape respirator, either the air-purifying or the self-contained.

GÖRAN BERNDTSSON: Why should I break the tradition? Göran Berndtsson from SEA, have you considered to classify this in some other means than 15, 30, 45, and 60 minutes because the reason why I raised this is because the end users

are going to expect that number to be the performance and that's not necessary true. Maybe classes should be 1, 2, 3, 4 or it's only a test method as against a certain criteria or go to step numbers.

UNKNOWN SPEAKER: I think, part of answering that question, I think gets into developing the guidelines for use associated with the respirator. I think along with the gas mask standard, we took the approach of identifying the rating as the tested period that you know you tested for 15, 30, 45 minutes and part of what we followed on with that program is the development of guidelines to assist the user in how to use the system and what that means in terms of, you know, some of the things that we've conceptualized is that to help an industrial hygienist or someone know, you know, CBRN 15 means. Means what? It means that, you know, that you'll provide 15 minutes worth of protection at this concentration and you'll get this breakthrough and you'll determine capacity for the system and basically what we're doing is we're determining system capacity for the filtration and I think the next challenge for us is to take a look at in developing supporting guidelines and information associated with this product to carry that type of a discussion forward.

GÖRAN BERNDTSSON: There is possibly a different audience here. I mean there is no fire fighter who doesn't know that a

30-minute (inaudible) doesn't last 30 minutes. There's a lot of people in this industry who understands that and here we're going to go out to public who might not understand that what you are testing it against. I mean it could last 50 minutes, escape respirator could last 30 minutes or 20 or 25 depending on what (inaudible) could last 12 or 14 or 7. So that's why I think it is, it could be misleading to a novice audience.

UNKNOWN SPEAKER: I appreciate, I appreciate your point on that, Göran, and I think part of the education process that's associated with the escape respirator, you know, falls into the analysis, the analysis and need for individuals or businesses when they make a determination that I need a respirator and part of that goes into if I need a respirator what kind of a respirator do I need and select a respirator based upon that need. You know one of the sidewalk conversations that we had earlier was somebody from one agency said they did their own, they did their own risk analysis and they made a determination that they weren't going to provide or they weren't going to purchase an escape respirator. It didn't make sense for their application and I think in dealing with this population that one of the criteria in looking, in looking forward and how it's going to be used is to raise the general understanding of the users as far as why do I need the respirator and then in turn how do I need to make that

selection of a respirator that will provide the protection that I'm looking for.

RANDALL TEMPLETON: It's Randy Templeton, DuPont. Your comments lead into my question and that is are we receiving, I'm sure you're in communication with OSHA on a regular basis, but is there a sense that there will be OSHA guidelines helping the general working population for which this standard is being written to assess their requirement to supply their employees with this product? We can develop a standard and we can design products and we can certify products against that standard, but who is it for? It seems to me that there's a limit for voluntary decision to use that.

UNKNOWN SPEAKER: It might fall in NIOSH's realm.

RANDALL TEMPLETON: Exactly.

UNKNOWN SPEAKER: Thank you for that question. Actually I hate to put her on the spot, but we have a representative here from OSHA today, Caroline Freeman, who we've been working with, you know, during the development of the standards process and may be she can address that a little better than I can. So if you don't mind Caroline . . .

CAROLINE FREEMAN: Ah yeah, I'm Caroline Freeman from OSHA and you mentioned guidelines. Guidelines are certainly doable. We don't have anything on our agenda right now for guidelines from the agency, but we certainly would consider

guidelines. I don't know if your question is really directed towards requirements or recommendations or guidance or what we allow. Perhaps you can clarify that because certainly we can do guidance materials and think that they're important along with the training aspects perhaps even prioritizing what we . . . Who was the Federal agency who did a risk analysis and said that they didn't have any risk? Anyway, we would like to work with a, we would absolutely be in concert with NIOSH and working out guidance on these on these CBRN tests. We are very glad to see them. The more CBRN tested equipment, the more tested equipment that there is, the more we know and we can separate what we don't know and it reduces the need for professional independent judgment so certainly we'll be working on guidelines, no problem. We just don't have it on the schedule now. None scheduled now. We are working on a guidance document right now that will tell you what OSHA's standards currently require and CBRN tested equipment comes up with that guidance document. It's not a particular guidance document on CBRN equipment. This is in a simple, single-to-use document. What do OSHA's standards, safety, health, construction require in the event of an intentional disaster or other types of situations where PPE are required? What is the bottom line on the current patchwork of Federal standards that are out there for the workers and certainly we are

considering talking about CBRN equipment in that, but it's not specifically . . .

