Dragon, Karen E.

From: Rehak, Timothy R.
Sent: Monday, May 12, 2003 10:38 AM
To: Dragon, Karen E.
Cc: Kovac, John G.; Stein, Robert
Subject: Transcript for the PAPR Public Meeting

Karen:

Please insert the attached transcript for the Multi-function PAPR Public Meeting held April 14th in Arlington, VA into the docket for PAPRs (NIOSH 008).

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NIOSH/NPPTL Public Meeting to Discuss Standards for Respiratory Devices Used to Protect Workers in Hazardous Environments

MULTI-FUNCTION PAPR PROJECT

April 10, 2003 - 12:30-5:00 p.m.
Marriott Key Bridge Hotel - Arlington, Virginia

TRANSCRIPT LEGEND

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P R O C E E D I N G S

TIMOTHY REHAK: If everyone could get seated, we'll be ready to start in a moment here.

Good morning, I'd like to welcome you on behalf of NIOSH-National Personal Protective Technology Laboratory for attending this public meeting this morning. The National Institute for Occupational Safety and Health with the assistance of the University of Maryland is currently conducting research for new comprehensive standards for multi-functional Powered Air Purifying Respirators.

The agenda today, we have to strictly adhere to this because we have a number of outside speakers. First following my introductions and some administrative remarks, we'll have John Kovac with NIOSH provide an overview of the project. Then we'll move to Dr. Johnson, who will talk about the current status of the research they are doing. Then following a break we'll go to Kate Mackey with the University of Maryland. Then we have five outside speakers, Jacque Forrest with Centurion Products, Göran Berndtsson with the SEA Group, Mackey Shinomiya, then we have Joe LaMonica and also Joe Main. Each of the presentations should last approximately 20 minutes or so, then you'll have 5-10 minutes with questions and comments. The outside speakers, since we have a number of them, we have to limit you to 15 minutes, then we'll have time

at the end for more comments or questions. Any one interested in holding private one-on-one meetings with NIOSH, I'm the contact point, again, my name is Tim Rehak. I'm with NIOSH-NPPTL in Pittsburgh, PA. My phone number is listed there along with my e-mail address. All this information is in the packet of information that was passed out so you have it there.

The purpose of this public meeting, first, we're going to present the research activity for new standards for a multi-functional PAPRs. They include: respiration, vision, communications, wearability, hearing protection. The research is being conducted by the University of Maryland for NIOSH.

Logistics: Hopefully everyone signed in outside before you came in. You can get a list of the attendees afterwards; they will be all typed out, if you need to know who was in attendance. One thing I want to point out, this meeting is being recorded and will be transcribed and sent to our docket office if any one wishes to get this information. Again, we're going to follow the agenda very strictly because we have a number of speakers that requested to talk. Anyone that has questions or comments, please use the microphone in the middle of the room. Give your name, who you're with, because it will be a part of the official record. Information again, here is the docket number, any information you request or need from

the docket office. You need to request NIOSH 008 that's the docket number for the PAPRs. Again this information, the mailing address, so forth is in the handouts. Basically, we want all comments to the docket office by June 1, if you wish to submit anything. Without further a do, unless there is any questions. I call on Mr. John Kovac with NIOSH to give the project overview.

JOHN KOVAC: Good afternoon, my name is John Kovac and I'm going to give you a briefing on what will follow this afternoon at the public hearing. The goals of this activity are to develop a new comprehensive test standard for certified multi-function PAPRs. The reason why we're undertaking this is that such devices may include protection against other types of threats or hazard, including vision protection, hearing protection, head protection and general isolation from environmental contaminants. Besides providing respiratory protection multi-function PAPRs must allow wearers to perform their side duties without posing any additional burdens. Problem is that is how to objectively evaluate candidate equipment. What we're looking for and what we will end up having are scientifically valid tests, for a device that will be certified by the government reasonably meeting minimum standards. We should note that appropriate standards with dealing with multi-function PAPRs are not yet available.

Examples of such technology is a Centurion helmet, it's one of many examples or will be among many examples, incorporating not only respiratory protection but head/face protection, cap lap, hearing protectors, and it was developed for application in the mining industry. In terms of what we can deploy to solve this problem and to resolve it in a fair way we have assets at the NPPTL. We are working with the human performance laboratory at the University of Maryland. They have a long history of research and all wearability issues of respirators. In addition, they are committed to taking the bioengineering approach to the evaluation of likely standards. We have collaboration with MSHA. Finally, we regard both equipment manufacturers, as well as BCOA, National Mining Association and the UMWA as our stakeholders in this activity. Our approach is broken down into phases, four phases over a period of 2 years. We're basically bridging between phases 1 and 2. Where we will have stakeholder interviews to determine the relative importance of various equipment quality such as vision, communication and head protection. We are going to define likely work scenarios so that we have a standard against which to test. Phase 2, we will develop appropriate test criteria and validate them in laboratory. Phase 3, we will have follow-up interviews to determine if there is any unseen problems we should modify what we're proposing.

Finally, as an administration activity file a report detailing the results of our investigations. Again, please remember this is a research contract. This is the first step along the road and not at the finish line. Our current status we have a sole source procurement contract with the University of Maryland and here is its contract number. We also have MSHA support of this activity. What we're going to explore next are the work that the University of Maryland is currently doing. That's all I have, so if there's any questions. Okay. Tim.

TIMOTHY REHAK: I'd like to introduce Dr. Art Johnson with the University of Maryland. He's going to be talking about the human factor's aspects of PAPR's.

ART JOHNSON: Thank you Tim. I'm going to talk to you today about the things that we're incorporating within our studies, as well as, some of the things that may be a little peripheral but still, nevertheless, important to respirator wearer in these studies. Then we're going to be breaking this down into two groups of talks. I'm going to be talking about basically about the research that we're be doing and then Kate will be talking about, after the break, more about standards that will be applicable to this project. The contract objective, you may have already seen this but I wanted to underscore this as being the contract objective because we are

suppose to recommend certification procedures and not establish those certification standards. So that a lot of the type of things we're doing will be related to the ability for us to recommend. Protection and performance, those are the two aspects of respirator wear that we've been interested in over the last few years. Last few years, that's actually probably about 30 years or something like that. Protection is one that everybody is interested in. Protection needs to occur, protection is there because there's airborne contaminants that somebody has to be protected against. On the other hand, respirator wear actually interferes a lot with the performance of the tasks at hand. It's that performance aspect that things that we've really been interested in over the last few years. We are not as much experts in the protection as we are in the performance because the performance is where you have hidden costs of respirators. That is, the cost of the respirators deal with the costs of initial fit testing, prescription of a respirator, cost of the respirator and so on. The hidden costs actually deal with the performance decrements associated with doing work while wearing those respirators. Those are continuing costs, and you'd be surprised they're probably a lot higher than you think. So those are both important and this presentation will deal with, first of all, existing standards, that will be Kate

Mackey's part, I'll be dealing with the human factors, user attitudes and practices and a questionnaire and some performance parameters studies that we'll be looking at.

The human factors that we've found that deal with respirator wear we have to look at the effects of the respirator on respiration, communication, vision, heat exchange, personal procedures such as eating, drinking, blowing one's nose, scratching one's eye, rubbing one's eye, what have you. Also the physical configuration of respirators interferes also with the performance aspects of them, especially in tight places. Anxiety level has been shown to be extremely important. Past results in our lab has shown human performance to be very directly related to respirator characteristics. What that means here is that the respirator directly affects the way humans perform the task that they're assigned. A very, very brief summary of our past findings say that, first of all workers in most cases and there is one exception to this, can not work as long or as hard while wearing a respirator as without so that's especially important when performing physical work. Heat also effects comfort and acceptability, that's another thing we've come up with and then anxious people should not wear respirators. You probably all know about those anxious people, there's a problem when they wear the respirators. Respiration is a problem at high

work rates but not at low work rates so at low work rates, we really don't have to worry about respiration of the respirators, it happens at high work rates, although they may be high work rates for short periods of time. We also need to simplify communications procedures because of the results we've obtained and some of the results from some of the questionnaires from some of the users so that communications seems to be the number one problem with wearing respirators. Also vision effects are critical but vision effects are usually very critical at light test rather than heavy tests. So, the question is, we've done all these tests in our lab and found out we've quantified, as a matter of fact, how much performance decrement is associated with these different factors of the respirators. The question is, are they the same as what actually happens for real workers in the real world. So we have attempted to put together a questionnaire to assess both user attitudes and practices and statistics here will provide both a quantitative analysis of things and then the user comments will provide the qualitative things that might be of interest. There were very, very few published, at least, results from user comments of the respirators that they wear. The questionnaire categories, we have in the questionnaire: we have a brief medical history of the users, a lot of different respirator types that they can

chose from as the ones they are familiar with. Which user groups they belong to, the work activities they engage in while wearing those respirators, their attitudes and their practices. Respirator types of these, you recognize them, I'm sure, as including whatever type you're interested in. User groups that we have or will be interviewing with this questionnaire are, of course, miners, fire and rescue workers are also in there, construction workers are extremely important because, in a lot of cases there are reports that construction workers don't wear the respirators they should be wearing. Agricultural landscaping turned out to be one of those areas that we've been able to get the questionnaires from so far. Medical personnel, if we can get those, manufacturing industry, pest management and others, if we could possibly do it, so those are our target groups. You can see it's fairly wide. The work activities that the people are going to be able to tell us about that they engage in while wearing the respirators are the duration of the respirator use, the frequency of the use, type of work activities and the contaminant types that they deal with. So this is a questionnaire that has a lot of questions in it, and it's a bit imposing sometimes. Well the user attitudes are important too because we have to know if they're with the program. We have to know whether they submit to respirator wear with a

positive attitude or whether they are suppose to wear those respirators and then first chance they get, when nobody's looking they take them off. We've seen both of those cases in our tests as well. The user practices, what do they do with the respirators? Where do they get the respirator? What's the frequency of the use of the respirator? Why do they have to wear it? How much knowledge of fit testing do they have? All of these are involved in this questionnaire. So the questionnaire responses, we hope, then will lead to a better understanding of which of the important aspects of respirator wear to deal with the performance issues of respirators.

