

(TAPE 1, SIDE A)

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

Cloonan: Without further adieu, Mr. Caretti.

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

stuff, some of it's in there, some of it's implied, but I don't really know how much is really done. It doesn't mean that manufacturers don't do some of this testing before they make the mask because it wouldn't make sense to make something that wouldn't be used or be useable. So what we did was we took a look at all the different procedures or tests or standards that were available that we might be able to adopt certain aspects from... to do some human factors evaluations. The list of eight that was pared down from many others that we felt were to be proposed first include those listed there. Breathing resistance, communications, field of view, optics, the LRPL and donning which was already discussed and we won't touch on any further in this presentation. Lens advisor fogging and two others that kind of crept in late were carbon dioxide retention and hydration, and those were considered to be as needed tests based on the design of the respirator system themselves. The first category under breathing resistance... these are values that are pulled straight out from those particular methods or standards. All of those are NIOSH standards or standard test procedures. Head form tests, constant flow rate, 85 liters a minute to measure inhalation resistance or in true form, inhalation pressure drop. Resistance would have to be calculated and the values come right out of data for cartridge canister type of filters. This is with the elements mounted to the mask system themselves, unless anyone... if that's incorrect Terry... please let me know. The change that we recommend or are thinking about is on the exhalation resistance side of the house for respirators. And the thinking there is, since we heard the term that... what we seem like we are going towards here is a pseudo-military respirator for these types of

applications. A lot of data that we have on military respirators actually has a little higher exhalation resistance than what's allowed in NIOSH standards. And, we really don't have any good reason why there's a... what kind of difference or why you couldn't go as high as 26 millimeters of water pressure drop on exhalation resistance. From a perspective of being able to tell the difference when you have a respirator on, whether it's a 20 millimeter exhalation valve or a 26 millimeter pressure drop exhalation valve. Base on the experience that I have, I would guess that probably 50% of you could tell and 50% couldn't tell. In terms of performance, there is ample data in the open literature to suggest that performance is not affected that much by that very small increase in exhalation resistance to that valve. It opens up possibilities for other design features that could be done with those valves. So that is the discussion point and that is what is being proposed at this time. Communications testing would be a new procedure or requirement for an APR and the proposal here is to really kind of adopt what's in NFPA 1981 with some modifications. Try to simplify it a little bit more. In NFPA 1981 has a communications test protocol and they also utilize some of the ANSI standard, S3.2, I believe is the correct number on that ANSI standard. And, what's proposed here is kind of a watered-down version of that test. And, to get the point across, we discussed this heated debate about whether this was required or not and really we felt that communications was an important, very important thing needed for any first responder, any kind of work going on, even in a warm zone situation or terrorist attack. And, to illustrate my point, I will now do my presentation with this mask on and you tell me if you can hear me or not. So, really what we are just

trying to get across here is that full-facepiece respirators come with a... some kind of mechanical device on it to help with speech transmission. Sometimes they don't come with speech transmission devices, you just speak through the exhalation valve. And, we thought that communications was important enough that a test procedure should be recommended. What we have here are the conditions, that would be masked and unmasked conditions, so we would go with constant background of 60 decibels. Now how about (?) at 60 decibels? The NFPA standard calls for 70. We're saying 60 because we think it's still loud. It's not quite as loud as 70 decibels. This room, right now, if I'm not talking with the HVAC system running, I would guess it's probably around 45-50 decibels noise. 60 background noise, actually, it's a logarithmic scale, so it is actually fairly intense. 70 is very intense. So all the numbers that are up here are based on that 60 background... constant background noise that the test would be conducted. We are proposing three listeners and five speakers. NFPA uses five listeners and five speakers. Why three? Just to make it a little more manageable to complete the test in a day so we can really pare down the amount of time to run the test. Yes, this is a test that requires human use. The procedure itself is not exactly the exact same speech intelligibility test that's in the NFPA. It's the modified rhyme test which is still an accepted speech intelligibility test, but it has some features to it that make it much easier to train the volunteers to speak the words of a test and how they are supposed to respond to the words being spoken in the test. The modified rhyme test is basically a word list of 50 words, each word is a one syllable word, and the operation of the test is the speaker is given a word list and they just say, "please

circle the word... bug” if that is the test word. And, the listener is given an answer sheet where they actually get six choices to choose from. And by phonetically balanced test, those choices may be “bug” which would be the correct answer, but the other choices could be “bun, bus, but.” So they may start with the same consonant, have a different vowel and end in a different consonant. And, when you run these tests, based on experience, you’d be amazed, even simple words like that, wearing a respirator, you do get some degradation in speech even without background noise. The idea behind the procedure is there would be listening panel of three subjects that would be that listening panel throughout the test that would be consistent. The speakers would rotate in and out of the tests to give the words. Now the question could be, “Well, how are you testing to make sure that the speakers don’t have a real strong regional dialect? And, how do you know the listeners can actually hear?” According to the NFPA and ANSI standard there are procedures required to certify that people can hear quote unquote “normally” and to make sure that the speakers actually can transmit the words that are to be spoken in the test. So that’s in the background. It’s not on the slide here. The data would be obtained, the speaker would come in; the listeners would be sitting there. If the speaker would have the respirator on, the listeners would have the same respirator on. If the speaker has no respirator on, the listeners will not have the respirator on. You run trials with and without the mask condition to analyze the data. Next slide. I hope this isn’t too confusing. I don’t want to insult anyone’s intelligence, though. I don’t want to... just a minute there. I don’t want to insult anyone’s intelligence, but I’ll just walk through fairly quickly in the

interest of time... the calculation here, this percent calculation, correct calculation right here is right out of a human factors engineering design guide used by the military to... since the listeners are given six choices, you can guess. And you are supposed to guess if you don't know what the word is, okay. The listeners are instructed that you have to make a best guess. And, that's what this equation accounts for as you take the total score out of 50, it would be the number correct minus the number incorrect, divided by 5. And this calculation here is in a reference so it is not just out of the sky. Multiplying by two gives you a score of... a percent score. What we propose to do is to run the trials, get all the trials run and we would calculate the number correct for every listener for each time a test was run with and without the mask. For every listener then, we would average their scores, unmasked and masked. We then propose, and this does parallel what's in NFPA 1981, to calculate what we are calling a performance rating which is really just, each listeners average score with the mask on divided by their average score without the mask times 100. And, then we would average that value... and we are shooting for an average performance rating of greater than 70%. What does that mean? What that means is that 70% value is basically an estimate to say that, with the mask on you speech is degraded by 70%. Speech intelligibility is degraded by 70%. Is that an acceptable value. Some people say it should be higher than that. The 70% is based on empirical data that we have on APRs, some commercial, some military APRs. Next slide. The next test that we felt was important from a user perspective or a wearer perspective is visual field. What is on this slide is pulled straight out of European standards, okay. This was

pulled out of EM 136. This is the exact section. What it is is it's a head form test. Respirator is mounted on a head form. The head form has a light bulb in each eye socket. It has a fixed inter-pupillary distance. The system is what is called a stollapatometer (?), and I believe the only source is Draeger to buy that from right now. But, you can have them custom made because in the specification, all the sizes of everything are supplied... the head form, the size of the perimeter. What this test does is you shine a light bulb through the visor of the respirator. If it's a single visor or dual lens. You have one light bulb off and one light bulb on, so you do a right eye and a left eye. It projects into a parameter and you map, basically, that field of view in 10 degree increments throughout that whole 360 degree field for the left eye and then the right eye. And then you calculate the field of view based on what the natural field of view would be without a mask on, and you'd compare the two, just like before. You would be dividing a mask value divided by the natural or unmasked value, which is a fixed standard in this test. It never changes. It's always the same, and you get a field of view of a masked condition. These requirements are right out of the standard, right in here. And you will notice there are two requirements, one for a visor, which is a full eyepiece, and one for a dual end (?) system. And, the numbers look kind of funny because overall field of view, what they mean by... for field of view would be the entire field of vision with the mask on versus the entire field of vision without the mask is a 70%. This is again allowing a 30% decrement in vision. It's okay. It's acceptable. This overlap value, what that is is if you were to plot left eye's field of view over the top of the right eye field of view, you would get an overlap in the

center area of vision and that center area is a rough estimate for three dimensional stereoscopic viewing, and that is what is meant by overlap. And you will see with a full visor, it's a very high value. It's 80%. With a dual lens, it's gets (?) way down to 20%. What I learned yesterday and today, is these are based on industrial types of masks that usually have a large visor that usually sticks out much further from the eyes just to promote better vision. If we are looking at pseudo-military types of respirators or if somebody wants to just take a military respirator and do this, those values are going to be very, very difficult to meet. So, obviously here, validation testing is going to be very key to set those numbers. This is one other test that came under human factors. It really is more of a material test and it falls in line again with vision and optics. It's an optical... it's an lens abrasion optical haze test and this again is a standard used by the military, but we are actually proposing to adopt just the NFPA 1981 standard. And, we are proposing to adopt that verbatim. As is. That standard relies on other test standards. It uses ASTM D10003 and it's kind of misleading cause it says "luminous transmittance of transparent plastics." This test has been done on polyurethane types of visors also. I have never done this test. I know we do this test in Aberdeen at SBCCOM, and I've been told that 14% value is a reasonable value. I don't have any basis to defend that. I do know that how the haze meter works basically is a light is shined through a sample of the lens and it really measures the deflection of that light after it goes through an aperture of some type, and it's measuring is haze. Now, you then abrade the lens material sample and you re-run the test and you get, usually, a deflection of some of that light if the visor was abraded, and that

deflection is allowed to go up to as high as 14%. Now this lens visor fogging test, this is new to everybody. And, this is a test that was requested... "hey let's propose something" so here's our proposal. In 42 CFR lens visor fogging, frosting, whatever you want to call it, is currently done for SCBAs per the manufacturer's instructions. Yes, my SCBA can go to minus 35 degrees Celsius. So we run a test to see does the visor fog or frost. We wanted to try to scale back a little bit because we thought for APRs we wanted to set those values up front. So the numbers here are really based on some testing we have done for the military and none of these values really mean anything cause I've never done any of this testing with a commercially, off the shelf, type of respirator. Two test conditions... a cold condition and a cool humid condition. We wanted to do it cold condition cause that's the condition where most likely what you're going to see... a cold respirator is going to be taken out of a trunk of a cold car, put on a warm face to go into the warm zone. That's the situation where you're going to normally see immediate fogging of the lens until somebody takes in enough breaths of cold area from the outside to clear the lens surface. The cool, humid condition is a condition that we've tested in house on some of our military respirators where we have been able to actually condensation on the lenses. And, able to try to quantify how that condensation effects vision. Two test participants per test condition, that is a reflection of what's in the 42 CFR so it's the same number of test subjects. Again, this is a human use test. We are proposing to do based on visual acuity tests. Why are we doing this? Currently there is nothing in the 42 CFR now you measure fogging. What's the objective measure of fogging?

There is no objective measure. Could be R-U-DAT (?) visual acuity is an subjective measure and it is to an extent, but it is a measure that is put out there. Someone would argue, why aren't you measuring field of view? We had proposed to put that in there in conjunction with visual acuity and we decided to back off on that. So, again, these are all things that are open for discussion. Each respirator would have to go under a four hour respirator environmental conditioning. In other words, it's going to go into the chamber part (?) the condition it's going to be tested. We are proposing then, once the four hours is up, the volunteer enters the chamber, dons the respirator, we measure visual acuity. That is most likely when we are going to see, at least under the cold condition, something happening on the lenses. Once we have measured visual acuity, the volunteer will then go through a work, rest, work, rest cycle of treadmill walking, and we are proposing to re-evaluate visual acuity after walking periods during each rest period. So there would basically be a visual acuity test on the individual before they would even go in the chamber as a baseline. In the chamber, there would be a visual acuity test right after donning and then one in the middle of a treadmill walk and one at the end of the treadmill walk. The data analysis goes back again to what we are calling this performance rating, where for each measure of visual acuity, we would divide the score with the mask on by that baseline unmasked score to get a performance rating and then we would average performance ratings for each subject, and the three times that it was tested under each condition. And we are proposing again a performance rating of greater or equal to 70%. What does that mean? Under those conditions, you are allowed to have your visual acuity

degraded by 30% and we think that that's fair, that you are still going to be able to see to do your mission. Carbon dioxide was one of the ones that snuck in there at the end, and this was kind of a as needed test. And, I'm going to let Terry go ahead and discuss this and the hydration procedures.

Cloonan: Carbon dioxide hydration. Obviously one of the concerns with carbon dioxide involves a utilization of any type of shrouded ensemble or suit as Mr. Wayne Davis attributed to the fact on how we might test them in a SMARTMAN configuration by cutting him off at the shoulders and implementing that into our systems test. One of our concerns is that when a product is submitted, is there any potentiality for CO₂ poisoning? And, what is the configuration of that product and how is it tested and how can we verify that when an end user dons it that there is not a danger of any type of CO₂ poisoning. Now one of the most important qualifying criteria here is that the facepiece in a full face tight fitting posture without any type of shroud or hood is not going to be considered eligible for a CO₂ test, so there are some minimum requirements. And, if you submit a product to NIOSH that does have a shroud of some type, it would fall under the worst-case configuration that we talked about before, and we would analyze it for a requirement to be tested against CO₂. Now this is essentially all draft and we are working this as we discuss it, but let's just look at it a little more clearer. NIOSH currently has a procedure which looks at carbon dioxide, and it's indicated to your front under the methods column. And that is essentially RCTAPRSTP 0064. Now Jeff Peterson is in the audience. He is a certification specialist from Morgantown who can clarify any real detailed questions about this STP and further on, looking

at the procedure, we want to emphasize that, again, that's it's optional. It's based on configuration of the application. But it is an adaptation of the Oakland Circuit SCBA test and that stands as good solid reason to look at it from a negative pressure perspective. It's a head form test. Now CO₂ is measured at the mouth during inhalation for three respiratory cycles, and now, of course, the oxygen concentration is a very important variable here and has to be greater than 19.5%. Exhaled air contains approximately 5% CO₂ and that's a clarifying criteria I am sure you are well familiar with. And the last standard there on the procedure is, it's applicability to the secondary neck dam (?) or shrouded neck piece on a non-powered... I say again, non-powered, gas mask with a tight fitting neck seal. Now, we can approach that last statement from two perspectives. The NIOSH protocol has essentially two procedures, 0063 and 0064. One of them looks at a powered tapper. The other looks at a tapper in a non-powered configuration. So it is important that we stress that this is a non-powered configuration. Now the maximum requirement, is the maximum allowable average inhaled CO₂ concentration less or equal to 2%. The generation of a lineal deflection plot allows us to look at the results of a three test respirator panel and we look at a calibration curve, we do some interpolation from that, we come up with a figure that supports a concentration less than 2%. Jeff, do you want to elaborate on that at all or do you feel that pretty much touches the basis of it? (pause) Hydration is another standard that we're... a human factor that we are kind of looking at in terms of being an optional requirement. As you know, from an industrial perspective, there is not a lot of drinking tube assemblies in industrial related products. And, NIOSH

does in fact have an industrial leakage test. And, NIOSH does in fact look at it from a mechanical perspective, and realizes the relevancy of a drinking tube. It does not necessarily look at it from a toxicology perspective, nor does it look at it from a systems perspective. So, on a hydration area of concern, we want to look at this from a three point analysis. We want to look at the NIOSH perspective, which is RSCTAPRSTP 0014 and we want to incorporate the US Army CAT methods out of Lee Campbell's lab as well as systems test to incorporate a drinking device into the overall system's test. We want to look at the ability to analyze the drinking tube leakage on dry, drinking tube valves, seats and seals. That essentially is the current NIOSH procedure. We want to then analyze contamination levels in the water over a 24 hour period, and that's a current chemical analysis team method that's in effect at Lee's lab right as we speak. The dry drinking devices analyzed separately under GB HD SMARTMAN system's testing. What that means is, when you go into the systems mode and you say that you have a canteen device that supports the drinking system that's on a submitted respirator, that canteen is dry and it is exposed to the routine contamination source in the SMARTMAN and it contributes or de-contributes from the breathing zone contamination. The current NIOSH method is 75 millimeters of water, via the GL Brighter (?) bubbler and that's pretty straight forward. The CAT method involves standard water samples being taken out of defined time and we can further clarify that, but it is a beneficial test, because that provides whether or not there is a toxicology leakage into the water system. All right. And those values are based upon CHPPM Mill Spec Usambered (?) values. The overall requirements are nine

trials, three trials per respirator, and the primary leakage concern is between the valve and the valve seat, a naturalnaucic (?) seed (?), 30 milliliters per minute.

Next slides. In summary, we looked at a maximum of eight human factors test with a minimum of six. Six basic human factors, that would five plus the LRPL (?). We have two optional human factors tests. Verification testing is in accordance with the NIOSH test matrix that is to be published. Human factors testing is coupled with systems environmental testing, so you can understand why that would be a very relevant situation and Andy pointed that out to us in terms of overall perspective. Our exhalation resistance, that is something that you may want to look at the provide some significant feedback on. Traditionally 20 millimeters has been a NIOSH position. The ability to go to 26 is going to provide a better enhanced respirator. You know, we appreciate your feedback in that area. Communications and fogging performance ratings, they are pretty much going to stay at 70%. But, I'm an advocate of 90%. But who is an advocate of 100%? The EN (?) perspective in this area as related to earlier at 100% in other areas.

Hydration... it's optional of course, but it's going to examine leakage, H2O analysis and a live agent test. The CO2 test again is optional and it's based upon the application configuration. It is based upon the worst case configuration... if you submit it with a butyl shroud or you submit it with some other device, whatever it's made out of, we have to take that in consideration. If you have a neck core, that may in fact cause some type of buildup, we have to consider that. So that's a viable factor. That overall covers the summary on the CBR and APR human factors. Subject to your questions. (pause)

Berndtsson: Goran Berndtsson from SEA, I am sorry if I interrupt your time schedule here, but it's a lot of important things we need to talk about. Is there any particular reason why you have chosen two different inhalation resistant machine (?) style and textile (...inaudible...) filters?

Cloonan: That's a standard NIOSH procedure for those types of devices. We really don't want to deviate from the current NIOSH protocol when it comes to negative pressure, why? The use of limitations requires that support the United States manufacturer's instructions is very important. How we utilize this product in support of domestic pre-panance on United States soil falls back under the NIOSH CFR use limitations. So, we really don't want to deviate from that but we would accept any reliable data that can persuade us to go into other numbers.

Berndtsson: I think that we started this discussion some... a year ago and I was told that a lot of the data here was to be based on physiological requirements and it should be not the designer's (...inaudible...) standard. I mean if we... things like this is very important. If it doesn't have a physiological reason, why have two numbers? No? For example. The other thing is that we are talking about exhalation resistance and all of this is measured at 85 liters and of course at 85 liters exhalation resistance you probably don't have a problem from going 26 to 20 millimeters or 20 to 26 millimeters. However, if the valve seats are too small and you increase your flow (?) to them, you will have a dramatic increase in exhalation resistance as the flow goes up. So it calls, really, for testing it at more than one flow.

Caretti: I won't argue with your statement Goran, but you bring up that if, if, if... and the 85 is just the standard value. You're right, if you increase flow rates, usually

resistance is flow dependent, but I would doubt a manufacturer, if, if, if, is going to make a lower valve... smaller valve seats in their development of the respirator. As far as the 26, it's only base on 85, correct. It's all for discussion.

Berndtsson: That's what we are doing here.

Caretti: You also need to also... if you're going to go with another flow rate, you change everything else. So, I mean, those are good points.

Berndtsson: I think it is important to consider that, because in the first place (?) we have got... we are building this for first responders and recovery workers, is that correct? Is this standard for first responders and recovery workers?

Cloonan: Recovery workers? The standard goal for the negative pressure product is emergency responders, yeah.

Berndtsson: Emergency responders, but people who cleaned up in the World Trade Center site, for example. People who was reporting in the (...inaudible...)...

Cloonan: Under crisis management, that's correct.

Berndtsson: That's correct, yeah. So, they were working pretty long hours under pretty tough conditions, in other words, breathing pretty heavily too, though, huh?

Cloonan: Well, that's debatable. I was there. I didn't see too many of them breathing too heavy. They were moving pretty slow, but anyhow...

Berndtsson: This is the consideration we have to take and we have to look more on the physiological factor. There is known data presented by David and particular Arthur Jones (?) and about restriction or reduction of the capability of man when you start getting high resistance in both inhalation exhalation, particularly inhalation resistance. We should take some of this consideration on board now

when we are writing a standard. The other thing I was going to comment on, is I do believe that... and correct me if I'm wrong here now, but the NIOSH standard for full face mask does not have an impact requirement on the lens... is that correct?

(Talking on the distance... inaudible...)

... okay, in that case...

Cloonan: Okay, sir. Thank you very much.

Caretti: Goran, there is data on inhalation by itself and exhalation by itself, but there is no data on changing both of them at the same time as of yet.

Graham: I'm Steve Graham with the US Army Center on Health Promotion and Preventive Medicine. The test with the Mustard and the drinking canteen and the rehydration systems. Is there any need to look at decon and then testing it again with the Mustard contamination. Cause I can view that some of these responders may be coming out of the hot zone through decon, then going back in and reusing or resupplying their canteens. I just wonder if that's an issue and as far as policy, I just had a question that... do you think at some point NIOSH might look at reviewing the policy to change the APF from 50 on a full face that might be used with a shroud or a hood?

Cloonan: So essentially you are asking for decontamination and then a live agent exposure again, and then an analysis of the canteen device. And then you are looking at a proposal or an answer or a position on the ability to change the APF at 50. Yes sir?

Berndtsson: Sorry to come back up again. Goran Berndtsson for your record.

Cloonan: No problem. Come up as many times as you like.

Berndtsson: Carbon dioxide. Carbon dioxide. It's very important because the carbon dioxide is the trigger for your next breath. (...inaudible..) We are talking about peak flows here, and if you have respirators with no (?) in the mask and if you don't have a requirement of having carbon dioxide for all devices, you could have a problem with the (...inaudible..) devices (...inaudible..) too. And that is also going to increase your breathing rate and your load on the person. I mean it is something I think you should consider for all devices, not only for the ones who have the shroud or whatever.