UNKNOWN SPEAKER: That's after the fact? Right?

CAROLINE FREEMAN: After the event.

UNKNOWN SPEAKER: The escape respirator designed anticipating the standard, what you just said(inaudible).

CAROLINE FREEMAN: So does all of this, the purpose of this document is to anticipate the event.

UNKNOWN SPEAKER: (inaudible)

CAROLINE FREEMAN: To participate, yes, absolutely and OSHA's reactions as far as, may be I don't understand the question because OSHA's reaction in terms of enforcement capability would depend upon the, certainly we would want to go for prevention and planning and training. We hope that the document we put out is a planning tool. We certainly hope any guidance we write on CBRN equipment is a planning tool whether it's planning to escape or . . . We hope these are planning tools and we would take a lot of consideration at the amount of effort employers or other groups have taken in setting up strategic plans. Does that answer your question?

RICH STEIN: Rich Stein, QPS, it appears that this document that we've looked at today is, I don't know, pick a number 70% complete and there are a lot of holes and if I understood your schedule, the next step is to have a full-

blown completed document which then we have no ability to comment on and change? Is that the system? Is that how it's going to work?

UNKNOWN SPEAKER: It sounds like a policy question.

LES BOORD: I think in line with some of the comments we've heard earlier relative to how we continue to follow through or perhaps drop the ball with the full facepiece, we would intend to keep posting this document and our guidelines there were middle and end of the month. I see no reason to not continue to do that. We do know that on June 30th we will have a revision because we've talked about some of those revisions today that are going to appear in that document.

RICH STEIN: But by revision, do you mean you're going to have a complete set of standards so that we can look at and say okay this is what they think is a complete standard then we can make our comments or is it going to be pieces again?

LES BOORD: I guess I don't understand the pieces. I think the concept is a, it is an evolving, whoops, excuse me, it's an evolving document so it does become more mature with each, with each revision level.

RICH STEIN: Okay, but then there'll not, at some point in August, there will be a completed document and that'll be it, it'll be done.

LES BOORD: The goal is that towards the end of August, we should be looking at a, I always use the word near, near final, yes, final.

UNKNOWN SPEAKER: I'll take both of those last two questions. I tend to go out on a limb. With regard to cautions, limitations, restrictions of use, guidance, NIOSH is working on the guidance on these escape hoods as well as on other respirators. We'll be collaborating with OSHA on those. We do have some drafts already available, but with regard to the escape hoods specifically, we've looked at the manuals on the three escape hoods that we've tested and they're excellent and if anyone would refer to those manuals and read them, they would see what cautions, limitations, and restrictions of use are in fact important. So they're on target. With regards to the second question, it is a fact that within 2 months, we will have a final standard. I don't think it's only 70% complete. I think it's almost complete and I would say 90% complete. The issues you raised today on the 2,000 protection factor we'll look at, but within the next 30 days, we'll be finalizing the standard and our implementation date is somewhere around the end of August and you probably will not have another opportunity other than what you send into the docket office to comment. We're seeing this as a near-complete standard. So unless we see a major issue that would delay our

implementation, we're on line for implementing in the schedules that you saw. Call me or write me a letter if you see it differently, but that's where we're going right now.

SAM SHEARER: May be I can give them something to delay it with. Sam Shearer, CSE Corporation, this afternoon I heard a couple of words that sort of caught my attention and one was a nose clip, mouth piece. We're thinking may be we can use those.

LES BOORD: There are escape respirators that do utilize nose clips and mouth pieces.

SAM SHEARER: Okay, we use that in CSE's unit. Could I ask for one more piece: goggles which we use in . . .

