Transcript from the

PRERULEMAKING TECHNICAL CONFERENCE ON NIOSH ASSESSMENT OF PERFORMANCE LEVELS FOR INDUSTRIAL RESPIRATORS

Held in Morgantown, West Virginia

January 9-11, 1991

Sponsored by the

Department of Health and Human Services
Public Health Service
Centers for Disease Control
National Institute for Occupational Safety and Health

AGENDA

NIOSH ASSESSMENT OF PERFORMANCE LEVELS FOR INDUSTRIAL RESPIRATORS: PRERULEMAKING TECHNICAL CONFERENCE

JANUARY 9-11, 1991

January 9, 1991 9:00-9:50 a.m.	OPENING SESSION	
9:00-9:05 a.m.	Introduction	Mr. Larry W. Sparks Facilitator
9:05-9:25 a.m.	Conference Goals	Mr. Larry W. Sparks Acting Deputy Director, NIOSH
9:25-9:35 a.m.	NIOSH Respirator Workplace Performance Research	Dr. Thomas R. Bender Director, Division of Safety Research
9:35-9:50 a.m.	Respirator Performance Assessment: Future Directions	Dr. Donald L. Campbell Chief, Respiratory Protection Section NIOSH
9:50 a.m.-5:00 p.m.	TECHNICAL PRESENTATIONS	Facilitator Mr. Larry W. Sparks
9:50-10:20 a.m.	Project Firesmoke: A Workplace Evaluation of Self-Contained Breathing Apparatus	Mr. Gary P. Noonan Chief, Protective Equipment Section NIOSH
10:20-10:30 a.m.	BREAK	
10:30-11:30 a.m.	Workplace Protection Factor Study of Half-Facepiece Particulate Air Purifying Respirators at Two Lead Acid Battery Manufacturing Facilities	Mr. Barry G. Pallay Chemical Engineer NIOSH
11:30-12:00 a.m.	A Model for Correcting Workplace Protection Factors for Pulmonary Deposition and Other Effects	Mr. Paul Hewett Industrial Hygienist NIOSH
12:00 a.m.-1:00 p.m.	LUNCH	
1:00-1:30 p.m.	Measurement of Respirator Performance	Dr. James S. Johnson Lawrence Livermore National Laboratory
1:30-1:50 p.m.	Outline of an Objective Method for Setting Assigned Protection Factors	Mr. R. M. Howie Institute of Occupational Medicine, LTD.

1:50-2:50 p.m.	Determining Workplace Protection Factors for Negative-Pressure Elastomeric and Disposable Half Mask Air-Purifying Respirators Phase I-Foundry Operations	Dr. Warren R. Myers Department of Industrial Engineering, West Virginia University
2:50-3:00 p.m.	BREAK	
3:00-4:00 p.m.	Determining Workplace Protection Factors for Negative-Pressure Elastomeric and Disposable Half Mask Air-Purifying Respirators Phase I-Aircraft Painting	Dr. Warren R. Myers Department of Industrial Engineering, West Virginia University
4:00-4:30 p.m.	Workplace Study of Powered Air-Purifying Respirators	Mr. Donald H. Burd Racal Health and Safety
4:30-5:00 p.m.	Performance Criteria Document	Mr. John H. King E. D. Bullard Company
5:00 p.m.	ADJOURN	

January 10, 1991

9:00 a.m.-12:15 p.m.	TECHNICAL PRESENTATIONS	Facilitator Mr. Larry W. Sparks
9:00-10:30 a.m.	Results and Methods from Eleven Workplace Tests	Mr. Craig E. Colton 3M Company
10:30-10:45 a.m.	BREAK	
10:45 a.m.-12:15 p.m.	Problems Encountered During Eleven Workplace Tests	Mr. Allen R. Johnston 3M Company
12:15-1:15 p.m.	LUNCH	
12:15-4:45 p.m.	TECHNICAL PRESENTATIONS	Facilitator Ms. Gwen L. Strickland-Cid
1:15-2:15 p.m.	Panel Discussion—Feasibility of Workplace Testing and Alternatives	Mr. Donald H. Burd, Racal Mr. John H. King, Bullard Co. Mr. Ronald E. King, 3M Company Mr. Donald P. Wilmes, 3M Company
2:15-2:45 p.m.	Workplace Protection Factor Study of Negative Pressure Full-Facepiece Dust Respirators During Asbestos Removal	Ms. Susan N. Tannahill Environmental Health Division University of Strathclyde
2:45-3:00 p.m.	BREAK	
3:00-3:45 p.m.	Evaluation of Respirator Fit Testing by Controlled Negative Pressure Technique	Dr. Clifton D. Crutchfield Division of Community & Environmental Health University of Arizona

3:45-4:15 p.m.	Limitations of Current WPF Studies and OSHA's Experience with Simulated WPF Studies	Mr. Ching-tsen Bien OSHA, Directorate of Technical Support
4:15-4:45 p.m.	Feasibility of a New Method to Determine Respirator Protection Factors by Breath Analysis	Dr. Clifton D. Crutchfield Division of Community & Environmental Health University of Arizona
4:45 p.m.	ADJOURN	
January 11, 1991 9:00 a.m.-4:00 p.m.	TECHNICAL PRESENTATIONS	Facilitator Ms. Gwen L. Strickland-Cid
9:00-9:30 a.m.	Validation of a Simulated Workplace Protection Factor Measurement Protocol	Mr. Robert A. da Roza Lawrence Livermore National Laboratory
9:30-9:50 a.m.	Concept of Simulated Workplace Testing of Respirators	Mr. Barry J. White The Jefferson Group
9:50-10:15 a.m.	Philosophy of Respirator Testing	Mr. Alan Hack Los Alamos National Laboratory
10:15-10:30 a.m.	BREAK	
10:30-11:00 a.m.	A Simple Test Method for Respirator Cartridge/Canister Effectiveness Against Specific Chemical Challenges and Work Conditions	Ms. M. F. Suzanne Pinette TRI/ENVIRONMENTAL, INC.
11:00 a.m.-12:00 p.m.	Reinstallation and Justification for Using Laboratory Face Fit Testing as the Principal Means for Respirator Selection	Mr. Trenton A. Niemeyer FILCON Corporation
12:00-1:00 p.m.	LUNCH	
1:00-1:30 p.m.	The Process of Assigning Protection Factors Used by the ANSI Z88.2 Committee	Mr. Thomas J. Nelson Du Pont Company
1:30-2:30 p.m.	Open Discussion-Questions, Comments, Concerns	Dr. Donald L. Campbell Chief, Respiratory Protection Section, NIOSH
2:30-3:00 p.m.	BREAK	
3:00-4:00 p.m.	Open Discussion-Questions, Comments, Concerns-Continued & Closing Remarks	Dr. Donald L. Campbell Chief, Respiratory Protection Section, NIOSH
4:00 p.m.	ADJOURN	

DAY 1 - TAPE 1 - SIDE A

January 9, 1991

MR. LARRY W. SPARKS: Good morning. My name is Larry Sparks. I'm the acting Deputy Director of NIOSH, and I'd like to welcome you to Morgantown and to NIOSH's Appalachian Laboratory for Occupational Safety and Health. We're pleased that you are all here today. Monday morning when the snow was coming down I thought we might not be able to have this meeting. I'm glad we decided to press on and keep the meeting scheduled, and I'm very pleased to see that many of you—that you were all able to make it here.

As you arrived here in Morgantown you may have seen evidence that this is a site in transition. Construction is underway here of a three-tiered parking facility, and shortly site preparation will begin for a seven-story new laboratory building. That parking will be necessary for the new staff scientists, researchers, an so forth that will occupy that new laboratory facility. And in that, of course, we will have an opportunity to update and expand much of the laboratory work that we are doing in this business—in this respirator business. So, as you can imagine, we're very excited about that opportunity.

Today, here, we're also probably talking about a construction process. As we build toward the day when we can accurately and routinely assess the workplace performance of respirators prior to certifying them. NIOSH is understandably concerned about the level of worker protection provided to wearers of NIOSH

certified respirators. Several years ago field research studies began to show that the level of protection provided in the workplace may not be as high as levels predicted from laboratory based research. NIOSH acknowledges that none of the current certification tests are proven indicators of overall respirator performance in the workplace. As a result of the growing uncertainty of whether NIOSH certified respirators provide an adequate protection to the millions of workers who rely on them we've established the goal that future research and regulatory efforts would focus on developing accurate measures of actual workplace performance.

When NIOSH initially proposed in 1987 that workplace evaluation of respirators be performed as part of the certification process, many respirator experts who commented on the proposal felt that suitable protocols for workplace were not available and therefore the workplace testing was not currently feasible. A concensus developed in respirator community that regulatory requirements for workplace performance testing would be premature. As a result NIOSH has modified that proposal. Workplace testing is **not** required in 42 CFR Part 84 which will be soon, we hope, promulgated to take the place of 30 CRF Part 11. However, NIOSH still feels strongly that assessments of workplace performance of respirators needs to be done in order for us to feel confident that certified respirators provide workers with adequate levels of protection. Therefore, NIOSH is beginning the process of gathering the necessary information to include work-

place performance testing or validated simulator workplace testing in the certification program.

This technical conference is the initial step in that lengthy process. A step that we hope will effectively lay a foundation for future activities. We are here to focus specifically on the question of how to best ensure adequate levels of workplace performance from certified respirators. NIOSH scientists have been conducting research aimed at developing and evaluating methods for measuring workplace performance. This research is moving us toward our goal. We are here today to present our research to you and to hear about your concepts, research, and recommendations regarding workplace performance testing, simulated workplace performance testing, protocols, sampling techniques, and other technical issues surrounding this important topic.

We are happy that many of the leaders in the respirator protection community both from this country and Great Britain are present here today. Business, academia, and government are represented here in this audience. We are encouraged by your presence and participation and are confident that together we can progress in dealing with this vitally important matter.

Results of this meeting will be used by us to identify research needs in order to close those gaps—those knowledge gaps—design, and perform future research, and, when feasible, revise certification regulations to include workplace or validated simulated workplace testing. Dr. Tom Bender, Director of the

Division of Safety Research, is here with us this morning. He is going to kick off the first part of this next three (3) days where we are going to present to you first what research we have completed, is underway, and what some of our plans are. The length of this meeting was decided by the response of the people who wrote in or called in or however, and said they wanted to speak. And we have attempted to sign every person who requested an opportunity to present a place on the program and the amount of time that they asked for. Some of you may note there's a little more time assigned to you than you asked for, and part of the reason we did that is, we did want to provide an opportunity for questions and exchange as a part of this process. This is not a policy decision-making meeting. This is a technical conference, an opportunity to exchange information and ideas. My role here as Facilitator will simply be to try to keep the process moving, keep us roughly on schedule, see that people have an opportunity to say the things that they want to say. So, as the Facilitator, I will be guided by the agenda and the clock.

There is some time on the last day which is not assigned. So if people have come without saying in advance that they would like time to address this group, please see Don Knowles, he's back there in the uniform at the back of the room, and we will try to assign you some time in that allocated time after the break on Friday afternoon. So we've held open some time there in case we have some last minute folks here. As you can see, we're making a transcript of this session, so I would ask that each

speaker identify themselves by name and affiliation, if they have an affiliation, so that we can properly record that.

If, in fact, you use some audiovisuals or other presentation materials, we've provided projectors adn so forth for that. If you will provide us with a hard copy of that material we will try to include that in the transcript. We cannot guarantee that we are going to be able to do that simply from your presentation. That may not be possible.

We are going to videotape this partly for two (2) reasons. First, so that we can get a visual copy of some audiovisuals used, but there is also an overflow room. We didn't know how many people would show up and it's possible to view this meeting in that overflow room by TV monitor. So we've provided that as a backup. It looks like we're going to be able to accommodate everybody here and that's good. I'm pleased that we're able to do that, but we wanted to provide for that. Let me see if there are any other announcement kinds of things.

There is a message board outside the door where we will try to receive messages for you. We have the audiovisual stuff here and Don is prepared, if you want to chat with him in advance, as to what those capabilities are. There is a lapel mike, for instance, if you want to move about, and that sort of thing.

There is coffee and water outside the room. We would ask that you register each day so that we have a sense of who's here. I believe those are my technical announcements.

Tom, do you want to start us off? Thank you.

DR. THOMAS R. BENDER: Thank you, Mr. Sparks. Good morning, and I also welcome you ot Morgantown. When I came in through the crowd at the beginning of the meeting I was reminded of boarding an aircraft that may be overbooked. It looks like that's not the case. If any of you want to upgrade to first-class there are a lot of seats up front. It's hard to get up there because of the projection equipment. There is a door here which I hope is unlocked. But anytime some of you have to go and come and want to come in here and sit up here, please do so. If some want to move up now, I'm serious, please come forward.

Our division, which is one (1) of the seven (7) division of NIOSH—one (1) of five (5) research divisions—was structurally realigned slightly in July and some of you are old friends and have known the division for some time. So I thought I would mention an opening. We have four (4) branches at the present, and two (2) of those branches tend to deal with injury prevention adn control and two (2) tend to deal more with the area of worker protection, although there's considerable overlap. One (1) branch deals with surveillance and field investigations, a second with analysis and field evaluations and interventions, a third with protective technology—the topic that relates with what we're doing today most closely—and certification and quality assurance, which, of course, is also related.

I wanted to introduce right at this point some other staff members that aren't necessarily on the program but have been real critical in organizing this and whom you may want to talk to from

time to time during the three (3) days.

Dr. Al Amendola is the Deputy Director. He's currently helping out in the Division of Respiratory Disease Studies as well as serving as Deputy Director and coordinator for this meeting. I wanted to make sure you knew he was here. Dr. Jack Parker is the Chief of the Protective Technology Branch, and Nancy Bollinger is the Chief of Certification and Quality Assurance Branch. Harland Amandus—Dr. Amandus—is the Chief of the Field and Evaluations Branch, I'll just point him out because he is here.