Cloonan: You're saying mandatory nose cup or did I miss something there?

Berndtsson: Mandatory requirement of carbon dioxide. If you can do it without a nose cap that is fine, but if you can't then you have to have it, yes?

Cloonan: Okay.

Pfreim: Dale Pfreim, ICS. Terry, going into the haze lens abrasion requirement that you have outlined, you've got a criteria for 14% post-abrasion. Do you plan on having a criteria for substrate haze as received, similar to cartridge as received.

Cloonan: That's a good question. I'm not sure exactly what the pre-requirement is when it is tested before the test starts.

Pfreim: I suggest that you also put a requirement in for pre-abrasion criteria for forward scattered light in addition to post-abrasion.

Cloonan: I think some of that is in the ASTM...

M: I do believe it is.

Pfreim: ASTM D1003 is solely a test methodology. There is no criteria.

M: I apologize, like I said, if this test is not... I can tell you that I know based on data that I've seen, like a polycarbonate lens out of the box is usually about a 2% haze value and a polyurethane is about a 3% haze value, but that could be a number, a ball park number.

Pfriem: We need to specify it. No matter...

Cloonan: That's a very good point.

Pfriem: Also, in the haze test, the NFPA criteria, that abrasion method, as you know, it demands a flat substrate, which in most scenarios what you are going to get is a surrogate emulator of the lens and what our experience has is that, well, there's a fair percentage of chances that the geometries of the final lens don't match the coating conditions of a flat substrate to which the manufacturer is going to submit as a surrogate, therefore, since the geometries of that lens after it is coated aren't flat, your abrasion characteristics are going to be different. It's just something you might want to consider. Because that test does demand a surrogate and an emulator... it can only test a flat substrate. Also, in addition your first slide said optics as a generality, but yet you are really only looking now for post-haze after abrasion. Will there be any requirements for refractive astigmatic or prismatic power criteria?

Cloonan: Currently at this time, no.

Pfriem: You may want to look at that as well. Similar to what you have on... most of the military masks RFPs SOWs. In addition to haze, there is no requirements for neutrality and chromaticity characteristics which are going to come into play with any kind of outcerts (?) that may be a part of these masks, or they may be finished

standardly with some kind of non-neutrality characteristics and for a first responder, going into an unknown condition, chromaticity and neutrality is going to be important. It should be probably in the specification.

Cloonan: Your point on outcerts (?) is very well taken.

Pfriem: Finally, the fogging... I think you're going to find, and if you go back to what kind of haze you're looking for and the amount of denigration you are willing to accept on the fogging test being 30% after 12 minutes at a 14% haze value, if you correlate that on a snellin (?) test of individuals, you'll find that those don't correlate. So, I would ask that you re-evaluate your 14% criteria.

Cloonan: Well, the haze is based on the material of the optics (?) itself, where the fogging test is a human use test. And to correlate those two is not as simple as you are implying.

Pfriem: Well the correlation study would be quite simple to do.

Cloonan: Well, actually you are almost comparing apples and oranges in the sense of the haze as using an objective measure of the optics of the lens where the visual acuity test is a subjective response from the person. Yeah, you can correlate, you're right...

Pfriem: But the reason you have a test is to... the reason you have a haze test is to quantify the amount of visual degradation that you're going to get on a second derivative function on line contrast sensitivity. In other words, how can I resolve an object? And it directly correlates to how I can resolve that object, either on a snellin (?) eye chart, on a circle chart, whatever. And the performance criteria, what you are looking for, to which the person is seeing through... what he's going

to be subject to after this fogging assessment and also what you are willing to allow after post-haze abrasion, is what I'm saying, those two don't correlate. So you may want to look at that. Cause you're not asking for the same performance parameters. Then one other subject on the fogging assessment. You're doing the assessment after a 12 minute scenario of exercise, non-exercise, is when you are reassessing the visual acuity of the live person. And, although I have not performed this specific scenario, but intend to, what do you find, what is the fallout percentage that you find after 12 minutes, because our experience with hydrophilic type coatings is after two-three minutes, you've more or less reached normalization, stabilization period and at 30% degradation, you know, everything is going to fall into play and you are not going to have any fallout, however, with 12 minutes and you are not doing this in sutoo (?) you are doing it after the fact. You are allowing for 12 minutes of up to 100% visual denigration. So you've got 12 minutes of blindness you are allowing for.

M: Well, the timeframe is kind of... what is not percentage... it's also to see, well, if you do have initial fogging, will the lens clear in that timeframe.

Pfriem: 12 minutes is a lot of time.

M: And you're right, it clears fairly quickly, and the 12 minutes was... quite honestly in compromise to the 30 minutes in 42 CFR.

Pfriem: I would suggest you look at that issue as well.

M: Then... that's what validation testing has to be explored.

Pfriem: That's the end of my comments.

M: What was your perspective on 30?

Pfriem: Forget it. I mean, five minutes... five minutes most coatings are going to stabilize. What you should be looking at is the anti-fog performance within the first three to five minutes. There you are going to separate the performance variability of these coatings both from a cold to hot in a fogging environment... 12 minutes is really senseless and I think your data will even show that cause you're not going to see any fallout especially at a 30% denigration rate after 12 minutes.

M: The data is not senseless. But the data for the very cold environment with longer duration is more from a military perspective in looking where the icing is occurring over time. So that's why it was the 12 minute timeframe. No, all your points are very valid points.

Pfriem: And I'll try to look at these issues myself more closely and get you some hard data on the issues where it's just conceptual. But the other concepts, there is hard data available. Thanks a lot.

M: Thank you.

Maughan: Wes Maughan from AEGIS, North America. You are probably not expecting to hear what I am about to say. I think, having worn some of this equipment, in various, like many of the audience, I think the 30% degradation on visual is way too low a standard. You operate in an environment, you're first responders, you're military, whatever the target audience is for the equipment being tested, visual is how they work, and a 30% I think is way too low a threshold. We want systems that maintain as close to a 100% as is reasonable to expect and deliverable from a manufacturing perspective. The other issue is, I think, you talked about the cold environment. I'll use the Gulf Coast as a perfect example. It can be 95 and 95 and

you don't do something and it will smoke on you in a nanosecond, okay, so I just want you... I'm not going to tell you how, that's your guy's job to take a look at that, but I think there might be... it's worth looking at additional scenarios that represent a real world environment that we are going to operate this equipment in and expect it to perform, so that's all I have to thank you.

M: Got time for one more, right John?

Heins: Bodo Heins again. I also want to comment on the exhalation resistance. If you are requiring 26 millimeter of water gauge (?) then you fence out as possibility that a canister can also be abraded (?) through in and out and sometimes will have to increase the service time. And, if you stay to the 26 millimeter then you require an exhalation valve which is not every time necessary. Second comment, and also why have the exhalation resistances in this case to be less than the SCBA standard which is as far as I know, 65. Second... is he (?) allowed 2% CO₂ buildup (?). It's a very low value and if you look into other standards you will see that you are sometimes much higher where it is allowed and if you won't increase it then you should differ between a short term respirator and a long term respirator. For a short term respirator it doesn't mind if you have a 4 or 5% CO₂, you will never realize it yourself. So, when you are staying to the 2%, then you should differ between short and long service time. Thank you.

M: Thank you very much. To be followed by Frank Payla and Paul Gardner. (pause)

Payla: Thank you Terry and Dave. Good morning, my name is Frank Payla and I would like to introduce a colleague, Mr. Paul Gardner from SBCCOM. We are going to present the proposed NIOSH concept to test the CBRM APR rough handling and

durability testing. The overview here is we will start with a... we'll talk about the proposed, the purpose and goals and assumptions and types of tests and rationale for the tests. Next slide. For the purpose of this test is to test the APR for durability and rough handling and to detect any initial life cycle failure modes that may occur from typical use. These APRs will be mostly worn by multi discipline emergency responders, including fire fighters, emergency medical technicians, decon crews and medical staff, so it's very difficult to predict the operational mission and what environmental and transportation conditions they'll be stored in once they are issued to these responders. The goal is to ensure the CBRM APRs provide adequate respiratory protection after being subject to normal, what we feel is normal transportation, storage and rough handling conditions induced by the user and detect any initial life cycle failure modes. Next slide. When we were developing these test standards for the durability, obviously we had to take some assumptions into account. So, some of the assumptions were made about the operational conditions of the APR. These tests represent conditions induced by the user that APR may experience from the point of issue. In other words, we feel that manufacturing, packaging is adequate during transportation and storage, up unto the point where the user receives it and they take it on hand and they'll use it an store it according to their conditions. Again, they mainly represent storage conditions imposed, such as in back of a trunk of a police car or stored in a fire truck or a canister being dropped. These tests, basically, they do not represent the actual conditions in the operation mode of when these APRs are perhaps while they are being worn, maybe being bounced up against an ambulance or maybe in

the police mode, maybe in the low crawl or a shooting or any of those or looking at operational requirements as far as interfacing with other equipment. They basically pertain to a lot of the storage. These APRs will be tested in the ready to use configuration as recommended by the manufacturer. This could be in the loose (?), could be in a carrier or some sort of storage container. And, Mike touched on it earlier in his discussion about the canisters will not be put on the respirators until an emergency situation occurs and the responders will be required to put the canisters on the facepiece, don the respirators and go into meet the situation. Although, this occurs, there is still responsibility placed upon the users that they must maintain in the spec their respirators according to title OSHA title 29 CFR 1910, so they still have an obligation to do that. We believe this is a reasonable use condition for APR storage by the users and their requirement for manufacturers to design their respirators to meet for these tests. Also the manufacturers to provide maintenance and care instructions to define a way for the users to inspect and test the APRs to ensure proper operation when needed. Again, these respirators are not for industrial setting, but for emergency CBRM use. Next slide. With the assumptions continued here. The test conditions are tailored to realistic US meteorological weather conditions, US roadway conditions, and typical first responders use for rough handling conditions. We are not testing worst case, and a lot of these conditions were chosen from the MIL STD A10F and there was extensive studies and work done by the military to go ahead and document weather conditions throughout the world. Most of these conditions for, especially the cold conditions will cover the European, except for

the Article circle and even the hot weather conditions in the United States are very hot. I think other hotter conditions would be such as the Sahara Desert, but those were pretty much extremes. The tests are not intended to represent the entire life cycle but to rather identify potential initial life cycle failure modes. We used MIL SPEC A10 as a principle guidance document because most of the test and procedures were already established. Again, I must stress that these tests were not trying to represent military use conditions, but they were tailored to what we feel was normal first responder use and reasonable conditions within practical... MIL STD... I know a lot of people think that if... since we are using military, MIL STD we are automatically testing our... the respirators to guide our standards to make it as rugged as the military respirators. We are really not. MIL STD A10 emphasizes that you should tailor your tests to indicate the items, what the items will actually be subjected to. What kinds... types of platforms the items will be on. Next slide. This time... Mr. Gardner, do you want to go into further detail on the test protocol?

Gardner: Thanks, Frank. Frank mentioned that I work at SBCCOM. I work in the respirator protection technology team there under the research director and this is actually a new area of mine. I've been about a little bit in this area, but don't know all the specifics and details. I know the military does all these durability type of tests. But for this draft, the test protocol is pretty straightforward actually. And, what I'd like to emphasize... well Frank did have to emphasis... that these were tailored to the... what we thought as the initial type of use environment, that the first responders would experience as far as the items concerned in a storage

configuration. Breaking down for environmental storage conditions, we have a high temperature, a low temperature and humidity. Again, we go to A10 method 501 for the high temperature. It's a diurnal cycle and it varies from 35 degrees to 71 degrees centigrade. It's a 24 hour cycle, diurnal. It's for three weeks... three weeks... well, I'll go into rationale later, but that was chosen for... based on experience. Low temperature.. this is method 502.4 out of A10F. Basic cold. It's held at a constant temperature. It can be done various ways, but we elected to use just a constant temperature, three days exposure. Humidity... this actually comes from the previous version of that document, E, the profile and it could be found in the methods 507.3. It's a natural diurnal humidity cycle and the (... inaudible...) for five days. These are minimum values recommended by the regulation. And actually this E... humidity method is less than what's in the current version F so it's a less extreme version than what occurs in the current version of A10. Next slide. As far as transportation, vibration...again we are drawing from the MIL STD there method 514. It's done three axis (?) vibration separately. And there is 12 hours per axis. It's done on a constrain mode and this total 36 hours, 3 times 12 is representative of 12,000 miles transported US roadways and vehicles. Next slide. The drop test, well, that's just... it's no standard procedure, but we sort of adopted what is traditionally done and modified somewhat. Simply a three foot drop test, but we do repetitions, two repetitions as each canister is only dropped once, once, so you need a total of six filters to do the test. And it is dropped two times each axis, so that's a total of six drops, six filters. All right. A little bit of rationale to go over real quickly. When we were exploring what we could do as

a... I mean, the whole purpose of these tests is to give us a relatively comfort level of the durability of these items. Not to design a test that would duplicate the whole life cycle. We are just looking at initial life cycle failure modes that we could potentially... the user may experience these items in storage in the first few months, basically. We are relying on regular inspections and maintenance programs that... to identify items that may have some sort of problem that may come along through it's use in some specific environment. Those uses are going to vary tremendously in the conditioning, and some people have these in drawers and never touch them, other people will be banging them around, throwing them around, so again, these tests were tailored to really minimum requirements as recommended in AD10 (?), not military type of tests exposures and durability requirements. And, for US environment, US only, not global. The high temperature... simulate a storage into a vehicle trunk that's under induced conditions. South... the diurnal cycles representative of the southwest in the summertime. And we picked three weeks based on our experience on traditional mass materials and when failures do occur under these type of environment storage. The low temperature is a minimal requirement, basic cold condition that's in AD10 (?). Doesn't cover the extremes. Alaska, I think it may cover Juno or something, but that's about as far as it goes into Alaska... Minnesota and those areas. But those are from climatic profiles that are documented in AD10F (?). And, it's the three days is the minimum exposure period recommend. Committees, again, that comes out of E, that's a typo there. It should be A10E and duration is based on what they say is a "quick look" at the item to see if there may be...

identify any potential failure mechanisms due to humidity and storage. Vibration again is to simulate 12,000 miles on US roadways and rough drop... the rough handling, we felt we needed something for the canister. We felt that the likely scenario when these things are going to be assembled, since they are going to separate, the filter is going to be separate from the mask typically, in the manufacture ready use configuration, and they... the user would have to assemble them and if they did drop them, which is a lot likely we want to get an indication of some durability on that canister. We were concerned that by not having something in there that possibility we were trying to reduce that risk. Next slide. Now what Andy was asking, as far as the sequence of these tests or these exposure conditions, it would following, hot temperature, low temperature, humidity, just like I'd briefed him, vibration, and then it would go into the performance requirement testing, which would be system gas life testing, excuse me, system agent testing, canister gas life testing, I believe resistance and then efficiency filtration, particularly efficiency DOP testing. 72 is a typo; it really should be 78 because there are six more canisters, would be (...inaudible...) we call them would be associated with these six facepieces which would be put in separately. So filters are separate in packed filters and then they would go through the various tests at the end of the cycle, at the end of exposure period. This is the intent. That's what we are putting out as a drop. For the drop test would be separate canisters. They wouldn't be pre conditioned at all, they would just be simply... experience rough handling drop test and then we do some sort of... two tests we thought and we hadn't clearly defined as far as this organic vapor, if its

cyclohexane (?) whatever, how long would the test be, the regular gas life test or the shortened version of it. We are really looking for channeling effects.

Something that would really indicate some kind of loss in integrity, not gas life capacity, that will be done obviously in these tests. So the time frames...

(END OF TAPE 4, SIDE A)

... tests. Those would be done here. Just want to see if there's any loss of integrity, basically after a drop, on each filter. Next slide. And this just shows the matrix. Everything sort of wrapped together. Convenient reference points for all... reference chart for those various methods that we are proposing. Some footnotes. Basically what I just discussed. If I didn't mention, was the six filter drop test would be unpackaged conditions, okay. When they are put into... on the... through the environment sequence test, they would be packaged, the filters. That's what assume (?) whatever the manufacturer comes in and packages the filter with that item, and they would put in the ready to use... whatever the manufacturer determines the best way to package the item for the user, not to ship it, but for the user to use it, how they want it, if it's in a carrying case or just lose, that's up to them, they can come in and put it... but it's gonna be put through this test. In vibration they're going to be unrestrained, I don't think I mentioned that, but it would be unrestrained on a platform with a perimeter to keep them from falling off on the end, but they would come in contact with each other, so you have going around... vibration. Anyhow, that sums it up. I... Frank and I will take any questions that you have right now. (pause)

Tape 4, 6/19/02

Parker: Jay Parker with Bullard. Just a quick question on the cartridge, rough handling. Are you going to look for release of carbon from the canister or cartridge.

Gardner: Are you talking about a finds (?) test... to see what it finds or generated from that or are you talking about purely a visible inspection... or if there's any lose carbon coming out from the...

Parker: Well I thought the Europeans do that in their mechanical strength test, that if they do see any visual evidence of...

Gardner: Collected on a filter or paper.

Parker: Literally visual or in the packaging actually is typically how that's evaluated.

Gardner: But it's not a shaker test. It's not on a shaker mechanism? I'm not familiar with that standard. There's no mechanical shaker.

Parker: Right, but you are dropping it and...

Gardner: And then you are looking at it.

Parker: Right.

Gardner: Okay. Just want to clarify that.

M: My question concerns something that Alex said earlier where he was looking for an eight second don in his protection factor testing. As I understand it from everything that's been said here, you're expecting the user to have this mask without filters attached in his carrier with the filter packaged, because it has to be packaged to keep it dry otherwise your as received filter tests don't really make much sense.

Gardner: Correct.

M: So it doesn't seem a awful lot of sense in having in your protection factor tests an eight second donning time where you've got to take the filter out of it's packages, put it on the mask, take the mask out... you've taken the mask out the carrier... go through all that sequence in eight seconds. The Army ... they're only supposed to take it out of their carrier in nine seconds and you've got the filters attached already. So there's a little bit of a mismatch there, I think.

Gardner: I'm not sure... someone else can answer that. I'm not sure of the eight... anybody's locked in on eight seconds. I think I saw something that was put up there as what the military does now...

M: What I'm saying is I don't think in Alex's protection factor testing for this type of device where he's... the scenario is that the filters are not even going to get attached to the mask. You need a timed donning procedure in your protection factor tests if the scenario that you've outlined is going to be...

M: Good point. Well taken. Thank you.

Gardner: I don't disagree with that.

Berndtsson: Goran Berndtsson from the SEA. I don't know if I misunderstood. You said the... can you clarify, Paul, again, you said that you are going to do on this vibration test, the filters would be sitting on a plate.

Gardner: Sitting on a platform, yes.

Berndtsson: I thought Mike said before that this was the purpose was that it was going to be tested as it was applied. So if the manufacturer was applying it in a bag with field test (...inaudible...) so can you clarify that?

Tape 4, 6/19/02

M: Right, I mean, if that's the recommended use configuration, let's say for an entire APR system, and if it's the bag, yes, we will test them as such.

Gardner: But not to find any packaging requirements or... I mean that's up to the manufacturer, so if they...

Berndtsson: To protect... say for example that they supply a kit for the police car which has a special bag with... to protect it for the road because the purpose there was to simulate (...inaudible...). If you don't take it out of the package and putting it on this vibration test, aren't you doing something different to what you said before then?

M: Okay, so you are saying that... so there would be spare filters, right? We were looking at taking the (...inaudible...)... if you have one system test and let's say for instance if your respirator was in a mask carrier...

Gardner: We have a system... there's six items that go through the system test. They will have their associated canisters somewhere packaged with them. I don't know that depends on the manufacturer. They will be very close to that item.

Berndtsson: You don't understand my question. I mean, am I right to say that the purpose of it is... was to say if the equipment was arriving on a rough road in the United States...

Gardner: To simulate road miles.

Berndtsson: And is not going to be unpacked up until it is going to be used, is that correct?

Gardner: Unpackaged...?

Berndtsson: In other words, the filter is going to be staying in it's package and it will not be that you break the package of the filter when you are going to put it into the mask for using it. Is that correct?

M: What it is is... when there is the manufacturing packaging that when you ship to the user, excuse me, and then they'll go ahead and they'll take it out of the manufacturing pack and put it in the ready to use configuration, as you recommend, and then they'll go ahead and put it in the back of your police care or fire truck or ambulance or whatever, and that's what this testing is going to represent. Okay. How you define it. Now, the filters are not going to be opened, per se, and exposed to the air.

Berndtsson: I understand that, but didn't Paul say that we take it... we packing... when we putting it on the vibration test it will be the filter and a couple of filters sitting on the plate at the same time. Isn't that contradictory to what you were saying before then?

Gardner: No, it's in the ready to use configuration.

M: It's ready to use configuration. What we are looking at. We are looking at these systems in the ready to use configuration on a platform as replicating the test as the first responder would have them on their vehicle.

Gardner: I mean, as far as the separate filters, I'm not sure.

Berndtsson: (walking away from mike) I get all confused because you are saying...
(...inaudible...)

Gardner: No, no it's not separate. It's in the ready to use configuration. Well, we don't know the manufacturer may come with a package with four or five filters in it and

it's packed... or it may not even come next to the filter. So it just depends on the way it comes to us.

Berndtsson: (away from the mike) (...inaudible...)

Gardner: Right, right. It's just that we... I don't know yet, we haven't worked out the details. I don't know if it will require the mask actually be in that box. It all depends, you know, on how it's configured. You know, why would you have to (...inaudible...) masks, respirators. We just need a filter in that pack instead, you know, I'm not sure. It depends.

M: I think what we are talking about here is the first responder has a respirator and he keeps it in the trunk of his car. We will test it in that configuration, that it's normally stored in the trunk of the car. It might be in an over pack with the filter separate from the mask and kept that way in a zippered container or something and that's how we would test it in the vibration mode. Does that answer your question?

Berndtsson: (away from the mike) Yes, but that (...inaudible...)

M: No, but that's what he meant I believe.

Gardner: I'm not quite sure what I said, but... the intend was, yes, it's a ready to use configuration.

Heins: Excuse me, it's Bodo Heins again, I think the confusion is what is ready for use.

Gardner: Right.