We also have, this is now a new topic, not associated with the questionnaire but we also have some ideas about some differences between users and we're checking those out as well. We have noticed, some of you may have read our papers in the American Industrial Hygiene Association Journal dealing with the affects of respirator resistance on performance time of people wearing those respirators. I think we did mention in those papers that since we usually run about 12 to 15 or 16 subjects in those tests we usually report the overall results of those tests. But if we look at some individuals within that group of subjects, we found that some of those subjects are very unaffected by the increase in respirator resistance, even if we're increasing it by a factor of 2, 3, 4, 5 over

normal respirator inhalation resistances sometimes the subjects don't seem to be affected by it. So we are wondering if there's some other factor here that deals with something internal to the human being that gives them the motivation to continue working, while still wearing a respirator. That would be extremely important information for a lot of individuals. It would be extremely important for fire and rescue workers, first responders, for instance, because those are the people who are probably going to survive. It's also going to be important to employers, because in that case, you'll want to know who those people are because those people are going to be the ones who are affected less by the respirators. For those people who are in unions and stuff like this, people on the worker's side you'll want to know about that too, because you'll want to know which people probably, you won't have to give that much attention to. The questions then are how is performance related to the type of personality that individuals have? That's going to be the subject of a study that we're going to be running, hopefully, this summer. One of my grad students, as a matter of fact he's here, Frank Coe, he's right up here in the front, he's going to be trying to do this study. Trying to look at personality type and see if that really affects it. Because it may not be anxiety as much as personality types that

affects the use of performance while wearing a respirator. Another planned research, actually one that's undergoing right now, is to look at the performance and emotional aspects related to lens color in a respirator. It is highly likely that lens color does affect both performance and also the emotional state and we'd like to know that too. The question you might have is to how that relates back to our multi-function PAPR but I think this is a more general question and certainly could relate back to the type of facepiece that you have on the PAPR.

There's some continuing research we have. I've had a grad student here working on mathematical modeling to predict the performance time. This could eventually lead to being able to design respirators and being able to test them without going through the prototype stage, which would really be cost saving for the respirator manufacturers. So we're using this approach, we have the existing standards that we'll talk about; we're talking about perceived importance of different human factors. We're talking about user characteristics that influence the performance and we're talking about the affects of respirator design, which is the wearability issue. So with the multi-function PAPR, we have actually several different types, the Centurion helmet is not the only one that we'll be looking at. We also can have, the Centurion is a lose fitting

but we also can have tight fitting but the problems with both of those are a little bit different. Each one of those will then offer respiratory protection, vision, hearing and head protection.

There's a tight fitting, this is an example of a picture of tight fitting PAPR. Of course, we have the loose fitting PAPR that we've already seen before the Centurion System. Now with the multi-function PAPR tight fitting, we think there are some performance issues to look at, with loose fitting there are some exposure issues. For instance, with the loose fitting it's possible, we think, to over breathe the fan, the air that is blowing in by the fan, and when that happens then the air actually has to come from the outside. And because it's a loose fitting PAPR the air comes and circumvents the fan and the filter as well. This is where the instantaneous breathing rate exceeds the air flow that is supplied by the fan. The contaminated air then comes from the outside and exposure then could be an issue for some contaminants. It's important because what we're trying to do number one is to protect the workers and if people are actually going to be breathing more than the fans are supplying then the question is how much and how important this can be. The exposure to the contamination then, the doses that people get then are the flow rate, the breathing flow rate times the concentration,

313 times the time. That's the dose that they get. There are
314 some published contaminant dosages that are out in the
315 literature, the PEL's by OSHA and the TLV's from ACGIH are out
316 there. But it seems like in both of those cases that the flow
317 rate seems to have been assumed for the times that we're there
318 because they talk about concentrations and they talk about
319 times but they don't talk about flow rates. We plan on
320 assessing this by measuring instantaneous breathing rates
321 during exercise, comparing the breathing rates against the
322 PAPR fan rates and then seeing whether over breathing occurs.
323 We're going to be using treadmill testing for this. We're
324 going to be testing at 80-85% of the maximum oxygen
325 consumption, because in that case it's fairly intense
326 exercise. We expect no more than a 15 to 20-minute maximum
327 duration of people working at this rate, so that kind of gives
328 you an idea, if you have to quit after 15 to 20 minutes of
329 work then you are probably in this neighborhood. We also have
330 found that the subjects are very sensitive to respiration
331 during this time and we expect high breathing flow rates. So
332 that's the testing procedures that we'll be undergoing. This
333 is a little bit of one of our past studies. The test one for
334 over breathing we've used the SEA tight fitting PAPR for this
335 and we used this because it had a nice data acquisition system
336 associated with it. We tested at that particular rate we

337 talked about before the data logger was recording
338 instantaneous pressure and their flow rate measurements. This
339 is some sample data that we got.
340 You may or may not be able to see that but I will
341 interpret a couple things for you. First of all, 10% of the
342 flow rates are above 530 liters/min in this particular sample.
343 20% are above 470 liters/min in this particular sample. The
344 question is if somebody is breathing at these rates, are they
345 going to be exposed to contaminate levels and dosages that are
346 going to cause them a health problem. However, because the
347 SCA still gives some resistance to the flow and that means
348 that in our past results, we've seen resistance means
349 hypoventilation. We're going to do this test in a number of
350 different ways. The second one, we'll be using a half-mask
351 with a Fleish pneumotach. A Fleish pneumotach is a flow-
352 measuring device with very, very, low resistance. We will be
353 measuring the air flow that way, and also we'll be measuring
354 it directly by this means. We have a portable breathing
355 chamber that we've constructed. We haven't tested yet but we
356 have constructed it. We're enclosing the head and the mask, a
357 separate inlet for the fan and we're measuring the net air
358 flow in and out of the mask. This is a picture of the
359 portable breathing chamber, which looks like it's a container

upside down, over somebody's head and that's exactly what it is. And this is a block diagram of what it is.

The PAPRs there, the fan air comes in through a separate inlet. The air that is being breathed actually comes in through another pneumotach and if the air flow becomes negative, then what we will be seeing is over-breathing because that means that the air will be coming in a different pathway than the fan could supply. Now again, that's loose fitting exposure issues. The tight fitting, we have performance issues, when the breathing rate exceeds the fan flow rate and the subjects draw extra air through the filters then the question is there, what kind of equivalent resistance's are we talking about. I think Göran was the one that asked me the question. I didn't have the answer to the question Göran, so we're going to run the test. We're going to find that out, because if the resistance that people have to breathe through is only operative during the breathing cycle, we really don't know how it affects the breathing cycle. We are going to find that out. So we are going to perform those tests and what we're going to do then is see whether or not these things can enter into our recommendations for the performance standards and certification for the users and the mask itself. The standards that we've been talking

about deal with the users the focus that we'll be looking at here is focusing on the masks.

So again, this is our approach. These are the phases that we've already seen in the previous presentation. Most of our work right now is in Phase 2 although this particular session happens to be in Phase I. So we're kind of in transition here. We're going to be obtaining comments at the end and the final report. I'm told by NIOSH that they probably will be looking at our monthly reports and so on to be able to draw some initial conclusions based upon the results that we get. These are the people who have consulted and we want to acknowledge their input into our efforts thus far. That's about it. Maybe it was 25 minutes. That's my presentation and I will be glad to answer any questions if you might have them. Yes, Jay.

JAY PARKER, BULLARD COMPANY: The device that you are going to use to put over the person's head to measure the air. It would seem to me that might affect the person in any exercises that they're doing. You know that it may provide an additional decrement in the equipment level that they're wearing.

ART JOHNSON: Well, Jay in that case the objective of our test would be not to necessarily determine what the performance time was, because you're right, if we would put,

just the weight of the thing, on their shoulders might provide enough decrement in their performance. What we just want to do, we just want to check the air flows, in this case. So even if the person, we won't have the person on the treadmill until such time as they decide voluntarily to quit we're just going to have them on the treadmill until they reach steady state. In which case then we'll be measuring the air flows and so we're not looking at performance, we're looking at the flow rates.