LES BOORD: The requirement for the CBRN escape respirators, both air-purifying and self-contained, are for a unit that does provide eye protection in the form of a head covering. So it really is an integrated system that could include a nose cup or a mouth bit and nose clips with a hood.

SAM SHEARER: I'm just wondering if I have goggles on, why do I need a hood?

LES BOORD: Yeah. We're looking at the actual head protection, the percutaneous exposures for the agents on the head.

SAM SHEARER: Yeah, but I have hands, arms, all of that that could be exposed.

LES BOORD: True, but I think the experts will tell you that the eye is probably a little more sensitive than skin . . .

SAM SHEARER: Yeah I know, but if I have goggles on, I'm sealed around. So that's protected.

UNKNOWN SPEAKER: (inaudible)

LES BOORD: That's a good comment. As it is now, it is stated as a hood, head covering.

SAM SHEARER: Okay, I lost!

JAY PARKER: Jay Parker with Bullard, you know I was struck a little bit by the fact that you're allowing a nose cup which you then say means that you have to be clean shaven and there's going to be a warning to that effect. Yet you're also saying that you know the unit has to be a hood so that people with beards can wear it. So I think there's a little ambiguity there that you might want to think about a little bit.

LES BOORD: Yeah, I think that's a good point and I think that the facial hair issue is still an issue that still needs to be addressed through the proper cautions, limitations, and restrictions of use and the presence of facial hair can be damaging to any seal, okay, whether it's a nose cup or whatever.

BODO HEINS: Bodo Heins from Draeger, what turnaround time do you expect for the R&D testing? You only said that it's probably two, but if I look to the actual, then I would expect it mostly a year until we would get results from it and that is much too long for a development.

LES BOORD: The research and development program that we were addressing is the R&D program that we've implemented and instituted for the CBRN evaluation. That program is a 3-day test period. So and I think that is pretty well defined with the information that's on the internet and I think also provided in your information packets today. The, so the idea is the research testing is 3 days. You're in; you're out. The test data is yours. You have the data to utilize. The only conflict in scheduling that we run into is priorities relative to certification testing. So on a given day, if there's certification testing scheduled, that would have a priority and I think until this point that hasn't been a major a major issue.

GÖRAN BERNDTSSON: Göran Berndtsson, SEA, I'm not really clear on that question to OSHA and may be I can refresh that again. Will OSHA have the requirement for buying hoods for escape purposes? If it is yes, that's fine. If it is no, would it have a guideline saying that if you buy escape hoods, they should be NIOSH approved, yes or no?

UNKNOWN SPEAKER: Is that what you wanted to know?

CAROLINE FREEMAN: Thanks Göran, these decisions will be made at a high level after careful consideration and discussion with NIOSH. This is a major question before OSHA now. As I said, as CBRN-tested equipment comes out, there's a sigh of relief by this Federal agency in terms of the need for personal judgment. So we'll be making that decision at a high level. We've been asked by several first-responder communities. Well are you talking about escape hoods only or CBRN in general?

GÖRAN BERNDTSSON: (inaudible)

CAROLINE FREEMAN: CBRN in general and escape in particular, what NIOSH is doing has tremendous impact and with the findings from NIOSH in their hands OSHA will certainly take appropriate steps and this will be made , this decision is being made and will be made at a high level with a lot of careful consideration. There's money issues out there and there's possibility and likelihood of the events and who is the target and how much time do we have in a situation where we probably have some certainties. We'll be moving fast on that high-level decision.

LES BOORD: Thank you Caroline. As mentioned a little earlier, we do work closely with OSHA and they are aware of what we're doing and they are pretty much informed on the

progress that we make and as Rich mentioned, the project to identify specific guidance documents, cautions, limitations, and restrictions of use is something that we are looking at and we've identified resources to do that and actually carry out that function.

Okay if there are no further questions, what we'd like to do . . .

UNKNOWN SPEAKER: I'm actually going to do something different. I'm going to say I think you do a really, really good job. I'm pleased to see how this is developing as a partnership with the industry and this meeting, I think, is very, very helpful. So I thought I . . . I want to say that.