Heins: Ready for use is normally that's the custom (?) it only has to pick it... fit it to his face and then breath through that. You need something different I think.

Gardner: We struggle with that. We struggled that term. Anybody come up with a better term? Put it in please.

M: We're just thinking that the... he's not going to be carrying it around in the back of his police car the way that it is shipped from you. Maybe it will. Maybe that's how you recommend it to be stored in the back of the car.

Heins: ... not to add something, then it's not ready for use.

Gardner: No that's not the best terminology probably, but... we're trying to find something.

Rockhold: My name is Jarrett from Onyx, I'm a user. I feel like I just went through drug rehab. My question is, in your rough handling procedures, and I think this kind of goes with everything. The confusion when, I believe Mike, the first presentation when along, said he was going to test the canisters... as they were freshly opened... out of the package and make sure that they were able to sustain all the tests. Now you guys are saying the safe handling and the storage of them is for the material... err, for the canisters to actually still be enclosed... you guys are going to test them that way. In an ideal world, they're... the canisters are still going to be inside the sealed package. If this was an ideal world, we wouldn't be having this discussion here today. The first responder is going to be actually, more than likely, have the canister attached to the mask, yet you are going to do the rough handling test with the canisters dis-attached from the mask. That's the extra weight of the mask, that it's gonna be that way in the car... I would recommend that you might want to have the canisters attached to the mask and drop test it that way, because that's how the responders are going to carry it in their trunk.

M: Yeah. Well the systems... on the six that are going to be tests, the canisters will be attached to that, I mean... okay, they'll be with it... they won't be attached, but they will be within the carrier.

Rockmore: Right, but you gotta realize that you're gonna have... I'm not going taking away from anyone, but you're going to have a police officer in there who may not... his first job is not... is to protect, but as a scared (?) factor because he's not... that's not his job on a day to day basis as to protect himself from hazardous materials... he's gonna probably, pre-readily have those canisters attached to his mask.

Gardner: That's a good point. I just want to let you know we do consider... we do recognize that and as... very much part of our discussions. I don't know... well maybe Jon has a... what they end up... why we just went that way, I mean...

Dower: This is John Dower, NIOSH. One of the issues that we are going to be dealing with is the standards and the manufacturers are only going to be working with this because this is a common issue that we both share... is how people handle these respirators once they are provided to them from the time that they receive them to the time that they actually put them into use. And, one of the information that those that are in the manufacturing community know, is that once you open the filter to the ambient environment, it begins to degrade and it's protections begin to change. And, depending upon what are the parameters on how that environment is changing is going to have a great effect on what's going to be the protection capacity of that filter once that it's going to be employed. So, one of the issues that we will be dealing with in this standard are the cautions and the limitations and the restrictions of use that try to guide the users to know... that's not the way

you ought to be storing the facepiece. And, to that end, we would welcome any assistance you can give us with how we ought to phrase that wording and guide the end users to really change that mindset. Okay?

Reed: Afternoon, Robert Reed, Center for (...inaudible...) Preparedness, Department of Justice Programs. Just a couple of questions, and I've been watching the testing procedures in this first responder... training first responders just a couple of questions. And, I think this is probably in your alley. When you are talking about rough handling tests, buckle assemblies... buckle assemblies come in different qualities and variations. Elasticity, the head band too. I've actually seen certain masks... I'm not going to say any brand name, but when they've actually put it on and pull on the tab, you can actually see whichever configuration seat (?) that's actually popped off... rough handling. Okay, that's... just something I did see, and then once again, sweat (?) or elasticity of the head piece and there's many different configurations out there from the manufacturers, nobody's addressed that. Also, impact on the lens... we're gonna have people out there... SWAT teams... they are going to be low crawling on the ground, possibly hit that lens or the outcert (?) and damage that lens and I haven't seen that addressed. And, also the last issue is... perfect world once again, you have the canister in the package... you put that on, and understand why, degrading of the... the humidity, heat, whatever it may be, and I understand the process behind that, but here's something else too... it's going to get thrown in the trunk of the vehicle. It's going to be in the carrier or in a package. Now they have a tendency over heat and time to lose their flexibility, so is there going to be any kind of test incorporated

where, worst case scenario, it sat in a trunk of a car... a squad car for three years and then they go to pull it out and it no longer fits the face.

Dower: Well, you see that's what we are trying to replicate. But, sitting in it for three years is not an answer too, because they do need to go ahead and do care and maintenance on this. I mean, there is still... still an obligation to do that. And, then as far as the other one, as you were saying, that was what we are talking about... you're talking about the operational use, well... which is very difficult to do because there is just so many disciplines out there to go ahead there and go through this battery of tests. I mean, it almost sounds like a military respirator testing, because they have to go ahead there.. they have to look at their mission or operational requirement, what other equipment do they interface with... it's so vast, so we're trying to touch on some of these tests for the durability of the respirator.

Gardner: Well, it really is a trade off and it's not, you know, we are not looking at life cycle type of... we are really doing something that gives a comfort level that we have a certain degree of acceptable durability of these items. It's not meant to simulate any kind of... all the use and rough handling... that is not the intent of the protocol we are proposing here. I understand... we looked at that, you know, it's really... (...inaudible...) when you start looking at all types of test you can do, it sounds almost like a military... well, yeah, impact, no.... well, that's... yeah, that's different, as far as environmental storage... this is just sort of storage. It wasn't really a rough handling. The only rough handling quote we have is the drop test of the filter. But the impact's different... impact is a different issue. We

are at... somebody mentioned that earlier in a comment and we're going to look at that.

M: Take one more please.

M: Thank you.

Becker: Okay. Adam Becker (?) from Marine Corps Systems Command. I have a... one quick question which is just a little off topic, but I haven't heard it addressed... is the decontamination compatibility of the face blank (?) materials, whether the... if it's covered by current regulations for this industry or whether the masks are soon to be disposable after a single use. If you could address that, please, thanks.

Dower: We were... (pause, then laughter). Okay. That was going to be as recommended by the manufacturer. I know there is different interest out there... a lot of the user community... don't want to go ahead there and have decon... or disposal procedures after every use, they want to be able to reuse it, so again, this would be based on a lot of the manufacturer's input.

Gardner: But... wasn't the intend... was we thought this was going to be one time use as far as the filter was concerned, definitely. (pause) Face piece... I don't know... we've talked... we've hashed that back and forth, I mean... if it's going to be used again, then they got decon issue. We was looking at the practicability of somebody actually thought they got exposed. They identified, let's say, Mustard... but would they really want to use that respirator again afterwards.

M: I think that goes back to where we were discussing yesterday that, you know, in the comments that were received from the manufacturers as well, that, you know, decon is something that we're going to have to work together over the long term

to address. I think kind of it at this point, we are running about an hour behind schedule. I think that we should probably break for lunch. Come back about quarter after one and we'll try to get through the non-controversial interchangeability issue... (laughter)... and... we'll roll from there.

(break) (long pause on tape)

M: Okay, I think what we're going to do, since it's 1:20, we're going to get started. Just wanted to advise you that we're going to make a little change on the agenda, even though we are 45 minutes behind schedule... as far as the attendee presentations go, we're going to move... Ron Herring is going to follow... Bob Weber from 3M, and then Evan Hensley, and we're going to take a short 10 minute break and then... (...inaudible...) will do a presentation and we'll just need a few minutes of that time to get set-up, so we'll take a break following Evan's presentation. One thing that we wanted to mention, I guess, with one of the questions that was raised at the end of the session this morning, was really the decontamination, and at least, I think one thing, one point that we needed to make was that when you look back at what we did on the SCBA standard, you know, there's a six hour requirement that was identified... I didn't know if you knew you were in an agent environment that the period of time that you could use that device for six hours assuming that, you know, you got your bottle, you know, got new bottle or got your air bottle refilled. We are anticipating that for the APR we are going to have a similar... you know, assuming that, you know, that the concept holds that the systems test is going to be for six hours, you know, likewise there will be a six hour duration imposed on the APR, so... (pause)

Boord: Okay, we'd like to start of with a brief discussion on the interchangeability. By the way, my name is Les Boord. Few minutes here... (pause). What's that? How about that. Yesterday we talked in our opening remarks and the overview of the project we talked a little bit about the interchangeability. What I'd like to do is go into that discussion a little bit further today to establish what the thought processes are going to be and how we are going to arrive at defining a provision for evaluating interchangeability. But just to recap a little bit about how we get to this point and how we get to the topic of interchangeability... and it really is stemming from the inoperability concept, it was a major issue from the responders to the World Trade Center, Pentagon and Oklahoma City and so forth. A real strong message or theme that came out of the debriefing from those events, obviously, was to address inoperability, and the inoperability can really be looked at or considered from a pretty broad spectrum, so when you mention the term inoperability it could be interpreted to apply to replacement, normally replacement components... replacement parts typically uses in a respirator... visors, valves, etc. We're taking a narrower look or interpretation of the inoperability as it applied to air purifying respirators and our concept is that the inoperability is achieved through interchangeability of the filter canisters, the consumable part of the air purifying respirator. So we are doing this, primarily, in response to the feedback, that was derived from the World Trade Center, and as mentioned yesterday in some of the other discussions, there are other factors that really enter into the picture and effect the identified need for this provision, the logistics, the training, the support... these are all crucial... crucial elements and

crucial parts that really need to be addressed as well. The interchangeability is one avenue for a solution to improve the operable characteristics or operating parameters, let's say, at an event such as the World Trade Center. In our CBRN/APR standard, we intend to have the provision that will be an optional requirement for the manufacturer requesting approval of his respirator. So, it's not an across the board requirement that every, every CBRN/APR respirator will have interchangeability provisions, but instead the standard will have that as an optional feature. It will apply only to the CBRN/APR respirators, so it's not crossing any of the other classifications of respirators or into other types of respirators. And, along with that since it is CBRN related and tied to the CBRN/APR respirator, you... by addressing the interchangeability, we're also assuming that all the other requirements that we have identified for the CBRN respirator are in place. So, basically we are looking at this as a additional requirement when requested by the manufacturer. And, again, it applies to only the consumable filter, so the mask mounted cartridge or the chest or back mounted canisters. The other concept is that the interchangeability provision is intended as an emergency type provision. The comparison again, yesterday, was made relative to the interchange of compressed air cylinders on a open circuit SCBA, and this would be envisioned in much the same fashion. The details of how that will be implemented and worked out, we are addressing with OSHA. But to... to look at the topic of interchangeability in our standard, we will really approach it from two aspects. And the first is to define the requirements for the mechanical connector or the interface between the mask and the filter or the filter

and the rest of the system, let's say. Because it's not necessarily just attached to the mask. So the first... the first step is to define that mechanical connector, but then once that's done and to also identify performance requirements that we may want to check to ensure that we have some... a good level of interchangeability between facepieces, canisters and canisters and facepieces. John... go to the next one. I'd like to start with the mechanical connector... cause that's the easiest to address. One of the... one of the, let's say, not so desirable aspects of doing an interchangeability topic is that you do have to become more design restrictive. So, at some point you need to actually define what that interface or what the connector needs to be. Our approach will be to pattern it after the methods that are used in the European norms, the European standards. And as it turns out, the 40 millimeter thread, which is the common thought that most people have when you talk about an interchangeable filter is identified in EN148.1. So, our thinking is to go along and utilize that standard. It is an existing standard. It's in place. It defines the thread, the specifications of the thread, the male and the female portions, the length of the thread. It also addresses the seating gasket at the base of the thread. So the features, the mechanical features of the 40 millimeter thread are pretty well defined in that standard. The female portion of the thread would be on the mask and we are looking at a single connector on the mask. So the mechanical provisions then will pretty much be drawn from EN148.1 and .1 is important. As far as the other provisions or other characteristics that we need to look at to ensure that we do indeed have interchangeability, I think it gets a little more complex when you start to do that. If you just stick to the European norms,

the EN148.1, EN136, EN141, I think that it really falls short of defining the essential requirements that you need to ensure that you have this provision in place. So from an operational point of view or from a functioning point of view the interchangeability aspect of the standard will need to address the breathing resistance and the breathing resistance as it is apportioned to the mask and to the filter canister, and I think this is pretty obvious. Because if we have breathing resistance restrictions on the system, the respirator system which we are still approving, the CBRN respirator system, which will have total breathing resistance. Then when we start to do interchange between masks and filters and filters and masks, we need to make sure that we have some constraints on it so that we maintain the physiological performance relative to breathing resistance. What we will most likely do to establish these is if you do drill down a little further into the European standards and into the European norms, I think if you go to EN136 and 141, there are actually definitions for individual resistance requirements, breathing resistance requirements for the masks in one and for filters in the other. Now those resistance rates are certainly at different flows and different characteristics than what we're looking at, but I think we can really use it to build a percentage relationship between the individual components and the total system. So breathing resistance will be part of it. Another aspect is the canister size or the filter size and constraints that you need to place on that, because if we are looking at a mask, mask mounted filter, mask mounted any component, really the weight and some consideration for the maximum weight needs to be address to always have and preserve the integrity of the mask and the

way it's designed to work. Both the weight and the physical dimensions or the overall physical size of the canister then become important. To define the weight consideration, we can really... also look to the European standards for that, and I think there is a maximum weight currently defined within EN141 that is 500 grams for a mask mounted filter or a mask mounted canister. So that seems to be a good direction to go there. Physical dimensions, though become a little more complex. What we need to do is identify a method to determine what the maximum physical envelope for the mask mounted filter can be. Whether it's a diameter or maximum opening that the canister needs to pass through. But some kind of criteria that would define what the maximum physical size of that canister is. Then we need to have some consideration for the impact that, particularly the size, may have on the field of view or field of vision. As we heard earlier in our human factors' discussion, we are leaning to the field of view requirement and test procedure that's currently used in the European standards and the thinking that we have here is that if we have the field of view established, if it's already a requirement for the CBRN respirator system, then we should be able to establish some limitations for that field of vision when you start to do the interchangeability. Particularly when you take this large canister and put it on to the mask that it needs to preserve the field of vision within certain... within a certain percentage of the original requirements. So field of vision, I think, will need to be addressed. Then finally we need to develop a way and define a test and requirement... requirement and a test that evaluates the effectiveness of the facepiece or the mask when you utilize the canister that's maximized, the

maximum weight canister or the maximum size canister. And, the possibilities for doing that are actually... I see two opportunities or two possibilities for establishing that requirement. And, the first one would be to do perhaps a negative pressure test on a mask assembly or a mask that is submitted for interchangeability using a filter weighted to the maximum weight. So by doing that you would effectively establish whether the weight, the leverage, the pull of the canister distorts the facial seal in any way to effect the ability of the mask to create the seal. So a negative presume leak test on a mannequin or otherwise would be one way to do that. Another way would be to do, and this gets a little more involved, and a little more complex, but another way to do it would be to develop a modified LRPL test, respirator protection level test, where we would actually evaluate masks if there are multiple size masks or more than one size mask being offered for the interchangeability, then to test the multiple size masks using the maximum weight canister through an LRPL test. And, it may be... may be a full LRPL or it may be a modified LRPL. But, I see those as the two possibilities for establishing that requirement. So with those in place to establish the ability of a respirator to comply or to meet with an interchangeability requirement, I think these steps and these provisions would do that. So the approach would be, define the mechanical connector, leaning toward the EN148.1 which is the 40 millimeter thread, and then in addition to that to define these performance characteristics that would be evaluated for both the masks and the canisters. Any questions? (pause)

M: A comment more than a question. I know that this has been made an optional suggestion, recommended practice in the proposed rulemaking, and we have heard that yesterday's presentation from ISCA that they are opposed to mandatory requirements for interchangeability. But the user, the civilian emergency response community has been abundantly clear that they want interchangeability of respirators, compliant respirator parts. And, they have been very outspoken with my own organization, NFPA, and outspoken with the IAFF, International Association of Fire Fighters. And I think NIOSH has heard many of the same... I don't think it's going to go away and I don't think we would be prudent if we just bury our heads in the sand and say, that this is the end of it. I think it's going to back and I think it's going to back very strongly.

M: Thank you Bruce for the comment.

Parker: Jay Parker with...

M: Talk loud... (pause)

Parker: Yes, it's working. Jay Parker with Bullard. I just have a question about the threads in the sense that the European standard is really geared for the mask mounted cartridge, so when the mask instead has a front or back mounted canister, there typically is a connecting tube of some variety and then you're going to have to get into whether the thread on the canister is... should be a female thread, you see, so, I think you do need to consider specifying the case where you have the larger chest or back mounted canister and how that's going to work.

M: Yes. I agree with you and I think on the mechanical connector one of the things I did identify is I think the standard will need to specify female connector, 40

millimeter thread on the mask. Male portion of the 40 millimeter thread on the canister. And, then to actually address the provision for where you have both the mask mounted canister or a body mounted canister, and that particularly gets tricky when you have a mask that can be used either way.

M: I had a question. I just want to clarify (... inaudible...)

M: Okay.

Payla: This is Frank Payla from NIOSH. Your position of interchangeability, saying that the first responder community wants it... are you... what's your position on as far as with the option. I mean, is it... is option favorable to you? I mean the way we are approaching it, is that a favorable way to go about it or do you think it should be mandatory?

Teele: I think, Bruce Teele, NFPA... I think we were surprised NIOSH went with the optional way. It's not a mandatory requirement, everybody can chose to ignore it. If everybody chooses to meet it, that's wonderful, but I think if NIOSH doesn't set the benchmark high enough it may be ignored and that certainly would not be what we hear the emergency response community saying. Not at NFPA anyway.

M: Any others? Thanks.

M: All right, well my presentation will be very brief because I think we pretty much beat this over pretty well this morning as far as the test requirements for the APR. A couple things I did want to summarize to bring back the concept that we are addressing. This is a three tier process that, you know, initially we have to address the extract requirements from 42CFR, you know, we are going to have additional requirements for human factors and also with the rough handling type

applications and also specific systems tests related to penetration, permeation, gas life and also the LRPL. One thing that we really didn't cover as part of the discussion, was the... just on the topical sense was the any test requirements that were going to be necessary to prove out the interchangeability concept as, I think, as we go along over the next couple of months, we'll be able to further refine the type of testing that we foresee in that area. One other... I guess the one point I think Andy's question from this morning was answered... whether or not we anticipated doing the penetration and permeation testing following the rough handling. The answer to that is yes.

M: (... inaudible...)

M: Well, what we envision with the systems test is the same way at the SCBA testing is done. That you have three masks will be subjected against GB; three masks will be subjected against HD. (pause) One thing that we mentioned yesterday and didn't really cover in detail today, but I just wanted to bring up as an additional point, was the crisis test for the system. And we had discussed as far as having the capability, and this is referenced in the concept paper, the capability to use the system with higher flow rates that the... our thought process is we are holding the challenge constant but we are altering the flow rate. And if you are familiar with the NFPA testing, we are going to run the crisis test at a constant 100 liters per minute for the duration of test. And I think you'll.... With the NFPA testing, if you recall, that that indicates peak flow of up to 300 liters per minute. And, I think that as you see as we go along, and again, this is no.... it's just easier to read this in your concept paper, as far as... we are still working the definition of the

total amount of material that would be required for the certification test, but as we currently have it conceptualized, I think you can see that, you know, that you're probably talking in the range of a minimum of 6 full systems with a maximum, you know, to include the human factors and the other testing that... probably, you know, in the 10 to 12 range. And the canisters at a minimum right now, I guess the presentation identified 78, and you figure, you know, probably in the 80 to 100 range... that's on the test requirements are fully, are fully identified, you know, using this scenario. So, if you can keep that in mind, at least in terms of your analysis of what we are proposing and if you have opinions or counter proposals or other data that you feel that we should consider, you know, please, you know, forward that to us via the docket office and we'll address it in part of the preparation of the standard. Does anybody have any questions?

M: I'm sorry John, I don't know if this is the right point to talk about this... have you talked about field of view at all? The field of view requirements in EM136 are based on a large industrial mask whereas listening to all the discussions here, what we are talking about, especially from some of the responders, the police force, is looking more towards a military type mask. Now the field of view requirements in EM136 are for a full single visor, something like 70% total, 80% overlapped; whereas for a twin eyepiece, go to 70%, 20% overlapped. And that by and large was brought about because if you do have one of the old style, military style masks with twin eyepieces which has got the eyepieces fairly close to the eyes for weapon compatibility and everything else, then you do get small overlapped field of view. Now in the more modern military masks, that overlap

field of view is increased and sometimes the more modern military masks have a single visor rather than twin eyepieces, but the ability with a very, very small eye relief which you need for very weapons compatibility, a good sighting with the rifles, all the things that the SWAT teams want to do... even with all those good things the chances of getting with any military mask, an overlapped field of view of 80% with a single visor meeting all the other military style requirements I would say is unlikely, at worst impossible, I would suggest. So I would look very carefully at just adopting EM136 as it is for that requirement. Because I think you will eliminate most of the things that the first responders are telling everybody that they really want, which is almost a military style mask for some of their activities.

M: Okay, well, we'll take note of that and as we continue to move along, we'll redo some addition additional research.

M: Thank you.

M: Thank you.

M: (...inaudible...) I do not know the exact dates from it, but we do have a mask with two visors and as far as I can remember, they also have 80% and more field of vision overlapping.

M: Okay, thank you.

Duncan: Paul Duncan, Scott Health & Safety. I had a question about the 26... the increase to 26 millimeters water on exhalation resistance. Is the plan to still leave the portion of 42CFR at 20 and then just expand it to 26 just for the CBRN?

M: Terry, do you or Dave want to address that?

M: The vision for the CFR is not effected by the field (...inaudible...) So basically... thanks, yeah. Existing provisions of 42CFR for industrial based or industrial use, air purifying respirator, we're not affecting that at all. We are looking very specifically at a standard and a certification program that would be for CBRN air purifying respirator.

Duncan: But then the possibility exists to basically create a product to create a mask with a exhalation resistance that goes up to 26 that you could no longer... you could not use that same product for your other industrial air purifying applications.

M: It may not meet both approvals, you mean?

Duncan: Yeah. Okay.

M: Okay, our next present is going to be Roland BerryAnn, and he's going to spend a brief time discussing the implementation process.