JAY PARKER: I have another question too, if that's Okay. The flow measuring device that you mentioned, are you going to put that in-line on the respirator are you going to insert that in the breathing tube.

ART JOHNSON: The Fleish pnemotach? Well we hadn't planned on using it with the respirator. We planned on using; we have a half-mask that we put on people which doesn't have much resistance. It's not a filtering half-mask. We'll put that in line with that and then the half-mask is only there to collect the air-flow. We'll also put that pnemotach in line with that chamber over the head, in order to be able to measure the flow rate but not used directly with the respirator.

JACQUES FORREST, CENTURION SAFETY PRODUCTS, LTD.: I'm a little concerned about your over breathed air assessment

because certainly in our experience fan air is not directly related to breathable air. There is a considerable influence in the volume and is (in?) certain loose fitting PAPR that is around for the individual to use before the fan actually gets overloaded. I think just sticking a fan on a box, you're not actually testing the right way. If I might be rude, there are other ways of achieving, I think what you're trying to achieve, with a much better emphasis on the mask than you're actually going to get with your proposed test method.

ART JOHNSON: If you have any better ways, I certainly would like to hear them. But before then, what I want to emphasize, is that we actually have three different ways of measuring the same thing. We're measuring with the SCA, and as a matter of fact, the data that you saw there was with the SCA device. Then we'll be using the over the head chamber and then we'll also be, without any respirator, just this half-mask, as I was talking about just previously. Just having a person on the treadmill, running with the Fleish pneumotach and we'll just be assessing, at that point, we will just be assessing the breathing rate the flow rate that people are breathing with. We'll also know that the flow rate that the fan could supply and so it's a matter of just subtracting the two. Now that's three different ways of doing the same thing.

We'll see whether or not any one of those agrees, or if they don't agree. Did you have a different way?

JACQUES FORREST: Can I ask just another one? Which has a lot of experience on our side of the water and I'm stealing some of my thunder for later on, but I think one of the down sides we have with the current respiratory standard, is that the devices can be tested in pieces and ultimately they ought to be tested as a whole. The only test that I know that that can be done is the total leakage test in the European standards and there they have people wearing the whole device, not just part of the device on treadmills doing exercises and against wind currents and everything. Now okay it's a laboratory-based test, I grant you, but it appears that with a number of volunteers doing that, you get a much better idea of the efficiency of the device than you do by testing just the fan in isolation or the filtering isolation or the head piece in isolation or whatever else is tested in isolation. I do think the one thing that ought to change is that the whole device is tested for its efficiency on people.

ART JOHNSON: Okay, probably I'll discuss this with you later because I'll be interested in hearing your ideas but I do think that at least with one of these ideas with the over the head chamber, the whole device will be inside that.

JACQUES FORREST: I think for some of the devices, you'll need a bigger chamber.

ART JOHNSON: Okay, maybe so.

JAY PARKER, Bullard: There is another way to measure that and that's by pressure, as in the ORC study. Where we measured the pressure in the respirators and we were looking for negative spikes.

ART JOHNSON: Were they loose fitting?

JAY PARKER: Yes, both loose fitting and regular hoods.

ART JOHNSON: You must have some very, very sensitive pressure transducers then.

JAY PARKER: Yes, there are some out there that can do that. You have to decide though on the response time that you're looking for.

ART JOHNSON: I don't see any further questions.

TIMOTHY REHAK: Thank you Dr. Johnson. Before we go on break, I just want to remind everyone again, all the presentations from the public meeting today will be posted on the NIOSH website and they will also be available from the docket office. Remember the docket number is NIOSH 008 for the PAPR. Just one last thing I want to say to the guest speakers. If you have a PowerPoint presentation that you want to use for your presentation for your talk, please see Bob

Stein so he can load it on the computer. We'll take a half-hour break and be back here at 1:35.

(BREAK)

TIMOTHY REHAK: If everyone could be seated, we'll get started again and stay ahead of schedule. Okay I'd like to introduce Kate Mackey, Dr. Johnson's Assistant at the University of Maryland and she'll talk about existing standards for the PAPR.

KATE MACKEY: Thanks Tim for the introduction. As Tim said, I'm Kate Mackey. I'm with the Biological Resources Engineering Department at the University of Maryland and along with Dr. Johnson and the rest of our team, we were looking at performance and protection issues with the multi-function PAPR. As Dr. Johnson briefly touched on before, we had four major components to the way that we've approached the study thus far. The perceived importance issue was the questionnaire component of our study, which is on going. The user characteristic's portion deals with the personality and human being factors: the issues that might affect their ability to wear a respirator given their personality aspects and further respirator wearability which has to do with the performance testing aspects that he spoke of. The current talk that I'm about to give deals more with the existing standards things that are already out there and things that we

haven't necessarily looked at testing. So like I said, we broke it down to performance and protection. Dr. Johnson spoke to you mainly about the performance aspects. These are the things that we did testing in the lab and we have future planned testing to do. The protection aspects are covered in the literature already and so what I'm about to talk to you about is essentially a literature review of existing governmental standards. Specifically, the Code of Federal Regulations along with other standards such as ANSI standards gives the protection guidelines for respiratory protective devices as well as other personal protective devices. The general categories that we looked at for the multi-function PAPR specifically because it has so many components included respiratory protection, vision, hearing, head protection, but then also some human factors aspects and then additionally intrinsic safety aspects because this device could be used in the mining community and just as a general way to go through the presentations so that you can follow along. The way that I'm going to address each of these standards categories is for each one if there's a Code of Federal Regulations that applies, I'm going to cover that first and then if that refers to a standard in particular, I'll cover that along with some of the testing methods that go along with those standards and then finally I'll wrap it up by giving you just a brief

548 listing of the International Standards that might apply, but
549 I'm not going to go into any detail about any of the
550 international ones.
551 So the methodology that we used when we were looking at
552 the existing standards was essentially to do a search to look
553 for applicable domestic and international standards that we
554 might be able to use for the multi-functional PAPR. We
555 identified ones that might be applicable and these were
556 generally for protection categories and then we also tried to
557 look at possibilities for growth and for development of new
558 standards to make recommendations and these would be more
559 performance aspects such as the human factors aspects.
560 So the first group of standards that we're going to look
561 at is the Respiratory Protective Standards and these are
562 covered in 42 CFR 84 which is under NIOSH Respiratory
563 Protective Devices and it covers aspects such as procedures
564 for NIOSH approval; certification for respiratory meeting
565 construction performance and respiratory protective
566 requirements; and finally inspection, examination, and testing
567 methodology. Specifically contained within this CFR, there
568 are a few different aspects. There's actually many different
569 aspects, but a brief sampling of them is listed here and I'll
570 give you some specifics. For breathing tubes, it goes into
571 details such as the tubes should not restrict head movement,

they shouldn't kink, they shouldn't affect the user's wearability, so the person should be able to perform their task while they have these tubes if that's a component. Harnesses should be easy to remove and to replace. Facepieces need to be impact and penetration resistant and also not to impede vision. Weight requirement ranges between 16 and 18 kilograms depending on whether there is a cooling device associated with the respirator. It also states that head and neck protection should be provided if necessary in that work environment. A specific standard for air velocity and noise levels is also given and that's that inside the respirator it has to be less than 80 decibels of noise which is applicable for PAPRs that have a fan head piece within the helmet such as in the Centurion helmet so that would have to comply with that. The fan couldn't be louder than 80 decibels and then they also require an end of service life indicator that says when the canisters are going need to be changed. Additionally, within that same CFR, there's respiratory protection standards that are for dust, fumes, and mist and it gives minimum requirements for the quality of the breathing air as well as testing procedures.

A second CFR that deals directly with the respiratory protective aspects is 29 CFR 1910, subpart I, which is an OSHA document for personal protective equipment and in this

596 document it gives guidelines for respiratory selection, fit
597 testing, and the user seal check. Specifically for the fit
598 testing that's also outlined in a very detailed format in
599 ANSI Z88.10, which I'll go into more detail in a few slides.
600 So the domestic standards for respiratory protection begin
601 with ANSI Z88.2 which gives guidance for proper selection,
602 use, and care of respirators, and also requirements for
603 establishing and regulating respirator programs. So this
604 standard is written primarily for people who would be
605 establishing and regulating the programs such as an employer.
606 A second ANSI standard that would be applicable for a
607 respiratory device such as the ones we are dealing with is
608 ANSI Z88.4 which is for protection against coal mine dust and
609 that also has a reference in it to the Federal register which
610 somebody had brought up that this might not be the correct
611 citation. However, I checked the document and it refers to it
612 as this and but it is easy to find. Essentially it gives
613 doses for coal mine dust so that is available in there. The
614 mine operator responsibility and employer responsibility is
615 also gone into so it looks at respiratory protection from the
616 prospective of both the person who's enforcing it and the
617 person who has a personal vested interest in it.
618 In ANSI Z88.7, color coding of air purifying respirator
619 canisters, cartridges, and filters, this is just more along

the lines of a way of rapid identification and consistency among manufacturers that's important so that people know what they're dealing with and they can find things easily and maintain safety.