So, as a long-time preventive medicine and public health professional I've had no trouble recognizing the importance of the issues surrounding workplace performance testing of respirators. Our division is responsible for ensuring that resporators meet certain minimum performance requirements as tested in our laboratories. Yet there is evidence that these laboratory tests may not always reflect how these respirators when actually used in the workplace will perform in protecting workers. We have often faced this issue in other areas; vaccines, chemopropholactic agents, engineering controls, and so on. In the field of respirator research and certification we need to deal with this issue. Similarly, respirator manufacturers who are responsible for the integrity of their products and respirator users whose health and safety depend upon the performance of the respirators they wear are also concerned about the workplace performance of respirators.

We at NIOSH believe that a dialog focused on this issue will be very useful. We intend this meeting to be a constructive exchange which will lead to the resolution of many of the difficulties now associated with workplace performance testing. The Division of Safety Research, which uses the acronym DSR, has taken steps to better evaluate the actual performance of respirators and the efficacy of respirator protection programs.

To begin teh dialogue we will start off today following Dr. Campbell's opening remarks with three (3) presentations reporting DSR research findings related to the workplace performance testing of respirators. As a background for these presentations I want to briefly tell you about some of our plans in the areas of technical assistance, ancillary to our research program, that relate to the question of WPF testing.

We are looking at ways to measure workplace protection factors—WPFs—aspart of the Institute's ongoing health hazard evaluation, or HHE Program. In that program NIOSH conducts industrial hygiene field studies upon request by workers or employers in order to assess possible health risks in specific work sites. These requests are often triggered by concerns of worker overexposure to toxic air contaminants. In some of these situations workers are wearing respirators. A direct measurement of in-facepiece concentration in these situations is quite appropriate in assessing individual exposure. A measurement of the ambient concentration is also necessary to determine if the respirator was selected properly. The ambient concentration,

when taken with the in-facepiece concentration, reveals if the individual respirator is providing the necessary level of protection. HHEs that provide opportunities for this type of evaluation will help us develope better measurement techniques and determine respirator performance in the workplace.

Since making and comparing these measurement constitutes the WPF determination one such evaluation has already been scheduled. Measurements will be made of the exposure of health care workers who are administering aerosolized [riboviren] to infants with severe viral respiratory illness. Since these workers wear disposable half-masks the HHE will also result in the generation of workplace protection factor data that's useful in understanding the protection level provided by that type of device. Beyond that particular effort I hope to see WPF measurements performed routinely when such opportunities arise within the HHE program.

The first of the three (3) NIOSH research presentations I alluded to earlier will be given by Gary Noonan, who will report on a project which was undertaken to evaluate the performance of positive pressure SCBA used by fire fighters. Gary will present some of the solutions to problems that were encountered in evaluating these devices during actual fire fighting activities.

The second presentation will be given by Barry Pallay who will discuss WPF studies he has conducted in a battery manufacturing facility. Barry will be presenting not only the results of the study, but also developments significant in selection of the methods for conducting WPF studies.

The third presentation will be given by Paul Hewett, who will discuss techniques that correct for the effect of pulmonary deposition in measured WPF values. We belive his work will be useful in conducting future WPF studies, and the work of both Barry and Paul will also lay the foundation for referencing WPF results to a particular particle size. This will provide the basis for comparing different WPF studies when the challenged aerosols are of different sizes.

Finally, we look forward with great interest to all the presentations, and I hope that when these sessions are complete that we will be pleased that this meeting was held.

Again, let me welcome you to Morgantown, and express my appreciation for your contributions and your interest in this important topic that we will be discussing over the next three (3) days. I will turn it over now to Donald Campbell. Don is the Chief of the Respiratory Protection Section in the Protective Technology Branch.

DR. DONALD L. CAMPBELL: Thank you, Tom.

As we consider the question of workplace testing and respirator certification it may be useful to try to look down the road to where we'll ultimated end up. To that end I would like to discuss two (2) basic questions. First, in the distant future, what will we likely do in terms of workplace testing as a condition of certification? Second, how can we best get there from here?

For this discussion I would like to consider four (4)

versions of respirator certification regulations. The first was the August of '87 proposal which contained requirements for workplace protection factor testing and simulated workplace protection factor testing. The second is what I call the next regulation. And NIOSH has already committed to going forward with this next rule which will contain neither workplace protection factor or simulated protection factor requirements. The third, which I'll call the following regulation, is the focus of today's meeting, and presumably that will address workplace protection factors in some form. The fourth is what I'll call a distant future regulation. This rule results when all of teh technical questions have been resolved and the dust has settled on all of the associated issues. This is the rule that I'll briefly discuss here today. And these last two regulations may, in fact, turn out to be the same. But for today I'll make no assumptions about the outcome of this meeting and the associated rule-making process, and proceed to discuss this distant future rule.

So the first question is where will we likely end up? And it is my best estimate that at some time in the future routine certification tests of overall respirator performance will be conducted in the laboratory with so-called simulated workplace performance tests. Some call these chamber tests.

These tests will have been validated in two (2) regards. First, the test will have been validated in that they have been demonstrated to be relevant. Relevant in the sense that they

have been shown to be a reliable predictor of workplace performance. This demonstrated relevance is what is absent from laboratory simulations available today. Relevance has been hypothesized but not demonstrated. As a result, we are not confident that there are meaningful predictors of actual workplace protection that would be received by workers using respirators in the workplace. If we did have such a validated test I suspect we wouldn't be here today.

Secondly, the laboratory tests would have been validated in the sense that they have been demonstrated to yield reproducable results. Reproducable from one laboratory to another, and reproducable from one time to another in the same laboratory. Once a laboratory test has been validated in these two ways it would, I believe, have some real practical advantages over workplace testing. Those include, of course, the reproducability I just mentioned. They could also be used routinely by manufacturers, NIOSH, and possibly users of respirators. Those tests would be less expensive, they would typically be associated with faster turnaround, they would be a useful respirator design tool for manufacturers, and they would be useful as a research tool in addressing questions associated with the proper use and selection of respirators.

Because of these significant and numerous advantages, I believe that we will ultimately end up using laboratory tests to measure protection provided to respirator wearers. However, because of these significant practical advantages associated with

laboratory simulations, there is a strong temptation to skip the validation process and proceed with a plausible laboratory test. I suggest that this would be a mistake. Plausibility should not be a replacement for demonstrated relevance.

The second question I would like to address briefly is how do we get there. I suggest that comparison studies are necessary to demonstrate the relevance of a particular laboratory test. Comparison studies would be used to investigate the relationship between laboratory tests and actual workplace protection provided to individual workers. Only with a demonstrated predictive relationship between the laboratory test and the actual workplace performance test would there be confidence in the ability of the laboratory test to predict workplace performance. To my knowledge, none of the comparison studies that have been done to date have shown a meaningful relationship between laboratory simulations and actual workplace performance. In that regard I would suggest that at any time a workplace study is conducted there is a golden opportunity to also conduct these comparison tests. This probably requires a portable version of the laboratory test. This would allow a comparison of workplace results with simulated test results for the same individual workers. Ideally, the comparison would be done without redoning the respirator between the two (2) tests. This would eliminate the doning to doning variation which would tend to mask the relationship between the two (2) tests, and increase the number of tests that would be required. However, the most important and the most difficult

part of a comparison study is likely to be the workplace test itself. Thus, my recommendation to anyone doine a workplace protection factor study would be, don't miss the opportunity to go one (1) step further and include such a comparison test. In order to demonstrate reproducability inter- and intralaboratory test validation studies would need to be conducted. Inter-laboratory test validation would involve some form of roundrobin testing between a number of participating laboratories.

In comments I have heard in conversations and elsewhere I got the impression that some believe that NIOSH as a matter of policy is committed to workplace testing and discourages consideration of laboratory simulations. NIOSH is, I believe, only committed to workplace relevancy in whatever form that takes. For those reasons I thought it would be useful to begin discussing the process of developing validated laboratory tests that predict workplace protection. Thank you.

(Off the record discussion.)

MR. GARY P. NOONAN: Good morning. My name is Gary Noonan, and I'd like to talk about Project Firesmoke today. No systematic attempt has been made to evaluate SCBA performance under actual fire fighting conditions. And toward the and NIOSH and FEMA entered into an interagency agreement whereby we would attempt to do this. The FEMA--the portion of the subagency of FEMA that was cooperating with us is the U.S. Fire Administration. And they assigned a project officer, Bob McCarthey who many of you know, and I was the project for NIOSH--project

officer for NIOSH.

As you might well know OSHA Standard 1910.156 requires the use of pressure demand SCBA by fire brigade members performing structural fire fighting activities. The protective capabilities of both demand and pressure demand SCBA have been questioned. The purpose of the project that we were starting to do was to investigate the protective characteristics of the pressure demand SCBA during actual fire fighting episodes. The primary respiratory hazards that fire fighters face are high concentrations of carbon monoxide in addition to many other contaminants. But that was the primary one that we were concerned with. Most exposure estimates exceed the current ACGIHSTEL of four hundred (400) parts per million for fifteen (15) minutes. They also exceed dramatically the ceiling level that NIOSH has set of two hundred (200) PPMs and the IDLH that NIOSH has of fifteen hundred (1500) parts per million. It is not uncommon for those levels to be exceeded in fire fighting.

Laboratory experiments have shown that in mass pressure and pressure demand SCBA might go negative at work rates experienced by working fire fighters. Negative in mass pressure--I'll modify that and say **could** permit in board leakage of contaminants instead of will.

By collecting two (2) samples, one (1) in the facepiece and one (1) in the breathing zone, we could come up with what we could determine a workplace protection factor number that could be calculated from that. These were the parameters that we

started with in trying to lay out how we would conduct this study. And in talking with FEMA and others these are the basic tenets that we started off with. We went down a number of paths to try and determine the best way to measure the performance of these devices, and what we attempted to do initially was to measure the contaminant inside the face piece in a real time manner. And in order to do that we looked at a number of devices that would give us an instantaneous reading. We looked at carbon monoxide decimeters to try and determine if they would give us that low-end sensitivity that we needed.

What we found out, after many trials and errors, are that in the high ranges in the percentage range, one to ten percent (1 - 10%) range, it was not a problem to measure CO quite reliably and sensitively enough, at the high range. But when we got into the lower ranges that we would encounter inside the facepiece of a properly functioning SCBA we ran into some real problems with sensitivity at that low end and the tenth a part per million range, and we never were able to get those devices to work adequately enough to do what we needed to do. So, again, we spent a lot of time trying to come up with methods of measuring the performance of these high performance devices. And we did, by the way, use--we wanted to measure the most protective of these devices, the new NFPA compliant SCBA.

Some of the logistical problems that we had to contend with in this study--we assumed that we could rely on the fire fighter to turn on this sampling apparatus when they were responding to a

fire. As it turned out, because fire fighters are primarily interested in saving life and property, and not necessarily in sampling, we didn't have real good luck there. Not surprisingly, you know. So that was one of the things that we had to modify the way we had started to do business. Now, later on in the project, with the help of MSA and Scott Engineers, I think we determined ways that we could switch this device so that it would sample only, say for instance, on the first initial inhale breath. That would start the sampling. Then we could probably turn it off by some method, also, similar to that. But we just didn't get to that point in this project. So what we determined that we had to do, and what we did, was we responded directly with the fire fighters when they would go on these sampling runs. So it's kind of every kid's dream. We got to dress up like fire fighters and ride on a firetruck, and that was quite a bit of fun, actually.

Some of the other problems that we ran into were the protection of our sampling equipment. We realized that it had to be quite durable and we heard horror stories about what could happen to some of these--we had seen what happened to SCBA--and we had heard stories of how equipment can sometimes be handled on teh fire ground and some of the rigorous conditions that it's exposed to. So we wanted to ruggedize these devices and we, again, working with some of the manufacturers we were able to ruggedize the sampling apparatus and they were able to affix it to the self-contained breathing apparatus.

We went with the Pittsburgh Bureau of Fire up to this particular site and went through some preliminary runs with the project, and they put our sampling devices on firefighters and went in to sample in areas such as this. And at this time we determined in that Tygon tubing probably wasn't going to work very well, that silicone--when it all melted away we decided that silicone would be a better choice. Those are the kinds of things that we learned as time went on and we got quite proficient and good at the sampling techniques. But we, in fact, were not able to come up with a reliable method of getting what we would consider a workplace protection factor number. And the reasons being that many times when firefighters--if you would turn on the apparatus on the outside of the fire building, many times they would not be able to wear that unit when they would go up three (3) and four (4) and five (5) flights of stairs, so that you would, in effect, be getting a sample of both the inside--the facepiece air--and the outside air into this time weighted average sample that we were collecting. So we couldn't really determine that all of that sample was in-facepiece.

So, with that point in time, we determined that we would not be able to do a workplace protection factor, but rather a program protection factor study. And we did that by collecting real time in-mass pressure measurements. We had a student on a contract at the Engineering School here design for us a portable data logging unit that would measure pressure. And we had mounted that device--in fact it was just a small battery operated computer

that was able to log pressure during these fire fighting episodes. Now that has had some applicability in other workplace protection factor studies, and I'll describe that later. The sampling apparatus requirement in order to affix this thing to a fire fighter that was actually involved in fire fighting was that it be lightweight, of minimal bulk, it be self-contained, and reasonably insensitive to extremes in environmental conditions. Some of these slides may not be in exactly the order that I had originally hoped they were in. I had somewhat of a Kodak moment when I came in and dropped all of my slides on the floor, and mostly got them back in order, but they're not quite in the right order.

We had, again, in conjunction with some of the respirator manufacturers, had--we had designed a sampling package that we wanted to affix to a breathing apparatus, and they then helped us determine methods to best secure it to the apparatus. And in conjunction with manufacturers and the International Association of Fire Fighters and others who were familiar with fire fighting activities, we designed or packaged a unit that would fit onto the back of a fire fighter and would not preclude him from doing his work, and be of minimal impact on how he did things. We also had all of these things switched by one (1) external switch to activate the units.