BerryAnn: Thank you John. Unlike John, I won't promise to be brief. Those of you who know me know why, those of you don't will soon find out. (chuckling) That was a joke! (pause) Okay, go ahead, next slide John. I want to start out with a brief overview of the existing approval program structure. Under the existing regulations we have respirator classes defined with requirements for all the classes, conditions of use specified for each of the classes. We have the ability to add additional requirements as necessary for... to the equipment either through rulemaking or existing authorities that we have in the regulations. Go ahead John. Basically, respirator use defined into IDLH and non-IDLH situations. The IDLH are unknown atmospheres, SCBAs or airline with escape bottle, an escape only gas mask and for the C-Burn (?) we are talking full facepiece protection and that's

basically what we worked on the SCBA that we introduced. Non-IDLH you have known atmospheres, controlled concentrations, air purifying respirators are allowed, and again we are talking on these the full facepiece for protection. And as we have stated before, I just want to reiterate that the respirators that we are talking about here are gas masks... they are not intended for entry into IDLH. They are for the non-IDLH situation, but again, we are adding the capability that if you have an unanticipated second event or situation such as that, that there is an emergency contingency for escape from IDLH. I think I am being brief. Okay, implementation. This is probably where people start getting interested. One option is a notice in comment, rulemaking, formal processes that we go through, publishing federal register notice of proposed rulemaking, the public hearings... err public meetings that are associated with that, consideration of comments, and going out with the final rule. Or, the other option that we have been trying to use is using existing authorities that we have under the regulations and we have various authorities... 84 110 is one we intend to use specifically on this, where under the gas mask provisions, we can add new gases and vapors to those that are already identified in the regulations. We've done that in the past... with things like CS and CN tear gases. 190 is for chemical cartridges. It doesn't appear as though the chemical cartridge regulations is (?) standard perception of the chemical cartridge respirator. It's going to have the capacity that it looks like people are going to need for this type of device. 84 63 C gives us authority to add new tests and evaluations for different characteristics of respirators. Some of the tests that we are addressing here, like the shock test, you know, the drop test,

rough handling test... we envision adding under the authorities of 84 63 C. 84 60
A has a... allows us to use existing requirements which are applicable to one
class. If we think that's applicable to a second class, we can basically replicate
that into that class. Okay. As far as the biologicals, radiologicals and other
particulates, we see adding that as basically existing part 84 regulations to cover
that for P100 and as you've heard several times the current thinking is that with
the uncertainties of the situation, a mechanical filter is what we will be looking
for, but the additional areas that had been considered in some of the analyses that
have been done in looking at the hazards, looked at a... as far as biologicals, long
term viability of captured biologicals... migration and (...inaudible...)
aerosolization inside the facepiece, performance, degradation of the filter due to
chemical exposure. At the current time, we're going with the mechanical, while
the first two researches indicated, it's not a problem with biologicals and we are
going under the other research context that a particle is a particle as far as
aerodynamics size, so there isn't a distinction between radiologicals, biologicals
or inorganic materials. And as far as the degradation due to chemical exposure
because of the uncertainties, again we are talking about the mechanical filters
rather than electrostatics. And, again, any additional testing requirements we
would look at... 84 63 C as the preferred method for adding the testing for this
particular product. As far as chemical agents, again we are looking for this
particular class of respirators, the 110 under the gas mask criteria. And, let me just
say at this point, reiterate what Les just said, this is not... these... we are talking
about additional requirements above what's in part 84. There may be some added

gasses that we already have provision in 84 that... we are talking about different concentrations because of this usage, and haven't thought it all the way through, but the reasonable thing to do would be to have this... with this particular usage replace the other levels, like the breathing resistance, the 26, then we would allow the 26, rather than the 20, but then... it wouldn't meet the standard 14, you know, 14G approval. It would get the special CBRN. But again, as we go through and become firmer on our requirements and probably the next time we talk, that will be clearer. (pause) And, you know, the agents, you know, as was said in the earlier presentations, the agents were selected based upon vulnerability assessments and modeling, set up the test parameters. Additional test permeation, system integrity would be warfare agents, we are looking at under the 84 63 C additional testing provisions, and again, it was mentioned earlier about special conditions of use. We suppose that there will be additional conditions of use on these units. Any... you know, any additional information and guidance you can provide would be appreciated. (pause)

M: (...inaudible...)

BerryAnn: That's good. (laughter) That was the plan, Alex. Okay, sorry about that. Is this better? (laughter) Okay. See that what happens when I talk fast. (chuckling). Okay. As far as the real issue, the implementation issues, we... we've been trying to develop and improve upon with every opportunity the policy implementation where we involve public... you know, we invite public involvement in the development of our policies. We try and provide as much notification as we can, and this includes, you know, stakeholder meetings, public meetings, you know,

we just had two glorious days of... putting our concepts on the website for people to look at and I believe Les has announced a commitment, what is it? Every two weeks will be an update? Every two weeks? There will be an update of that and so you are getting as transparent as we can make it, which to be honest with you, you know, you are seeing our thought process as it evolves. A bit riskier than rulemaking, where you don't see it until there's a final consensus. So, but we think it's a good process. We think it encourages and facilitates stakeholder involvement, and that's how we get a better product. And, you know, another thing that we encourage is an exchange of information with the applicants when we do go out with this, and people are preparing, or even before we get finalized, people are anticipating products, please come and talk to us. So, we have common link on the thoughts so that we get things ironed out as quickly as we can and avoid any differences that can be stumbling blocks. You know, when everybody is looking for the green light to start testing, and you say, "Oh, wait. You only sent 6 instead of 12." You know, we found on the SCBA, I think we settled a lot of potential problems ahead of time by people talking through what they intended to submit, how they intended to submit it. And, you know, we got a common understanding of what we looking for and what they were expecting. We also had experience with NIOSH and SBCCOM, two federal agencies, communicating with each other and, you know, us trying to learn the SBCCOM system and they trying to learn our system. I am sure nobody in this room can understand how two federal agencies might have a different language, but... (chuckling)... just a little bit. And, two other issues that I threw on the slide was laboratory capacity with

Tape 4, 6/19/02

air purifying. We are anticipating that we're going to get more products coming in than what we had for the SCBA. So we are doing everything we can to try and increase at laboratory capacity with, you know, federal labs. Where one of long term goals in our program is to have...

(END OF TAPE 4, SIDE B)

Tape 5, 6/19/02

(TAPE 5, SIDE A)

BerryAnn: ...develop that program, we think that will hopefully come on line and help us as well in this, but there may be some capacity concerns early on in the program. Simulants. I know there's no interest in simulants. We haven't heard that, but we are working on a simulants program. There's, I think there's, the message is there's a lot of work to be done to find simulants. They're material dependent, it appears. There's an, and you know, we're very glad one of the participants here gave a presentation yesterday on the work that he's doing on simulants and what he's learned in the approach he's taken, and I think that's, that is an indication of the type of interaction and sharing of knowledge that we see in this process and we're happy about. What's going to result from this simulant product? I think it's too early to tell. I don't want to close the door on using simulants in a certification program. I don't see at this point eliminating live agent testing as part of the certification. I don't, but... depending upon what we find in the simulant there may be a role for simulant in the certification testing as well. That's it. Any questions, comments?

M: How does NIOSH intend to address the issue of warning properties?

BerryAnn: Address the issues of warning properties for end of service life?

M: No. I mean respiratory protection in general is based upon utilizing or targeting for materials that have the ability that you can sense in some way that they're breaking through, at least that's been my understanding in the past. And a lot of the materials that we're talking about here with chemical

warfare agents will not have those type of warning properties so I was interested in how you all were going to address that.

BerryAnn: Okay. In 1998 when OSHA went out with their new respirator use regulations, 1910 134, 29CFR 1910 134, they, their new regulations required a change out schedule or end of service life indicator for the life of, for determining the service life of a cartridge or canister. NIOSH in 1999 adopted a policy that was in agreement with that. Okay? So, how you would have a calculated change out schedule, I don't know. That's part of what has yet to be done. We are working with OSHA and we will be working, as we progress, on those type of issues. We're going to have a close working relationship with OSHA, and probably NIST will be involved in that as well, on just how we're going to facilitate that.

Berndtsson: Yes, to add to that, maybe, as we have said many times, that this is a once only filter we're talking about here. Maybe there should be recommendation of a maximum of that once only so it doesn't go on for 24 hours.

BerryAnn: And again, what John said earlier after reconvening after lunch, is if you're talking about live agents, we have a limitation due to the permeation concerns.

Smith: Simon Smith, 3M Canada. Wondered if you had any thoughts so far on labeling and marking requirements?

BerryAnn: Yeah. And they're all scary. (chuckle) No. On the SCBA it was a bit easier because it was a Part 84 approved respirator, plus NFPA, plus the CBRN, so we put the little CBRN label on it. On this, we'll probably have a similar notation and anticipating that your next question, (chuckle) you know we're

talking about a two phase program. First step and then a more complete second step, later on. We just started bouncing around. We don't see obsoleting the first round, you know, it's going to be, if you will, a building block, where we're going to have basic, then we're going to have additional protections on top of it, so some of the respirators may be the same basic respirator, maybe a different cartridge that gets approved, or it may be a different, may have to be a different, totally different respirator. Whether its going to have to be an A and a B, you know CBRN A, CBRN B, but it will, I would say 98% probability that there will be a CBRN-type label on the SCBA and a way of distinguishing the first step from the second step. Any suggestions on how it's great to get that on there from the manufacturer's perspective and from the user's perspective, we can shuffle the papers any way it works best for you guys.

Smith: Thank you.

BerryAnn: Did I guess right on your second question?

Smith: Actually, it was slightly different. Just it was, if a product is capable of beating existing industrial requirements under the current Part 84, and additional the CBRN, can it be labeled for both or will it have to be distinct products?

BerryAnn: Yes.

Smith: Right. Thanks.

Newcomb: Bill Newcomb from NORTH. I would like to suggest that since the use of this device, these devices, is going to be slightly different than the uses that we've

Tape 5, 6/19/02

been used to with APRs, that NIOSH mandate the wording for the cautions and labels, and limitations that go on this product.

BerryAnn: Bill. Bill. Don't. I need a little bit of clarification if I could. When you say mandate, are you saying that...

Newcomb: ...The exact wording that has to be used...

BerryAnn: ...okay, so...

Newcomb: ...uh, for cautions and limitations and the use limitations for this product, since it will be used in situations that are unlike normal APRs would be used, and also things like, if it is to be used only once and not used a second time, that type of information. If that's the intent, then that should be, you should specify the language that's to be used.

BerryAnn: We should have a standardized cautions and limitations that are special for this application?

Newcomb: Yes.

BerryAnn: Okay. Appreciate that. Thank you. Thank you. (applause)

M: Okay, I think at this time we've run out of presentations from NIOSH, so we'll (Laughter) thanks, Bob... so I think at this time we'll move into the attendee presentations. Our first one is going to be by Lt. Colonel Graham with the Chemical Biological Incident Response Force and I believe his entourage will participate as well.

Graham: Good afternoon ladies and gentlemen. I'm Lt. Colonel Scott Graham. I'm the executive officer for the U.S. Marines Chem Bio Incident Response Force and we call entourages "teams" and my team members today with me are Chief

Warrant Officer 4 Robert Murphy, he's a fire and emergency services officer within the Marine Corps, Mr. Sam Pitts who's a retired CWO4 MBC officer, and Mr. Adam Becker who's from Marine Corps Systems Command.

TISWIG is also sponsoring us, but unfortunately some conflicts they weren't able to attend with us today, but representing them is Aaron Richardson, who's a Battelle employee who's in support of TISWIG operations. Today I want to talk to you about three projects that are very near and dear to our heart and are also contained in our research development acquisition plan. We're trying to work with a number of partners to develop some solutions, but before I introduce those projects and turn it over to some of my team members to explain some details, I want to talk about our organization just a minute so you have a frame of reference on who we are and what we bring to the fight. We were established in 1996 in response to, primarily to the sarin gas attack in Tokyo. Our previous commandant, General Krewlak? Took a look at the Marine Corps inventory to respond to a similar type event and how we could offer assistance to the nation, either overseas or in the U.S., and found that we needed to organize a force that could accomplish what CBIRF can now do. So, in 1996 we embarked on a process of standing up an organization in about three months' period of time, ourselves and the Navy, Secretary Danzig, recent Secretary of the Navy, was also heavily involved in the development of CBIRF. Obviously things don't stay static in either the threat environment that we live in or our response to it. Over the course of time from 1996 to today, we have evolved greatly. Our original name was Chem/Bio, and focused on

those two threat patterns, but as you can see from this mission statement, it's been greatly expanded. This is recently endorsed by our current commandant, General Jones on 17 January of this year, and we are an all-hazard response unit now, although our name doesn't normally imply that. What's significant I want you to take from this mission statement is also who we're responding with and in support of. We are tasked, organized, and designed to support an incident commander, a local fire chief, chief of police, or we can go overseas and support a CINC combatant commander. We work a lot of different spectrums within the chain of command across the different priority scales, so we have military equipment. We have commercial off-the-shelf equipment in our inventory, to allow us to respond to lots of different hazards and in multiple different environments. And we rehearse, train and exercise a lot of different scenarios. Beyond who we're supporting, what we bring to the fight is articulated in the bottom half of our mission statement there. And, we can do agent identification and detection, we can search and locate victims and extract them from all types of hazardous environments, we can decontaminate them and medically treat them. And that makes us somewhat unique in that we bring that full spectrum of response to a fight. We either are prepositioned in advance of a potential threat such as the State of the Union addresses at the Capitol where we support the lead federal agency in that case, which is Capitol Hill Police, or we can be on call, no-notice type response. We've got about 100 marines and sailors on a one hour response timeline to do the no-notice portion and we task organize sometimes up to 300 people to do for

deployed in support of a national special security event, for example. So we have a broad spectrum, and as such, we run into a lot of training requirements. We do live agent training. We recently just came back from doing live chemical warfare agent training and we were involved for several months looking for anthrax in the nation's capital and in some cases, finding it. So we have some experience operationally with biological and chemical warfare agents. Next slide please. Partnerships are crucial to all of us being successful. One of the things that's been enjoyable for me to observe the last couple days here is the number of patriots that are involved in the defense of our nation from industry, the government, across a wide spectrum of backgrounds and resources. I believe in my two years in this organization that it's paramount that we continue these types of partnerships and expand them. One of my goals in presenting this presentation today is that we will stimulate some of you to become engaged with us on some of the projects that we're going to talk about. Many of you already are. We have a lot of different partnerships, and I'd like to really thank the folks at NIOSH, SBCCOM, and NIST for giving us an opportunity today to speak with you all about these because I want to accentuate the point that it's all about teamwork. That's a philosophical starting point for any Marine, and it's crucial, I believe, to all of us, to be able to stay ahead of the enemy, who's very creative, who's not limited or bounded by a lot of regulation and a lot of the things that we have to be constrained by, and work through. So we have our work cut out for us as a responder, and we have our work cut out for us as a nation. With that, I'll

turn it over to Chief Officer Murphy to talk some of the specifics about the three projects.

Murphy: As the Forest Fire and Emergency Services Officer for the organization, obviously I'm heavily engaged with our marines and sailors and our tactics that we employ, our techniques, and our procedures. There's one thing. There's many things that I emphasize to those marines and sailors when we're getting ready to train or we're going operational. One of those things that I emphasize very closely is the life saving aspect. You saw our mission statement. It's all centered around one thing and that's saving lives. However, we turn that, and I emphasize this to them every day, we turn that into two procedures. We save the lives of those victims, but we also have to save our own lives. We have to be able to be trained and equipped and organized to be able to get in there, get those victims out of there, and then be able to turn right back around and be able to do it again. So saving lives goes in two parts: the victims, and then also our own selves as well. Now, in our organization, as you saw with our mission statement, it's kind of this all-hazards response from the chem to the rad to the bio, everything in between, a high-yield explosive, with all the hazards that come along and are associated with something like that, an embassy coming down around you and so forth. And with that said, there's a lot that goes in that that you understand, going into this unknown environment: detecting, identification, sizing-up, hazard-risk assessment, all those things that go into that, and one of the jobs that I have is to force emergency services officers to be able to do that and be able to do it

in a very rapid amount of time, be able to come up with an incident action plan, a site safety plan, and look at our tactics and our procedures, our equipment, and how we're organized, and be able to get those marines and sailors into the fight as soon as we can to be able to save lives. So detect, ID, we're going into unknown environments so obviously we're bringing all the regulations and the standards and the equipment that we have to do that with and be able to make that happen. But yet we focused on three areas that we've seen over the course of time through our training and then through our actual real world experiences, like this picture you see up here on your right hand side in DC. When you're in the Longworth Building and you're about three or four hundred yards into that building on the 4th story, you're in that thing pretty deep. And to be able to concentrate on what we were doing there, obviously we weren't working with victims, fortunately we weren't working with victims in that scenario itself or that situation itself. We keyed in on some areas in this training in these operations that we've been on where we get the biggest bang for our buck when it comes to saving lives. Now I mentioned that we do all those other things at the same time, but when it comes down to kind of warm zone operations, you're dealing with your medical management for our organization, we are, your decontamination, a lot of our search and extract of our victims are all into that kind of area, we have to be able to give our marines and our sailors some equipment and some tools to be able to facilitate that as much as we can and as long as we can. These three areas that you see up here, this improved filter, this rehydration, and this

heat index. Again, you just pictured that long building that I described earlier and those marines are operating for an extended amount of time. We do that on a SCBA, if we're using SCBA, but by time you get into the building and you turn around you work for five to ten minutes you're coming right back out and getting into decontamination, so that's not really happening. The environment allows us to go into a negative pressure respirator, however, with the negative pressure respirator and the amount of work that's associated with that, these three areas we really got to look at. Kind of like that all-hazards response in our filtration system, we've got to be able to get our marines and sailors rehydrated. They're down there working for an hour or two hours, we've got to continually to rehydrate those personnel so they can stay sharp, be effective and know what they're doing. Also when we're dealing with the mentality of the Marine Corps and the sailors that we operating, these marines and sailors are going to do everything that they possibly can do to continue to operate to get the mission done. They're just going to work, they're going to work, they're going to work until they basically drop. We want to prevent that from happening. The leadership role that we have in the body that you see in front of us, has a responsibility to take a look at the environment that we're operating in, look at the hazards that are associated with that, the humidity, the heat, the time of day, everything that goes along with that, and we've got to be able to somehow project that this operator can go in and work in this environment and they can work in this environment for a certain amount of time so that marine doesn't have to go to end state and pretty much just drop

doing what we're asking them to do, so we can be able to calculate somehow that, in this type of environment they can work for two hours. They can work for three hours, or maybe they can only work for 45 minutes. Allow me to be able to pull that marine or sailor out of that environment, get them rehydrated, reconstituted and then be able to get them back in the fight in a more physical state to allow us to sustain the operations. So, kind of I explained the why and what we're trying to do here, these are the three areas that we're going to be talking about to get that extended strength and ability to keep our marines and sailors sharp working downrange, and I need to be able to provide the tools and the equipment so they can perform the job that we're asking them to do. So with that said, I opened up with about saving lives, you know, I ask you out here in front of me. Between standards and industry everything that we're doing around here needs to focus around one thing. Standards, we need to see, do our standards and our test protocols actually facilitating that of saving lives, both the lives of the responders that we're putting down into that environment, and also to be able to save the lives of victims. And then I look at industry here, and I say, "Industry, are you giving us the equipment that we need to be able to utilize in an effective manner?" So today we're saving lives at this ratio. This country was tested a few months ago, and we say the New York City Firefighters saved an enormous amount of lives because of the equipment they were able to utilize and the tactics they utilized employing into that situation. So that's the benchmark that we have today. We need to be able to leave this meeting right now and set that benchmark even higher,

Industry, by the equipment that we need to be able to utilize to be able to do that should allow us to facilitate getting into that environment and operating in that environment for maybe a longer time, but to be able to do it maybe with a little bit more ease so that we can get more of those victims out of that situation, and getting them back in, as well as saving the responder as well. That's kind of a bar I'd like to set. NIOSH, NIST, SBCCOM, I thank you for, what an opportunity it is to be able to bring the Operators together, Industry together, and Standards together, to be able to get this common platform. That common platform that I'd like to put out in front of you today is that life saving. Everything that we're doing today, is it to raise that benchmark so we can get out there and save that life a little bit better than we did today, and definitely better than the way we're going to do it tomorrow. So I think you for that opportunity. I'd like to introduce Mr. Sam Pitts, who's going to speak specifically about those three distinct areas that I talked about here, and get into a little bit more of the technical data that we need to be able to provide that. Thank you. (applause)

Pitts: I'd like to reiterate to everyone here, we appreciate this opportunity and I am painfully reminded that I'm probably a living example of Homo Neanderthal in front of this august body of Homo Sapiens. I'll do my best, please bear with me. Our first protocol is the improved filter canister. And the reason we do this is because, characteristically and by standard operating procedure, we put our marines, soldiers, sailors, and other warriors into battle with a respirator, essentially, where the enemy is trying to maintain Immediately Dangerous to

Life and Health concentrations of chemical agents to murder us at this cyclic rate. So, this is our number one requisition priority. We're looking for broad protection from all the war gasses, the classic war gasses, and a list of TICs and TIMs that we've discussed at length here today. We'd like to see all agent concentrations held at the IDLH levels. We'd like to have these tested at realistic human respiration rates, and I think that's perhaps where we're falling down here. If we're talking, geez, I can respire at about 30 liters of air per minute talking about politics, marines carrying casualties over broken terrain or up and down steps of buildings can have respiration rates sustained of 150 to 200 liters of air per minute. We even see spikes, momentary as they may be, in the neighborhood of 700 liters of air per minute. What happens to the life of a filter if you're respirating through it at those elevated human cyclic respiration rates? Right now, I don't think we have the answer to that. If we knew that our C2A1 canister was good for 5 minutes in an IDLH concentration of the blood gasses hydrogen cyanide or cyanogen chloride, if we knew it was 5 minutes, that would be a step forward in the right direction, and perhaps in low, moderate, and heavy workloads, or respiration rates, if you want to get into those three parameters. That would be great. Right now, it's unknown. We would like to see these respiration rates, again, from 50 to about 700 liters of air per minute. We'd like to see them in about 50 liter per increments, and human respiration cycles. We would like to see military mask and PAPR applications as we have discussed repeatedly here today. We would like to see the filter failure times in minutes at those rates. That's important to

us. We plan on doing some NAV AIR SYS COM testing and some commercial testing with some folks that will actually delineate the respiration rates and patterns of our marines at the Chemical Biological Incident Response Force. There seems to be a lot of drama about this 700 liter of air per minute peak flow rates on some folks' part. Next slide, sir. Rehydration and protective equipment. We want to do this to extend the strength and endurance of our marines and their mental acuity while they're down range. Unlike civilian firefighters who perhaps would go into a hot zone for maybe 30 minutes at a clip, we may be required to go down perhaps for more extended periods of time, then come back out for a brief respite, and then be thrust back into that hostile situation again. So rehydration to us is perhaps a little more acute to us than some other folks. We would like a hands-free drinking system adaptable to all the participating manufacturers of cots, SCBA, rebreather, and PAPR face blanks. We'd like to see something that universally would punch through the face blank and would be adaptable to a bladder type reservoir and allow us hands-free drinking while wearing any one of the cots, face blanks. Next slide sir. Our heat index calculator. Right now we have lots of data on our Level C protective ensembles, that is the permeable suit that we wear in DOD for certain occasions. We have lots of data on that. But we don't have lots of data on Level A and Level B, maximum downrange times before there's physiological damage to the individual. A heat index calculator we envision something like a slide rule or a whiz wheel or even a little hand held calculator, where we can input on one

axis perhaps the ambient weather conditions at the site, on the other axis perhaps the protective ensemble that we are wearing. And this whiz wheel or calculator would give us a maximum downrange time in that particular ensemble, with its associated respiration gear, at those on-site weather conditions, the maximum time before we have physiological damage. Next slide, sir. All three of these protocols are being supported by the TISWIG and the Office of Naval Research that are helping us tremendously to get this through. The status report, basically, on all three of these protocols. Our improved filter requirement. Currently the statements of work are being revised by ONR and SBCCOM with SBCCOM and at TISWIG. They're fully engaged in the supervision of this important initiative and we're going to establish realistic respiration rates and filter failure times in minutes. This information could possibly lead to developments in the filter canister that would give us vastly, or maybe marginally, increased downrange times. If we just knew when the filter was going to fail, that would be a step in the right direction. At realistic respiration rates. A rehydration protocol. Our kickoff meeting occurred on 31 January, and we also have accomplished a subsequent preliminary design review on 28 March. Next week we're going to have a look at all the prototypes that are being submitted to us from the industry folks. On the heat index calculator, we have looked at several industry inputs to this, quite a number of them, we've down selected, we're in the process of narrowing down the finalists right now. We will also take a look at those finalists next week. Again, I'd like to thank everyone for this opportunity.