LES BOORD: Thank you. We can take a few more of those comments. What we'd like to do is according to the agenda, we had a comment period and we didn't have any official participants and what we have is we've scheduled the discussions on the QA Module to begin at 2:45 pm, so we're running about 5 minutes ahead from our break, but what we should do is I think let's take that break and let's resume at 2:45 pm at which time we'll take up the QA Module discussions. Thank you.

ROLAND BERRYANN: We're ready to begin now about discussions about the quality assurance module that will be coming out as a proposal this fall and I'd just like to make a

few comments. The first one should make everyone happy is due to popular demand by participants, we're going to start tomorrow morning's meeting with the manufacturers to talk about the certification process and possible improvements to it till 8 o'clock rather than 9. Please hold the cheers down. I know. Okay, uhm, what we're going to do here in the next about an hour is we're going to update everybody on what we've been doing on the quality assurance module and basically we have been revitalizing our efforts in the development of the concepts for the quality assurance and administrative provisions for a proposed rule that we intend to come out this fall around October. And, the first change has been personnel changes. Matt Boyer* was heading the project previously and when the transition to NPPTL, Matt did not transfer with the program and we've been lucky that Bob Stein and David Book who's joined our program and QA program have assumed the task of taking on the project and moving it forward and we're very pleased. They've been doing an excellent job. They've been building on the work that Matt did previously and what we're going to discuss today is, as I think a lot of you probably remember a few years ago, we had some public meetings and talked about the concepts. They were I think in 2000 as Rich said before the 9/11 events, relocation of the lab, and several other things that kind of slowed down the progress,

but the good news is there's a new ISO standard that came out in 2000 that we're revisiting and looking at as to how we can implement that into our program. David's going to tell you about that. So we've done reassessments of the ISO standards and how we think we can implement those into our process, upgrade the standards. We've had some limited experience in the use of private sector auditors in doing quality assurance auditors and we've been reorganized into the NPPTL from our previous structure in the division of respiratory disease studies. So today's presentation, like I said, is going to focus on the changes and the concepts from which you saw and heard a few years ago and the concepts, the complete concepts, will be mounted on the web page within the next few weeks. So with no further ado, here's Dave Book. By the way, we value him so much. Ask any questions you want while he's here because next week, we're sending him to Toronto.

DAVE BOOK: It's so nice to be loved. As Roland pointed out, we're trying to create a summary of what we've done. Most of this has been done through presentations and small group discussions rather than the formal paper and posting process that has been being used with the other standards that have been introduced. We're trying to catch up to that and get that information out to you on the website. These slides should be available with the packet that's coming later so

we're playing a little catch-up here, but I think if you bear with me, you'll get some new information.

Looking back, where were we? Let's get these up. Okay, from 1972 to 1995, we really had no new respiratory standards introduced. In 1995, we introduced the 42 CFR and a number of things happened with that. First off, it itself was a standard for particulate filters and it was nice to have a newer standard, but it also introduced a modular process where we were looking to update the standard on a regular basis and it really began our standard development activities. Since 1996, you've seen the results of a number of those. The CBRN self-contained breathing apparatus standard is out. The CBRN air-purifying respirator standard is out. We've talked here extensively about the CBRN escape respirator and the self-contained self-rescuers so you know there's a bunch of activity on those fronts. And this is the new one the Quality Assurance Module and it's technically the Quality Assurance and Administrative Module, so you'll find a number of things outside of strictly quality assurance that are kind of attached here because it's an opportunity to move to role making and we like to take advantage of all opportunities.

I'm not responsible for the little swooshing sounds. The, we, as Roland pointed out, we began this process in 2000. We had stakeholder meetings with individuals and groups. We

actually had an announced conference with private sector laboratory folks and auditors to get their input to what they thought might be an approach to using their skills efficiently and effectively. And we had a . . . We had a public meeting in August on this subject. What we're trying to do is update you with information that's happened since that time. Since then, ISO 9000 has moved on from the 1994 standard to the 2000 standard. The 2000 standard requires both a process focus and an effectiveness focus and we think those are really critical to some of our decisions subsequent to that. And, of course, the laboratory, the NPPTL laboratory itself was established a year and a half ago, and, of course, we have new personnel which is why I'm here and Matt isn't. And we're actually pretty excited about the new personnel. They came with a lot of experience from the industry and a lot of academic back-ground also, so we had the best of both worlds in that we got to see the experience of the long-time Federal employees that had worked on the respirator community and some new fresh faces and ideas and they worked really well together.