So, again, the project came down to collecting real time in-mass pressure measurements, and by collecting air samples both inside and outside the fire fighter's SCBA. Additionally, we

determined that it was necessary to take a pre-shift and post-fire expired carbon monoxide breath sample. This in order to get some kind of a base line. We tried to get non-smoking fire fighters. We had a lot of success, but some places we were unable to, but we did want to know what levels of carbon monoxide were in their expired breath both before and after the fire. So we had them take an alveolar breath sample on the way to the fire and they just dropped that bag on the fire apparatus and then went on and did the sampling exercise for us.

The data logging unit itself recorded pressure measurements every fifty (50) milliseconds nd the accuracy of the low pressure sensor was plus or minus .02 inches of water. The data was then either at the fire scene dumped into an IBM PC compatible type computer and then the software that we had designed with the sampler allowed for data interpretation. Again, the dynamic range of the sensor was plus or minus five (5) inches of water column, and that was determined to be adequate for what we were doing. And then again, the data logging unit was a small portable data logging unit.

We determined from--the air sampling location was the small silicone tube that you see. This is a Scott respirator that was used in two (2) of the sites that we went to, New York City and Boston. And we took the air sample from that Tygon tube that was affixed or drilled right through the regulator in this case, and then the pressure sample was out of that copper tube. Now how we determined the place to take the pressure (off-record discus-

sion). So here is the--again, there is the air sampling point and there is the pressure sampling point. We had done a number of laboratory investigations prior to our going to the field to determine the best place to sample for pressure primarily. We pretty much took the work that Warren Myers had done when he was with us and located the air sampling point directly in the area of the filter between the nose and the mouth inserted somewhat into the facepiece, which is what Dr. Myers had determined to be the best location. The pressure area, again, we took a number of readings around the peripheral seal of all of the facepieces that we were using and determined that we would use an average of those of that location. And so in this particular instance that point was an average of the area around the facepiece sealing area. I the MSA facepiece the air sampling point was right here and the pressure sampling point was up in here. Again, we measured all around the facepiece and determined that that was an average location that would be well-suited for what we were doing.

The sampling boxes themselves--this again is on the Scott self-contained breathing apparatus--included our portable data logging unit, two (2) low-flow pumps, a number of batteries, and then the pressure sensor was located right here. And then all the associated tubing that went out to different locations on the breathing apparatus. And the air samples then were pumped through this box into a sampling bag that we affixed to the outside of the respirator. This is that same configuration on

the MSA breating apparatus. Again showing the data logging unit, the two (2) pumps, the pressure sensor, all the associated wire and things. This is the main turn on switch. THis is a port that we could dump the data directly into the computer--the IBM portable computer--that we took with us. This was a status indicator light that was on all the time the units were on when we wer in standby mode. What we did was then determined who was going--who we were going to sample on, and that varried from city to city. For instance, in Boston we went with a rescue unit. In New York City we went with a truck and an engine company. In Phoenix we went with two (2) engines. We determined who we were going to sample on, and then we put these units, and then they sat on the rig--on the fire apparatus--during the time that we were hoping to catch a fire, and were in a stand-by mode. Then when they would get a response we would go with them and when they got to the fire scene we would turn on this device. They would don it, we would turn it on and start sampling. That's how it went.

Pressure data was then analyzed using the percentage of time that the pressure in the facepiece remained positive. I think that was one of the slides that happened in my Kodak mode. Any negative excursions would then be noted--I'll show you a tracing in a moment--and attempts would be made to correlate such excursions to breaking the facepiece seal, high work rate, or other physical phenomenon. I must admit that when we went into this project we weren't expecting necessarily to see any negative

excursions in these high performance breathing apparatus. We, in fact, did see some very momentary negative excursions, and we're still in the process of determining exactly what those mean as far as protection to the fire fighter. I think, again, the air sampling--and I think I already mentioned this--we used two (2) three (3)-liter [tedlar] bags that were connected to the face-piece and one (1) to the breathing zone. We had the bags located in a fire resistive, and then a reflective PBI bag so that they wouldn't be effected by the heat and radiant heat load that they were exposed to. We learned that after a while, too. We had them just in a fire proof bag initially, and there was quite a bit of radiant loading on the bags, and they did crisp up quite a bit.

Here, then, is the pressure tracing that we would take showing from a positive five (5) to a negative five (5) inches of water column on this axis. Adn this axis then would be a thirty (30) second sampling of the sampling time. THis particular one is, I think, a post-calibration curve taken in Packet thirty-five (35) which would indicate about seventeen and a half (17 1/2) minutes into the sampling period. It shows it would have had the capability of showing the minimum and maximum ranges that it reached. The negative area under the curve, there again, is the start time of seventeen point five (17.5) minutes, and it actually would calculate breaths per minute for us also.

THis is another packet of information showing one (1) of those negative excursions that occur. Again, not for a very long

period of time, but it also shows the breathing rate working right around about one and a half (1 1/2) inches water column.

We got so that we could determine quite a bit of things that was happening. We couldn't determine any words, but there are some frequently used words on the fire ground that--we almost picked one (1) up here, I think. We got so we were pretty good, but not quite that good.

QUESTION: Gary, what units were these?

MR. NOONAN: This is--I can't tell from--on June 28th I can look up and tell you, but it's one or the other. Again, here shows three (3) momentary peaks--negative peaks. Now, we did experience some--I guess this again is just a pretty typical breathing curve. Again, this one's showing that at that particular point in time this person, this fire fighter, was working--breathing--at fifty (50) breaths per minute.

Now this is another kind of interesting use that we can make of this device in workplace testing. If you'll notice, this is during a--about eleven (11) minutes into the sampling period, and since in normal workplace protection factor studies you would like to observe what's going on and observe the person you're sampling on, this lets us get at that a little bit in a fire fighting situation, for instance, where we're not able to go and watch the person's face when they're actually doing the work. But what we are able to tell is that something happened during that period of time. This person was going along quite well, at a fairly high work rate we would assume from the breaths, then

all of a sudden we can see a negative spike, and then it goes to ambient for a while, and then it comes back up in another negative spike. And that's what happens when you take off a facepiece or something happens to break the seal dramatically on that facepiece during a fire fighting episode. Now this has some-- Barry Pallay has used this same device in subsequent work and it's quite a nice method of measuring and monitoring a worker in addition to just observing them at all times when they're wearing the devices.

Again, we went to--this is in New York City, and we were at about 126th and 3rd Avenue, which is in Harlem. We decided that our big white trailer ought to be inside and they were able to accomodate that.

MR. GARY P. NOONAN (Con't) . . . so the power. So we had quite a nice area to work in. It varied depending on what cities we were in what hours we sampled. We knew almost for certain that when we would leave the fire station that no doubt there would be a great fire and we would miss an opportunity to sample. And so we tried to stay during the hours that were determined to be the most--the busiest hours--but, again, realizing the fact that we did miss some fires unless we could stay twenty-four (24) hours a day. And then a typical phenomenon happened, I guess, that's been described by everybody that we went to. When somebody's watching for something to happen it hardly ever does. So that was another thing that we ran into.

We did get quite a bit of work in New York City. We got quite a bit of work in Phoenix; Boston, not so good, and Cincinnati, not at all. We stayed there for two (2) weeks, and they were talking about closing fire houses unless we left. So we decided we better leave.

We had two (2) of our own people doing some sampling in addition to our respirator sampling. We had an environmental component of this project and this--I never did get very good at taking pictures outside of fire scenes, but this shows two (2) of our scientists and they were wearing our modified breathing apparatus. In addition to that, they were also carrying a sampling package in the front of them that they were sampling for many other kinds of fire ground contaminants. And that will be--

that's going to be reported in a different journal article that should be out fairly shortly. It's been accepted so I would expect to see that out. And what we have (inaudible) down there was--we wanted--there was some discussion about the analytical techniques changing between when--I believe the last studies that were done were by Burgess and Silverman in the Boston area, and with the changes in analytical techniques in the ensuing years, we wanted to get some of that--to confirm that data. And, in fact, that data was pretty much confirmed, that what they were seeing back ten (10) years ago we're still seeing today, and that the analytical techniques were in fact probably good enough back then.

Again, I don't know what happened to my photographic technique, but that's a big ladder truck in New York City. That's again, one (1) of our people and what they were carrying to do the sampling with. Again, this is New York City, upper West Side. We ran into a whole burned out portion of New York City that a lot of reoccurring kinds of fires, and a lot of very unstable structures and buildings. It's not a--that's not a very good place to fight fires.

This is the house that we were stationed at in New York City. It's, again, Engine 35 and Ladder 14 in Harlem. That's a fire.

The air sampling analysis was done by means of a Fourier transform infrared spectrophotometer, and we had that with us in our mobile laboratory and were able to do that analysis almost

within about a half hour of when we took the samples in most cases. We would inject the gas samples into this cell and then it would be acted upon. We would collect an [interferogram] and we were able to then later analyze the data.

These are the fire ground contaminants that we were most interested in measuring in the environmental portion of the study. And we had have pretty good results on carbon monoxide, carbon dioxide, etcetera, all the way down the line. This is one (1) bit of information that we have that--again, since this is primarily a respiratory study, this does show the mass concentrations and the ambient concentrations for these elements that we analyzed for. But, again, this is not a classical work place protection factor study, but rather, because of the logistical problems that I described, more of a program protection factor study. Which probably, again, has the most relevance to the fire fighters' health; not the performance of the device, but how, in fact, it is used.

In conclusion, then, we can say that we learned a great deal about the use patterns of respirators in the fire service. We were operating under some assumptions that proved to the untrue. We were making--we had made some assumptions in how these things were used, and it was reported to us how they were used. And it wasn't, in fact, the exact way that we had it described to us. We learned a lot about sampling and we got quite good at it toward the end. Although we were probably best at it in Cincinnati. By that time we had learned that we had to have check

valves and everything else in line. But, again, we got no fires in Cincinnati. It was kind of a moot point. And we did confirm the environmental sampling work that had been done by Burgess and Silverman years before.

This will be reported on in the Peer Review literature. I would assume in the next couple of months we would hope to have something prepared for a journal and out.

Yes, Harry.

HARRY ETTINGER: Gary, did you get the protection factor measurements? You reported on the pressure variations--spikes--but I didn't notice any measurements of effective protection factor.

MR. NOONAN: We will probably--we will be able to report that when we finally get it.

HARRY ETTINGER: What problems did you have? Did you have enough sensitivity?

MR. NOONAN: Yes, I think we did, yes.

HARRY ETTINGER: Did it vary from substance to substance; carbon monoxide to benzene?

MR. NOONAN: Yes, it did.

HARRY ETTINGER: Major variations of fact of three (3) or more?

MR. NOONAN: Probably not, probably not.

HARRY ETTINGER: . . . idea of--can you get an effective protection factor out of the kind of study you did, or did you learn enough that if you did it again you would be able to get

it?

MR. NOONAN: Yes, I think that, again, we became much better at this as time went on. And we would probably be able to do subsequent studies and gain a lot more information. This was, again, kind of a range finding study. And although it wasn't intended to be that way initially, it worked out to be that way.

Yes?

HARRY HERMAN: That data you showed seemed to be pretty good except for benzene. Did you figure out why? Was benzene typical on all of them . . . ?

MR. NOONAN: Well, again, the data analysis is still going on and we haven't looked at all of those things. However, in this particular one we did think that for whatever reason he had his mask off during the time that the benzene came up. We did learn that there were quite different contaminants under low energy fire conditions. So some of the things that we will be able to report on are the times such as when the fire is just building up and when it is being overhauled. There are many, many bad actors out there during those particular times that are mostly consumed under the pyrolysis during high energy fires. So I think we will be able to make some recommendations as to the use of--typically a lot of fire fighters didn't want to--didn't wear their breathing apparatus until they were in heavy smoke or something of this nature. And that--on the floor below or on the fire floor itself they would put the unit on when they observed that it was quite smokey. And, in fact, they may have been being

exposed prior to that time in high dosages.

(Inaudible question.)

MR. NOONAN: I think. But again, twenty-one (21) parts per million benzene, and then twenty-two (22) in the ambient. And the only explanation we have was that there was a break in the facepiece seal, and the only explanation would be that that benzene was present primarily during that time; that it came up around the time he had his facepiece off and then went back down. Any other questions? Yes.

(Inaudible question.)

MR. NOONAN: I can't recall right off the top of my head. I can find out. It will be reported in the literature, but I just don't have it.

Anything else? Thank you very much.

MR. SPARKS: Two (2) things. I'd like to remind you--it's not an easy habit to get into--to identify yourselves when you ask questions. We're running a little ahead of schedule so I'd like to open it up for questions on things to any of the representors that you had so far.

TRENTON NIEMEYER: Was there any attempt to do any blood samples to measure carboxyhemoglobin?

MR. NOONAN: No; however, we did get quite a close correlation between the expired breath sampling from the literature that we--then we could determine carboxyhemoglobin levels from the expired breath samples. So there is quite a close correlation.

MARGIE ZALESAK: Did you look into the possibility of

decomposition of (inaudible)?

MR. NOONAN: Composition of the mask?

MARGIE ZALESAK: Did you look at the possibility of the mask facepiece itself being (inaudible)?

MR. NOONAN: No, we did not. However, they were all brand new, again, high compliant devices that met the latest NFPA standards. But I understand what you're saying. Were we getting any off gassing of the mask itself? Did not measure that. The data that we have would not indicate that we were, though.

TOM RUANE: Was that one (1) sample, or was that an average?

MR. NOONAN: That was just one (1) sample of a nozzleman, I believe in New York City. And that's just one (1) of . . . five (5) samples during that particular fire.

BOB BRENNAN: Gary, do I understand it, though, that is the total analysis of a three (3)-liter bag that was the total contents of which was acquired over a period of about seventeen (17) minutes?

MR. NOONAN: That's correct. I'm not sure about the time-frame, but it may have been somewhat more than seventeen (17) minutes.

BOB BRENNAN: So when we say that it is not an average, it is in fact an average of an exposure over seventeen (17) minutes, although it's a sample of only one (1) man's work in seventeen (17) minutes?

MR. NOONAN: That's right, and there was a face seal break during that particular point in time--during that particular

sample.

MR. --: That was definitive or is it assumed there was a break?