Tape 5, 6/19/02

NIOSH, SBCCOM. It's a rare and distinct honor and privilege to speak to everyone and to listen to this dialogue that's going back and forth, I think, is extremely helpful. And we're all working on the, towards the same goal. Perhaps from different perspectives, but this reminds just of democracy in process, and I think you're doing well. And we appreciate your support. Sir. (applause)

Graham: In summary, I'd like to point out a couple of things. As a leader of not only marines, but soldiers from Tech Escort and airmen from a number of different Air Force bases in the DC area, during our biological sampling operations, as they were called, looking for anthrax in the nation's capital, some of the building there, I had a real dilemma that touched base on several of these issues here that we've talked about today in these three projects, and the dilemmas were: how long could I keep my marines and sailors downrange in the different protective ensembles before I had to be concerned about them becoming casualties themselves while they were trying to prevent further spread of the contamination to other areas or locates its presence. Now this was a real thing for me. We had a couple marines become dehydrated significantly during wearing of PAPRs with Tyvek type suits, and I believe that's attributable to the ambient heat in the buildings, the ventilation systems were turned off as you can expect, and there was a lot of radiant heat in October during our first several days in those big office complexes. It was a real tangible thing to me as a commander working these issues. Secondly, I've had a great deal of experience operationally as an infantry officer. A lot of

these threats are emerging and very difficult to define. It takes all the best minds that we have applying against this problem, which is, again, very encouraging to be here with you the last couple of days, because what all of us need to keep in mind, and what I always tell the marines when we assume the duties as the initial response force who's in the one hour alert phase, "When we respond to the next attack, we're going to be someone's child, somebody's father, somebody's mother. This is very real, in-your-face work that we're contending with, both the physical demands and the restrictions some of the equipment puts on us and the fact that the mental stress that's involved with dealing with these agents or hazards that we're contending with. It's a different stress than infantry operations in the Gulf War, but it's equal or as demanding in many ways. So we're faced with a great challenge, but I'm confident in all of our capabilities in this room and the others that are supporting us that we're going to overcome these challenges that we've been talking about the last couple days. And we're going to be better. And we're going to be more prepared. It's not just us in the military, but our brothers in the first responder community in the fire houses, the police stations, because we're just one small organization who's got a lot of capability, but we have a limitation of time/distance tyranny. We can't be all places at all times. We've got to spread this capability to respond safely at a much greater rapidity than we have now to all of our first responders. I thank you again for the opportunity to speak with you, and it's been a privilege to be with this great

Tape 5, 6/19/02

group of people. Thank you. (applause) We'll take your questions now at this time.

McNamara: John McNamara from OSHA Medical Office and as you know, the heat casualty issue is complicated by physical exertion and I know you're all aware of this, but for the rest of the audience, when you add physical exertion to the matrix, you are talking about exertional heat stroke, which can occur in a matter of minutes and be just as serious as the other kind of heat stroke. Whereas, heat exhaustion can occur from those factors you mentioned, ambient temperature, dehydration, that kind of thing, so when you add physical exertion to the matrix, you're really talking about a lethal, potentially lethal injury, which is something that you have to respond to immediately with a Med-Evac.

Graham: Absolutely. This last summer, or summer of 2001, we did an exercise with the Fire Department of New York that required our marines to ascend six flights of stairs, extract victims that were probationary firefighters who were going through their training, and I've never seen a bigger group of people, than these probationary firefighters were. They all were over 200 (pounds) and by the time our marines extracted these big dudes out of the sixth floor of this building and worked them all the way down the ladder wells and out and gave them to their fellow marines to move them from the outside of the building back to the decon line, it was extremely physically taxing in July in 80-90% humidity and 90+ degree temperatures. We were extracting them for the majority of about six blocks over broken terrain, urban terrain, and the

marines were physically ran through all their canteens of water that they took downrange with them, I had to resend water downrange to the ones that were still extracting casualties. Over a period of about two and a half hours, we extracted over 90 of these probationary firefighters that were assisting us in this training, and extracted them through decon, got them to medical stabilization and all that. I had a force of approximately 120 marines doing this task over a two and a half hour period of time. At the end of that time, we were completely exhausted and spent, between the marines I had in Level A and the marines I had in Level C which at that point was our Saratoga suits with our M-40s. We were done. And we would have had to rehydrate, look at people medically, we had a couple people that were coming close to becoming heat exhausted in those environments, so it's a real challenge and it's a very real thing. And I appreciate your comment, sir.

M: Colonel, what would be the different ways that local or state first responders or governments would reach out to have your force support them, either pre-deployed or in an emergency situation. Can you give some insight into how that might work?

Graham: Certainly, sir. We support a lead federal agency as the doctrinal approach that we use. Normally, that's the FBI or FEMA or somebody like Capitol Hill Police. We're requested through one of those agencies to support and we will be the request chain goes from Executive Secretary, usually for the Secretary of Defense, through Joint Forces Command in Norfolk, down through our chain of command which is Marine Forces Atlantic in Norfolk, Second

Marine Expeditionary Force in Camp LeJeune, North Carolina, and the Fourth Marine Expeditionary Brigade, which is also in Camp LeJeune. That may sound fairly cumbersome, but it's not. It can move pretty rapidly with classified or Stu3 (?) phones communications the requirements. If there's an event that requires our type of support based on the threat, then we can be pre-deployed in advance and those deployment considerations can be worked through well in advance and we've done a number of those kinds of things beginning way back in the Atlanta Olympics through a number of different national special security events. So there's really two ways that can happen. And if all else fails you can call that number there and I'll make it happen if it's required. But one of the things we have to be careful with is not deploying to a ruse or not deploying to a false alarm because obviously there's not very many of us and we need to be making sure that we're doing the right thing. So there's a lot of checks and balances in our deployment order process to prevent us from being mis-assigned. Yes, sir.

Caretti: Dave Caretti, SBCCOM. Sam, this question's for you. I understand the desire and there is a real need for testing at realistic flow rates. I question the 700 liter per minute flow rate. It'd be interesting from my perspective to know what is the frequency of occurrence of flow rates that are that high, and in your increments of 50, if you so choose, just to help you understand the real need of a standard to test at that high of a flow rate, if the frequency of occurrence may be less than half a percent or anything like that.

Tape 5, 6/19/02

Pitts: As I stated earlier, it's a good question and you're not the only one who's brought that up about 700 liters of air per minute. I've consulted with a couple of physiologists who have supported us in the past, and with men that are in good physical condition, these flow rates are not unheard of under very heavy work loads and again, only for moments. As far as percentages above and beyond, like say the 50th percentile, and I'm speaking in Neanderthal, now, I don't know what percentage off the top of my head that that could be. You probably have a better idea of that. We only set these parameters up here because we don't know, we don't know with our current C2A1 canister, at what point that canister will fail in an IDLH concentration of anything, compounding that, making that problem more acute, as I'm sure you know, is our respiration and physical exertion rates. If we were to, perhaps we don't want to go with 700, perhaps something a little bit lower, the physiologists tell me that it is not, NOT, out of the ordinary to have sustained breathing rates for maybe five or six minutes at 300 liters of air.

Caretti: I don't disagree with you, I'm a physiologist myself, I don't disagree with that. I'm just curious to see the frequency of occurrence, what the conditions may have been. I've been in the business for 11, 12 years with negative pressure respirators, and I've never seen that. Doesn't mean it doesn't happen...

Pitts: ...yes, sir...

Tape 5, 6/19/02

Caretti: but I haven't seen any literature and I just, just questioning, you know. I'm not telling you it doesn't happen, it'd be interesting. It would help us if we knew how often, what were the conditions, so, it helps everybody to understand that.

Pitts: Those are the extreme parameters that we threw out, with this protocol and getting funding for, we're asking for as much as, the widest parameters that we can get from you. If you tell us that we're outrageously off the mark, certainly we could adjust that down, but we wanted to get as much information as we possible could to determine if failure times of all the filter systems, whether its on a PAPR or an M-40 or whatever, was our purpose, sir.

Berndtsson: I'm not going to ask you, I'm going to help you. In my presentation...

Graham: ...Sir?

Berndtsson: Yeah.

Graham: If I may, as a follow up. Thanks, Sam. Sir, the other thing is that, we appreciate that we need to establish that better, and we're committed to having some of our marines and sailors put through their paces and try to validate their respiratory rates. I had a couple different, we're taking that project on a couple of different ways, because we, too, want to know what the right answer is and we're searching for that very diligently and we need a lot of help like yourselves and Mr. Davis, and a lot of other people that are already contributing to this effort. And, as mentioned previous on some of this dialogue we've been having. This is still in draft, too, and we're still searching for some of the parameters, we're still looking a lot of the different issues, so,

Tape 5, 6/19/02

we're no means at clarity, we're just presenting the issue, and this is helping us refine it. Even this question that you've given us, so thank you. Yes, Sir.

Berndtsson: Ja, I'm Berndtsson, SEA. I'm going to cover some of that in my presentation, couple of presentations of mine today, so we may be get some answers to that already today.

Graham: Good, sir.

M: One comment I'd like to make is 90% of our hazard risk assessment prior to going into a contaminated environment, whatever the contaminant may be is happening right now, we're doing it right now. You're doing that for me, you're helping me do that right now. Our marines and sailors are back at CBIRF doing that right now, and what I mean by that is we're looking at our equipment and we're looking at it's limitations, and we're putting all that together. Now what we're doing is we're putting, you know, what is the difference between my technical rescue marine going into confined space doing air monitoring everything, I'm not saying I'm putting him in a negative pressure, don't let me, I'm not implying that, doing everything that's required to do that, but I'm looking at the physiology effects, I'm looking at the heart rate, the respiratory rates, all the things that go into that job, as compared to a decontamination marine as compared to our medical personnel who are working in the warm zone doing medical management, search and extract, all those kinds of things, so that then if we get to that KISS method, "keep it simple" I can already have some sort of command system in place so I know that these marines working in this environment under these, this contaminant

at this level, keep it simple, the breakthrough time should be this, if they're doing this it should be that. Because we have all that other high speed equipment and technology mass spectrometers and flame ionization detectors, all those things in place to help put this all in together. That allows us to have a simple, simplified, where Sam is going with this, a simplified method, to keep it simple, right, we're working out of our hip pocket, this is not a command system that comes up with all kinds of computers and all kinds of things. This is four or five of us on the back of the tailgate of a pickup truck when it's pouring down rain and we need to be able to pull something out of our coggle pock(?) and say, you can last this long, the breakthrough time is going to be this, it's going to be that, keeping it very simplified for us, and we're doing that now, prior to the incident taking place. So, sir, your comment is right on, and I appreciate all your help with that.

Graham: Okay, one quick rider to that and then we'll close. Again, we are searching for answers. We've been in this game, dedicated heart and soul since '96. A lot has changed. Some things we've gotten clarity over time. This is how we get clarity. And the end state of it is, again, as Bob said earlier, protect our marines and sailors so they can rescue people. It's life saving. That's the bottom line. Keep that in mind as you're working these issues. We're going to save somebody's life together. It's going to happen. And we're going to be much better for it. Thank you again, appreciate the opportunity, sir.

M: Okay, we're going to keep the presentations moving along without really taking a direct break. There are some refreshments in the back of the room if

you're interested. If you could do it inconspicuously during the presentations, we'd appreciate it. What we're going to cover next is a few presentations from the 3M Corporation. First presenter is going to be Mr. Craig Colton.

Colton: This topic came about as we had some discussions with people in our lab and NIOSH as a result of that often-expressed concern about are biologicals different and are they filtered by respirators differently than other aerosols. So we have a co-worker of mine who's done probably most of the work that I'm going to present, Dr. Nicole McAula(?), but I'm sort of the messenger in this case. It was her expertise then, that allowed us to go and examine this by looking at a literature review. The objective of doing this was to review some of the recent literature and look at what it says about some of the recent, or NIOSH-approved respirator filters. This review, I'll say, is just looking at the recent years, only going back no more than 10 years, of which a lot of the work that I've reviewing was driven by the TB situation and the impetus to use respiratory protection for that particular hazard. I'm not going to spend a lot of time with the details of the tests, and that, these are published studies that I'm looking at and they've been described in the literature. I will provide the references for you. The short part of the talk is that these studies seem to indicate that the filter biological, they filter the biological aerosols just as they would non-biological, or very similar to non-biological aerosols. And that the prediction, if we go and look at their performance, it seems to be predicted by that of their certification, so there seems to be nothing new. Next slide, please. The theory that we've used for filtration and that of biologicals is current

aerosol and filtration theory, and that indicates that the particle size parameters are the things that are important, such as size, shape, density, and that. Sort of refer to the comment yesterday that a particle is a particle. And there's lots of places where you can go and get information on this theory and how it works. I've listed one reference there by Heinz, which explains a lot of it, in fact there's even models there that you can put into like an Excel spreadsheet and use it to calculate or predict filter efficiencies. So that's what we would expect by theory, is this the case? Hopefully, these studies will shed some light. The first one I have here is one done by Chin and other co-workers, published in 1994. The one criteria that I want to mention is that these are filtration studies, we're just looking at filtration capabilities or filtration performance of the respirator filters. They challenged filters with mycobacterium chelonae they were using as a surrogate for TB. They also did some testing with polystyrene latex spheres of about the same particle size. They evaluated four filtering face pieces, face piece respirators this time, that utilized electrostatic media. Now, this included also a high-efficiency filter that was certified at that time. Now this study's old enough that the types of respirators we're talking about are those that were certified under 30CFR Part 11. They did some testing using Anderson samplers so they could sample for viable organisms as well as using the aerodynamic particle sizer. Next slide, please. This is a chart that we created from their data. This isn't found in their study, but the data that make this chart is. Basically what you have here is filtration efficiency on that axis, respirators going along the bottom axis, and

then you'll see, hopefully you can see, three marks there. One indicating the filtration efficiency from viable sampling, another from total aerosol sampling using the APF, and one using the spheres. And the thing that's obvious here is that the sphere's predict performance of the respirator with regards to the biologicals, in fact they had very good correlation between their microbiological data and the spheres, with the spheres being perhaps a little bit on the conservative side. Next slide. Next study in this review is one work done by Brissou(?) and others in 1997 where they challenged filters with mycobacterium abscessus. Now this is the same organism that was used in the previous study, but the nomenclature experts changed the name of it between the publication of one study and the other study. It's still the surrogate, being used as a surrogate for TB. They tested it at different flow rates, and different relative humidities. The filters were preconditioned for 24 hours at 85% relative humidity in this situation, and they tested a lot respirator filters, both what I'll call purely mechanical filters and those that incorporated electrostatic media. And the reason I made this distinction is an electrostatic filter still uses mechanical filtration principles and the electrostatics are there to augment its filtration. They tested, like, about 16 respirator filters in this particular study here, and when they challenged them with the bacterium here, all filters performed what you would expect for their class, there wasn't anything surprising about those results. Next. The next study is one done by McAula and others. It used the same techniques as the previous study, in fact, it was part of that original piece of work. In this case they challenged filters with

three bacterial aerosols, as well as latex spheres. You might note that as far as looking at the shapes, they chose some to get a little bit different shape of the type of organism and then, as we, because that's certainly one of the issues about biologicals. They evaluated a mix again, of the various respirator filters and then they tested them at the different flow rates and humidities. What they found was, those NIOSH-approved filters that the filtration efficiency was as expected for the criteria or the class that the respirators were approved for. The other thing that they noted was that a change in flow affected penetration of all the particles similarly. In other words, it's more evidence that indicates that the bacterial challenge is behaving like the non-viable organism. Next slide. As they looked at the different shapes, they found that the rod-shaped particles tended to be less penetrating than the equivalent spherical particle when they both have that same aerodynamic diameter and that's what we found for non-viable particles as well. They had very good relationship with their data where the spheres predicted filter penetration of the biological aerosols. If testing biological aerosols, they found that the total particle sampling, as opposed to just using the viable samplers, and that is appropriate for determining aerosol penetration. The advantage to that is that it's simpler and easier equipment to use. Non-biological aerosols, then, tend to be good predictors of the biological aerosol filtration behavior, and again the reference is at the bottom. Next slide. Another study by Keehan(?) in 1998, now they challenged some of the new respirator filters in that. They challenged those that were listed as N95 particulate filters, and these were all those that used

electrostatics to augment filtration. They tested against a couple of different bacterial aerosols, as well as sodium chloride particles and latex spheres. They used a couple of different flow rates. When they looked at the filter efficiency, it was greater than 99.5% when challenged with the biological aerosols, and this is an expected result based upon the particle size. I can go and say that the respirators performed as certified when challenged with the biological aerosols. And that, one of the things that's been stated about 42CFR84 filters is that the class level that is printed on there, that the respirator is expected meet or exceed that level, so an N95, you'd expect to show that same degree of efficiency or greater for aerosols in the workplace. Next slide. The next study was one done by Willicky(?) and his co-workers published in 1996 where they looked at a surgical mask as well as a dust-mist respirator. Again, this was one that utilized electrostatic medium. They looked at four different bacterial aerosols or microbiological aerosols here, as well as corn oil. Again, different shapes and tested them at different flow rates. Their results indicated that the corn oil particles penetrated equivalent, or the same as those equivalently-sized spherical bacteria. And that the spherical particles are consistently more penetrating than the rod shaped. So that makes the particles, the spherical particles anyway, a more severe predictor of those irregular rod shaped bacteria. So, from the information at least that's been published and that, the conclusions that I think can be drawn from these studies is that these experiments demonstrate that there tends to be no difference in the filtration of biological and non-biological aerosols. So, it's support for that "a particle is a

particle” concept. The evaluations that are reported on have been conducted over a range of test conditions, like various flows and relative humidities, using different biological species, different filter types and filters with varying types of filter media. When aerosol generation and sampling are conducted properly, then the bio-aerosol samplers can be replaced by direct reading aerosol monitors to increase reproducibility and ease of testing and decrease cost and variability. Further, the non-biological particles with the same size, shape, density, tend to be appropriate surrogates for biological aerosols. Okay. Finally, then, I think this indicates that since current certification test methodologies utilize that most penetrating particle size, those appear to be appropriate tests for predicting the filter behavior of both biological and non-biologicals. So that test concept, at least, I think is right. The information as I mentioned supports the “particle is a particle” and then the idea that we can set performance standards for filtration efficiencies and that for these types of hazards. Thank you. This last slide is just the references all on one page, done mainly to put them in one place for you guys. Thanks. (applause)

Capon: It’s Andy Capon from Avon. I’d like to reiterate that the setting of the performance standards here is the important thing and let the filter manufacturers work out whether or not the performance standards can be met with whatever media that they require. I’m still slightly confused about the P100 mechanical requirement as opposed to if the performance standard is set and the P100, even better than P100, ultra P100, and I’m not going to use P4, but an ultra P100, can be demonstrated, then from what you’ve said and all the

Tape 5, 6/19/02

research papers that you've demonstrated is that that should be sufficient irrespective of the type of media. I wondered if you could comment on that?

Colton: I guess my comment in the short order is I'd agree with you. I think that's exactly what the information indicates and I appreciate your comment.

Hodous: Tom Hodous with NIOSH. NIOSH actually funded a number of the studies there, with the Willicky(?) as well as some at Dugway proving ground. One of the issues that we were trying to raise at the time of TB was still a question and appreciate any comments you have. One was the idea can some organisms penetrate, grow through a mitosis or migrate, or physically damage filters, and then would there be some off-gassing so to speak that might be a hazard? My recollection is that whatever test we'd done did not seem to indicate that any of those were a problem.