Okay, the impact of the new QA Module, there are a couple that really rely on the manufacturers or the approval holders, would like to be able to encourage the youth of contemporary manufacturing processes and we'd like to be able to replace some outdated quality requirements. We don't want to be in

the position of having manufacturers out there saying we could do this better except as NIOSH requires. So we're trying to get past some of those hurdles. We've also, we run a number of audit programs through NIOSH. One of which is a . . . and as we go out into the field, we really have found significant nonconformance rates. The statistic that's quoted most often has to do with the product evaluation program where we find 40% of the products we look at out of compliance. Well at first (inaudible), that's really bad. Most of those are label or documentation problems which don't affect product, but 5% what of our product audits do reveal a significant health/safety performance problem that requires a retrofitter recall and we're going to . . . we'd like to be able to get that figure done. We hope this will help to do that. Also internally for NIOSH, we've hope the new standard development will allow us to use our internal resources better to utilize outside resources better, and of course, there's that fee issue we'd like to be able to retain those so that we can keep the program viable and that's part of the proposal.

These are the slides . . . these are what was actually presented in 2000: these two-section slides and I'm just going to go through the objectives here and then as we get a little later, we'll see what our proposed mechanism was and what our current mechanism for meeting that objective are at

this point. Sometimes they've changed; sometimes they've stayed the same so that'll give you some idea of where we're being consistent and where we're having new thoughts. We'd like the quality assurance program to be consistent with international standards. I don't think there's any disagreement with that from this room as far as I've seen. We got a number of products specific quality assurance requirements, quality plans, sampling procedures, quality production records. We had specific recommendations in those areas and you'll see how they've evolved. We'd like to validate a quality system prior to approval. At this point, the only validation step we have is a paper validation step and we're seeing that's not always effective.

We'd like to be able to audit our manufacturers on a more frequent basis. That again goes back to what we're seeing as end-product questions. Semi-annual site audits was the most frequent requirements. We're not actually planning on showing up every 6 months, but we'd like the authority to show up that often if we like you a lot. And annual product audits and we see those two as tied together. Trying to be able to see what you're system is doing and what you're actually producing. The fees question we'd like to recover and retain fees. We'd like those fees to be for the approval processing that we're currently doing. There's a new records maintenance fee.

We'll talk about that in a bit. Quality activity fees, we'd like those simply to cover our costs and we'd like to retain the fees within the program. This is consistent with what we've done with the CBRN program so again we see old programs and new programs walking hand in hand down pretty much to the same path.

Label adequacy for air-purifying respirators, there was in 2000, there was a significant requirement to make them simpler to really put on there what the users need.

Okay, so where are we at today? The QA Module, itself, is relatively mature. We've worked on it in house a lot. We're fairly happy with where it is and we're comfortable bringing it forward to say, let's see what you have to say; let's see how we interact; and hopefully we can go from here to CFR language fairly quickly. It's a hybrid process. It's like the CBRN process, but it's a little different. It says periodic posting of concepts. Well, the first period will be pretty soon. We're getting to that and again we're taking the opportunities to interact both electronically and in person.

Alright, probably the first and biggest change, when we talked last, our approach to being consistent with internal standards was to incorporate the ISO 9000 elements into the body of the CFR. So you would have this whole extended NIOSH-specific ISO-like thing to comply with or to audit to. We've

decided to bite the bullet and simply incorporate ISO 9000/2000 by reference. What this means is that those of you out there who are ISO certified are registered at this point should have a compliance system and shouldn't need to do a lot of NIOSH-specific things. There are some. We'll retain some NIOSH-specific things, but not nearly as much as if we'd taken the other approach. Those of you who are not ISO registered, ISO is a standard. It can be applied whether you're registered or certified or not. So you'll have to create a quality manual as you do now and simply have it meet those elements. We'll leave that there.