MR. NOONAN: No, we can show that from the pressure tracing that we have associated with that same sample. So we can show a portion of time that that facepiece was off his face. Not just a negative excursion, but actually off his face.

MR. --: And yet the only data effected was benzene? (Inaudible discussion).

JIM JOHNSON: Gary, what have you learned from this experience that you would do different for the next phase, say Firesmoke II?

MR. NOONAN: Son of Firesmoke? Well, we got quite better, again, at sampling, and I think that we made a lot of headway in that area. We were assuming a lot of things that had been told a lot of things by people, but nobody had ever actually tried to do this on fire fighters. You know, we learned a lot of things. I mean, I could go on and on about check valves in the lines and things. We assumed that those pumps were checked internally and were told that they were and it said in the literature that they were, and they're not. So we got a bleeding off of some of the samples over time that we didn't expect. So once we installed check valves then we were able to preserve our bag samples until we could get them under analysis. But, again, on the turning on and turning off of the device I think that that could be handled better. It's not a very desirable method to turn it on in the

street when the fire fighter is going to run up three (3) flights of stairs and then put the mask on.

JIM JOHNSON: What about the overall concept of putting a unit on the fire fighter and--you know, this is a pretty sophisticated study that you're involved in, putting weight and making an inconvenience to the wearer. Do you think it would work? I guess what I'm getting back to is, there is inherent problems in interfering and becoming an intrusive part of a guy's work. Especially somebody who is in an adverse environment. You've had the most experience with that. What do you think? Is it a reasonable thing to do or would it still have these follies built into it when you get out there to try and do it?

MR. NOONAN: Well, as you know, anytime you observe something it's going to probably change it. They pretty much got used to--I would say that they got used to having us around and having that device on them. And it was of minimal interference. We really never did say, gosh, this thing is a lot heavier than what I'm used to wearing. It really only did weigh about three and a half (3 1/2), four (4) pounds. So, I think that probably not much effect in having the device on them. And you can see that they did start acting different after we had been there for a period of time, also. I think they got into use patterns that they--they weren't trying to do anything special for us, I guess is what I'm trying to say.

R. M. HOWIE: Would it be possible in your follow . . . if you do any, to actually use the pressure logger to switch on the

sampling pumps?

MR. NOONAN: I think so. Yes, I believe that would be one (1) of the methods. I think the Scott device lends itself to turning it on, because on the first initial breath that device starts the air flowing. And I think we could do it that way. Turning it off, again, I--yeah, I think we could if we had a better logger that could actually switch things. I think that could very well be done.

KEN KLOUSE: Did you get a feeling for the maintenance repair . . . apparatus used . . . fire fighters (inaudible)?

MR. NOONAN: Well, again, we were using our own units, although they were very similar units to what the fire fighters used. They were the latest units, but I would say on the organized fire departments that we went to--and again, those were Boston, New York City, Phoenix, Pittsburgh, and Cincinnati--that they do have--that the masks are fairly well maintained. I think they're very well maintained, probably. The things that we did note some problems; we were doing some fit testing while we were out also, and some of the fire fighters that had their own facepieces that they really liked this facepiece and it was theirs and they had it stuffed away in their wall locker and would use it, we did one (1) of those that was completely eaten away underneath, and he didn't have any idea, and we couldn't quite figure out why we were getting such a low fit factor in the fit test. And as it turned out on a physical inspection, the rubber was just separated on an internal lip underneath here, and

he hadn't noticed that, and that wouldn't be picked up by a routine maintenance anyway, because it wasn't in the maintenance loop. Now some of these devices are treated rather severely. They hang on the units and they get dropped when people come out of a fire, and they are not treated they way the manufacturers would like them to be treated, I'm sure, and that we would like them to be treated. But the did seem to perform quite well; the units that we saw in use. Again, you know, without having a measure, they were providing air, and I am assuming that they went back into the maintenance loop and were checked out on measurement devices that are available to the . . . . They were providing air, so I guess--and the didn't look to be in that bad a shape from a visual inspection. Any others? Thank you.

MR. SPARKS: If there are no other question, I think we will take a break and reconvene at 10:30.

(Whereupon, a break was taken from 10:20 a.m. until 10:30 a.m.)

MR. SPARKS: We have two (2) more presenters. We'll start with Barry Pallay. The two (2) presentations that you are going to hear are connected or interrelated. And so we'll hold the questions until after the second presentation, because I think that will answer some of the logical ones that will come out of the first presentation.

BARRY G. PALLAY: My name is Barry Pallay. I would like to welcome you to Wild and Wonderful West Virginia. I hope you enjoyed your commuter flights into Morgantown.

It is a pleasure to have the opportunity to describe workplace protection factor studies that we have conducted at two lead acid batter manufacturing facilities on workers wearing half-facepiece negative pressure respirators to protect themselves against lead and other particulates. I'd like to acknowledge the contributions of my colleagues in NIOSH, Dr. ... Bowerman at Element Analysis Corporation, Troy [Grice] and Gail [Rarick] at East Penn Manufacturing Company, and Warren Myers of West Virginia University, formally NIOSH. Can you remember back that far Warren?

To review again, the workplace protection factor is a measure of the protection or performance of a respirator when it's property worn and used. It is the ration of the concentration a worker would inhale of a contaminant when he is not wearing a respirator over the concentration he would inhale when he is wearing a respirator. Our objectives have been to develop

and evaluate methods and procedures to conduct workplace protection factor studies, to implement those methods and procedures and measure WPF values, and then to determine and compare the fifth percentile and other statistics from the resulting distributions.

Before I begin, let me take a few minutes and talk about some problems and biases; some that we've seen, some that people have discussed. The first, of course, is sampling bias. And it relates to coming up or the bias relating to estimating the coming up with the best estimate of the concentration outside the facepiece, the concentration inside the facepiece, and the adjustment of that concentration for things like pulmonary deposition. For example, sampling bias would include the bias associated with deposition on the walls of the cassettes in the particular case--in our case, aerosol sampling. But it would also relate to any losses in the sampling line or in any other sampling apparatus or sampling device. We found that cassette wall deposition was very significant. Probe inlet line losses; we found they were very small, less than five (5) percent. And so we essentially neglect them. Warren Myers has talked about the bias due to non-uniform mixing inside the facepiece of a respirator. We won't be talking about that this morning in my presentation.

Although it's not a bias, one does experience low concentrations in the facepiece of a respirator, and that causes problems in that eliminates certain analytic methods that one might

ordinarily use or more commonly use. It means that one has to pay particular attention to the analytic method errors, because of the low concentration values. It means that contamination of the sampling media become very important to examine before and during the study. We found that back-up pads and other materials in some cases were very significantly contaminated. Another problem that one has to pay attention to is obviously any penetration through or by the cassette filter, particularly in the in-facepiece samples.

Now, it's important, we found, to correct the concentration one measures in the facepiece for the deposition in the pulmonary system when you're sampling during the entire cycle--the breathing cycle--of the worker. We'll talk about that in a minute. As a matter of fact, it's kind of interesting for me because probably about three (3) years ago I chaired the public meeting on the workplace protection factor study that we're going to discuss. And I promised, at least some of you in here, that we would take into account pulmonary deposition. And I'm pleased we have.

There are an infinite number of workplace variables, including state, size, composition, hopefully not an infinite number of brands, but certainly an infinite number of environmental conditions, and particle size distributions. So one has to be careful when one compares from one study to another that one is comparing apples and apples. For example, one could have a hypothetical work site with a concentration of particle size of lead let's say of ten (10) micrometer, and in another part of the plant particle

size distribution with a geometric mean of let's say one (1) micrometer, with the same model of respirator for the same worker for the same work conditions, environmental conditions and so on. One obviously would find that the performance of the respirator, or the WPF value was lower where the geometric mean was one (1) rather than ten (10). And so we'll talk a little about how do you standardize for particle size distribution which would enable one to compare from one study to another, at least from the standpoint of particle size distribution.

Now, we're looking at the performance of a respirator when it's properly worn and used. Obviously, as you all know, often times a worker will pull the respirator off his face for part of the time, maybe wash his face, take a drink, and in many cases actually not wear the respirator during a portion of the work day. And so it is important for us to keep in mind that we need to worry about relating the workplace protection factor with things like program protection factors, as Gary has mentioned, for effective protection factors. And I think that we'll--I'll take a few minutes shortly and talk about the use of the pressure measuring device that Gary alluded to which I think is a way to in fact relate workplace protection factors to program and effective protection factors.

And finally, back to the future, as Don Campbell alluded to, we would hope to have simulated workplace protection factor tests that one could perform in the laboratory under very rigid condition that one could perform on the worker that would correlate

with the WPF values that one measures--that we currently measure in the field. Hopefully some folks will have some data that may bear on that. We did some measurements along those lines. I'll say a few words about them. Don Campbell was responsible for that work.

Let's look at what we did at these two (2) lead battery facilities. We took personal samples to measure the concentration on the lapel, CO; the concentration inside the facepiece, CI; worker blanks on all the workers; we sampled at two (2) hours, two (2) liters a minute using polycarbonate filters. Here's a worker, and I guess it was Plant A dynacast. As you can see he's wearing a half-facepiece respirator. The personal cassette is right here--in-face cassette--the ambient sample taken here, and the worker blank here. I think this worker is in Plant A, pasting. Again, personal sample. We drew air across those cassettes with Alpha I sampling pumps.

Of course you can see the first problem that we experienced when we began. The moisture from the in-facepiece samples. Now in subsequent studies we eliminated that moisture using resistance wire and batteries we mounted on the workers. And I'm pleased that I think some others now are following that and using the same approach. Here's a smelter worker we sampled. I'll just point out that we're measuring particle size here with an impactor, and we'll talk about that in a moment.

The personal samples, then, were collected on twenty-five (25) millimeter cassettes using a polycarbonate filter, .8 micron

pore size, to collect the particulate. We developed a nonporous ring which we used to focus the deposition down the center area of the filter so that it would be more compatible with the analysis method that we were using to look at the filter, and supported this with a plastic support bed. And, of course, problems arose that I mentioned earlier regarding contamination of some of these things. We found filters were contaminated from the manufacturer. There was significant contamination from the plastic support pads--rings. We used the resistance wire, as I mentioned, to heat the cassette to eliminate moisture in subsequent studies, not in these two (2) that I'm talking about here.

Now, we also took area particle size samples using PIXEA International impactors. Here is an example of what we attempted to do in most cases, that is put the impactor very close to the worker we were sampling. The impactors were nine (9) stages with a back-up pad. They had cut-offs of sixteen (16) micrometers, four (4), two (2), one (1), point five (.5), point two five (.25) and so on down to point 0 six (.06). Now, in some work that I'll describe shortly, we compared the particle size distribution that one measures with an air impactor with that one would measure with an impactor mounted on the individual. And in those cases we eliminated these two (2) stages and then caught everything with the after-filter so that we wouldn't have to draw the vacuum, and we could use the personal sampling pumps to take those samples. Those are, by the way, single orifice devices.

Now let's take a look at what we found. We found that the

lead particle size distribution was trimodal. Now here you see the data from the impactors. We used a curve fitting procedure developed by Paul Hewett and Mike McCauley--Paul's going to follow me--this presentation. You can see this is the distribution for--the mean for four (4) impactors at Plant B Enveloping. Now, often times the particle sizes reported, as for example, a geometric mean. In this case I think it would be approximately eight (8). But, for our work that geometric mean is not at all sufficient. We need to know the individual particles--the actual particle size distribution. In this case this is the ambient distribution. Now, we make some assumptions using relationships, for example, from Heinz and [Belling], that would take this ambient distribution and manipulate it to an estimate of the in-face particle size distribution. So let's take for discussion purposes now, that this is transformed and a portion of this modified is in-face distribution. It's important, then, for us to know that over the particle size distribution, because at each point we can calculate the deposition in the pulmonary system and we can then at each point correct the workplace protection factors for that particular deposition. In addition, we can take a range of an interval--particle size interval--and compute the individual WPFs at several points here so that we could compare the WPF from one study to another and eliminate or at least attempt to eliminate the effect of particle size distribution.

Now, here I just illustrate that we're looking at the particle size distribution at six (6) different areas of the

plant, two (2) smelter areas, two (2) pasting, one (1) enveloping, one (1) dynacast. And although you can't discern the individual ones on this overlay, you can see that the distribution is trimodal, by and large, and it is different in different areas of the plant. Here you see the particle size distribution for Plant B enveloping--again, the mean for those four (4) impactors--and in this case we're looking at the distribution by element for lead, calcium, iron, silicon, arsenic, aluminum, antimony. The point I want to make is that in each are of the plant the particle size distribution is different by element.

Now we analyze the impactor stages and the personal sample using proton induced x-ray emission spectroscopy, which was performed at Element Analysis Corporation in Tallahassee, Florida. You're looking at the proton accelerator here. We chose PIXEA because it allowed simultaneous analysis of sodium through uranium, low detection limits on the order of one (1) or two (2) nanogram per square centimeter, small sample requirements on that same size order, it was nondestructive, cost effective. So we could look at the filters afterwards and look at particle size distribution, or analyze with other methods as well.

Here is--the samples are placed in a carousel. This is evacuated and then filled with helium. Here is the proton accelerator and the detector. Now, we also measured in-facepiece pressure on several or some of the workers we sampled. Now, we did that more extensively in a follow-on study to this, but we did do some workers here in these two (2) facilities.

. . . talk about that shortly. We measured pulmonary deposition as well with the Division of Respiratory Disease Studies, NIOSH, principally to look at the variability of deposition inter and intra-subject variability. And we also measured--we did simulated workplace protection factor testing as well.