Colton: My comment is I remember those studies. I don't know if any of them that indicated that that was a problem. There's been limited studies, though, on like a survivability, and that, so as far as I think of something like a spore, I don't know of any reason why it's viability would be changed when it hits a filter, so then you still have concerns about how you're handling it, and transferring the material which then indicates that we need use guidelines along with these issues as well. That's it. (applause)

(END OF TAPE 5, SIDE A)

(TAPE 5, SIDE B)

M: ...are also from 3M.

Tape 5, 6/19/02

Weber: First I want to say it's a real privilege for giving us the opportunity to talk here and next slide, please. What I'd like to do today is talk about two things, and this is the scope of my presentation. First, it's a need to have performance based standards, and by the time I'm up, my time is done here, I'll probably say performance based standards at least 20 times, so please count them for me. Secondly, what I'd like to also address is some of the performance issues that have been raised regarding electrostatic filter media. Next slide please.

There are, been many possible scenarios that really been laid out that can yield high and low agent concentrations, therefore, it is really impossible to design one device that will protect the wearer from every conceivable situation marked by terrorism, and I think we're all in probably agreement with that.

The other thing I'd like to point out is that we have to really work hard at balancing protection against the workload and the wearability. We also have to really take into consideration the entire equation of protection, and that involves the sum of the efficiency of the capturing the contaminant, the fit of the device itself, and more importantly than anything, it has to be worn, so wear time is also a critical component. Trying to define the intended use of these devices is a difficult and daunting task and we've been hearing about that for the past two days. But we must proceed to have a real understanding of how these devices are going to be used before you can develop a performance standard. As I just said a moment ago, we need to balance that protection against expected use. Performance tests need to represent the expected use conditions. We need performance based standards without

design constraints. Design specifications really prevent new technologies from coming forth. They also prevent that next generation of products that are going to be smaller and lighter weight. So it's extremely important that we keep design constraints, whenever possible, outside any type of standard. Next slide please. What I'd like to do know is to look at four standards or guidelines around respiratory protection that have really been developed around the whole chem/bio/nuclear protection. And the thing that I want to point out as I review these and I'm going to do it rather quickly is that they are all performance based. Next slide. The JSGPM and the JSAN parameters are really the next generation military mask. As you can read, and I'm not going to go through there verbatim, the scopes are very similar. They're providing protection against chem/bio warfare agents, radiological particles, and also toxic industrial materials. Very similar and they're both performance based. Next slide please. What I'll do now is just kind of real quickly highlight some of those performance requirements. And this does not include all of them, I just chose a couple of them that I thought were pertinent. There's a weight performance requirement, there's a bulk, vision, communication. They also, both documents address wearability. There's also a long term aging requirement. The next requirement I think is also critical and it has to do with the performance of the chemical cartridge or the canister. And in that document, or in both of those documents what they have done just as was pointed out here this morning, with the chemical component of the concept paper that's being proposed by, or concept standards that's being proposed by

NIOSH, they're looking at a performance based. Here, JSGPM and JSAN are also looking at performance based. So, what they've got is, for chemical warfare agents, they have the agent itself that they're going to challenge it against, the challenge concentration, the flow, the RH, endpoint, and time. It's not a surprise to any of us. As far as Toxic Industrial Materials, again, they have the agent, the challenge, the RH, the time, the endpoint. Again, it's performance based. And with regards to biological and radioactive particles, both documents are performance based once again. They have a DOP loading, and they have a particle size, and a minimum of efficiency. Next slide please. This next requirement that I'd like to talk to you about is really the C2A1 which goes on the M-40. It was pointed out yesterday that the C2A1 has a specification in there that it has to either, I'm not sure if I heard this correctly, it either has to be mechanical based or it has to be Fiberglas, and I'd like to say that that's not correct. The mill spec that the C2A1 is designed to today, and the citation is up there, it describes a performance requirement for the C2A1. It covers the mask canister used to protect against, again, chem/bio/radioactive particles performance based. In that document itself it has airflow resistance, and again this is not all the requirements, this is just some of them, it's got aerosol filtration, liquid agent permeation, gas service life, accelerated aging, and so on. Again, its performance based. It does not specify Fiberglas, it does not specify mechanical filtration. Next slide please. The U.S. Soldier Biological and Chemical Command a few years back, actually July 2000, developed an interim in-house guideline for qualification

testing of escape hoods and this is only an interim, and they did it because NIOSH had not yet gotten to the point of developing an escape hood standard, which they're going to be getting to shortly, so it's an interim. But I think what's really important with this document, and this verbiage I'm going to talk about, comes from the document itself. This performance criteria were established based on a thorough review of available military industry standards and acceptable practices for evaluating respiratory protection equipment. So here we have SBCCOM, they developed the guidelines, and again, it's a performance based type of guideline. You can see there, they address chemical warfare agents, TIMs, particle size, vision and communications, and so on. What I've just done is given you a highlight of these four different types of performance standards that are probably on the cutting edge of what we know today about protecting one from chemical and biological agents. What I'd like to do now is to kind of switch gears a little bit and talk about some of the things that have come up regarding mandating materials and design specifications, and what I'd like to first say is, it's not a good approach. As I mentioned before, I just covered four different, what I would say, leading edge type of guidelines and specifications, and specifying materials or how a system should achieve the desired outcome really, as I noted before, inhibits those new technologies and those smaller, lighter-weight types of products. Some examples of specifying materials or design would be if you were to specify one type of carbon, and specifying Fiberglas filter media or mechanical filtration for a particulate filter. What I'd like to

point out what happened in the mid-1990's when NIOSH felt compelled, and rightly so, that there was a concern about the performance of electrostatic filter media against oil. And NIOSH could have taken the approach of saying a mechanical filtration. They could have taken the approach of saying Fiberglas, but no. What NIOSH did when they came up with food(?) 42CFR, they said, let's have a performance based standard with 200 milligrams loading. So, what we're trying to say today, right now, is NIOSH should still continue to have that philosophy of performance based. Next please. So filtration criteria for CBRN air purifying respirator, needs to be performance based, not material or mechanism based. Why is this even in question? As I noted before, if you look at maybe materials for face pieces, some people have questioned silicone, some people have reported concerns on filtration media such as the electrostatic filter media. Next slide please. What I'd like to do is just briefly go over some of the oil issues and kind of address where the industry is today with this in some of the studies that have been done. With respect to the P series test requirement, as I noted before and you all are well aware that there's this 200 milligram loading out there, it's really an overestimate of a workplace environments known to contain oil aerosols, however, it's a good approach in the fact that it's a conservative one. The other important item here is that subsequent research in this area of the effects of filter media against oil, really supports the P series test as a relevant performance test. Next please. To take that a little bit further, NIOSH, in a document that they put out in 1999 estimated that the mean level of a

workplace is 1 milligram per cubic meter of oil when oil actually exists in the workplace. If you look at the moderate work rates and you look at loading, you could have up to maybe 50 or 100 milligrams loaded on a filter that was used for 40 hours. Subsequent research by 3M, which actually is in the process, which just has been submitted to the AIHA journal on a P-95 respirators validated that the filter was still greater than 95% efficient after 200 milligrams loaded with metalworking fluid. So there is data to support it and there's a lot of other data that also support the fact that the standard today with the P series is a good standard to alleviate some of those concerns that have come up because of oil loading. Next please. What I'd like to do now is not so much focus on the title saying particulate filter media designed for demanding performance applications (...inaudible...) 3M electro filter media. What I'd like to point out here is that a couple years ago we were approached, somebody approached us to develop, they had a design specification on performance and they were somewhat concerned about oil. And so, we design electro filter media. We challenged against mill pro 830, which is a metalworking fluid. We loaded, on the axis down here I don't know if you can see it, it's the total milligrams loaded. We loaded 200 milligrams of the oil, we let it sit for 7 days on the filter media, and then we proceeded to load 1360 milligrams of DOP. As you go through and look here there was no change in penetration, so as we loaded the oil itself, the mill pro, there was no change in penetration, it was essentially 99.99+. And then as we loaded the DOP onto that same filter media, after it had been aged, again, nothing happened. What

this points out is that we were approached with a design-performance type of specification. And we designed a filter media for it. So to go forward and to say that you can only have Fiberglas or only mechanical would be a mistake, because if you design a performance standard, somebody will make that product or that component to meet that performance. Next please. Recently, in the last couple years, there has been some concerns about degradation of electrostatic filter media with solvents, and Roland alluded to that here. At the 2002 American Industrial Hygiene Conference in San Diego, NIOSH had a report where they exposed N&P electrostatic filter media to saturation levels of IPA, ethyl acetate, acetone and pentane for varying amounts of times. And I'd like to read the actual stated conclusion as it was written in their abstract. It said, "This research shows that electrostatic respirator filters can be degraded by these organic vapors at saturation levels. However, this degradation is not a concern because workplace concentrations will be much lower than saturation." Next please. The thing that I'd like to point out is that NIOSH had some data. Now to take that data and to turn it into information and into knowledge, they haven't done that yet, and that's the key whenever you have data. What they did is they showed that the filter media degraded, but the challenge was really outside the scope of the performance of the system. So what do I mean by that? They reported that they saturated the filters and if you look at the saturation level, and I'll just pick on in IPA right here, they challenged it at 53,000 parts per million. In one of their abstracts they said they did it for 8 hours, and in a poster session it said varying, so I'm

not sure how long they exposed it. But, no matter what they exposed it to at a saturation level, and once you saturate things, you're pretty close to actually dipping it, especially as you change this temperature. The IDLH is 2,000 parts per million. Now, as I mentioned before the reason why I, we believe that this design does not match the anticipated use, is that a dual cartridge, and I just pointed out the 3M dual cartridge, that would have lasted in that environment for two minutes. So, in reality when you start looking at these challenges, they're nowhere in line with the system. And again, I'm going to go back to the fact that, as you design a standard, it's important that you have the system in mind, and it's important that you don't overdesign some components in that whole system. Because if you do, you're making a big mistake. So, can you go backward? That's okay. I'd like to point out that the experiment did find a failure point, and it's important to know. I don't want to say that not knowing when these things fail isn't important, but to draw any firm conclusions and to extrapolate that to possible say mechanical filtration, and I'm not sure this is the logic trail that NIOSH is using, is a mistake. Now you can go to the next one. Now, at the 2001 American Industrial Hygiene Exposition, 3M did a study with solvents and with electrostatic filter media and we tested an N-95 and a P-95 and we challenged these filters with MEK, toluene, cyclohexane and IPA. Right here, this is the OSHA PEL, right here then, what we did is we exposed it to 10 times the PEL for 4 hours at 32 liters a minutes. So for example, where NIOSH challenged their filter media that they tested at 53,000 parts per million, we challenged at something a little bit more reasonable at

4,000 PPM. However, that's still above the IDLH. That's still outside the performance of that system. And we had it there for four hours. Dual cartridge respirator would have probably lasted about 60 minutes against IPA. Next please. This chart here you have DOP on the bottom and you have penetration here, and this is what I'd like to focus on. This is the control filter, hadn't been exposed to anything, as you load the DOP on it, we saw that you started at a little bit above 2% penetration, went up to about 2 ½ and then as you began to load more oil on it, it went down. Next please. Now, this is the filter, the P-95 filter that was loaded with IPA at 4,000 PPM for 4 hours. You can see here, it's a similar curve. We got about 1.8, goes up to 2.0 and drops down to about maybe 1.1, 1.2 penetration. So, next slide please. So, really the isopropyl alcohol vapor had really no adverse effect, and I didn't have time to report on the other solvents, but we had similar results with the other solvents. Now, in summary, when you start looking at the oil and I call it the solvent issues, the oil challenge is, we strongly believe that the NIOSH standard that exists today and all the relevant research that has been done to look at the effects that electrostatic filter media has when it's challenged with DOP and other types of oils. It's a good test and we strongly endorse it. As far as the solvent challenge, I just briefly reported and we don't have time to go in depth here, the two studies reported different challenges, different outcomes. Now, I really suspect after I leave here today that a concern will still exist. I'm sure I didn't sway anybody. But, what I want NIOSH and what we really strongly encourage NIOSH is that, if there is a concern, then develop a test method to

identify the desired performance, and, in doing so, make sure, please, that that solvent concentration that you may want to challenge the filter to is somewhere in the vicinity of the challenge concentrations that you're using for possibly the gasses and the vapors. Don't go to these wild extremes just to find the degradation point. So you need to have a test method that represents the real world use and to take into account the performance of the entire system, not just that one component. Next please. So, to have a performance based standard without design constraints, that's number one. We feel strongly that it's a disservice to the user to specify materials or operating mechanism. We also feel strongly design specifications prevent new technologies. As I pointed out on the first couple slides, understand, and I'm an industrial hygienist by training, so I understand and I've been doing this for over 20 years, that protection is an overall, there's lots of components to it, and it's understanding how the components work, how the device fits, and the wear time all have to be considered. And over-designing components can throw these other things way off kilter. The other thing I'd like to point out is that over the last few days, I've really witnessed what I thought a real good logic trail with determining challenge concentrations and endpoints for the gasses and the vapors that we're talking about for some of the human factors tests. Very good, concise logic trail of why, where you're proceeding. And I think Roland mentioned the fact that the process that you're going through right now is we're really witnessing your thought process, and it's good. However, what we haven't seen is any logic yet in why you would require

mechanical filtration or specify Fiberglas or wherever you're going with this. The other important thing to point out is that electrostatic filter media, hopefully this doesn't come to surprise, uses mechanical filtration because electrostatic filter media uses impaction, sedimentation, interception, diffusion. It uses all those same capturing mechanisms. Now with electrostatic filter media it adds one more. So, electrostatic filter media enhances mechanical filtration and that's a very important point. The last thing here that I'd like to point out is manufacturers, industry, military, users, regulators, really for the last many, many years have come together in working with industry, in working with responders, and it's really a joy to see us all coming together and to have a nice, good, open dialogue and we just want that to continue, and finally, we strongly feel, and I think I can speak for the rest of the manufacturers, that we have extensive knowledge and expertise on a lot of these components, more so, probably than NIOSH or the military, in some cases, not all cases, because we have to make these things. We have to study them. We do a lot of research. So, it's really important that we keep an open dialogue going back and forth as you proceed in writing your standards.

Thank you. (applause)

M: Real quick question. Hopefully it's quick. I haven't, a lot of this information is coming out with vapor exposure to electorates, it's new, it's been briefed I guess at the Industrial Hygiene conference, and the information that you've collected, I don't believe that's any of this is in the open literature per se, at least the latest. But the question is, you may know more than I know, do you

Tape 5, 6/19/02

know if classic mechanical pleated Fiberglas media has been run through this same test protocols for these evaluations?

Weber: I'm not sure that it has. At least we haven't. Now NIOSH might have, I'm not sure...

M: You didn't, the information at the conference then was not...

Weber: It was not and the other thing I'd like to point out is the fact that, just as you can do with different types of rubbers and polymers where you can compound them and put different types together to make something even better, you can do the same thing with filter media. You can take Fiberglas, and you can take electrostatic filter media, and you can combine them and you can make a hybrid, and you can make a hybrid that will perform extremely well, so it's important to understand that if you use the word "mechanical filtration" it's going to be difficult really to determine what is mechanical and what isn't mechanical, because it all is.

M: I understand. I'm just looking at purely the Fiberglas mechanical and traditional...

Weber:I haven't seen it, maybe NIOSH...

M: ...because as you know some of those use glues that could be subject to degradation through solvents.

Weber: Yeah, absolutely, yeah. I wanted to talk to you before, I was going to say this...

M: Okay, Bob, this may not be the time for all of our conversations, but I have two specific questions. The first speaks to the issue of the electrostatic

treatments on the fibers. If the primary concern that we have, as you well know, is the abundance of research that's out there, some of which was under incredibly conditions, can negate the electrostatic treatments on the fibers, and then look at the filter efficiencies of the filter after the electrostatic treatments have been negated. Have you done any research to look at that issue?

Weber: We have looked at a lot of different challenges with electrostatic filter media. The thing that's really important to understand here is that in the last 10 or 15 years, there's been so many advances in how you put that charge on, and how you keep it on, that the filter media that somebody might do research on today, that they bought off the shelf today, and if they have done studies on that, sure you can report on it, but you cannot lump that all under one category, because somebody else's filter media could actually be better. Or, the other thing to understand is that you design filter media, you design any component to meet a performance specification. That's what you design it to, and then try to meet those other things that people want, so, to get back to your question, yes, we have done that kind of work, and we'd be more than happy to sit down and share what we've got with you.

M: Okay, second question. It's my expectation that in the field of electrostatic treatments, 3M's probably on the upper end of the learning curve. So, have you done any research to compare electrostatic medias from other manufacturers to know if the electrostatic medias are really all fairly equal or is there some dissimilarity that we would need to recognize and account for in a performance standard?

Tape 5, 6/19/02

Weber: You know, we do look at other media that's out there, but historically, 3M's approach is that that's not, we don't report on that. We know it, it's something that we would more than be happy to share with you to help you understand, so we do have some of that information available. We don't do an extensive amount of it. It's sort of like looking over the shoulder, we don't usually look over the shoulder, we go forward, but...

M: Okay.

Weber: ...we're more than willing to sit down and share with it, but it's not something that we like to go out in the public domain with it, just because it's something that we intended that's not our ethical philosophy, so.

M: Thank you.

Berndtsson: Goran Berndtsson again. Very good Robert. I agree with a lot of what you're saying. It's very important that we're using the right level of contaminant. What is equally important that we are testing the filters in the kind of (...inaudible...) that we want use them. You said just a minute ago that we are making filters to meet the test. We are testing at 85 liter continuously. So you're making filter material performing at 85 liters. Do you know anyone who breathes at 85 liters all the time?

Weber: Well, Goran, what I'd like to... I did bet somebody that you would ask that question, so I won. Thank you. I owe you a buck okay. I'll split it with you. Getting back to your question. I'll go to the point that it's designed to meet 85 liters a minute. That's what it's designed for. Which is, in fact, a buffer when you start looking at flow rates and I know it was just talked about, these

Tape 5, 6/19/02

higher flow rates... What I'm getting at is if it was changed to 135 or 150 liters a minute, fine. Filter media will be made to that. It can be done. It can be done.

Berndtsson: So in other words, you would agree that we should have more than one flow requirement to test against?

Weber: No. I didn't say that.

Berndtsson: So you mean that...

Weber: What I'm saying is that, what I'm saying is the fact that I believe 85 liters a minute is a flow rate that has enough buffer to it that you might get these spikes that occur once in a while, but when you start looking at dose, you have to look at dose. And that's something, Goran, that you'd often don't look at when you do your 85 liters a minute and you want the 300 liters per minute. Because dose is what's important. And, you might get the instantaneous spike once in a while, but it's instantaneous. It's, the standards today are time weighted average standards.

Berndtsson: I will not comment on that because I will explain it in a second.

Weber: Okay. Thank you. (applause)

M: Next presenter is going to be Ron Herring from Mine Safety.

Herring: Some people collect baseball cards. I collect cans with mill spec threads on them. I have to apologize first of all, on a couple of the overheads you're going to see here, because obviously we received the June 14th or 15th update when we walked in here, and I had every intention of going home last night, and updating those overheads. But then when Jim Genovese was talking last

night about the railcars of chlorine going down, and wiping out two stadiums full of people, I was sitting out on the deck and I hear this train whistle about a mile from my house. So instead of updating the slides, I went down to my basement and dug my bunker a few feet deeper. (Laughter) First of all I'd like to thank NIOSH, SBCCOM, and NIST for setting up this public meeting for the purpose of discussing their standards, or I should say "our" standards development efforts for full face piece air purifying respirators used to protect emergency response workers, particularly against chemical, biological, radiological, and nuclear agents. The National Personal Protective Technology Lab has an important role in developing standards that protect our first responders. By creating the environment where you collect information from all stakeholders in a public forum, our nation is better served and the resulting performance standards will absolutely provide the framework for innovative quality products that our nation's workers can depend on. And I hope this once again becomes the rule in rulemaking and not the exception. The first part of MSA's comments is probably best titled "Lessons Being Learned from the CBRN and SCBA Standards". When I walked in yesterday and I registered my name tag said "Ron Herring, Mine Safety Administration" Actually, I was quite pleased that I'd joined the government, and Terry Cloonan would finally listen to me (Laughter). Oh, apparently that doesn't work. Sorry. Well, anyway, the first part of MSA's comments here is "Lessons Being Learned from the CBRN and SCBA Standards". We've been wrestling with this for quite some time now. We've dedicated significant,

significant resources toward it, and I'd like to share some of our findings on this. In NIOSH's letter to all respirator manufacturers dated December 28, 2001, announcing the CBRN standard for SCBA a promise was made that NIOSH would follow a flexible program for test and evaluation of SCBAs for a limited period of one year. This flexibility was appreciated and continues to be required since the standard, as developed, provided no mechanism for manufacturers to test their products during development or prior to submittal. Now under normal circumstances manufacturers design their products, run tests, and submit documentation of results prior to our submittal to NIOSH. But due to our inability to test our products against chemical warfare agents, we are unable to reliably predict the outcome of the testing required by NIOSH. Nor are we able to sample our production to assure that it meets those requirements. This highlights the need for NIOSH to identify and recognize surrogate agents in their CBRN approval process. And this should be NIOSH's number one priority in their efforts to develop CBRN product standards. Until such time as the appropriate surrogates are identified, NIOSH must keep their promise of a flexible SCBA CBRN approval process and follow this similar path for the CBRN full face piece air purifying respirator standard. This is in everybody's, everybody in this room, everybody in this country's, best interest. Because I don't even believe that we have the lab capacity in the United States to provide for the research and approval time that's going to be required for the SCBA standard and for the gas mask standard. The next lesson being learned is the need to publicly validate the

protocol. Manufacturers and the user community need to trust the results and the repeatability of the tests. While I did not want to go into details here, I can assure you that we've wasted time, money, and may even have some misleading results due to the fact that the CBRN SCBA protocol was inadequately validated. Let's do this for the right way on the CBRN full face piece APR standard, and thoroughly validate the process and publish the results. Finally, under lessons being learned, we request that you publish and provide the public the opportunity to comment on the most likely use scenario and your rationale behind the test conditions. We want to avoid unrealistic conditions that might drive the size, and the cost, and the performance of these products beyond the market's acceptance. Quite frankly, we all have this backwards. We should be defining the response scenario first, and then developing products for that response. MSA's comments on the proposed CBRN full face piece APR standard are focused in 4 areas, one of which I already covered, but let me say it again because it's that important. It's that important so that we can get products out to the market in a timely fashion. NIOSH needs to make their search for surrogates the number one priority. It's more important than anything else that you're working on today. It'll speed up the time to market of product. The next issue that I'd like to cover relates to section 6A, or I believe it's still 6A, of the draft standard or concept paper I should say, and it's titled "Interchangeable Consumable Filter Cartridges and Canisters", and Les, I appreciated it when you finally got up there and said, "Are there any questions?" and you took a step back, waiting for the long line

of people to go through there. I guess part of it is we're not sure yet. I hear from the user community; I understand what they're looking for. And to a certain extent I understand why interchangeability might make sense to some people. But let's take a moment. Let's take a moment and really define the problem that we're trying to solve here. September 11: a day that will remain in our hearts and minds for the rest of our lives, with four terrorist attacks. Thousands of innocent lives are lost. When it would have been all too simple to feel sorry for ourselves and wallow in our own self-pity, our first, our nation's first responders, these heroes, demonstrated a level of bravery and commitment that, in many ways, saved our nation by providing an example for us to look up to, of duty, honor, and courage. And recognizing that there are lessons to be learned from this disaster, the National Personal Protective Technology Lab should be commended for setting up the Lessons Learned Conference in New York City on December 9 – 11 that I was fortunate enough to be able to attend. The resulting report and discussions that we had in the breakout session, Bruce, I don't know if you're still in here, but Bruce Teele and I were in the same group. In the resulting report there were comments related to a shortage of respirators at the World Trade Center site. Before we venture into this tangled web of regulating interchangeability, or at the very least, regulating the environment where interchangeability is possible, I believe that we should spend some time on the root cause of that shortage. In the hours immediately following the September 11 tragedy, there was absolutely a shortage personal protective equipment, not just respirators.