ANSI Z88.10 gets into the fit-testing methods that I spoke about earlier in the CFR and there's a few different methods that they go into and I won't go into too much detail, but they use either a smell test which has to do with banana oil as the chemical agent, taste in which they use either saccharin which is Sweet n' Low a sweet taste or a bitter taste, bittrex, so the person is to don the mask and then determine whether or not they can taste either of these things, and finally (inaudible stannic) chloride is used as an irritating aerosol, is more of a tacital sort of test. This is a brief listing of different European norms and then the Japanese standards that are similar to our standards for respiratory protection.

The next category that we're going to look at is the vision protection standards which are covered under 29 CFR1910, Part I, which is also the personal protective equipment same as the respiratory one from before. It talks about protection from eye and face hazards which lists including flying particles, molten metal, chemicals, acids, caustic liquids, gases and vapors, radiation, essentially

anything that you wouldn't want getting into your eyes. It also talks about side protection from flying objects. It talks about prescription lenses and that they are required to be used in such a way that the facepiece is compatible with prescription lenses. If radiation is an issue, it requires that you shade against that. It also requires that the manufacturer identification be clearly labeled on the device. This particular CFR requires compliance with a specific standard, which is ANSI Z87.1.

ANSI Z87.1 provides minimal requirements for eye and face protective devices and then it also gives guidance for selection, use, and maintenance for either the employer or for the person who is going to wear it themselves who selects it. It also gives several very detailed testing procedures that can be followed to assess these devices. Now I'm going to cover about three of the tests just to give you a sampling of the type of tests that you can find in these standards; however, there's many, many more. The first is the high velocity impact test in which low-mass projectiles are fired at a test head form wearing the ocular and they do approximately 20 trials, 10 per each pupil and 1 failure is allowed. So if 1 failure of the eye piece out of 20 is recorded, than that still passes, but if any more than that, then the device would fail. In the high-mass impact test,

everything is kind of reversed. Then you have a high-mass projectile with a very low velocity and there's only four trials for that and if any penetration occurs, then the device fails. They also have a flammability resistance test in which a flame is applied to the device repetitively and they check how long they have to apply the flame in order for a maintained flame to occur. Some other tests within this standard that I'm not going to talk about in too much detail are the drop ball impact test, the corrosion resistance for metal parts, penetration tests for plastic lenses and windows, and then there's a whole series of optical tests using optical methods. Of course the list of international standards goes on and on. There's ISO and (inaudible) standards, European norms, one in particular that I wanted to look at because it dealt with fogging of the ocular was in the BSN 168 where they have a method of measuring fogging which includes using the eye device above a hot water bath and measuring the transmittance values and looking for a decrease in transmittance.

The third set that we're going to look at is the head protection standards, which are covered in OSHA's Personal Protective Equipment Section of 29 CFR 1910. Primarily this deals with protective helmet requirements for potential injuries from falling objects. And secondarily if this

applies to the situation to reduce electrical shock hazards. So if you're in an area that has that that has to also be considered. This CFR also has a specific standard that it refers to, requires compliance with and that's ANSI Z89.1. ANSI Z89.1 requires that any devices that are purchased after July 5, 1994, are complied with in the Z89.1. It covers the types and classes, materials, and physical requirements of the device, performance requirements and then also another set of very detailed testing methods, which we'll cover some of.

The first is the first transmission test in which several helmets are tested. They are preconditioned hot and cold. They are put on a head form and they're subjected to an impact test and the force transmission values are recorded based on the pressure transducer inside the head form. Just to give you some numbers to get kind of a ballpark the average force that's transmitted through the head form should be 3780 newtons. However, no individual trial can exceed 4450 newtons, so there's a little bit of a range. In the Apex penetration test it's a similar sort of test, but instead of looking at force transmission to the head they're looking for actual penetration of an object through the helmet. In this case, any sort of penetration would indicate failure of device. This is similar, the off center penetration test, rather than looking at the Apex of the head which is directly

on the top you would look below the dynamic testing line which would be off to the side which would simulate a side impact. Other tests covered in this standard include impact energy attenuation, a flammability test that's similar to the one for the eye pieces, chin strap retention requirements, and then again if it's necessary electrical insulation requirements. These are some of the international standards that cover similar items. The last physical component that we're looking at is the hearing protection standards which are covered in OSHA's occupational health and environmental control 29 CFR 1910, Subpart G. In this case noise exposure is computed based on an 8-hour time weighted average. That is a computational method based on criterion level, which is a decibel level that is selected based on OSHA's requirements. A criterion duration and exchange rate, which is a rate at which whether the decibel increases or decreases by that amount. The time that you could be exposed to it would be either doubled or halved depending on whether it was increasing or decreasing and then the threshold level. It also goes into methods for measuring the adequacy of hearing protection attenuation. The final thing that it addresses is the noise reduction ratio method that's given by the EPA.

The domestic standards that deal with methods for measuring hearing attenuation are given by ANSI Standards

S12.6, S12.19 and S12.42. And these are just different methods that you can test the attenuation of noise levels by hearing protection devices. Similarly, there are several international standards that give very similar tests. After we looked at the difference physical characteristics we also wanted to look into some of the human factors aspects. Dr. Johnson talked mostly about the performance aspects and this kind of goes more along the lines of what he's doing. The only human factor standard we put into this group because we felt that it was important was one that's based on communication. In ANSI S3.2 it measures the intelligibility of speech over communication systems. This standard is not meant for respirators or for hearing devices necessarily per se. It's meant for a very specific group of people in which you have a speaker and a listener. There are lists of words and they speak back and forth and try to see how well they can identify what each other is saying, and perhaps in terms of evaluating the ability of a person to communicate while wearing a device such as a multi-function PAPR. A standard such as this one or similar to one might be employed.

The final category of standards that we looked at was the intrinsic safety aspects. This is particularly in methane rich environments in mines this would be applicable. These standards are covered in 30 CFR 18.68. There's a whole series

764 of tests that are outlined, they're very specific for the
765 circuitry components. There has to be a lot back up within
766 the circuit. There has to be stability against shock and
767 vibration. The circuitry sizes, the capacitance elements and
768 everything have to be large enough that they deal with amount
769 of power that's being supplied. They're tested at 1500 volts.
770 With this series of tests the circuit is considered
771 intrinsically safe if no ignitions occur during testing. So
772 as they apply these voltages over the circuitry parts if
773 there's no spark that causes an ignition then the circuit is
774 considered intrinsically safe. In summary, Dr. Johnson's
775 aspects that he discussed with our lab testing dealt with
776 performance. They deal very much with the user issues. How
777 the different aspects of the user such as personality and
778 human factors go into determining how well they can use the
779 respirator and how much it impacts their ability to perform.
780 Protection certification can be done with existing standards
781 because they're already out there. They focus much more on
782 the mask and less on the user. I have the same consultations
783 and acknowledgments as Dr. Johnson. We'd like to thank NIOSH
784 very much for all of their continued help and support along
785 with MSHA for giving us a lot of feedback on the presentation
786 specifically. Are there any questions?

TIMOTHY REHAK: Next we'll move to the outside speakers. First we have Jacques Forrest. He's the Technical Director of Centurion Safety Products a firm which has been manufacturing personal protective equipment for over 124 years, Dr. Forrest.

JACQUES FORREST, CENTURION SAFETY PRODUCTS, LTD.: Good afternoon, I took old technology and decided to put my presentation on overheads. Perhaps as you all got a copy you can read through it with me. As you just heard Centurion Safety Products is a UK-based manufacturer of personal protective equipment offering head, face, hearing, and respiratory protection to wearers. It's been manufacturing this sort of equipment for 124 years and it's selling its products worldwide. It is pleased to be offered the opportunity to submit both verbal and written comments to the meeting which forms part of the research NIOSH is conducting to enable it to review and modify applicable standards for the above products. Centurion Safety Products has a design philosophy that provides products against known expected risks in the industrial workplace. This philosophy provides the correct equipment for the correct hazard. Highly visible in the design process, is the consideration for the wearer's comfort and the wearer's acceptance of the equipment. Centurion Safety Products has a testing philosophy that respiratory protection is so vital to the wearer that the

effectiveness of the complete ensemble hoods, filters, seals, etc. should be testing together. And thereby can provide more consistent respiratory protection than testing the various parts in isolation. These two philosophies have enabled Centurion Products to provide equipment worldwide but offer exceptional respiratory protection at an affordable price to the purchaser that does not alienate the wearer.

Centurion Safety believes that NIOSH has the power to issue temporary license mandates to recognize the acceptability of respiratory products approved by other respected recognized approval bodies. The benefit of this would be to enable and specify a wearer quicker and easier access to a wider, more acceptable, comfortable and user friendly range of respiratory products. However Centurion Safety believes that NIOSH has not at this time been presented with a significantly persuasive argument to utilize these powers. Centurion believes that there are pressing markets needs that warrant the issue of relevant temporary license mandates for certain respiratory products. With the completion of the revision and republication of 42 CFR Part 84, these temporary license mandates could be withdrawn if the products did not comply with the revised legislation.