Here is the pressure device we used. Gary showed--illustrated--the use of a similar or a modified device for fire fighters. In our case we mounted these devices on some of the workers, we recorded the in-facepiece pressure with a transducer, and then we measured--every hundredth of a second we took the means, and recorded every tenth of a second, and then stored the data in the logger and dumped it to a laptop at the end of the work period. The traces, for example, looked like this. In this case the worker is probably talking right here, and then working more normally in this situation. We used--the pressure traces can be used, for example, to validate that you were measuring the workplace protection factor, because if, obviously, a worker pulls the respirator off, then you're going to see it zero out for that portion of the work period. As a matter of fact, you can use it to probably begin to, I think, estimate effective program protection factors, because if you leave the device running during the course of the work day and the worker removes the respirator for a portion of the work day, then you're obviously going to get those zero (0) readings, and in conjunction with ambient concentration measurement, you can then hopefully begin to get the relationship between effective and program

protection factors, and WPF values as well.

Now, in addition there were some other interesting applications. We had a worker who had high blood lead levels and felt that he wore his respirator during the work day properly. We were able to show during the course of the work day on that particular worker--we were able to show him in fact that for a good deal of the day he was talking, he pulled it away from his face a portion of the day. So we were able to illustrate to him very dramatically that in fact he had high blood lead levels, and one of the possible explanations was he really wasn't wearing the respirator properly. So it turned out it was a very useful tool for--the workers found it to be very useful, particularly since--you know these devices are very uncomfortable and they're wearing them often times in very hot, humid conditions. This kind of thing illustrates to them very graphically that in fact the device is really serving a real purpose.

Now we measured pulmonary deposition. As I said, the objective really was not necessarily respirator related, it was to look at the variability of deposition inter and intra-subject variability.

We had about fourteen (14) exercises that we ran in the mobile lab in a quantfit chamber that we ran at the same time we were measuring workplace protection factors. The objective was to have a worker work at the work site and then walk over with the respirator in place and go through these series of exercises, hopefully to see if we could see a correlation between either

individual exercises or collectively a set of them, with the workplace protection factors that we were measuring on those workers. Don Campbell is responsible for that particular portion of this study, and unfortunately I think the preliminary indication is we're really not seeing a relationship. But I would hope that maybe some others in their work have seen some correlations, and I know there are some things going on relating to why respirators don't seal very well, and maybe some of those pressure kinds of approaches may shed some light on this. And I'm hopeful maybe we can hear some positive things about simulated tests at this point. But in any event, you see a worker here in the mobile lab getting ready to go into the quantfit chamber. He's coming right off his job at this point.

Let's take a look at what the distributions look like. We took--we made two hundred twenty-two (222) observations with the range of WPF values as you see here. Now of those two hundred and twenty-two (222) observations--this is the log probability distribution that we just looked at--the 222, the red curve. Of those, a hundred and sixty-one (161) had concentrations above--on the filter, concentrations above the limit of detection, and sixty-one (61) had concentrations below the limit of detection. For the purposes of display here I brought those values up to the limit of detection which in PIXEA was close to one (1) anagram per square centimeter. So I think it's rather conservative--you know there's something in there, you don't quite know exactly how much, since the limit of detection is so low. I think it's

prudent to consider that those are also worthy values that you don't necessarily want to completely eliminate. The point is, we computed WPF values separately with this distribution, with this one, and then we also combined them as well.

There were a hundred thirty-two (132) subjects so that some subjects were sampled were observed twice, some three (3) times, and some four (4) times. What you're looking at now is the distribution re-plotted--that is, in the blue--where we've taken the means of the observations of each subject and re-plotted as mean values. Now in this particular case we took arithmetic means, but we also have distributions where we took geometric means as well. And they do make a difference. The noteworthy point that I want to make is that you do--that there is a difference in the fifth percentile when you manipulate--when you look at the subject means. In the case of taking the geometric means for the subjects the curve is about half way between this. But a significant effect on the fifth percentile, which is something we obviously are concerned about.

I've been a chemical engineer for more that twenty-two (22) years, and one of the things that we chemical engineers like to do is make mass balances around systems. So when I began this work and discussed what was traditionally done, I found that everybody was measuring the concentrations on the filter alone. When I looked at our samples and looked at the walls of the samples, we found there was significant deposition on the walls of the cassettes. So much so that when you re-plot the data, you

look at the fifty (50) percent--for example, if you were the median person here, the fifty (50) percent person, your WPF uncorrected would be approximately twelve hundred (1200). When you correct for the wall deposition, the amount of lead that was in that cassette that wasn't included when you looked at the filter, that concentration drops down to approximately three hundred (300). So the concentration in the facepiece would be four (4) times what you would have suspected had you just worried about the deposition on the filter. Now, obviously, other methods, whether they're aerosol, whether they're gasses, or whatever--the point that I want to make is it's very important to make mass balances around any of the systems you look at.

Now the distribution--and the differences occur over the range, and they occur whether you look at them as two hundred twenty-two (222) observations or as a hundred thirty-two (132) subjects. So the same general trend is seen, just a little difference at the fifth percentile values.

So what we have now is, we need to worry about the--here's the uncorrected WPF value. We need to worry about the deposition on the walls of the cassette, so we now will look at the WPF distribution for wall correction, and we need to fold in the deposition in the pulmonary system as well. So, for the two hundred twenty-two (222) observations taken individually, one would go from--if you were the fifty (50) percent person here, you would go from twelve hundred (1200) down to three hundred (300). When you made the final correction for pulmonary deposi-

tion you would drop to approximately a WPF of two hundred (200), so that the concentration in the facepiece when you made these corrections would be six (6) times what we would have seen had we just reported on the uncorrected values. The same is true if you look at it as a set of a hundred thirty-two (132) subjects.

To review, then, the in-facepiece concentration adjusted is equal to the concentration that you measure with whatever analytic procedures you use--in our case, filter and walls were the most significant corrections--plus the correction for pulmonary deposition which is significant, plus the probe and line losses--which we found were less than five (5) percent, so we're not including them--plus the correction for sampling bias, the nonuniform mixing in the facepiece. And in our particular work I'm not including that, that wasn't the--Warren has talked about that a great deal. I'm not going to include that in this particular work.

Here we look--we measured WPF at Plant A enveloping and Plant B enveloping, Plant A pasting, Plant B pasting, Plant A dynacast, and so on. And what we found were the distributions were different from one area of the plant to another, and that in each area of the plant the distribution, when you made the corrections, were different, too. For example, Plant B enveloping--this might have--I think it was something like twenty (20) or thirty (30) workers. The geometric mean for this value was about eight hundred (800). When you make the final correction for pulmonary deposition it drops to about two hundred (200).

Very significant. The point--I'm not so hung up on the actual numbers, but I wanted to make the point that there are a lot of variables involved and when you look at different areas of the plant we're seeing clearly different distributions. We found that the distribution varied by brand. There were three (3) brands we looked at.

Now let's take a look at what the actual data points looked like. Here we're looking at two hundred twenty-two (222) points. This is log to the base ten (10) of the corrected ambient concentration regressed on the ambient concentration from the filter alone. Ninety-five (95) percent of the variability in the log of the ambient concentration corrected for wall deposition could be linearly explained by the logarithm of the ambient concentration with filter alone. So obviously there's a very strong relationship here, and in fact, the equation provides a good estimate of the ambient concentration using filter and walls based on the ambient concentration from filter alone. So this was very nice. This was very satisfying.

We weren't so fortunate in looking at the in-face concentrations. A lot more variability in the data. Here we're looking at the log of the in-face concentration corrected for filter and walls, regressed on the in-face concentration from the filter alone. Just like we looked at before. And here we see that only sixty three (63) percent of the variability in the log of the corrected in-face concentration could be explained by the linear relationship with the log of the in-face concentration. Now you

could probably do a little better with a quadratic term here, but probably not too much. So, this equation provides a poor estimate of the in-face concentration. And, again, it just points out that one really needs to make these--at least for our data set, for the plants that we visited, under the conditions that we sampled, this is the kind of relationship that we found.

When one corrects for pulmonary deposition the coefficient of determination stays about the same, about point six three (.63), so you really don't change things very much. The same conclusions, again, that there is a relationship between CIA and CIF. You wouldn't want to use that equation.

Now, here we're looking at the WPF, which is now taking the numerator and denominator of those relationships that I just pointed out before, and as you can expect, here we're looking at the log of the WPF corrected for wall deposition, regressed on the log of the WPF with filter only. You see that seventy-one (71) percent of the variability on this term could be explained by the linear relationship with the log of the corrected--the WPF corrected--for--uncorrected, excuse me--so that obviously this equation provides a poor estimate of this value. But there is obviously a relationship here.

Now, when we make the correction for pulmonary deposition the coefficient and determination are about the same so we really don't effect things much. You will notice that the end has dropped. It was two two two (222), it's now two hundred fourteen (214) observations because we had seven (7) folks that we really

didn't have very good particle size distribution data on, so we can't make that pulmonary correction.

Here we're looking at the percent ambient--the log of the percent ambient wall deposition regressed on the ambient concentration, and we see that essentially none of the variability could be explained by a linear regression on the ambient concentration. No relationship here. We see that twenty-two (22) percent of the variability in this case for the percent in-face wall deposition could be explained by the linear relationship with the in-face concentration corrected for wall deposition. In this case twenty-two (22) percent.

Again, when you--well, let's look at WPF and ambient concentration. We've had a lot of discussion about that. For our particular data, again under the conditions that we sampled, we found that the log of the WPF uncorrected regressed--we regressed it on the ambient concentration uncorrected--found twenty-five (25) percent of the variability in this term could be explained by the linear relationship. Obviously a weak relationship. We found that when we made the correction for wall deposition about the same coefficient determination of point three two (.32), so no real big changes. And again, when we corrected for pulmonary deposition, again about the same.

One of the things I eluded to before was that--if you recall the trimodal distribution for lead that we saw before; let's say it was that--if you remove particles for each of these data points--if you take particles greater than point five (.5) out

and less than point four (.4) out of the calculation for each of the data points, and then you recalculate those concentrations just at particle sizes between point four (.4) and point five (.5), we thought that by doing that we could eliminate the effect of particle size distribution and see if, in fact, there was a relationship between WPF and ambient concentration, but perhaps it was masked by the distribution of particle sizes. And in fact, when we did that here, we see about the same relationship as before so we really see a rather weak relationship with ambient concentration. So much of the variability would be explained by other factors.

Again, we did the same things when we looked at the effect by brand. That is, we eliminated the effect of particle size distribution--attempted to--and, again, we see about the same relationship as we did before by brand. We tried to, in a sense, standardize or normalize the data.

Now we're going to take a few minutes and look at the features of the distributions. So we're going to look at the means, the medians, some other characteristics of the distribution, and we'll also look at the fifth percentile, which is obviously something that certainly NIOSH and others are very interested in looking at. So what we have here, then, is we have the three distributions, the WPF, the corrected WPF, and the pulmonary adjusted WPF distribution. We're looking at it as two hundred twenty two (222) observations and as a hundred thirty-two (132) subject means. And what we see, of course, is that the

geometric means and the means and medians all drop significantly when you make the corrections for wall and lung. We see in this case that the geometric mean, or for most of these values, in this case the geometric mean, is quite a bit higher when you look at it as a hundred thirty two (132) subjects.

Now you can look at it two (2) different ways. One is you can take the arithmetic means of those subjects and then re-plot, which is unfortunately what we have here. Or you can take the geometric means of those replicates. When you take the geometric means, in fact--unfortunately I don't have that slide--you'd see this number--these two (2) are much closer. At least half the distance closer.

So in any event, the point that I wanted to make is that you do see differences in some of the statistics relating to the distributions. You also see in this case a log normal distribution you would expect would have a geometric mean which is very close to the median. And in these distributions what you see is, for the uncorrected WPF values you see that that's not the case all. You see that it is the case for the corrected distributions, two eighty-seven (287), three 0 nine (309), and if I had a slide on the one thirty-two (132) for geometric--calculated with a geometric mean for subject means--you would see these numbers very close to each other, very close to the two eighty-seven (287) and three 0 nine (309). So what this is saying is, in fact what you could observe when you look at the log probability distribution, that for our set of data, under the conditions we

tested, the uncorrected WPF value doesn't appear to approximate a log normal distribution, but in fact, these latter two (2) distributions do.

What I'd like to show you now is just take a moment and let's take a look at the inter and intra-subject variability of the data. What we did was, we took the distribution and ran analysis of variance on it, and what you see is for those three distributions. You see the variability among, within, and total. And, not surprisingly from what we've already looked at, you're seeing that the variance is dropping quite a bit when we make the correction for wall deposition and pulmonary deposition as well. In any event, these are the numbers. And the general trend is actually similar to, I think, a paper that was recently published on inter and intra-subject variability in California. I think it was in one of the Journal articles.

Now let's take a look at the fifth percentile distribution. What I've done is calculated the fifth percentiles using non-parametric approach, and using for the latter two (2) we've calculated them assuming the distributions are log normal. So here we're using order statistics and we're counting up to the fifth percentile values, and then reading off those values. So here are the three (3) distributions, and what you see--of course you see the non-parametric approaches are very similar. In this case all I did was just took a log probability paper, plotted it, and then interpolated at the fifth percentile. So, in fact, these numbers are about the same. And in this case you'd see

similarities with these two (2) set of numbers. And what you see--of course, aside from this point here. What you see is that as you go from the uncorrected to the corrected values, your fifth percentiles drop as you saw from the graphic illustration. You also see that, as you would expect, since this is assuming log normality here this is a very bad assumption for this particular distribution. And so you see a big difference between this set and this one. So, in fact, if you have data that is not log normal, or you wonder about it, obviously in this case it is much better to use these particular approaches.

Now, if you look at the distribution of a hundred thirty-two (132) subjects rather than as arithmetic means, but geometric means, I will tell you that the gap between these narrows by half. Unfortunately I don't have the slide here. So, for example, if you looked at the set of one three two (132) using the geometric means you would be halfway between these two in each one of those areas. Now there is, obviously, a closer similarity between these numbers and these. And, again, I'm not taking into account the nonuniform mixing in the facepiece.