After all, this was an event larger than anything that we could have imagined. The transportation infrastructure of this country in the United States was shut down, and the immediate personal protective equipment needs of the site had to be filled by the inventory from local safety equipment distributors. Probably, those of us who deal with distributors, a limited inventory of personal protective equipment. Interchangeability would not have helped. The only way to improve the availability during the initial hours of a large scale event is to create emergency stockpiles of equipment located in hundreds, probably thousands of locations throughout the United States. But as we know from the Ran Report, the shortage seemed to last for days. We estimate that the respirator industry, the industry that I work through here, shipped over 100,000 respirators and probably 200,000 combination filter cartridges to the World Trade Center site in the first 48 hours of the terrorist attack. Easily enough to support 1000 workers for one hundred days even if they threw them out every day. In short, it was less of a supply issue, and more of a logistics and training issue. Multiple government agencies were taking responsibility. Rescue workers didn't know where to get the products on the site. And if they got it, they were not familiar with it's use and maintenance requirements, resulting in products being discarded long before they should have been. We would absolutely better serve our first responders if we developed an emergency logistics program to address large scale events. This logistics program should address site security, product distribution, training, fit testing, and safety enforcement. Without solving this problem, the shortage problem

voiced at the Lessons Learned Conference, whether you use a den thread or not, will repeat itself, and God forbid we have another event like that.

Regulating interchangeability will not help. In fact, it will put first responders at a greater risk. MSA fully supports the comments by the ISCA, but I'd like to provide some additional detail in regards to interchangeability. In the development of a respirator, MSA considers the whole system, and we try to optimize the product for size, shape, position, weight distribution, balance, resistance, comfort, fit. Regulating the face piece filter element interface is design restrictive and will hamper the optimization of that system.

Additionally, the mixing and matching of a manufacturer components is not a realistic goal that will not provide the desired results. The slide, you take a look up here and you can see some of the samples here, these are just a few cartridges and canisters currently available with an EN148 NATO thread, the NATO thread that is being suggested here. However, they have a variety of approvals, weights, and breathing resistances. In order to get an adequate fit, some require 4, 5, or 6 point harnesses on the full face piece. Some require breathing tubes and body harnesses because they're too large or heavy to be worn on the face. By regulating the interface, NIOSH would seem to be endorsing their use in any configuration. And by endorsing their use in an event as large as what September 11 was with the confusion that surrounded it, will be endangering the lives of the first responders. NIOSH should maintain a systems level approval approach, focusing on performance and not design. NIOSH should also support the development of emergency logistic

programs to ensure product availability, proper training and fit, and enforcement of the emergency events. The third point I'd like to cover is that NIOSH should not recommend, and I'm glad to hear, and this is going from some of the early comments, but NIOSH should not recommend or approve air purifying respirators for entrance or use in IDLH or unknown atmosphere. This is beyond the accepted-use conditions of air purifying respirators and forces test concentrations well beyond the accepted assigned protection factors of the products. The graph you see here, actually was from the May 28 rev of the concentrations. But the first, it kind of demonstrates two issues here. APF for the full face pieces, that's the red line that you see going across there is not consistent with the APF required to meet the test concentrations and the end points in the proposed standards. Now some of this has changed obviously with the data, some of them have gone up, some of them have gone down, but they are beyond the design criteria of a full face piece respirator. And second, it also demonstrates that the ratio of the test concentration over the endpoint falls far below the 10,000 you might expect out of a product that's approved for IDLH atmospheres. In short, the tests do not support the use of full face piece APRs for use in IDLH atmospheres, and I'm glad to hear that this is out of consideration on the NIOSH standard right not regarding IDLH and unknowns. For response to CBRN events with IDLH or unknown atmospheres, SCBA with chemically protective clothing are the only responsible recommendation that can be made. Finally, we'd like to make a general comment on the performance requirement on this concept. Although

the details of the standard are not finalized, it's apparent that this standard is creating a whole new category of respirator worthy of the attention to detail and input, not the bureaucracy that is associated with a formal rule-making processing. In summary, we support the comments provided by the ISCA, the Association represents a vast majority of respirator manufacturers in the United States, and their comments were developed and represent a consensus of its members. MSA recommends that NIOSH position the search for acceptable surrogates as their number one priority. This will increase the speed in which these products come to market. It will provide a mechanism to assure quality control. We recommend that NIOSH maintain their focus on performance requirements and not dictate the face piece filter element interface. We hope you appreciate how regulating the interface could lead to product misuse, thus endangering first responders' lives and increasing the liability risk for everybody involved. Developing emergency logistics, site control, fit testing, and training will be a far more effective mechanism to assure that first responders have access and knowledge of the products that they need. Even the systems level test that you have in this program right now that are being proposed actually negate the concept of interchangeability, unless we're all prepared to test every single possible configuration that you can imagine, and I can only assume that gets into the tens of thousands of possible configurations. We ask that you not approve any APR for entrance or use in IDLH or unknown atmospheres. This obviously exceeds the capabilities of any APR. SCBAs would be appropriate. CBRN totally encapsulating suits

are the appropriate level of protection for this application, and their use should be encouraged. Finally, we understand the need for speed. Boy, do we understand the need for speed. But the changes that you've recommended here are significant enough that the detail associated with the formal rule-making process should be followed, not the bureaucracy. We can't afford to make mistakes that slow down new product development. I thank you for your time and attention. MSA looks forward to future discussions with you. I heard the gentleman from the Marine Corps talked about this as a team. I look at this as a team. I hope that we have more opportunities as the year goes on for us to have public comments and discussion just like we're having here today. Appreciate it. (applause) Any questions, Goran? (Laughter) You guys are getting tired, now.

M: We'll have one more presentation and then take a break so we can set up for Goran's presentation. Evan Hensley, I'll have a (...inaudible...) representing ChemTex, oh, I'm sorry.

M: (...inaudible...)

Cloonan(?): Huh! Huh! Huh! Okay Mr. Herring. Thank you very much. Thank you, thank you, thank you. (Laughter) In relation to your statement about the validation test for the CBRN SCBA program, can you provide specifics and details related to your assumption there?

Herring: I can, Terry. I don't think we want that in a public forum, but you and I can sit down and talk about this in great detail.

Tape 5, 6/19/02

Cloonan(?) Oh, I would greatly appreciate that, being that we are in a public forum.

Thank you.

Hensley: Good afternoon, I'm going to be brief here, I know I'm the last one before we have a break...I guess we're going to get these proceedings recorded, I'm not safe here now, but, my name is Evan Hensley with ChemTex(?) Corporation. I've got the privilege of meeting quite a few of you in the room, many more people than I did when I presented this in April of 2001. The people at Aberdeen know us more as Harris Manufacturing; ChemTex is a wholly owned subsidiary of Harris Manufacturing. We're the primary butyl manufacturers, we don't make the butyl, but the butyl products, in America. What we're doing basically is we could offer a hood that would fit on any respiratory face piece. These hoods are going to be accessories that are really going to help augment the protection that the respiratory device is going to allow for and provide, and I'm just going to go through a few of these samples here, and I will leave them here for anyone to look at or entertain questions during the break. There's basically two styles of butyl that are used. The heavyweight butyl is used for suits primarily, but we also manufacture for some hoods and heavy industrial applications. Several years ago, most of the respiratory face pieces were all ovals. It was very easy to make a two dimensional shape that would fit on them, and we've cut these to fit on several things as the industrial customers have asked us to, but as the shapes have become more complex, this is a government hood where we bond a second skin into a butyl hood and it provides augmented protection for that gas mask

Tape 5, 6/19/02

to allow protection for the wearer's head, eyes, ears, neck, etc. These two, this is the M-40 hood, it's got a bungee attachment here that fits around the face piece. We've also done double bungee attachments here. And this is a negative pressure, where we've taken, a negative pressure hood where we've taken a nose cup half face respirator with canisters that have been tested for six hours at Aberdeen and built a butyl hood onto it so it's going to provide a lot more protection than just the respirator would by itself. Here's another version of a military hood, it's referred to as a Level A hood. It's got a little brim that augments the protection for any splash again. We're providing protection from vapor as well as liquids with these products. I know it's gotten late, didn't want to do a big sales pitch on anyone, but the last product I have here...As the shapes of visors have become more complex we've had to go to different design concepts to be able to fit on. What we've done with this hood is, we've actually vacuum formed a perimeter piece that fits on, this is not a fielded unit, but this for virtually any respiratory face piece, we can vacuum form a perimeter onto it and gives us much more design flexibility as far as possible solutions to any face piece design or shape or anything else that you might have. Don't know if I should throw this over to questions or not, but are there any questions out there that I could help with? I know it's almost break time. If anybody needs to see me, all my information I guess will be in the proceedings, and I'll leave these products up here if anyone's interested in looking at them. All right. Thank you very much. (applause)

Tape 5, 6/19/02

M: All right. At this point we'll take ten minutes and let Goran get set up. Thank
you.

(END OF TAPE 5, SIDE B)

Tape 6, 6/19/02

(TAPE 6, SIDE A)

M: All right, at this point, we have one final presentation, by Goran Berndtsson of SEA. Following his presentation we'll proceed into our open comment period and then a wrap up to be conducted by Les Boord. So at this time, Goran.

Berndtsson: Thank you. I thought, to start with, if there is anyone in the audience who still doesn't know who I am, I actually, me and my wife started Safety Equipment Australia some twenty years ago, and we have in the last couple of years moved over to the United States, so we are permanent residents here now, and we're running a company in Australia, one here, and one in Europe. So, I'm going to talk about PIAFs. Peak Inhalation Air Flow, and why is PIAF so important that we need to change the way we test APRs. I'm going to do it again; I'm going to go back into history because for some reason we seem to forget what our grandfathers did one day. So already in January 1943, Leslie Silverman (?), Robert Seeley (?), George Lee (?), and Katherine Drinken (?) and Dr. Thornton Center Carpenter (?) from the Department of Physiology and Industrial Hygiene at Harvard School of Public Health and the Nutrition Laboratory of Carnegie (?) Institution of Washington published a report and the report is "Fundamental Factors in the Design of Protective Respirator Equipment Inspiratory Air Flow Measurement in Human Subjects With and Without Resistance." In the introduction to this report, it was identified the successful design of protective respiratory devices such as canister (...inaudible...) chemical warfare depend upon a number of physical and physiological factors. Two of the most important of those are the maximum rate at which air flows during each inspiration to a

particular canister or filters and the length of time during which this maximum flow contains. Ladies and gentlemen, that was 60 years ago and we are still ignoring it. The opening statement of the conclusion reads, "The result shows that the percent flow rate for elevating the efficiency of protective canisters is inaccurate, etc." Already then, they measured PAFs of 294 liters per minute. This was before the technology of computers and high frequency microprocessors were available. At SEA we started to look into PAFs in the early '90s. We did this in aluminum smelting(?) industry in Australia and New Zealand. We built an airflow meter which was attached in front of the regular filters used in the smelters. We then collected PAFs, volumes, and heart rates of people performing the ordinary work. The collected information led to concerns about physiological and heat stress issues in the smelters. Over the years, we refined our measuring and collecting techniques. Today, we can measure PAFs of up to 500 liters a minutes, with an accuracy of +/- 10%, as well as a total volume. Following are some graphs of our work in a real smelter in South Australia. We data load him for about 90 minutes when he was doing manual labor including jackhammering. We choose this because this type of work is possibly well representing the work performed by the first responders and recovery workers at World Trade Center. The data logs we are using have a capacity to record on 3 channels at 50 hoods for approximately 90 minutes, and the software can display the total (...inaudible...) as well as a small part of the data. We are also capable of calculating both the percentage as well as the volume which each flows faster than a certain flow rate, or above a certain level. For example, particular filters are tested at a constant

flow, 85 liters. We have talked about that the last couple of days. And also they are velocity dependent. They will perform differently at different flows.

Therefore, we need to know as the report referred to above both the flow rate and the time which equals the percentage of volume and total flow which are over 85 liters per minute. We also need to know how long the person can sustain the PAFs above the flow we are now testing at. There have been arguments in academic papers that PAFs of level exceeding test levels can't be sustained for more than a few minutes. With the data we will show that this is not true. We can also show that the almost every person, fit enough to wear an APR can sustain breathing rates 2 – 3 times the flow rates we use for testing. What we have up here now is just 90 minutes of data, and it looks like, it's squeezed into one graph so it looks like a different blue colors of field, and may be a bit difficult that I'm going to be able explain how it works. So up in the right corner, which is up here, it reads the number of 11,701.1 which is the total volume of air that was breathed through the system in those close to 90 minutes. This is a positive pressure demand APR, the person breathing as freely as if not using an APR, but it is not forcing more air through the system that is actually requires. So this number of liters of air is what he would have been breathing if using a negative pressure APR with low enough pressure drop over the filters, as well as over the exhalation bulbs(?). As I described earlier in this document, we have started to do (...inaudible...) on negative pressure APRs and surprisingly, we all recorded PAFs just 10 – 15% lower than we are recording in positive pressure mode. We find many examples in the literature, for instance the textbooks of Work Physiologies by Paula

Warstein(?) and Carl Rudle(?) in the book (...inaudible...): "Pulmonary Ventilation During Exercise from Resting Values of 6 Liters to 100 – 150 liters per minute in extreme cases 200 liters. This is minute liters, is not PAFs. Maximum volume ventilations has been measured up to 211 liters. Well-trained and fit athletes can utilize some 95% of that during exercise. But for less fit subjects, only about 60 – 70%. That is still 60 – 70% of 210 minute liters. Not peak. So Warstein and Rudle also say that moderately well-trained individuals may walk around for about 1 hours with an oxygen uptake of about 50% of the \dot{V}_{O_2} (?) max, maintaining the oxygen uptake, heart rate and cardiac output at approximately the same level as attained after 5 minutes of exercise. Well-trained athletes, including marathon runners, can exercise for hours with an oxygen uptake of 70 – 80% of the maximum. This is contradictory to what we have believed, however. What some people have believed. Another textbook Nunn(?) "Supplied Respiratory Physiology" 4th Edition, he says, "The average, fit young male adult should have a maximum breathing capacity of about 170 liters, but normal value depends on body size, age, and sex, and ranges between 47 and 253." For men, and 55 – 139 for women. Nunn also says on page 83 that PAF, in the more usual types of breathing, the peak flow by minutes volume rate is tends to be more in the range 3.5:1 to 5:1, not 3:1 as we commonly are calling, eh? Then we might think that these sports people and motivated by winning and glory, but the persons with the data from the lead smelter who used 11,701 liters of air in 90 minutes equals about 130 liters per minute. If we were 15% wrong in our data, still 110 liters a minute. The only motivation has is his pay envelope every Thursday. Of

course, he was not breathing at the flow rate all the time. And as we can see when we look on the data closer, he did not keep his respirator on all the time. When talking with the spotter who followed the person to record what tasks he was performing, the spotter confirmed to us that from time to time, of old habit, the person lifted off his respirator when he was talking, so he lost some air, which we of course calculated out. So, unfortunately this is a common practice when APRs are worn, and the need for communication is required. So the APR data log (...inaudible...) free flowed and then we lost some of air, no? So we need to look on this in a little bit more detail. So what we have done here is that we have, of this 90 minutes, we have a 10 minute span that goes from the 35th to the 45th minute, and in this particular 10 minutes, we have a figure of 863 liters up here. That's not 86 liters a minute. But there is peaks here, this 300 liter line. This 400 liter line. So we (...inaudible...) we can also calculate how much of this had higher velocity or higher flow rate through the field than 85 liters. The green line, which is the line here in the lower part of the graph, represents 85 liters. If the horizontal axis represented time and the vertical axis the flow rate, all air above 85 liters line is flowing faster than 85 liters per minute, and all below is flowing slower. Do you agree with that? You have time in one direction, and you can't see it, time in one direction and we have speed in the other, so if it goes faster all the air goes faster through the filter. So in this instance, the volume of air flowing faster was 519 liters, 60% of what he was breathing in this 10 minutes, so it's moving faster than 85 liters. So how much faster? Some of the air goes just a bit faster, but surprisingly, a whole 332 liters per minute, or 38% was flowing faster

than 170 liters. And, 101 liters, 12% flew faster than 255 liters, which is 3 times the rate we are testing particulate filters on today. So let's have a look on another section where the worker is not working that hard. Between the 26th and 27th minutes. The total volume of the air during this minute is 34 liters. You can go to the next one please. This is actually 1 minute out of the same graph you saw first. And he's taking a breath. So his total requirement here was 34... up in the right corner it says 34.7 liters. It was a minute (...inaudible...) through the same time of equipment. But it's interesting isn't it? You still have two perhaps above 85 liters in there and there. And that, actually represented 2.6 liters or 7% only on these two breaths. This frequency of breaths is 19 breaths per minute, according to the physiologist your limit is somewhere between 50 and 60, so of course, he didn't work very hard and you can see that on the depth of his breaths, and his speed. One more sample. Here the person's breathing frequency is about 38 breaths, jumped something? Something, something, ah, you gone to fast, no? Back again will you. No sorry. Okay, sorry. I'm not very good on this. (Laughter)

The reason I think this sample is important, the sample we're going to look on, is the difference in peak flow within one minute. The smaller one begins just over 100 liters, and the highest one is just under 500. It is very difficult to argue that there is some kind of average PIFs. This is very representative of the data we have collected over the years. In this sample, the total volume of 63.7 liters or 67% of the air flows faster than 85%. Please go to that screen. So what we're seeing here, this is one minute where the worst breath is just touching under 500 and the smallest one is just going over 100. And this is an ordinary worker in a lead

smelter doing his ordinary work, driven by a pay package and this is how it looks gentle, ladies and gentlemen. This is how it looks. So what does this mean to the users of APRs? If we don't test APR at a higher, more representative flow rate, it is likely that the filter capacity is not what a user would expect. Equally important, he or she may not even be able to breath through the respirator after pressure drop would prevent him or her from getting the air through the filters. Below we have a graph, where we have measured a few different manufacturers of P100 filters purchased on the market in the United States. We used to calibrate the test bench, and in this test we used a constant flow, the horizontal axis for the air flow of the vertical axis for pressure drop in millibar, and we can go to the next one. Three of the filters were large single filters to use standard thread, the others were for two filter APRs to compare the pressure drop and we needed to separate how we interpret the result and the three single filters are the ones where the curves go all the way to 360. So what we have here is speed, or flow rate through the filter on that axis, and we have pressure drop on that axis. So we test, and we try to represent and look on something like 400 liter, but we only got them up to 2 or 360 liters, so and of course, what we are doing is this 3 filter up here is single filter respirators, the others are twin cartridges, so what we've done here is that we can only test them to 200 liters, representing 400 liters because you're only taking one filter at a time, and the 2 one here is actually, this are called pancake filters, is electrostatic filters, P100s is out on the market now. And of course, they are not that big different at 85 liter pressure up, but look what's happening as soon as you start to try to get some air to them. Okay, can we go to

Tape 6, 6/19/02

next? If we don't believe this is really on the first responder, let's have a look on some exercises we performed together (...inaudible...) fire brigade. Can you please go to... When we are setting up the next we're going to show (...inaudible...). Does anyone have any questions, I perform much better when I get challenged. Yes, Dave.

M: I don't if you have time while they are setting up, the data's definitely interesting, but I'm curious as to the mechanism of how it was derived, uh, what was the test set up in as much detail as you can explain it?

Berndtsson: We are using, today we are developing, we have developed a breathing apparatus, it's a positive pressure demand breathing apparatus, part of that breathing apparatus we are constantly measuring how much air goes through it so we can calculate and give advice over the chance of the filters. We are using the same mechanism for measuring how much flow actually goes through the unit, but we adding it an external data log, collecting that data.

M: Alright, so all data was derived through your demand flow PAPR?

Berndtsson: The data, oh yes.

M: And the electronics associated with that.

Berndtsson: That's correct.

M: All right, and how was that system then correlated and cross-validated to a national reference...

Berndtsson: ...All the systems, and in particular the ones we're using for data logging are calibrated to an accuracy of +/- 10% on a straight line. We doing that

M: (...inaudible...)

Tape 6, 6/19/02

Berndtsson: ...pardon?

M: Full scale?