Product-specific QA requirements in 2000, we were looking to add specific end process controls. We decided that the manufacturers had a much better idea what their processes looked like than we did and we're simply asking that you upgrade your systems through your ISO 9000 process through your corrective actions, your preventive actions, your internal audits that that should meet that requirement.

There was a large discussion on sampling, sampling plans, and approaches on those subjects in 2000. What we'd like to do is to allow for a transition from a sampling and inspection mentality towards a statistical process control approach. Right now, I got one thumbs up anyway. Right now, the current sampling plan is based on military standard 105D which has

evolved to ANSI Z1.04 and Z1.09, Z1.9, it's okay you know what it is. We're going to allow a transition period for those manufacturers out there use to that, working with that, dealing with that. We think we might upgrade the quality levels a little bit for consistency, but no major standard for a transition period. The, we, there are a number of manufacturers who prefer to use a sampling plan or in position where they're purchasing a lot of their components and really can't do process, statistical process control of their suppliers. So we've left that option available through a zero-defects sampling plan which will go forward and that's really part of military standard 1960 for those of you who are working in this area. We think that provides the end user a little better protection. It should be a little simpler to use. It's, we're always going to need some sampling plans. Our preferred approach is to do statistical process controls specifically to monitor processes and we're measuring around CPKs and again those we looked at military standard 1916 which also lists a very comparative set of CPKs for minor, major, and critical components. That's very similar to what we've been doing. So we've adopted basically those levels of CPKs. That's sampling plans in a nutshell. I'm sure I'll have questions and we can expand on that a bit.

We wanted to incorporate first-piece inspection and tests. We're going to have limited implementation of that. There's still some in-house debate about what's a first-piece inspection, how long does a process have to be down before you start doing that. We're going to need some dialogue on that. We wanted a complaint notification program so that NIOSH knew when you were having major field problems because we get kind of blind sided with this stuff occasionally. We've left that in. We haven't changed that.

Retention of quality records for the life of the major components, that seemed like a reasonable requirement and we really haven't modified that since we talked last.

Now a day* quality systems prior to approval, we were looking at having a manufacturing site audit before granting an approval. That seems like a prudent thing to do. We've retained that without significant modification.

Audit frequency consistent with current quality practices, the original plan was to authorize RAB accredited auditors. That's a little bit redundant since they're already been screened and approved and vetted and all that good stuff. So we're going to use them. We're not going to try and set up our own accreditation of an accreditation program. And we've had some experience with that over the last year and a half where we've had external auditors doing some of the field

audits for us sometimes accompanied sometimes alone. And that's going fairly well and we've learned a lot about how external auditors are going to approach the audits that we've been doing internally for years. And the mind sets are a little different. So we're hoping to be able to incorporate that information. We wanted to use authorized accredited labs. We've retained that. Again, we've had some experience with that, some limited experience with that with SBCCOM folks. We haven't expanded that at this point outside of Governmental laboratories but again the interaction has been valuable to us and we're looking to do that on a test-by-test basis not as a blanket laboratory approval program.

Recover and retain fees, obviously, from this slide we had a lot of good ideas in 2000 and we've kept them all. We'd like to recover the cost for approval process. Those fees will go up, but there not the kind of changes you've seen with some of the CBRN fees. We're just trying to cover our actual real costs not that we're doing anything else over there in CBRN mind you but I know there's been some sticker shock over there. We'd like to have a maintenance of approval records fee and that's really two-fold. First off, it recovers our cost for doing those services, but the other thing is it forces us to be in dialogue at least once a year to see whether the check came in or not. We've been having a lot of

difficulties with folks who've been maintaining obsolete approvals even though they haven't manufactured a respirator in 5 or 10 years and then you get to where they've gone out of business and you have this whole kind of gee I didn't know, gee you didn't tell me kind of scenario goes on. So that at least creates at least an annual dialogue to say you haven't sent me a check you're really still in this business and we'd like to recover the cost of the products audit and compliance investigations. One of the sneaky things we might ask for is when we do product audits is to have the manufacturers supply us with those devices, those respirators. Right now most of you've been very good about that and it's been a kind of a goodwill-okay-sort-of deal. We'd like to formalize that.