I just wanted to show the confidence intervals on these numbers, and, again, we're only looking at the one three two (132) values computed as arithmetic means among subjects. These, in fact, would be closer to each other--we're looking at the three (3) distributions, of course, this is the confidence intervals. This would drop down, they would overlap a little more. But the point I wanted to make is that when you compare

results from one study to another it's important that you compare apples and apples. In this case I wanted to just illustrate in the case of computing the distribution of one three two (132) you barely overlap in the confidence intervals. I'm not so concerned about these numbers or some other numbers, per se, but the point that I wanted to make was; very important when we talk about the results on one study and results of another that each of the people that conduct those studies make some effort, probably in reporting them, to do so in a way that we really can inter-compare the results of the studies.

Now, in summary, we have measured two hundred twenty-two (222) observations, two (2) lead battery facilities--the results that I'm reporting here. We found very significant biases due to cassette wall deposition and lung deposition. We have used an alternative sampling method using a ring to focus the deposition on the filter. We used, at least in subsequent studies, a heated cassette to eliminate the effect of moisture. Probably you may be seeing some of the effective moisture in some that we looked at here. We used in-facepiece pressure measurements, particularly in subsequent studies, to validate the WPF measurements and also to begin to look at the feasibility and practicality of making those connections between WPF . . .

BARRY PALLAY: (Con't) . . . why some workers get very, very high WPF values and some get very, very low WPF values. We found--and, also, very important to measure particle size distribution. We spent some time developing methods to prepare quality control samples for the analytic method that we used. Again, very important, and, again, in our case, since we found a lot of deposition on the walls, we spent some time looking at wall washing techniques. And I'm really pleased that some others are in fact using heated cassettes. I think a lot of people now are beginning to look at the walls and washing the walls of cassettes. At least when they're doing some similar kinds of work.

Now, again, I hesitate to give one (1) number because you see that things vary depending on where you are in the plant and so on and so forth. But, if you look at the means you would find eighteen (18) percent was deposited on the walls of the ambient cassettes and sixty-one (61) was on the in-face cassettes. Again, had we used the heated cassettes we probably would have improved that number. Hopefully, however between the walls and the filters we caught it all. Particularly since we washed the filters. And that's why in our particular study the corrected WPF, corrected for filter and walls, are probably really the ones we really ought to look at. The correction factors vary anywhere from about six (6) to around eight point two (8.2) times the WPF. That is for pulmonary deposition.

The particle size distribution varied by element, by plant

area, it was trimodal or greater. Lead had quite a high geometric mean, and it significantly biases the WPF results. We computed the fifth percentile several different ways, and again, I'm not so concerned about the individual numbers per se, but I am concerned about pointing out that the numbers change depending upon how you do the analysis. So it's very important to be clear about how one runs those kinds of analyses. And that hopefully several different approaches be included in results when one reports them.

In conclusion, unadjusted WPF values substantially overestimate the true WPF value, at least in our case. Wall and lung deposition losses were significant we found. And I guess that others--I think a group of French researchers--have found the same thing, and I think others have, too, now. The particle size distribution varies by element and work area, and WPF is specific to the ambient particle size distribution. I would recommend that one measure wall deposition or, in the case of other methods, one carefully do mass balances around the systems when one makes these kinds of measurements. So it's kind of really a general recommendations, not so specific necessarily, to wall deposition per se. I would recommend that one measure area of personal particle size distribution.

I'm going to take a few minutes now and I'm going to describe--as time permits we're looking at some of the assumptions that we've made. One of the assumptions we made is that the area particle size distribution provided a good estimate of the

personal ambient particle size distribution. So, in a moment I'm going to look at that assumption and some data relating to that. As I've mentioned before, I would recommend that we standardize criteria for data analysis, at least when we compare studies. I don't recommend at this early stage that we all follow the same procedures, per se, but certainly when we compare from one study to another, I think it's important that we have some standard methodology that we use. That one calculate adjusted and unadjusted WPF values and correct for wall and lung deposition, and that, as I said before, one consider calculating adjusted WPF values for a narrow range of particle sizes so that one can compare from one study to another.

I want to take a few moments and, as I said, as time permits, we are looking at the assumptions we make in these studies. One of them was this assumption here. What we did was, we took workers and we put impactors on those workers that had the same internal--they were identical internally to the impactors we used for the areas samples. Now this is an illustration of a PIXEA International impactor. Now at the time we used the larger device mounted on the workers. It's kind of interesting. They called it the bomb in describing what they were wearing. But we encouraged PIXEA International to develop a smaller device like they have, and I'm very pleased that they have now. But this has the very same internal dimensions as the larger impactor. So what we did was, in these twelve (12) areas of a third facility we measured the--let's take one (1) area. Let's take cast-on

strap, second shift. What we did there was for that worker we measured the particle size distribution from an area impactor placed very close to the worker--very close proximity. We looked at the distribution for lead, sulphur, calcium, silicon, phosphorus. In fact, other elements, too, but these are the ones that I show you. These were the principle constituents. And for that same--for that worker--we put the personal impactor on at the same time. We measured the particle size distribution using the personal impactor. Same elements. We compared each stage for each element. In this case lead; personal impactor; the distribution; the area impactor distribution. We did it for lead, for silicon, again, calcium, sulphur, phosphorus, and in fact any of the other elements that we had. I just wanted to illustrate that.

What we found was that for each stage of personal and area impactor for each element, they were--most of them--were significantly different from personal to area. However, when you integrate all the stages, and then you compute a correction factor, what we found, again, looking at the correction factors that we computed, we found that the area and personal differed anywhere from zero (0) to about sixteen percent (16%), with, I think, it was an arithmetic mean of around eight (8). So, basically, if it's difficult to put a personal impactor in the course of doing the WPF work what this is telling us is, that it's okay to use the area impactor as long as you understand that there is a little--there will be some difference, obviously,

between the personal and area. In our case, nor more than sixteen percent (16%). And, in light of the variability of the data, that's probably okay.

Now, what I showed you just previously was the distribution, or the correction factors for lead. I just wanted to take a moment and show you the correction factors for the other elements as well, because you obviously can do them for the other elements, too. And it looked pretty similar, although, in fact, actually lead had the highest effect. And, again, it was because of the particle size distributions.

We were concerned with the change in pressure during the course of the work period. We were also concerned with the change in the concentration during the course of the work period. And, unfortunately, we weren't so fortunate with our equipment in looking at the temporal change of concentration. We intended to use a PIXEA International streaker to measure the concentration over the course of the work period as well. Some equipment problems and so on prevented us from doing that. But the same approach that we illustrated with pressure measurements probably ought to be considered when one does these studies with concentration as well.

That concludes my overview of the work we did at two (2) battery facilities. Paul Hewett is going to describe how we make the WPF calculations and how we correct the WPF calculations for pulmonary deposition or for other effects. So, I think what we'll do, because what he's going to talk about bears on what

we've done here, if Larry will agree, we'll go on to Paul's presentation, and then we'll take questions afterwards.

Again, I'm delighted that you all are here, and I'm looking forward to learning some things about workplace protection factors. Keep in mind that these are just two (2)--I've just described two (2) studies, and basically I view this as a mosaic, and we've looked at a little piece of that mosaic. Hopefully with some others here and elsewhere, we'll begin to put some of the pieces together to get a more representative picture of this whole area of protection factors. Thank you.

PAUL HEWETT: First of all, I'd like to thank my co-authors on this, Barry Pallay, particularly John Gamble, who recruited me for this. I'm in the Division for Respiratory Disease Studies, and John's a friend of mine, and I was doing some computer work that related to what he wanted to do which was correct WPF values for lung deposition. So he recruited me and I got involved in that manner.

As Barry has mentioned there are numerous biases in the conventionally measured workplace protection factor. Barry has mentioned the cassette wall loss bias, Myers, et al. has described a sample probe placement bias due to improper or ineffective mixing within the respirator. There may be a negative or positive analysis bias, but this can be corrected for if known. What I will discuss are corrections for lung deposition and sample inlet losses.

The conventional WPF is, as we all know, the ration of the

ambient concentration within the worker's breathing zone to the in-facepiece concentration, ideally measured during inhalation. But me measure continuously during both inhalation and exhalation so that that measure is biased by the amount of particulate loss due to deposition in the lungs and at the inlet of the sample probe.

What we propose doing in addition to the conventional WPF calculation is calculate an adjusted WPF, where we estimate the true in-mask concentration during inhalation. The way we do this is divide up the concentration measured in the mask to that which is found during inhalation and exhalation. And the concentration measured during the inhalation phase is equal to the true concentration modified by sample deposition at the inlet of the sample probe, and any sample bias, which can be positive or negative. Concentration measured during exhalation is modified by particulate loss due to lung deposition and also sample deposition at the inlet probe.

Through a little bit of algebraic manipulation and integrating across all particle size distributions, we can derive correction factors for the inhalation phase and the exhalation phase of this sample cycle, and come up with a means of estimating the true in-mask concentration during inhalation. We've prepared a paper on this, and as soon as we can get it through the NIOSH review process which will be about the year two thousand (2000) we will submit it for publication.

Critical to this correction process is an estimate of the

in-mask particle size distribution. Now this is a quantity or measurement that's pretty much impossible to make. But it can be estimated, this in-mask particle size distribution, by taking the ambient particle size distribution derived from either a personal or area sampler, and take the produce of that and a leak penetration curve. Now this leak penetration curve comes from data developed by William Heinz and Peter Bellan in 1987, I believe it was. And this is followed by a correction underneath in the denominator to adjust the area of the in-mask concentration to unity. The data that we used for estimating sample deposition at the inlet of the sample probe comes from work by Lou, et al., in 1986 or so, I believe. And these are values that I've interpolated from the data that he reported. Somebody else might interpolate a different value, but the results are pretty much the same.

Basically, what we're doing, we're taking the ambient particle size distribution, multiplying it times a leak penetration curve, to estimate an in-facepiece particle size distribution. Once we have that in-facepiece particle size distribution we can then estimate the fraction of that that will be lost due to lung deposition for any particular particle size. And also estimate the portion of the distribution loss due to deposition at the inlet of the sample probe.

To do this we have to have a lung deposition curve, and we have chosen to use the prediction formula developed by a research group in Germany. In this case, Rudolph Vetal in, I believe it

was 1988 that it was published in [Inhaled Particle Six], I believe, to calculate our lung deposition curve. Now they have developed what I call a marvelous set of equations for predicting a lung deposition curve given any particular tidal volume and respiration rate. And the values along the curve fall pretty much within the reported values by other researchers. So because we can use their equations and calculate a continuous curve which is easy to integrate, that's basically the reason why we adopted their value. Simply because they're easy to use and probably represent state-of-the-art as far as lung deposition calculation equations go.

Also, we wanted our model to be fairly robust. It's difficult to measure the tidal volume and respiration rate of individual workers. So we wanted to define a reference worker. And in this case we chose a tidal volume of one point four five (1.45) liters and a respiration rate of twenty (20). These values were chosen for two (2) reasons. One (1), we wanted to keep pretty close to the ... definition of a reference worker, and also we wanted to have values that would be characteristic of a worker wearing a respirator working at a moderate work pace. So I reviewed three (3) pertinent articles on pulmonary function parameters while wearing respirators, and felt that this definition of a reference worker was appropriate.

Our model is on a computer spread sheet at this moment, but it can be easily broken down, and in fact, in our paper we do it, to a simple table format that can be hand calculated by essen-

tially anybody. So we're trying to make our model accessible to any researcher that wants to use it. Not some pie in the sky, difficult to interpret, model. Basically, our model predicts that--well, let's assume that we have a workplace protection factor normal conventional value of one hundred (100). That is, the in-mask concentration was one hundredth (1/100) the ambient concentration.

Our model would predict that for different geometric means, different GSDs we get sometimes radically different adjusted workplace protection factor values. For example, in the case of a geometric mean of roughly two point five (2.5) and a GSD of one point five (1.5) the model predicts that the adjusted WPFA is only slightly less, say ten percent (10%) or so, than the conventional value. But, if the geometric mean was increased to ten (10), the WPFA--the adjusted WPF--would be half of the conventionally reported value.

We plugged into the model the parameters of various real distributions that comes from a table compiled by William Heinz and Peter Bellan in a subsequent article, and you can see that these values--these distributions came from coal mines, cotton plants, metal fumes, lead fumes, from a variety of work environments, and you can see that our model would predict that the WPF--adjusted WPF--for these particular distributions would be quite a bit different from the conventionally measured WPF.

One of the critical aspects of our model is the adoption of this reference worker definition. We wanted this definition to

be fairly robust, applicable to many workers in different work situations. So we looked at variation--what would happen if we varied our worker definition--and here we contrast a high respiration rate and a low respiration rate while keeping the tidal volume the same as our reference worker definition. We also contrast a low tidal volume and a high tidal volume, and found that the model would be--different lung deposition curve, the value--the WPFA predicted by the model doesn't vary much from that of our reference worker prediction.

We also varied the time of inhalation. I should have pointed out that in our calculation of a corrected in-facepiece concentration we had coefficients for the inhalation concentration and the exhalation concentration of point five (.5) which reflects the assumption that inhalation and exhalation are roughly equal. Well, that's not true, so we contrasted a high time of inhalation versus a low time of inhalation, and it did effect the prediction of the model. But if we roll the differences in tidal volume, respiration rate, and time of inhalation into definitions of light work rate and heavy work rate, we find that these extreme definitions give predictions, or give WPFA values very close to our reference worker. So, in summary, we feel that our reference worker definition is adequate for the majority of situations.

Another critical portion of the model is the leak penetration curve. And I used estimates of variability reported by Heinz and Bellan to contrive a high and a low leak penetration

curve. The middle curve is the one used by our model, and then recalculated estimates of WPFA using the adjusted low and high leak penetration curves, and found that only in the larger particle sizes were there any differences not sufficient, in my mind, to be worthy of note, and to conclude that the leak penetration curve that we're using is fairly robust and doesn't effect the model very much. Also, the model does adjust for inlet deposition. That is, the loss of particle primarily due to inertia at the inlet of the sample probe. Removing that adjustment from the model doesn't change the WPFA values very much. So we feel that the model could be simplified even further by removing that particular adjustment.