Berndtsson: Full scale. And we are doing that, the mechanism I can do indeed tell on the side, but it is too complex how we doing that to present it at this time. So, we get that going? What we did here on the 8th of May, was actually inviting or we agreed with New South Wales Fire Brigade to do an exercise. We hired a high riser in Sydney, used 25 floors of the high riser, and we wanted to measure how much air, and what peak inhalation air flows, those real fire fighters were using getting up 25 floors. We had done a similar exercise earlier in the year where we used SEA personnel and we got challenged, and said, "Yeah, but you guys want to show as much as possible, let's see what the real guys are doing." We were also told, of course, by their superior that we are not going to rush up the stairs, we are going to take it easy because we are going to have to have enough energy to do something when we get up. So there was 6 firefighters, there was 1 female and there was 5 males. We, just a little bit of introduction on the real fire engine standing out front and we had some film crew there filming the whole event and. Yeah. Any one want to ask questions when we go through this, I think.

M: I have a question about, did you ever try putting a flow, one of those flow rate things in an APR to see what the results are and how they compare with your PAPR?

Berndtsson: I'm not very good at presenting paper, but in the beginning I'm going to leave, this paper be available on the website from today, and I have some printed copies here, and there will be copy, I'm sure on NIOSH website. But when we started

this 10 years ago, we were using data loggers or flow meters who were attached in front of the combination filters on negative pressure half face piece respirators, because that was the type of respirator was used in the aluminum smelters, aluminum industry at that time. So we actually did not rely on the pressure drop inside a mask or (...inaudible...) air who actually flowed through the filter. There was no microprocessors or the capability we have today then, so the data was much more difficult to get accurate data. Difficult to transform the data from a very magnetic work field back into somewhere where we could analyzing it, and we ended up to build metal boxes with tape recorders because that was the only way doing 10 years ago.

M: It would be interesting to see the 2 charts together doing the same work rates...

Berndtsson: Since then we have built data loggers who is relying on very flat performing particulate field as which we actually can put in front of the existing filter on the exact unit you are using so you have two different systems to measuring exactly the same thing, which would then correlate together to calibrate a test bench with known volumes and frequencies. And I tell you Alex, we are measuring the right thing, ja, but I'm happy to describe that in full detail to you if you want, but I'm, by me standing up here I get short on all the time, so I can't come up with something that does not, I can't support. What we are seeing here now is that we are just starting, we have dressed up these firefighters, we put on hat, we using pulars(?), heart rate monitors, and we are now starting walking up the stairs. And, of course the peaks are not very high in the beginning here, we start all the data loggers and for the first four or five floors, you have an increase from 100 liter

peaks to 200 liters, and then we started to see one breath hitting 300 liters. And what you're seeing here is actually the total heart rate for that particular person, which is within the 5 first stairs, you basic go up to your working heart rate and that follows your breathing rate within the 5 first flights of stairs you get breathing rate up to that frequency as well, and then they are very parallel and that is exactly what a physiology books are telling us. You can actually compare breathing rate or oxygen uptake with heart rate. You can go to the next one. So in here now we're seeing that the persons start hitting constantly to 300 liters, and start hitting 400 liters. You can. This is the stairway looked the same all the way up, so we can jump to the next one. Now we are constantly just below 400 liters peak flows. As you can see here we have a date, time, 11:25:58, 11:28:47, so you can that way correlate where in this scale you have basically, we're very close to where you are (...inaudible...). Jump to next one. If you go on firefighter 6. If you (...inaudible...) firefighter 6. Fire. Oh. Go down, uh, up in the right corner, what happened here, this person actually out breathed what this particular data log that we had on this one, you see, stopped at 400 liters. So we got him to do it again. Huh? So we go to the next one. Up in the top there, you see in the right top corner? Exercise 2, put that. Here we get, we were very unlucky with this particular person because after 3 ½ minutes he run out of battery so he actually went up negative pressure all the way, so we only got data for 3 minutes, but what you're seeing here is that he was constantly up to 500 liters. Of course this was an extra test we had not cared for and a bit of panic that goes and you get someone in with a battery who is not fully charged, etc., etc. so, this is what happens when

you do live testing. I'm sure everyone who had done it knows this can happen.

What you're seeing here as well is that one of the, they always went in pairs, and they had with them in the equipment they had a 12 or 22 pound fire extinguisher and the tool bag who weighed 30 pound, and of course when the female went up with the guys she carried the heavy bag. She was used to it she told me.

(Laughter) But what happened on this particular case at the, halfway up the data logger we hooked up to the belt fell off, so they stopped and fixed that, and as soon as you do that, you see a reaction in the heart rate. It's very accurate. We slow down or change the speed, you see, we read it straight away. And you see that, of course, in your breathing rate as well. Next. And they are almost up on the top now, you see we are constantly just under 400 liter peak flows. Of course, this exercise takes less than 7, 8 minutes. But they didn't die when they took off the respirator it was still going these guys. And also our friends from CBRN, I mean, these guys they are well trained and know what they want to do and they have the power to do it. So, you've seen enough? Want to go to the next part? Exit. And close that one. Now start the Powerpoint presentation again, please. So what we're going to look on here. Can you, you have to jump if you, please, till you come to...Can you go forward? The exercise was, the purpose was to establish what the peak inhalation air flows was, of course, and how many liters they were, and how, if they could withstand it, it was any difference between the firefighters and the SEA personnel, and yes, the SEA personnel in some of them was to be faster than the firefighters up, but it was very similar curves, very similar volumes, very similar heart rates doing the same task. What this should be done

this now, we did it in the beginning of January, we did it now in May, all the results look very similar with the exception that a woman only carried 300 liters, and some may go to 500 liters. The majority of them sits between 3 and 400 liters. And that depends of course on how physically large you are, how well fit you are, and how determined you are to get up there. So what we have here is some little bit of statistics, as you can see, 35, 40, there's age, of course, two of them I didn't collect. 51, down to youngest person this is civilians in the bottom the youngest person was 22 years of age. You had 3 females all together and the rest were males doing this. Can you go to next, please? The maximum PIAFs was between 305 and 400 or 500, 490 liters. The total volume of air used was somewhere between 813 and 1217 liters. Average minute liters and the time. Can you go to next, please. So here we have some numbers, some average numbers, no? All this is in my presentation so you get copies of all this if you want. So, 154 liters, minute liters is an average, standard deviation of 14. Not very much. And if you took the whole, that wasn't the firefighters, took the whole group 169 and the standard deviation 12. Next please. So what do we have here? Now we compare it to PAPRs, no? Because you probably will be using something like that doing this kind of work. So we have 3 numbers in the top here, and of course now we are interested on what, how much areas above that level. Not how much goes faster than that level. Also we calculate in a slightly different way, and so we see, of the, above and this is in percentage, so the total breathing here, over 150 liters, 37 – 50% was above the capacity of full face mask PAPRs. It was still an average of 18% was about 200 liters and 4.3% was above the requirement for SCBAs. 300

liters. Next slide please. So, in regards to full face mask requirements for first responders, we need to test filters or complete assemblies for not only filter performance but also for pressure drop at more than one flow rate. Composing minimum performance should include pressure drop of at least 100 liters, 200 liters, and possibly 300 liters requirement for high work rates. It is equally important to establish an acceptable inhalation, exhalation resistance for those flow rates. If those levels are too high, the user will risk getting into oxygen, if the pressure drops are set too high, the user will risk getting into oxygen debt, resulting in an increase in the lactic level in his muscles which in turn leads to fatigue. As we experienced from the World Trade Center event, the rescue workers, I mean, obviously I missed one. Go on. Next one. The aim was to establish how... sorry. Not turning the page, I'm as tired as you are listening to this. So let me refresh that last sentence. As we experienced with the World Trade Center, even the rescue workers were more concerned about helping their workmates than keeping the respirators snugly fit on the face. Mainly because it was too hard to breathe and talk, too. Next please. In regards to PAPRs for the first responders, we need to ensure that we require air flows high enough to maintain positive pressure inside the face covers when perform typical tasks, including working in the open, overcoming not only the contaminant in calm weather, but also when the wind is blowing. Those requirements have sometimes been overlooked when arguing the performance of RPs that does not require snug fit mask. Thank you very much for your attention. If you have more (applause). Is there something I haven't covered? More questions? Yes, Andy.

Tape 6, 6/19/02

Capon: Goran, how many filters do you have on the SEA 400? Is it two?

Berndtsson: Two today. Yeah.

Capon: Two, so you divide the flow by, because half of it's going through each filter...

Berndtsson: ...that's correct.

Capon: ...and so what's the average per filter that's above the 85 or in European terms 95 liters a minute?

Berndtsson: It all depends on how hard you're working as it is a positive pressure demand system.

Capon: Yeah, I'm thinking in terms of standardization to do a test, is it a constant flow of 95 liters a minute, 3 times that if you're doing a breathing machine, that's 300, that's not too bad...

Berndtsson: But you know in Europe, in Europe you have an interactive flow requirement. If you're meeting interactive flow requirements...

Capon: Indeed yes, I know, I understand that.

Berndtsson: you do, we do.

Capon: Are you advocating in standards, particulate standards conducting particulate tests under breather flow conditions like the military conduct CK tests on military filters and the breather flow conditions?

Berndtsson: I don't know exactly what a, because we're not supplying military filters so maybe you can enlighten me on how they do. You meaning are they different at higher flow rates? Is that what you're...

Capon: The, I don't know who's really the expert, I should be the expert. We've got the Legend he can tell you because he does it all the time. (Laughter) You not

oblivious yet are you, you're okay, so... the Cyanogen Chloride requirement of a military canister is to test, not C2A1s but the new JSTPM requirement is to test at 50 liters a minute under breather flow conditions. What is it 33 breaths, the Legend will tell you, it's okay.

M: 33 breaths per minute at whatever it takes to get the proper total minute volume with the JSTPM, there are two filters so we test those instead of at 50 liters a minute we test them, each one at 25 liters a minute because that's what it would see if it were on the mask itself going at 50 liters a minute. So that's how we tested those against the, again we used the breather flow, the breather pump that I showed a picture of this morning which has sinusoidal breathing pattern.

Berndtsson: When it comes to the particulate size, of course I support testing particulate filters at all the working rates you expect a respirator to be used at. In our case, if we were using that respirator with particulate filter only, we maintain positive pressure demand system up to 600 liters.

Capon: I understand what you're saying...

Berndtsson: ...and of course when you are testing the gas filters, here we have a leak, not a leak, but we have a problem in history of studying. The only reliable tests we have on the effects of cyclic flow against steady flow against gas filters is the Gary Nelson work, which he did in the '70s mainly at the Lawrence Livermore Lab. Most of that was on organic vapors, no? And his conclusion was that there was not a significant large difference in the performance of the filters in cyclic nor steady flow.

Tape 6, 6/19/02

Capon: There's data from other sources, but I don't think this is the forum to talk about it. But the other thing I was going to say about the particulate filters under breather flow, if when you're doing Alex's protection factor tests, then there was a significant penetration of particles through the filters, particularly the rainbow passage, where you take in as much air in half the time, in the rainbow passages, you do when you're just doing a normal exercise. Then you could possibly see an effect of filter penetration at a high flow rate under that type of test. Now, Alex has individual test exercise data, and he could possibly say whether or not he could attribute any of the inward leakage that he sees is coming through the filter or coming around the face seal, or through the exhale valve. But, if there was a real concern, you would pick it up in PF testing.

Berndtsson: But, I mean, you understand now why it is so important to get P4?

Capon: P4 doesn't exist. That's the marketing ploy. (Laughter)

Berndtsson: Let me clarify that. We have, in Europe, there is possible to get your equipment tested and certified against a directive. As doing such, you specify which classes and how you're going to be testing it, and you have to challenge or show that you are covering every existing requirement and adding things to it if you so choose. So we tested at this pace of equipment as it is unique, it's not a PAPR, it's not an SCBA, it's a new type of respirator. So we tested and get it approved against the directive in Europe. And we specified that the filters which would be used for this particular piece of equipment should have something we call P4, which is a magnitude of 10 times higher filtration capacity at 95 liters than an ordinary P3.

Tape 6, 6/19/02

We then got approval and we are marketing, and allowed to market according to European Community as P4s in Europe.

Capon: If you took a C2A1 military filter, you could call it an ultra P100 in this country because the same thing applies.

Berndtsson: This argument doesn't belong here.

Capon: It doesn't belong here, no that's true. Thank you, Goran.

Berndtsson: Anything else, no? Thank you very much. (applause)

M: Well I think we've finally reached the point in the program where we have the traditional open comment period, so if there's any other items that you would like to express a brief opinion about, you're welcome to come forward to the microphone at this time, and if there's not then we'll let Mr. Boord provide conclusion. You better sit down.

Pappas: Alex Pappas, SBCCOM. I got a quick comment to the MSA representative. I guess he's not... oh there he is. He was saying he doesn't like the APR and CBRN standards and all that, yet, I've seen literature on the Millennium Mask, where it actually shows a person in a military respirator with a military suit and your literature actually says "military type respirator." Now, if you're only going to market for workplace, then why do you have "military type respirator?" That was my question.

Herring: Alex, Alex, Alex. Let me get my... let me clarify something for you here for a second, and I've got, well we're taped here anyway. I don't think I ever said that we don't want a CBRN APR standard. And if, did anybody hear that? So, let's throw that statement out, and if you could strike it from the record or however

you're going to do it on this. The points that we were making here weren't the fact that we're against this standard, the points that we're making are that we want the standard for us to learn from the mistakes of, I shouldn't say mistakes, the learning curve that we have on the SCBA CBRN standard. We want, we aren't in favor of interchangeability. It was very specific points, but it's not that we don't want a standard for CBRN APRs. MSA historically has supported the development of standards. We sit on most of the standards committees that are out there, and comment on a regular basis, just like we did today, on standards. So I think you may have missed the point, and we can talk about it afterwards if you'd like.

M: Anything else?

Teele: I'm Bruce Teele, from the NFPA. After being here two days and listening to all the various sides of this we realize that there's certainly a lot of work that has been done, a lot of progress has been made, and obviously lots of difficulties. If, to get it all in perspective, you might want to walk down the hall and see the other group that's assembling to meet to discuss problems, because they're discussing judicial discipline, so we might actually have the easy track in here, folks.

(Laughter) I'm not sure about that folks, but we may. Throughout these two days we have frequently heard the term "first responder" used in probably identifying fire, law enforcement, EMS and hazardous material teams who will be responding to terrorist incidents. I think we learned a long time ago, and certainly it was highlighted on September 11, that not only they the first responders, they are *the* responders. By the time significant other help arrives on the scene, probably the

incident is going to be *well* into hours old, if not days old, and I don't want anybody to leave here with the concept this is just a half hour or hour or two hour or four hour fix. It could be two days, three days, four days fix before something significant happens. Obviously, this is a meeting for industry. There were not very many civilian responders present, but there were some. There were two chief officers from Los, one from Los Angeles City, one from Los Angeles County, who were here with us this week but had to leave. We now know that there was some law enforcement folks here which I was not aware of prior to today, and we have Jan Dunbar with us representing the International Association of Fire Chiefs, I think he also will say a few words. NFPA is, like NIOSH and other organizations, works closely with the emergency response from the civilian side as well as other teams, but we're certainly the closest, or we seem to be the closest to the civilian side. I've also had an opportunity to speak by telephone last night and this morning with Richard Duffy(?), who, if you don't know him, he's Special Assistant to the President and Director of Health and Safety for the International Association of Firefighters. They're very much concerned and involved in this. Unfortunately, Richard Duffy's time had been previously committed to other meetings and he couldn't be with us today. He sends his apologies, but agreed on a couple of points that I'd like to make. In reviewing the document that was sent out, we noticed that there is considerable reference made to the crisis type, crisis time frame which intimates that this negative pressure APR respirator will give you protection in IDLH atmospheres. We urge utmost caution in representing that negative pressure respirators will give, especially not

self-contained, will give you protection in IDLH atmospheres. It runs absolutely 180 degrees what we have tried to indoctrinate fire and emergency service responders the difference between IDLH and non-IDLH atmospheres. And even if somebody thinks that it will give a certain amount of time for you to extricate yourself from an IDLH atmosphere, which it might, we see a problem in for the responder to identify when they have gone from the warm zone into the hot zone, and now that they are in an IDLH atmosphere. Unless you're doing constant monitoring of the atmosphere where the emergency response people are working, they may be in IDLH and not know it. A false sense of security could arise out of people thinking, "Ah, I've got this extra protection, they told me, it's right in here, I can go do something," Which maybe they should have absolutely no business doing. So we urge caution in that. We noticed that there were two types of devices with four cartridges listed. A 15 minute device, a 60 minute device, and cartridges with and without CO protection. We believe that the 15 minute would have been called an escape mask, and unless something's happened that I've missed entirely, we thought that NIOSH had that someplace else on their program for respiratory protection, but if this is to also include escape masks, then I think we should be looking at that 15 minute mask, respirator, as an escape device and not as an entry device whatsoever. The issue regarding should it provide CO protection and non-CO protection from the civilian emergency responder side, we recommend no CO protection. CO intimates product of combustion in the atmosphere, product of combustion has been, for a number of years, IDLH. We train them IDLH, and that the only acceptable respiratory protection is self contained breathing apparatus, so

we do not believe the need there is a need for carbon monoxide protection, and carbon monoxide would also, could also be an indicator and that you're already into an oxygen deficiency problem, which is another problem obviously with product of combustion that we cannot detect quite so easily. We recommend against that. We recommend, if we're not going to address escape, we recommend a single APR with the one you have marked for 60 minutes and for non-IDLH atmospheres and without CO protection. In general keep breathing resistance, both inhalation and exhalation to a minimum. It certainly adds to the stress factor and the tiredness that the emergency responders feel when they are fighting against increased breathing resistance, and I'll just, one more thing I will address although I already spoke about it earlier today, the interchangeability issue, is high on the agenda of civilian emergency response personnel. I hope, I don't say the decision is going to be, or the solution is going to be found here and now in this forum, but I don't think we can put it away and forget it, I strongly believe, NFPA believes, we move to take responsible positions towards that, and to try to find a solution that the emergency responders keep telling us, over and over and over again, especially since September 11, it is absolutely needed out there.

Thank you. Jan.

Dunbar: Jan Dunbar, International Association of Fire Chiefs, and to begin, I would like to compliment the comments that Bruce Teele has just provided this audience. There's a number of issues that we are closely associated with, and we obviously do agree between our two organizations and before I go any further, also thank you for hosting this meeting. I for one have found it an education for the last two

days, and I mean that truly. I've been taking notes like crazy, not only to be hopefully helpful for the purpose for why you called this meeting but so that I, too, could take home a lot of information. Let me pick up where maybe Bruce concluded his remarks with regards to interchangeability, if I might remind NIOSH and there's probably a number of people here that don't go back 20 or 25 years, but this has been a topic if I shall bring it up, that has been brought forth time and time again to OSHA and to NIOSH by the fire service community, with regard to interchangeability possibilities in the breathing apparatus arena. We know only too well, that for years and years and years it has largely been on the manufacturing or the industrial side where the resistance has been. But if that so be, we can understand that to a certain extent, but we would like to urge NIOSH, though, to at least draft their recommendation for testing procedures to allow for the possibility of the advancement of interchangeability in the arena. There are other examples in industry where interchangeability has been adopted and has been adopted very successfully. We, too, the International Association of Fire Chiefs, question why carbon monoxide is on the list. I come from a little bit different perspective, but I think that Mr. Teele presented a good argument where we do suspect that carbon monoxide, if there is a reason to use it as a testing criteria, is purporting to suspect the existence of carbon monoxide in the actual work zone, then that type of an APR breathing device is the wrong device that was chosen by the worker, and that is the attitude of the fire service. There was a point that I wrote down. I think it was yesterday or early this morning when someone was going over the humidity test, and the humidity test varied to a

maximum of 20%. I think the low was 8%, and I wondered why is the maximum humidity percent indicated, unless I have my statistics wrong here, at 20%? I would like to recommend that NIOSH take a look at that, also in lieu of the fact that many presenters have given us additional information throughout the rest of today, where they did conduct tests in humidity environments as high as 80%, and viewed their data on the screen. Also, 20%, 8-20% is about average more or less on the dry west coast, and not so much the rule on the east coast or in the deep south, where in the summertime, 80% is probably the lower limit to consider, and so I would like to bring that to your attention and to examine it. Also with regards to the definition or an attempt to the explanation of "short duration" it is mentioned that it is less than IDLH. Yet, the estimated work time in the test will be 15 minutes. That, too, implies to me that something serious then has happened to a wearer of the APR. This is potentially a 75% reduction in his work time. What is it that NIOSH has proposed that would reduce the work time by this significant factor of 75%, leaving only 15 minutes, and what is expected to be done within that 15 minutes? In your column, I think it's on page 2 of the information that was mailed out prior to this meeting, does not include, nor does the definition include, any inference to using this time as a means of escape or escape only. So that is a little bit confusing and I would like to ask that perhaps NIOSH take a look at that. That leads me to the other term that was used called "crisis panic demand". Here, this is perhaps the arena that NIOSH was looking at that would be suddenly above IDLH and with discussion with several others of you here, it has been explained to me that what was meant, that at least in this

Tape 6, 6/19/02

column, the crisis panic demand, was that escape time at the very minimum. I think that, folded with the 15 minute short duration, both need to be folded together. And to make it less confusing, to be more definitive in your definitions and to use terms that would be very clear in their inferences. It is clear in the first column where you reference the warm zone. That's a work zone, and obviously the time that is stated there that is in approximate relationship to the time spent working and doing things, therefore with regard to the crisis is that meant to be escape? If it is, then say that it is the emergency escape time. And then, finally, I wrote down here "phosphene." With regards to an earlier presentation, I am no chemist, but the comment was made that phosphene around 1,000 parts per million is air reactive. And I believe he's correct, I'd have to look that up, but I do know it is air reactive. That means it catches fire. Why test it then? And why test it at that concentration? Because on the screen the test amount was listed at 1,000 parts per million. I don't see the relationship or the understanding if you're going to test a chemical at that concentration on the supposition that we in the field would ever encounter that, at near that concentration that won't be true with phosphene, because it will consume itself and go away. And that concludes my remarks. Thank you very much.

(END OF TAPE 6, SIDE A)

(TAPE 6, SIDE B IS BLANK)