In 2000, we were looking seriously at air-purifying respirator labels. It was considered that they were too complicated and they provided the user with information that they never used and there was a cost problem there. We're not at this point sure if the needs and the demands for that are still there, whether we want to clutter up the QA module with a label requirement so we need your feedback on this. So if this is an issue for you out there, let us know and we'll see that we get in here and we get this passed forward. This is a place where we actively are encouraging you to send us notes and letters and comments.

Gee I wonder if there's a fourth one. Opportunities to improve, this is one of those is that we hope that by having these discussions that there'll be better acceptance of the rules as they come out and so . . .

. . . will substantially improve the quality, the reliability, our ability to verify that on an ongoing basis and we think that retaining the fees will help us as we move forward in our program.

Schedule, as in any schedule that involves Rich Metzler, it's ambitious. The QA concepts are currently being revised. This is, we've been working diligently on those. We're having our public discussion of the concept in June. We hope to have the formal document that outlines what we've been thinking, where we want to go, what our first pass of this might look like, post it on the website by the end of June. Those of you who have calendars know that that's soon, soon. The concept docket, hopefully we'll have that up by June and we can have some discussion over that, have those comments in by the end of July. We will piggyback on the next public meeting to have some additional discussion, do a whole bunch of internal pushing-this-through-Federal-Government stuff and hopefully have a notice of proposed rulemaking out by December/January. So that's an ambitious time schedule, but we think we can do that and we hope this is of sufficient interest that we will

get feedback quickly and voluminously so that anything we might have missed or passed by we won't let it linger very long. That's the end of that for now. Questions?

WILLIAM NEWCOMB: Bill Newcomb, North Safety, could you go back to that first slide?

DAVE BOOK: Maybe, ooh, let's see, you want to help drive Bob? You can go out and come back. Yeah, because I'm not going to slide; here you go. (inaudible) I assume you want the next first?

WILLIAM NEWCOMB: No, that's the one I wanted.

DAVE BOOK: Okay.

WILLIAM NEWCOMB: Is that really how you picture the manufacturers as dollar science?

DAVE BOOK: No, no, we picture them as generating dollars for themselves. I don't really know why the dollar sign was picked. I didn't pick it, but you can interpret that however you want.

WILLIAM NEWCOMB: On the NIOSH approval labels issue, we as a manufacturer have started to post our labels on our website; however, some of them are too big to get into a pdf file actually pulled on a website. So it's still an issue, but I think it's a good place to put them. Thank you.

DAVE BOOK: Thank you.

JAY PARKER: Jay Parker with Bullard, am I correct in that I think I heard you say that you're going to allow either the zero-defect sampling plan or increased sampling or higher or more stringent AQL levels under P105E?

DAVE BOOK: Right. We'd like to grandfather folks in who are current manufacturers to 105T or E for about a 3-year period as a transition. We would then like to have two possibilities for your sampling assurance programs: (1) zero-defect plan or an equivalent. There's always or an equivalent and/or to go to a statistical process control based around CPKs. So those are what we're viewing as a long-term answer to that question.

JAY PARKER: But you won't accept 105E with more stringent levels as I believe ISCA had recommended to NIOSH back in 2000 instead of zero-defect plan?

DAVE BOOK: We'll take it under advisement, but that's not, we'll go try to, that's news to me, and we'll go relook at that issue.

JAY PARKER: Thank you.

DAVE BOOK: I like this part where I say, "Seeing no other questions." Alright, what's next on our agenda?

LES BOORD: That wraps up the program for today. I think the only message or information is that if you fill out your surveys that are provided in the information packet, that

information is really helpful to us in building these meetings and also at the reception desk there is an attendance list available. So as you exit, drop off the survey form, pick up the attendance list. And, again, the start time for tomorrow is 8:00 a.m. Thank you.

(END)