In mind of the above-proposed radical approach Centurion Safety would like to submit that the following points be taken

into consideration when revising the testing and in use performance requirements. The revision of 42 CFR Part 84 should not seek to provide respiratory performance requirements that will take years to deliver. It therefore submits that the revision should be such that they allow authorization approval of equipment, which exists now, and provide real benefits to the wearers now. That because no one respiratory protection device offers the luxury of being capable of protecting against all risks that the standards are modified to allow devices to be approved against specific risks. I won't read out why that statement should be supported. The negative pressure devices, PAPRs, and SCBA devices should be approved to different performance requirements in different sections of the CFR. There are currently no recognized standards for such things as communications or wearability. Therefore, NIOSH should not allow the development of these to slow down the revision of the respiratory requirements of 42 CFR. And rather than delay publication of revised respiratory performance requirements that these are revised soonest to allow acceptable respiratory products into the market. NIOSH should restrict its performance requirements to those of respiratory protection. They are already in existence where respected performance standards both North American based and elsewhere in the world

for vision, hearing, and head protection. These should be cited in applicable regulations and policies rather than NIOSH's own requirements being written. NIOSH should constrain itself to areas where there are currently no respiratory standards or unacceptable standards exist. That NIOSH accept third-party approvals for eye, head, and hearing protection to enable good PAPRs to be approved. That NIOSH consider third-party approvals for respiratory protection where products can be proven to meet an efficiency standard for the protection needed for that particular application. That NIOSH consider classify PAPRs by the level of protection offered, considering their suitability for purpose. That NIOSH considers implementing a mechanism whereby 42 CFR Part 84 is regularly updated. Updating of the rules and or test methods to keep abreast of technology would enable inclusion of better and modern technology as and when it is developed. That NIOSH facilitates the introduction of revised standards by utilizing test methods for determining performance efficiency that are proven and recognized in published standards originating from third parties. That rather than testing the discrete components, e.g., filter, face, etc. 42 CFR Part 84 could greatly benefit performance requirements but based on complete equipment testing. This could involve utilizing panels of real people with a nontoxic test aerosol.

I thought of one other on the plane over, just to give you the benefits of my deliberations; I think there needs to be an ongoing performance-testing requirement written into the regulations. The regulations should not just consist of a type approval. There should be ongoing product surveillance. Not withstanding the above, Centurion Products submits comments to be incorporated into the revision of 42 CFR Part 84, 1995, with respect to particulate filtering respirators only. The attached proposed changes to 42 CFR Part 84, which if adopted with reasonable speed would enable a more comprehensive and effective range of acceptable respiratory devices to be available for selection by the appropriate specified end users.

Centurion Safety Products has proposals to make only on the following clauses, 1100d the scope, 1142 isoamyl tightness test, 1151 DOP filter test, and 1152 silica dust loading test. Because I'm only limited to 15 minutes I do not intend to take you all through the relevant support for this, but in subpart 1100d, the scope, we suggest that the PAPR respirators should be categorized into three levels based on the filter categorization. The current categorization in 84.1151 would suffice. For the 1142 the isoamyl acetate tightness test, we suggest that this test be replaced with quantitative test using the filters that are intended for use with the power

unit. This test might, for example, be similar to the tests employed EN 146 or EN 12941 or 12942 with limits based on the filter classification as per 84.1151. 1151: we suggest that filter classifications and test methods used for negative pressure filters N, R and P 95, 99, and 100 (Clause 84.179) are adopted for powered respirator filters with appropriately adjusted flow rates. Clause 1152: we suggest that either the minimum flow rate requirements for a loose fitting hood is dropped completely or reduced to 120 liters per minute. The total inward leakage test as described in Item 2 above would be conducted at the manufacturers declared minimum design flow rate thus demonstrating that the air flow is sufficient and the product effective. And we have a minor comment, which is editorial, there is a Table 12 but no reference is made to that table anywhere in the text. Thank you very much. Are there any questions? You're not dumbfounded surely.

TIMOTHY REHAK: Thank you Dr. Forrest. Next we'll have Göran Berndtsson. He's the CEO of SEA Group.

GÖRAN BERNDTSSON, SEA GROUP: Good afternoon and thank you very much for allowing me to come here and talk. I suppose I have a slightly different view than the previous speaker. I think before we start writing standards we have to understand what we are going to write these standards for and what the requirements of people are who need to wear these

respirators. A lot of you people have seen me before and you know now he's going to talk about peak inhalation and you are absolutely correct. However, I'm going to deal with it from a little different angle this time. What's happened over the last year or so we have been looking at using negative pressure respirators. That's what we're going to talk about because there were a lot of comments on the data and some of the information provided in the power unit. Let's have a look at the negative pressure respirator under similar conditions and see what the requirements are. So that's the data we're going to look at now.

The emphasis has been on negative pressure respirators and presented respiratory tests (inaudible). Nor can we be confident or certain the (inaudible) actually offers the protection the users expect and should be entitled to get from the product that is certified and deemed to comply with NIOSH. That's the situation we're all in today. We're testing to standards but we can't really ensure that the users are well protected even when respirators due meet the standards. What we did was design a study and simulated different work rates using an alga mated test bike. The advantage for that was that we could program it with a computer. We set it at different workloads. The equipment we were using was 5 negative pressure respirators and a positive pressure demand

PAPR. The pressure drop on those respirators, as we all know we around the world are checking pressure drop on exhalation and inhalation at either 85 or 95 liter constant flow. This graph shows a little bit of what's happening when we start flowing more air through those respirators. This is all measured in the millibars and you have flow rate in liters per minute.

That is exhalation on that side, inhalation on that side, and here is where we are actually testing respirator devices for pressure drop. And as you can see it is an enormous increase in exhalation as well as inhalation resistance as you start flowing more air through these devices. This is very, very important physiologically from the user's point of view. The test group we were using was 10 people, 8 males and 2 females. The age spread was between 17 and 54 years and their weight was between 61 and 96, and height between 169 and 193 that all in centimeters and kilos. You'll have to excuse me I haven't put it into pounds and inches but this is an international society so you will all understand. I feel that is a fairly representative group of our society out there. The test was divided into eight sections, each 5 minutes. Within that first 5 minutes we started at 50 watts external work load, peddling on a bike at about 80 reps. After 5 minutes we increased 25 watts and we continued to do that

979 until we reached 225 watts output or 85% of your (inaudible)
980 on your heart rate or if someone got dizzy or for any other
981 reason did not want to continue, could not continue any
982 longer. I apologize for having so much text in here. With
983 each section the first 3 minutes we only peddled the bike, no
984 talking, no other interference just peddle the bike.
985 The fourth minute we were reading the (inaudible)
986 sentence constantly for 1 minute. Most of the test subjects
987 managed to read that number of sentences twice during that
988 period of time. They were reading constantly as if we were
989 talking. The fifth minute between four and five we let them
990 recover that way catching up on your oxygen debit. Then we
991 increased it by 25 watts external, let them peddle again for 3
992 minutes, and did the same thing again. The (inaudible) volume
993 and peak inhalation was large. The average minutes/volume
994 started at 22.2 liters and up to 150 watts. The data I'm
995 presenting only goes to 150 watts, the reason I stopped there
996 I'll tell you in a minute. Up to 150 watts was 61.57 liters
997 this is minutes liters that's the volume of air you're
998 breathing doing those kinds of tasks. The peak inhalation air
999 flow on average in the third minute which was the first
1000 (inaudible) was 99.49 liters peak inhalation air flow. That's
1001 the flow the velocity the air is going through the system.
1002 And the peak inhalation air flows up 150 watts that's 268

liters, with a max of 533. Sorry the previous one was for the fourth minute (inaudible) the lowest we measured. There was the first talking prelude within (inaudible). Because what's happening is that when you start talking you are actually substituting inhalation for speeches so it drops. The volume of air dropped about 16%. Between 26 to 39 liters was the first of the third minutes, the 22.2 liter was the fourth minute, and then when you come to the fifth minutes it goes up to about 30 liters to catch up on the oxygen deficiency created. For anyone who is interested I have all this data available, I just a business card and I will send it to you.

So what happened of course between non-talking and talking in the first 50 watts is that we had an increase on peak inhalation air flow at 75%. We had a decrease of 15% or 16% in volume of air but we had a peak inhalation air flow increase of 75%. Then as I said in the fifth minute we didn't talk any longer we actually measured the blood oxygen level and of course what's happening when you are substituting inhalation for talking your blood oxygen level drops and on 50 watts you won't see that much in dropping. But when you saw it coming up to 150-175 watts you're dropping down to about 92%, 93% saturation of oxygen in your blood.