So, in conclusion, we feel that the unadjusted WPF can substantially overestimate the true WPF, and that our proposed model calculates an improved estimate. Not necessarily the best estimate. The model, we think, is basically correct, but can certainly be improved. As better estimates of lung deposition come along, better estimates of leak penetration, the model could be improved. But for right now we feel it calculates a good, a very good, estimate of the true essentially, but unknowable workplace protection factor.

Also, our reference worker definition should be appropriate for a variety of work situations. And, as Barry noted earlier, the WPFA calculated by our model is specific to the ambient particle size distribution. We recommend that both area and personal or personal particle size distributions be measured in

addition to CO and CI so that this type of adjustment can be made, and that both adjusted and unadjusted WPF values be calculated. Also, as Barry mentioned earlier, we would like to consider calculating adjusted WPF values for a narrow range of particle sizes, say between point four (.4) and point six (.6) micrometers, so that we can compare between studies; have some kind of reference WPF value that's independent of particle size distribution.

Further recommendations, we feel that leak penetration curves should be investigated for leaks larger than five percent (5%) which was the maximum size investigated by Heinz and Bellan. Furthermore, those curves were derived using mannequins and artificially induces leaks, and the actual leak penetration curves for real people with real faces might be somewhat different. We should also investigate the relationship between area particle size distributions and personal particle size distributions for whatever environment you're looking at. Barry was involved in looking at WPF values in a lead acid battery plant. The relationship between area and personal PSDs might be a little bit different in other environments.

And further, evaluate our definition of a reference worker. Is it appropriate? Should it be universally accepted? Probably not, it should be revised, but we have to look at better data or wait for better data to come along. Right now I feel that the reference worker definition represents pretty much state-of-the-art. That's the end of the presentation.

MR. HEWETT: I might mention--this is purely personal--you're going to be stuck in Morgantown for a few days, stuck. And if any of you play racquetball see me. I'd like to work up a game. I'd like to get both an industry and a company guy so that we could have a tri-par type round robin. But do see me after the day.

MR. SPARKS: Okay, questions for either presenter.

TRENT NIEMEYER: You were trying to make some adjustments for heavy workload and light workload rates, could you go a little bit further as to what you did there, and what type of measurements you used to determine what's heavy workload and light workload?

MR. HEWETT: I'm not going to rely on my memory, because I know how bad it is. If you'll wait just a second.

I have a draft paper--copy of our paper--and you notice it says, "Not to be cited, quoted, or otherwise read." Okay, our light work rate definition was a tidal volume of one point 0 (1.0) liters per breath, respiration rate of fifteen (15), and a time of inhalation of point four (.4), that is forty percent (40%) of the time was inhalation, sixty percent (60%) was exhalation. The heavy work rate was a tidal volume of two (2), a respiration rate of thirty (30), and a time of inhalation of point six (.6).

DON WILMES: I think part of your direction is making the assumption that the leak sites into the respirators are fixed leak sites. Have you considered investigating the type of leak

in a respirator? I think most of the experience is that a leak is a living dynamic thing that in essence goes from a huge hole to nothing, and if, indeed, that's the way a leak is, your correction for particle size in the respirator would be totally inappropriate.

MR. HEWETT: Not inappropriate, just not as correct as it could be. Let me expand upon that.

DON WILMES: I don't think you could really correct for it on a theoretical basis because the nature of the leak is a living, constant changing orifice. I think it would be extremely difficult to predict any particle size change that would occur from the ambient to the inside respirator, because it's going to vary from individual to individual, and in reality, you're introducing a very large error.

MR. HEWETT: I understand your concern. This is basically a theoretical model, as you mentioned. One of the problems with using a model is showing it's relevance, as Don was mentioning earlier regarding future criteria for approving respirators. And the leak penetration curve was derived using a mannequin and artificially induced leaks. Establishing it's relevance is something that I personally haven't considered, but it should be done if the model is going to be universally accepted.

DON WILMES: Wouldn't it be far more better to use your in-facepiece samples that are not destroyed and develop a method of actually analyzing for size the particles collected on the in-facepiece filters.

MR. HEWETT: Perhaps using microscopy, yes. We had talked about doing that, and, Barry, didn't we have some of those samples analyzed?

MR. PALLAY: Let me just mention that, if you notice, we had three (3) different distributions, an uncorrected--just from filter alone--then corrected for walls, and then lung adjusted. And the attempt here is to provide an opportunity to look at, let's say, raw data, and look at an estimate of what it would be using the best information we have available at the time. The model is very general, and as we get better--as we have a better understanding of what the leaks are and the relationship between leaks, if we can, then we just modify it. But we don't mean for this number and this model to be the final word in this area at all. In fact, it's probably the first word. And, in fact, we're going to make a lot of changes as time goes on. So, I absolutely agree with you, we need--that's probably the most important--that's a very important area, is to get an idea--get better estimates of in-facepiece concentrations, particle size distributions, and so on. So, yeah, this is just a strawman, if you will. It's an attempt to make an adjustment for pulmonary deposition, it's an attempt to have you all poke holes in it, and--no pun intended--come up with--suggest better ways of doing it, and as you do, we'll try to improve it and hopefully you will too.

DON WILMES: In your wall deposition corrections did you determine a nominal correction factor for various operations, or

did you indeed wash every cassette that you analyzed and determine for that each individual test data the correction?

MR. HEWETT: We washed every cassette and we did--every cassette we used we washed. You saw the actual data points for the ambient concentrations, and obviously, I think, ninety-five percent (95%) of the variability, at least in the log distribution, can be explained by a linear regression with the uncorrected. So in the case of the ambient you could probably--you have certainly a better handle on that relationship. But for our infacepiece samples, particularly since I hadn't incorporated the heat resistance wire, so to speak, to probably eliminate some of the effects of moisture. I'm much more comfortable, in the data set that I just showed you in these two (2) plants, to really use the wall corrected values. But in this study and in the succeeding one we washed filter and walls every time.

ROBIN HOWIE: Just three (3) minor points; . . . wall washing are primarily a function of using cassettes. If you used "open filters" you might be able to not have to correct for wall losses. Also, you have to . . . because you're interested in what's going to harm the body. On the position characteristic or on the leak penetration characteristic did you take any account of the hygroscopic nature of the dust? We know from the UK in using sodium chloride we use an ought point six (0.6) . . . micron mass . . . to test aerosol, which is almost total . . . in the body. From particle size calculations the deposition would be very much lower than the hundred percent (100%). What happens

to your model if you assume a hundred percent (100%) lung deposition vis-a-vis what you actually find? Is that a large enough difference given the variability that you find when . . . between subjects to be a necessary correction?

MR. HEWETT: If we assume a hundred percent (100%) deposition and you pretty much just have a doubling of the in-mask concentration, would you not?

ROBIN HOWIE: Yes, you would. What I'm saying is, if you assume hundred percent (100%) deposition, how does that compare with the correction . . . actually finding, which was between point six (.6) and point . . . ?

MR. HEWETT: Well, that would depend upon particle size distribution, and the difference would vary.

MR. PALLAY: Before we leave that one, again, as we come up with better models then we'll get closer to the true--our estimates will be closer to the true values. And so this is really not meant to be the final word, this is really the opening ..., if you will.

ROBIN HOWIE: But what I was coming to, part of the problem . . . you're actually using cassettes. If you could actually make your filter into the facepiece you can duck the problem. . . . preferable by technique not to have to make corrections and use a model.

MR. PALLAY: We looked at about twelve (12) different configurations, looking at, for example, using non-conductive cassettes, and looking at all sorts of other things. And I'm

certainly--if there are better ways of sampling then we are certainly open to those, and we don't mean to imply that the approach we took is in fact the final word on that either. We looked at a lot of different configurations and it just so happened we really couldn't do any better under the circumstance.

MR. HEWETT: Let me ask another question. You mentioned the inspirability curve. Are you saying that the lung deposition curve should be modified by that inspirability curve?

ROBIN HOWIE: No, what I'm saying--well, what interest . . . so you may well be sampling particles in the ambient which would not be inspirable.

MR. HEWETT: Oh, I see, so adjust the ambient particle size distribution by the inspirability curve. That would be easy to do.

ROBIN HOWIE: You're looking for an index of health effect, not a simple index of relative loss inside and outside.

MR. HEWETT: No, I think we're pretty much interested in that particle size distribution, forget the inhalability curve. Once we have it, we can then adjust for lung deposition. We can discuss it afterward, but I don't think that adjustment needs to be done.

MR. PALLAY: Let me mention, this is a tandem team here, and Paul has invited you for racquetball, and I will invite any of you for full contact fighting at the end of this--at the end of any one of these days, because I do that every evening. I'm teaching a class tonight, as a matter of fact, so anybody that

wants to do that, please come up after the meeting if you've finished with Paul and his racquetball.

HARRY ETTINGER: I have two (2) questions for Barry, but I'm afraid to ask it, whether the talk about full contact fighting was to sort of tone us down.

Two (2) questions. One (1) is, did you consider the fact that if you have two (2) lapel samplers side-by-side that you might get errors of the magnitude of maybe the pulmonary deposition? I have vague recollection that this has been looked at in the past, but people position themselves over whatever operations, and you've got a lapel sampler on the right and the left, will those give you differences comparable to some of the other differences we have seen? And second of all, could you please . . . .

MR. PALLAY: Probably.

HARRY ETTINGER: Is that the answer?

MR. PALLAY: There are, as I said, an infinite number of variables, and you've just pointed out probably two (2) very important ones. That's a very important one.

HARRY ETTINGER: It's a trivial one, but I think it could be very important.

MR. PALLAY: Well, I think as we saw from the personal are area impactors placed almost right next to each other we saw differences on the order of zero (0) to sixteen percent (16%), so I would say I'm sure that's probably true.

HARRY ETTINGER: And that's analogous of two (2) respirators

on--two filters on the respirator and the positioning of some of the workers in the photographs.

MR. PALLAY: Absolutely, and, you know, it's widely know that you have two (2) workers performing the same task, one (1) will have a very high WPF value and low blood lead levels, another--the same site--has very poor performance standing just about very close to each other. Again, it's a matter of work practice, and probably this difference between whether they're a little closer or a little further away, whatever, from the actual exposures probably plays a part. So I would expect--I agree with you.

HARRY ETTINGER: Second question. Could you elaborate a little bit more on the intra-person variability where you had workplace protection factors measured for the same individual twice or three (3) times you put on that view graph, and it went by a little fast? If you took the people who had duplicate tests or triplicate tests, how bit a variation did you have between the duplicate and the triplicate tests for the same individual using the same test protocol, etcetera?

MR. PALLAY: Harry, my better half is not here, and that's my statistician. Marty Peterson is the statistician on this work, and he is a significant contributor. He could not be here right now. He performed analysis of variance on the entire data set, and then computed these among and within variability. And for a discussion of that I would really defer to him. We can talk to him today.

HARRY ETTINGER: How could you characterize in non-statistical terms--were there major differences if you took an individual--the individuals tested two (2) or three (3) times, were there major differences over their--replications of their . . . ?

MR. PALLAY: Yes, there's a significant intra-subject variability. As a matter of fact, the within is larger than the among. And that's consistent with work that was just reported in the literature from California. Again, there is a large intra-subject variability that we notice.

The other interesting thing about it, if you think about it, too, is that most people are not going to be running replicates of samples. It's hard enough getting one (1) value. In fact, when you just do--I didn't show the distribution when you just take the first value you measure, but, in fact, I could have showed you an alternative distribution which is just based on the very first sample of that worker. And, yes, the statistics--you know, the geometric--these things change. There is a significant intra-subject variability.

However, as we talked about before in terms of sampling strategies, you know there's a relationship between the variability of the WPF and the number of subjects you would use, or the replicates of those subjects. And, in simple terms, you get--and again, my friend and colleague tells me never to talk about statistics unless he's present--there is a significant intra-subject variability. And I guess in terms of the strategy you use when you sample, you get more bang for the bucks when you use

more subjects, because of the way those terms--you know it's one over N (1/N) and one over NA (1/NA) and N is the number of subjects, A is the number of replicates. So, even if you have a large number of replicates--A--you still have that term one over N (1/N) on the other side of the equation, so you still--you're better off doing the more subjects.

Now, I purposely chose to do replicates here, because there seemed to be a lack of information about inter and intra-subject variability. Here, this is showing, obviously, that in some cases--now I would really look at the latter two (2), the WPFFW and WPFA because of the--I would not hold to the uncorrected values, because I think the corrections in our set of data is very important. So I would really put more stock in the middle or essentially the middle number; the bottom two (2) numbers are about the same. In other words, WPFFW and A. And in those cases you see, obviously, that within is much--is quite a bit larger.

We can continue this later.

JIM JOHNSON: Barry, I have a question a little more back--standing back from this a little bit--from this specific study. We've heard a lot of the details about experimental design and all the problems you're going through here with this type of an approach. Have you looked at . . . ?

MR. PALLAY: Jim, these are just what they tell me, engineering details.

JIM ___: Yeah, this is just simple stuff, take care of it. Did you look at biological monitoring as another feasible option,

especially since you had lead which is one of the most documented biological entities we can monitor for to get some idea of what I call the real true respirator protection factor?

MR. PALLAY: I kicked off this meeting about--and again, no pun intended--about this project about three (3) years ago, in this very room, in front of probably a good cross-section of some of the very same people. And we talked about different methods of conducting this kind of work. Yes, I think that there are other very promising approaches that are out there that one ought to consider. I frankly have my hands full following this more traditional approach. And I'll tell you, I think it's important to have maybe a critical mass of information on one (1) method before we move off it and start it in another direction. And I think probably some of those other methods have their own difficulties as well. So the answer is, as far as I'm concerned, one ought to have an open mind about the methods one uses.

SUSAN TANAHILL: . . . . Did you find that the intra-subject variability varied significantly from worker to worker?

MR. PALLAY: Yes, yes, there was a large variability in there, and I better take that slid off before anybody asks me more questions about it. Next time I come up here Marty will be here, too. But the answer is, yes.