This is a graph it looks quite a lot of course. But I thought I would show you how it looks if you put it all

1027 together on one graph. This is 25 minutes and what you're
1028 seeing here this is just the first about 5 minutes here. This
1029 is actually the first talking part, second talking part, third
1030 talking part, fourth and so on. And what you find if you are
1031 scrolling down and looking on half a minute or minute at a
1032 time is that you find that the minute after talking you will
1033 have about the first 30 seconds you will have a slowing of
1034 your breaths then you're stabilizing. Then as you're stepping
1035 up 25 watts you will have a minute to start catching up and
1036 then eventually stabilize. We come to the third minute you
1037 have a fairly stable heart rate as well as breathing rate.
1038 What are we getting out of this? We had 63 test data sets as
1039 we had 10 people, 6 respirators; a couple of the guys did the
1040 test more than once. We had an average minute liter of 26.39,
1041 average peak inhalation air flow of 99 just under 100 liters.
1042 A max air flow in that third minute of 252 liters and we had a
1043 max air flow of speaking of 402 liters.

1044 The question is, is this representative for first
1045 responders? If we go back to another ISO standard, which is
1046 about heat stress, actually matches heat stress and they
1047 describe 50, and what you can do with the heat stresses is
1048 that you can actually read physiology books you find that the
1049 normal case your external work is about 20% of your heat
1050 production. Some difference is actually when you jump on a

bike, a stationary bike you can actually get up to about 25% efficiency. What I have used here is that using 25% so you're using the heat stress where you are actually very well documented way of working out how much heat is produced by burning so much oxygen, etc. Then you can put that back into work rate on a bike. Then we can put some text in to what this means. Because 50 watts if ask any one of you go out and work at 50 watts what would that be. What is that? So what this ISO standard is saying is that consider these light manual work: biking, typing, drawing, sawing, bookkeeping, hand and arm work, small bench, tool inspections, arm and leg work, stamping, and if you're walking with about a speed of 3 ½ kilometers or 2.2 miles. Is that what a first responder does? Is that what a worker is doing out wearing respirators? I think it is not, I think that's far too low a work rate.

Let's have a look at what I believe is more representative. As a side issue I don't if you know but there is quite a bit of work going on around the world where we're trying to write an international standard for respiratory protection. There are a lot of countries involved and we are actually trying to use this as guidance for the new classifications on the ISO standard. The highest work rate actually has a metabolic rate of 520 watts that would represent about 150 external. Of course when you say 520

watts I can go back to, it is actually measured on the person an average weight which is a person of about (inaudible) meters high, so 177 centimeters. This is actually true to standard back to square (inaudible) body surface because that's how it's calculated. It all depends on big we are on where we're ending up (inaudible). But it is very, very good tools in this standard to work out. So 150 watts was probably more close to what a first responder would be doing. We're talking about intense shoveling; digging; climbing stairs, ramps, ladders; or walking at a speed greater than 7 kilometers or greater than 4.4 miles. That would be more applicable to the type of work we would have seen our first responders acting on, the World Trade Center for example.

So, what numbers are we looking on then? At that level we have an average volume of 57 liters when we didn't talk, 50 minute liters when we talked and recovery was around 53. We had peak inhalation air flows of 176 non-talking, 268 when talking and 217; that was actually consolidated bottom line is consolidated so you put the two together. And of course the max here 533 liters. Then of course the question is always going to be how many breaths are we going to have or breathe that much. You look in the right column there I actually looked on when I was looking on this data you can actually see how much of this air actually travels faster than the way

we're testing it today. Faster than 85 liters we actually with no speaking we have 92% or 52.9 liters of the 57 we were breathing flows faster than how we are testing it. It's not just one spike now and then it is constantly all the time. Because what's happening is the acceleration of the air is too fast you go up and your breathing goes like this and then you breathe out again. And when you're speaking it's even higher 96 nearly 97%. What percentage do we know how many of the population do we want to protect how many do we wan to be in positive pressure? Do we want to have 95 percentile in positive pressure? Do we want to have 50 percentile? I'm not here to tell you what, but very often we look at the 95 percentile, am I correct saying that. So 367 liters is what we need to supply to keep positive pressure to 95 percentile.

We also did a similar test, which we presented data about 6 months ago. They did and an agility test. Everyone familiar with an agility, it is a firefighter's entry level test to be a firefighter. The firefighters in this country reckon it is very typical work with firefighters. So we had a group of 47 marines who did such a test not far away from where we are today sometime in September/October. And when we did this testing at 95 percentile, that group actually required 427 liters of air. (inaudible) air flow rates (inaudible) exercises this concurs with the earlier findings

by the others and me as well as Dr. Kauffman in the study he did on the Marine's. He did that on M40 masks and Professor (inaudible) who did a verification of the data by an independent test financed by the Swedish government. The conclusion is the work which best represents the first responder typical work, 150 watts external, (inaudible) peak inhalation air flows all in excess of typical test flows. Raising the question, how well will the first responders be protected if we don't test the typical flow rate for this type of work? 150 watts external work a full 90% of the inhalation sequences is made up. In other words 90% of these workers flow faster than 150 liters. That is what we're testing PAPR's on today.

In order to maintain positive pressure, for 95% of the first responders we need to have a flow rate of 427 liters. So based on this data collected and presented by Mr. Kauffman, Mr. (inaudible), as well as what is published in modern text books in physiology and sports physiology I propose the following recommendation for the new standard for OPD's. To maintain the level of protection required when exposed to (inaudible) typically classified (inaudible), we need to maintain a positive pressure to 427 liters. The (inaudible) should have an alarm to warn the use of positive pressure can no longer be maintained during a substantial portion of the

generation cycle. In other words it will tell you when filters get clogged, battery water falls to too low, and the work rate is too high. If we have that we don't have to argue what is the correct effort. Questions?

JAY PARKER, BULLARD: I'm sitting here listening to your paper, which is presented like a scientific paper. However, you did not give any details on the methods of how you measured your airflow. You presented airflow data with up to five significant figures. So my first question is, how is the airflow measured, how is it calibrated, how frequently is it calibrated, and what other methods have you compared your air flow measurements to to validate those measurements?

GÖRAN BERNDTSSON: First of all we are limited to 15 minutes so I chose not to put it in my verbal speech. It is all covered in the paper, which will be available in the next few days at the docket office. Alternatively, give me a business card and I will e-mail it direct to you. However, having said that I'm going to give you a brief answer to your question. We have been doing this for many, many years. We're using a pressure drop over a known resistance. It is calibrated against a number of different flow meters. Because we have such a spread on the flow of measuring from a very low flow all the way up to 600 we are not accurate on all the flows that are calibrated. So we're focusing around the 200

liters and in the paper it tells you what the percentage of losses or inaccuracy on both sides of those. Of course we are a certified lab certified at NIOSH standard, a European standard, and Australian standard. We are under the same quality control system as any other lab. We have calibrated (inaudible) calibrated machines and flow meters and the instruments which all this is verified against. I don't know if this answers your question or not. Any other questions? Thank you very much.

TIMOTHY REHAK: Next I'd like to call on Mackey Shinomiya with KOKEN. I hope I got the pronunciation right.

MACKEY SHINOMIYA, KOKEN, LTD., JAPAN: (Note: The following is a summary of Mr. Shinomiya's presentation taken from both his verbal presentation and his paper copy Proposal of Incorporation of a New PAPR in New NIOSH Standards.)

We specialize in occupational health protector. Of our (inaudible) respiration and is a (inaudible) condition of test for (inaudible) respiratory protection provided by a new type of PAPR. PAPRs are good respiratory protection devices, which provide a high respiratory protection and low inhalation resistance. (inaudible) matter is part 42 CFR, Part 84, Subpart KK requires PAPRs to supply the wearer with a continuous, high airflow, of not less than 115 liters per minute for tight fitting facepiece and not less than 170

liters per minute for loose-fitting hood or helmet. This requirement will be to ensure protection even on heavy workload. However, this requirement makes PAPRs have a weak point. Such a PAPR which always provides a continuous, high airflow have weak points of causing an increase of exhalation resistance and a quickly clogging of filter. If those weak points are eliminated from PAPRs, it should further enhance practical use of PAPRs and users' merit.

By taking account of this, our company recently developed a new type of PAPR assembled with tight-fitting facepiece. This PAPR is equipped with a new type of blower, which controls the rotation of the blower fan according to the wearer's breathing. This PAPR, adjusting to the wearer's breathing in practical range, provides airflow necessary to ensure a positive pressure inside the facepiece, thereby, eliminates the necessity of continuous high airflow. It reduces the wearer's physiological burden and also gives the respirator users a cost merit.

Essential purpose of PAPRs' air supply would be to ensure a positive pressure inside the facepieces or hoods or helmets on the wearers' inhaling. Providing a continuous high airflow even on the wearer' exhaling merely quickens consumption of filter. A PAPR which provides airflow necessary to ensure a positive pressure inside the facepiece on the wearers inhaling

and restrains airflow on the wearer's exhaling is already available. It would be no longer reasonable to specify PAPRs' airflow only by a continuous high airflow. It would be reasonable to replace present continuous high airflow test by a pulsated airflow test that is determined by taking account of human breathing. As a study material of the New NIOSH Standards of PAPRs, we therefore suggest NIOSH to incorporate in New Standards such a PAPR which provides airflow following the wearer's breathing.

In our test, this new type of PAPR always maintains a positive inside pressure at an airflow that is approximately 2 to 3 times the actual breathing airflow, and this airflow is 30 - 70% the airflow provided by present PAPR. Figure 1 shows a simple schematic diagram of this new type of PAPR and Figure 1 through 6 show examples of data obtained in a test of this new type of PAPR.

Thank you very much for your attention. For future information, please contact our e-mail address. Thank you.

TIMOTHY REHAK: Okay thank you. Next I'd like to call on Mr. Josesph A. LaMonica, Consultant for BCOA.

JOSEPH A. LAMONICA, BCOA: Thank you. Thanks for the opportunity to make a few comments for consideration as you go about the task of writing new standards for PAPRs. My comments are limited to PAPRs used in coal mining. Since the

1243 1969 coal act we've been dealing with the issue of protecting
1244 our nation's coal miners from exposure to respirable coal mine
1245 dust. The primary means of doing this has been through
1246 engineering controls, primarily ventilation. There are times,
1247 however, when these engineering controls do not protect miners
1248 adequately. During these times the use of approved filter
1249 respirators was adequate but not comfortable for the miner.
1250 The introduction of a PAPR device, which was designed for
1251 mining, eliminated some the problems filter devices caused.
1252 So we had something that we could use during those times that
1253 engineering controls were not adequate. Some of the features
1254 of these PAPRs led to miners wearing the devices full time for
1255 a full shift at the face area where the coal is mined. The
1256 government showed that these devices did provide improved
1257 protection for the miner.
1258 Several years ago a change was made to the regulation
1259 that required the filters used in these PAPRs to be high-
1260 efficiency particulate air filter (HEPA). Unfortunately, we
1261 in the mining community were asleep at the switch so-to-speak,
1262 because we were not aware of this change being made. As a
1263 result of this change, a device that was getting the job done
1264 could no longer serve that purpose. In making something
1265 better by improving the efficiency we made it worse in its
1266 performance, a performance that was already adequate. To

accommodate the HEPA filter, we had to increase the airflow that required us to enlarge the air mover that consumed more energy that required a larger battery. Bottom line, more weight for the miner to carry. MSHA has proposed a dust regulation that will require NIOSH approval for not only the filter but also the PAPR itself. What we must be careful of, and the reason for my comment, is that we do not create a situation where the PAPRs can not be used or be used in a noncompliance mode. For example, the manufacturer of a PAPR is trying to obtain approval and maximize the product's ability to protect the wearer. One such device uses a neck shroud for this purpose. However, the miner is not comfortable using this shroud and removes it. Under MSHA's proposed rule this would be a violation and the operator would be cited, as he should be. But what if the shroud only provides added protection above what is already adequate without it. We need to be careful that we can have approved devices that provide the protection needed and are comfortable enough for the miner to wear. My second comment is related to the first and that is the issue of NIOSH regulation requiring the HEPA filter. That regulation does not have a provision that would allow a user to petition the agency for a variance if the case in point could be made or demonstrated that there would be adequate protection for a given situation. The

agency might want to consider this type of provision in future regulations.

My last point deals with a process of a direct final rule. To promulgate a regulation takes a long, long time. I think we have the research timelined out for 2 years or so. If you're really good you can get a regulation out in 18 months. So we're talking 3 ½, 4 years from now to have a regulation. The use of PAPRs in mining has an immediate need now. We're talking about a device that provides better head and neck protection, face protection, hearing protection, pre-HEPA filter respirable coal dust protection, and communications ability. I would suggest that if the mining community is in agreement to a pre-HEPA filter device that would only apply to mining, the agency consider a limited direct final rule that could be in place much sooner mesh with the MSHA proposed dust rule and be in place only until NIOSH publishes a new PAPR rule. Thank you. Any questions?

GAVIN BURGE, ADVANCIA, DC: I'm not affiliated with the mine but we do have a contract with the Federal Aviation Administration. Your comments, I think, were important and should be noted for the record across the board. And just for my information, maybe some other people perhaps in here don't know as much as you do about the subject. Could you please expand upon the requirement for the HEPA filter in the mines?

Why they are required and maybe some information with us also that aren't as knowledgeable as you are about the actual use of respirators in the mines when they do provide a, when they're heavier they may be uncomfortable and miners may not wear them as much. Could you comment on the actual use of the respirators in the workplace and how long over a work shift, for example, are they actually used? When people may not be under the direct supervision of the supervisor all the time.

JOSEPH A. LAMONICA: I'll defer your first question to NIOSH to answer in terms of why they require a HEPA filter other than it's more efficient and a better type of filter. It doesn't apply to our particular situation so I'll let them answer that question. Respirators in coal mines are only used in the event that there is a exceeding of the dust standard and only during the period of time that the condition or practice is abated. So it has very limited use. Unfortunately, PAPRs are considered respirators. It's a different animal. The old days of wearing a respirator in the mine, those of us that used to chew tobacco, they were a nuisance. You had to take the thing off and spit. They were uncomfortable, resistance to breathing, a lot of things were wrong with them. The PAPRs have sort of made some of those things go away. But if you look at it as a system, better eye/face protection, hearing protection, we can come up with

some communication systems that allow miners to talk to one another over distances, provides a safety factor in a mining situation. So an abbreviated answer to your multiple question.

JACQUES W. FORREST: Can I just add something Joe partly in response and partly not in response. Just two points, I almost put the phrase horses for courses in my presentation. I was advised by my American colleagues not to do it. But I think there is a definite need for horses for courses. There is absolutely no way a PAPR designed for a miner is going to help a first responder. And although Gören and I appear at logger heads there are some issues that I can absolutely agree with them on and other issues I don't think are necessarily pertinent to miners. When was the last time you saw a miner riding a bike reading out loud? They're doing a different job, completely different job. That's one issue. The second issue is that there are filter medium around that are very good for certain contaminates and unfortunately the current regulations don't allow the usage of some of those materials where they would be highly effective. There are very, very effective materials for taking out coal and silica dust which don't have to be high efficiency filters. Therefore don't require the bigger motors, don't require the bigger batteries, don't cost as much. This is exactly what I think miners are

looking for. Katie made a very interesting point when she said that the requirements, and I forget which one, are that they have to weigh between 16 and 18 kilograms. There is a device out there for miners that weighs 700 grams that offers head, eye, face, hearing and respiratory protection. Sorry it's not approved.

GÖREN BERNDTSSON, SEA: I think I mentioned briefly that we are writing a new ISO standard. Of course we don't know if that's ever going to be adopted in the United States. But we are however writing a new ISO standard. That's going to be entirely based on performance. The performance requirement is going to be entirely based on physical requirement for people. The primary testing is going to be respiratory protection. The secondary testing will be things like hearing, eye protection, and helmets. I think my point here today is you said that the PAPRs in mining industry give you a lot of other things but they aren't respirators. Of course the thing here is physiology regardless if you work a lot and I thought I'd proven that, showed that with the data without working hard you still get these kinds of peak flows, large percentage of your inhalation breath at the time you are actually holding. Of course if you are not providing enough air then of course you are going to be sucking it from somewhere else, that's around the edges of these loose-fitting devices. And then as

I spent a long time of my professional life in Australia, we have a lot of mining and smelting industries down there. It's very common that loose-fitting PAPRs are used in the lead smelting industry up until the body level goes up do they have to put the negative pressure respirators just to bring it down then they put it back into the helmet so it's easier to wear and more comfortable to wear and the body level goes up (inaudible) negative pressure goes down again and that is an ongoing cycle. Does it tell us anything? It should.

JOSEPH A. LAMONICA: The only comment I would make, you and I are probably worlds apart here in terms of where you're coming from, where I'm coming from. As I said up front our primary means of protection is through engineering controls, ventilation. That's our primary. This is something that when we get in trouble because we're over our 2 milligram per cubic meter dust standard and we may be at 2.5. Until we get that resolved we need a device to use. So we're topping it off with a supplemental device. It can not be a primary device for a multitude of reasons. So again I don't know that I'm responding to your comments. Any other questions? Thank you.

TIMOTHY REHAK: Our last outside speaker is Mr. Joseph Main. He's Administrator, Department of Occupational Health and Safety, with United Mine Workers of America. Joe.

JOSEPH MAIN: Thank you very much. I appreciate the opportunity to be here this afternoon to learn a lot. Trying to figure out what's going on with respirator approval process and what that means to the workers that I represent. I represent coal miners; a group of workers that have worked in dust conditions most of their life. And we spent most of our lives, those that are the health and safety professionals, trying to get those dust levels as low as we can so we don't need respirators. Interesting conversations here today. I'm probably going to walk away from here with more questions than I do answers. But it has raised a number of troubling concerns that I have with regard to plans to deal with PAPRs a respirator in coal mines. I just want to give you a bit of a background as to why that is a problem. Joe LaMonica and I have had a lot of conversations; he's my counterpart in the industry, over this issue for many, many years. We have worked earnestly to try to develop a worker friendly respiratory protection for miners that work for them. And the discussions have mostly been under a standard of which was set in 1969 that was designed protect coal miners by allowing now more than 2 milligrams per cubic meter of dust to be in the mine environment. In trying to figure out ways when we exceed that level, how miners would be protected. In along those lines I think we have some common thinking and common

positions in trying to achieve what we are by having a device that is worker friendly, gets the job done, and does protect miners. I think there is a large divide beyond that point.

I think people need to understand that and understand why and understand that there's probably going to be a lot more discussion about this whole respiratory protection issue. It is because in 2000 there was a proposal made by the government, not this agency NIOSH but the sister agency MSHA, to allow respiratory protection to be used as a means to replace in part environmental controls in mines. The 1969 Coal Mine Act originally passed mandated two things that the coal mining industry had to get their act together and get the dust levels down to no more than 2 milligrams per cubic meter with lesser dust exposures sought beyond that. If you have a quartz component in that it would even lower the standard even more. It also said to the mining industry you're not going to use respirators to achieve that, you're going to use engineering or environmental controls to get those dust levels down. That was in 1969 when we had far less technology and wherewithal to fix dust problems than we do today.

Some thinking started to divert from that in 2000 when a proposal was launched that called for the use of respirators on coal mining longwalls as a substitute for environmental controls that would allow the dust levels to double up to 4

milligrams. That proposal, as you can imagine, for miners was strongly opposed. It was wrong headed it was the wrong direction to go and it really didn't meet the interest of the miners nor we think the mining industry. That standard not only was opposed by miners it was contrary to findings of a fellow advisory committee that examined the means necessary to eradicate coal workers leumokoliosis, to eliminate coal dust, it was contrary to NIOSH findings about how to fix this problem. It just run against the grain of the whole intent of congress in this country. None-the-less the proposal was laid out, and it was thank goodness withdrawn. Unfortunately about a month ago another proposal came to the table. This time that proposal again wanted to replace environmental controls with respirators to achieve a certain measure of dust control, however you want to phrase it, in the mines. It also said lets just don't apply this to longwalls lets apply it throughout the mine.

It said forget about the 4 milligram let's quadruple it and let them go up to 8 milligrams. Now as I stand here today and it's like part in anger and part in disgust that before this government policy is leading us I have to say that part of this equation has now drawn in this whole PAPR issue because the PAPR is the golden goose here that's suppose fix this problem. I've been around this industry I worked in the

industry before the 1969 Coal Mine Act went into affect I know what dust levels were back then and I know how we worked hard to achieve those. I have been as administrator of health of safety for the United Mine Workers since 1982 been directly involved in the whole respirable coal dust program. I have met eye-to-eye with mine operator after mine operator that says Joe we can't get these dust levels down you've got to let us use respirators and we said no go back to the drawing board and come up with ways to do that. On longwalls over the years we have seen dramatic improvements. We've seen water sprays put on shields, we have seen better spray designs on shears, we have seen cutting speed changes, we have seen the cut bit changes, we've seen a number of things. But had we said yes we've exhausted engineering controls I can you where we'd be at today and the right thing for us to have said was no. Let's get the engineering controls in place as congress mandated in 1969. Let's deal with the respirator protection that gets us on those creeps up and down in the 2 range as they occur. And let's get a continuous sampling of coal mines in place so we know what the dust levels are. Let's build something that works and continue the gains that were made as opposed to abandoning the gains we've made in controlling the dust in the coal mines.

So as I stand here today my thoughts probably my discussions would be a little different than they were when we were talking about a 2 milligram standard being the standard of the day and how we achieve that with engineering controls and how we use respiratory protections to deal with excursions over the 2 milligram standard. Because I can tell you this my unions nor miners are going to support the outrageous proposals that we're seeing coming out of this government that calls for raising dust levels to 8 milligrams in this country and using a PAPR as an alternative device to make the difference.

Secondly, points have been raised as regards to the PAPRs yes what I have witnessed in mines, I'm in the mines quite a bit, I see what miners do and no they don't set at desks typing. They do manual work and some of the hardest working Americans you're going to find out there is coal miners in today's mines. Some of them work harder than many in this room can imagine and they breathe hard. And if there is an over powering of those devices we should be dealing with that. Which gets me to a number of questions that I have about how we test these, how we put them out for use. What is a real validation of these devices? This is not the direction that we can or need to go to help America's coal miners. We need to be discarding these outrageous proposals and getting back

to some common sense approach as we were in the past and try to fix a problem of developing a worker friendly device that works under the constraints of the limits set and start reducing even further that 2 milligram.

We need to go to 1 we don't need to go to 8. I think it's a standard that is an approach that is supported by many. Now it may not be by a mine operator that's want to crank up a lot of coal and run a lot of production on the section and not have to spend the money to put dust controls on, but that's the price of doing business in this industry. How are we approving these devices? We have miners out there that wear these devices or would wear these devices 8, 9, 10 hours a day some of them work 6 and 7 days a week. Is that healthy? Is there some impact on the human physique about wearing those? Have we done tests to determine that? What are the air flows we're actually checking these, the performance of these devices against? Is it sitting the typewriter for X-amount of hours? Or is it replicating the actual work that these miners do? The point that was raised about the skirts, in most cases where I have saw miners wear those they don't wear the shirts. If you go on the longwall where you have a lot of water coming off of your shields and off of your shear to keep the dust down you have condensation. Now I challenge any one of you to go to a damp location, encircle your head and with a reduced

breathing process see how much humidity you have in front of your eyes to what you can see out the other side. These are all things that need to be examined. The real workplaces are where these devices are used. What about the shield test? Once they are approved, is there any follow-up approval? What about the intrinsically safe issue? Over the last 12 months we got a number of mine fires and explosions in this country which are far from eradicated.

It's a common problem unfortunately we face. We have miners that are using these so called PAPRs in locations that are in by the last different crosscut that has the potential for an explosion. Are we testing those on any routine basis like we do all the other equipment, at least every 30 days, to make sure that it is maintaining its permissibility and its intrinsically safe status? How do we test units that are in use over a month, 2 months, 6 months that sometimes takes a pretty rugged abuse? I've seen mechanics that work on these longwalls that crawl in and out of these jacks, tight spots, tough conditions, tough terrain. What do we do to validate their continued performance with the standard? What is it we're doing to make sure that as these are approved we have a quality control that assures that the end-user is using that device as it was approved?

Because I can tell you what I saw in coal mines these units that are approved by NIOSH now which have the neck skirts are not being used in mines with that neck shirt on in many locations. What does that mean? How is it we find ourselves knowing the shortfalls of these systems that we now want to talk about taking this PAPR that has all these inadequacies and say let's not only double the dust standards we're going put this miner in let's triple them. Where is the common sense? I fail to see it. Yes we were agitated by this approach, can't believe that the government would be doing this to miners given the fact that tens of thousands of coal miners have died from a black lung disease they've got from breathing the dust. And given the fact its cost billions and billions of dollars to cover the compensation to those that have been disabled, where is the logic here.

We're going to have a number of questions to pose to NIOSH and some of the folks; we'd like to get some of the papers that you have. But until we get off of some of these crazy ideas I think there's going to be a lot of differences here on what it is that we're talking about, what a PAPR should do in a coal mining industry. I would urge the government and those that sell PAPRs, those that buy PAPRs, not to buy a product that fails to meet the test of adequately protecting the miner. And making sure that everyone

understands that what's happening here is that we have not the world that you've seen in terms of the dust standard that has been in effect since 1969 but an approach here to quadruple that dust environment that we're about ready to stick miners in. Thank you very much.

GÖRAN BERNDTSSON: Let's give you a little bit of the background. In 1989 we were asked by some the smelting and mining industry in Australia to be part of a study to start understanding the physical burden that was added to miners and smelting workers when they went from 8-hour shifts to 12-hour shifts. That is where we started looking on, we were actually setting out together with this company where we were video filming the process of what people were doing, we were taking heart rates; we would start learning about the peak flows and the understanding from all sorts of angles, heat extortion other different clothing, etc. That's where we start learning that these peak flows we were measuring were not even close to anything we are testing. That is the message. Since then I have been trying to refine the way and manage to refine the way we are testing. I have hundreds and hundreds of files where people being out in the industry, in the smelting industry, in the mining industry where we have measured heart rates, breathing rates, volumes, etc. It's a matter of fact no one (inaudible) hardly anywhere around the world are

testing respirators with possibly the exception of SCBA's. It's even (inaudible). That's the reason (inaudible).

JOE MAIN: I think that was a statement more than a question. I think it's pretty clear about where our concerns are at and what our great concerns are about the direction this country takes to protect workers when it comes to a danger or an unhealthy coal mine dust. Any other questions, we'd be glad to take any that you have.

TIMOTHY REHAK: That's the last of our outside speakers. If anyone is interested or would like to make a comment or ask any questions from the previous speakers, come up give us who and what organization you represent. Any final comments?

Okay on behalf of NIOSH I would like to thank everyone for coming to the public meeting today. Again you can contact the Docket Office, referencing NIOSH 008, to get copies of the presentations. Thank you.

(END)