ALAN HACK: First, to enlarge on what Jim Johnson said. If you look at biological monitoring with some other comparable technique then lung deposition, which you consider to be an error, is actually what the person is being exposed to, and

that's all you care about. The fact that the particle size changes from outside their mask to inside their mask, well, what's what the person is exposed to. So, ultimately, that is the truth. The measurement in the mask is not true, it's an attempt to find what it is. But what gets into the body is what you really want to know. Whether you can do is successfully now or not, that has to be your goal. Everything else is just a part.

And, in fact, to a more generic question. Of all the variabilities you discussed there was one (1) slide that had the three (3) respirators, and those three (3) curves were exactly the same. So from your limited data we don't need to do work-place protection factors, because the three (3) respirators performed exactly the same in the workplace. Plus, with numbers which are much, much higher in the assigned protection ... we're going to .... So, we're already showing that respirators do work in the workplace, and the question that we're first posing . . .

ALAN HACK: (Con't) . . . was the three (3) respirators.

MR. PALLAY: Well, there was--you know, that's a law of probability applied. You're looking at logs, you're not looking at linear scale. There was significant difference between the brands. At least one (1) as opposed to the other two (2). Well, I don't have the actual numbers on that particular slide. But, to comment on--yes, the half-facepiece respirators drop the concentrations--the ambient concentrations--quite well below the permissible exposure limits. If you look at the CO slide and the CI slide you can see that there were dramatic drops in those numbers, and so the respirators provided quite adequate protection for the workers. I guess I kind of view these discussions, again, as filling these pieces of the mosaic, and I think that as we get a real clear picture of this, with this study and some of the others, maybe we can move on to other areas. I guess we've come a way, but I think we do still have a ways to go. It's a matter of priorities, Alan.

MR. SPARKS: One (1) more, and I think--we're robbing this afternoon if we don't quit soon.

BOB BRENNAN: The last couple of statements are kind of blurring something that's bothering me. There's been statements made that with lead, for instance, you can get a real respirator performance picture by measuring the blood leads. It seems to me a while back it was pointed out that that's a program protection factor and what you're getting is whether the guy washed his

hands at lunch, as well as what the respirator . . . . Did this study include any kind of correlation between the respirator performance as you measured it and the actual medical experience on site as far as blood lead?

MR. PALLAY: I would have the data available to me as time permits to look at some of those assumptions. We looked at one (1) between area and personal. But, if the Institute were willing, I think we could look at those effects, too. I think that we also conducted another study that I haven't talked about here. But that kind of data is available, and we haven't analyzed, we haven't looked at that at this point. Some people have, and I would like to do that if time permits.

HASKELL MULLINS: I have a quick practical question, Barry, on your side-by-side comparison for your Cascade impactors. Did they compare well?

(Inaudible discussion.)

HASKELL MULLINS: My question is, is that during your particle size distribution measurements with the Cascade impactors did you do any side-by-side comparison?

MR. PALLAY: We have--you looked at--for example, I showed the mean of four (4) impactors on one of the slides. When I showed the trimodal distribution I just showed it in one (1) are of the plant. It was Plant A enveloping. And, in fact, I think we either had six (6)--we had possibly six (6) impactors. I showed you four (4) there. We have the data, we haven't looked--you're really talking about the variability of the data at one

area. We have it, we just haven't analyzed it yet, but that is one of the things that I would hope to do. So, that's, again, another assumption, and I would like to do that. I think preliminary indications are that the one (1) impactor works fine. We did look at that subject in a preliminary way, and found that one (1) impactor, for our purposes, served the purpose quite well, when you use it for the WPF application. In other words, you may find that four (4) impactors vary significantly, each one, in that same area. But when you apply the procedure that we follow to make the corrections you may find, in fact, that the bottom line, the effect on the WPF is very small. And we did find that to be the case in our--at least the preliminary analysis of this work.

HASKELL MULLINS: . . . two (2) impactors side-by-side.

MR. PALLAY: I understand, I understand. So, I guess, the preliminary indication is, one (1) is enough for this application.

MR. SPARKS: I'm informed that all of the people requesting to speak this afternoon have at this point checked in so we have a full schedule this afternoon. We would like to reconvene at 1:00 or very shortly thereafter. That doesn't give you much time. That's why I've been torn between letting the questions flow and keeping us on track. We very much appreciate your attention and your questions. And our people are around, and maybe over the next couple of days there could be some hallway and other kinds of questions about some of our ongoing work. I'm

sure they would appreciate it. So we'll reconvene at one o'clock (1:00).

(Whereupon, at 12:05 p.m. a lunch break was taken until 1:00 p.m.)

MR. SPARKS: . . . National Laboratory. He wants to speak from this point. That's fine with us.

DR. JAMES S. JOHNSON: Thank you. Well, it's been a very informative morning for me listening to some of the activities that are going on here at NIOSH, and I'm having, I guess for me--I started into this talk really trying to look at workplace protection factors, protection factors in general, and I come to you now to talk as an industrial hygienist, not as a respirator researcher. As in industrial hygienist, what's going on with this topic of workplace protection factors, and should a protection factor generally be in the certification process. And so I historically, just to get myself up to speed, say well, really what is the purpose of NIOSH respirator certification. This is from the industrial hygienist point of view. And I went back, I did a little hunting around, and in my library I got the first NIOSH certified protection list out, and up there they really say the purpose is to assure commercial availability of safe respiratory protection. If I do a little more reading around, say in more current jargon, just so we watch the verbiage change a little, we really want safe and effective respirators. And then Dr. Bender today noted that we really ought to assure an adequate level of respirator protection in this process.

So with those in mind you might say, well is this--how does NIOSH get into talking about changing some of these things. And so out of that same document I looked and I found that NIOSH here in Morgantown does some various things. And what I really wanted to jump down to is this morning summarized number six (6), I thought, very well. We had a good overview of some R&D for new test methods, and what I guess came to me this morning after listening, and I hope that I'm starting to gather this in and get a picture of it, is that, is the workplace protection factor really a topic for certification, or is it part of another area that NIOSH is in, and that's going out and evaluating the actual workplace and seeing if there is exposure problems there.

So I moved along and I think things are coming, then you might say, well what about history. And in the certification process I went back and I looked over some of the old test methods. And should the subject of protection factors be included in a certification process, I would put to you, it's already been there. It's been there since the beginning with the isoamyl acetate test. You might say the detectors were fairly subjective. But we have, in essence, been determining protection factors, simulated workplace protection factors, at a crude level some might offer, and even using the pre-silica test we had that. So that helped me look at the topic and say, well, okay, we've been doing it, it's worked well, why don't we continue, and maybe look at that process from the idea that we want to improve these tests that we have been doing for some time.

What considerations are important for the inclusion of any type of protection factor in the certification process? And we've heard Barry today talking about some of these. I'm sure you'll hear other people later as we talk about specific experiments as to what do we want. Do you look at the worse case as far as the set-up in the environment? Do you want typical conditions? Somebody out here is going to say what's typical? Do you want to have actual workplace conditions which we know are infinite in variability as we heard this morning. How do we work on this? What do we choose?

Well, I personally thing somebody's going to make a decision. And that's not bad. I think a decision will have to be made. I don't know who's going to make it yet, but a decision, I'm sure, will be made. And the important part of that decision process has to be in the certification that we get reproducible results. In other words, what Harry was talking to Barry about, what about that variability of the individual from test to test. Very significant in anything that you put in the certification process. Then when I choose Scott over MSA versus Survivair I certainly want to know that there are comparable results from item to item for me as the industrial hygienist now buying a certified product to look at.

And then the buzzwords are we want some validity to the actual workplace, which I'm not convinced--that's important, but I don't know that it's the focal point of the certification process. I don't know that, and I think it needs to be thought

about. We need to think about ease of determination, cost, and how should we determine a protection factor. And we've gone around about this in the respirator business for many years. Longer than I care to even think about. Do you do a maximum? Do you do a minimum, and do you do an average?

Now, with that in mind I want to show you some actual data that I'm right now in the process of trying to figure out what to do for an AIHA paper that's coming up. And I thought it would be interesting for the group here to ponder this. How do you interpret this simulated workplace protection data?

Let me tell you what this is. This is one (1) individual wearing three (3) different units--three (3) equivalent units--an FPA certified SCBAs. The data here is--this is a thousand (1000), ten thousand (10,000), hundred thousand (100,000). And right here you'll see we switched a little, because this is ten thousand (10,000) to a hundred thousand (100,000). This is a thousand (1000), ten thousand (10,000), hundred thousand (100,000). And I think this shows the problem in trying to decide how do we interpret data to set a protection factor. Very obvious here, everything's above ten thousand (10,000); simple. And if you want to be a purist, you say maybe we'll go up to forty thousand (40,000) and set that number and say that's what that one performed.

Now you get back and say wait a minute now, the time factor here is a minute, twenty-four (24), twenty-five (25). And what I should describe to you on the actual test, is this is SCBA leak

rates as determined at eighty percent (80%) of the person's maximum heart rate capacity on a treadmill. So he's huffing and puffin and we're trying to really come up with what's the worse case kind of a performance number here.

I also need to tell you that I'm collecting data everywhere between four (4) bits per second to a hundred (100) bits per second. And that's controlled by the computer program and what's going on there. So Bob da Roza will give you some more details, but Bob and I have worked on this project to generate the data, and now we're interpreting it.

So, here it is. What do we do? Some people might say, well very obvious. Right here it's down to almost a two thousand (2,000). That's it, do a peak. If we do an average most of these are well over twenty-five (25), thirty thousand (30,000) for a protection factor, and what's the appropriate one. Don't know. I'll tell you at the AIHA conference at least what we come up with. But it's an example of data that has been generated from a simulated workplace protection factor on an SCBA that somebody has to make some decisions on.

Now, what are the consequences of over restrictive or conservative protection factors from the industrial hygienist's point of view? Very positive is, sure, we assure worker protection if they wear the respirator. Because, remember, everybody can't do a job in an SCBA or a positive pressure air line. But we can be so conservative in our analysis of the performance that we get forced into that perspective. There's a fellow named Ross

Cusian who goes back a long way in the industrial hygiene business, caught me at one of the conferences about four (4) or five (5) years ago. And it was when I think NIOSH had just come out with their asbestos air line requirements and the decision logic, and Ross said, "You know, we really need to continue to look at air purifying masks and how they perform, because" he said, "I know what the regulator people are saying, but I know what I'm selling. And I'm still selling a tremendous amount of air purifying equipment, even though you would think you would see bigger spurts going into the air line and the self-contained breathing apparatus."

And the other thing I'd like to tell you is to check one of the better programs is watch your TV in the fire scenes. Fire department documents say you will wear an SCBA at all times when responding to a structural fire. Just watch the news. And there isn't a program that we're saying right now we've got that under control--I would say fifty (50) to seventy-five percent (75%) of the time I watch around the country the SCBAs are off. Or at least the mask is on the neck strap. And maybe ten (10) to fifteen percent (15%) when they're in the smoke, just like we heard from this morning, they'll put it on. So there's some other issues in dealing with protection factors and protecting the workers that we need to keep in mind.

Now the negative that concerns me is as an industrial hygienist conservative protection factors remove equipment that I don't have available to go out and use in my respirator program.

If I'm told the law says that you can only go up to five (5) for a . . . half-mask, or fifty (50) for a full face mask, that's it. I'm stuck. Whereas, in many operations I could get very high, or a lot higher protection factors, provide better protection, more acceptable employee respiratory protection, but I can't do it. So we need to be careful.

I think the air line is the best example of creating secondary safety hazards. You now protect the guy's respiratory tract and he falls over the hose and breaks an arm or kills himself because he's dragging that tail behind him. And I think there's costs that need to come into the whole process. So when we look at this whole idea of protection factors in the certification process I think these are very important considerations that need to be thought about.

Now, from my standpoint, what type of protocol best meets these needs? I'm willing to make a decision. I think a simulated workplace protection factor really makes sense. And that's in the laboratory, because the test facility--I've done this to emphasize a point--specified; test atmosphere, specified; detection instrumentation, specified; test procedures, we can specify them, we can go through a series of exercises and specify that. Likewise the data analysis.

Now, in my experience in the NFBA standards process where we're introducing now probably one of the most complicated tests that are out there, a flame and a heat test, it's going to be all specified. A new NFBA breathing machine has been specified in

detail and there's probably ten (10) or twelve (12) of them being used around the world right now very effectively. We just took care of a lens abrasion problem by getting in and specifying things tightly.

Now, I agree with the point that we need to go out and make sure what we do here is realistically tied to the workplace, but I'm not convinced that it has to be rigidly. That's the pushing, that the front issue. Because, to me, if we have inconsistency in the tests we got a bigger problem than trying to come up with a standard workplace to compare to. So, again, I'm back to saying the test and what it's to do is to guarantee safe equipment is very important.

The reason that we might see some problems in agendas on the certification process is they're used by a diverse group of people. In this group here, NIOSH is in this case, I believe, the instigator, the responsible organization right now, at least I think, for protection factors. Although OSHA certainly has a strong interest in protection factors in their program. So we have the upper three (3) . . . regulatory needs. Then we have the health and safety professional group that comes down through the next group. And of course, the most important one that we sometimes tend to forget in this group, is the end user. Can this guy live with what we're trying to tell him he needs? So in that case I think it's real important that we try and sort this out and say what are we really trying to do.

The thing that came to me this morning as I was listening to

the presentations and thinking about what I might tell you this afternoon is, how are we going to use this data we generate from say a workplace protection factor? Is it an equipment design problem? Which is the certification processes biggest concern. Or--we haven't mentioned today, and I want to underline a topic I think we need to consider--is a respirator program problem? Has the program failed in education? Very simple. What Gary Noonan told us this morning; you take the mask off to talk in the middle of the fire, you're not following the rules. There's a training problem or something there. Now that should not influence the certification process. And so, I look very strongly at the process overall.

And now let's jump into this next topic. How would an industrial hygienist, health and safety professional, look at protection factors that we might generate? We're going to fight among ourselves, we're going to disagree, we're going to come up--but how would we look at this. If I'm going to use it I want to know what type of a respirator am I going to choose in some kind of a concentration to start my selection process. Now, what I think is missed is the next question that's on my next slide. Are we done there? Does the responsibility to confirm respirator performance stop after the respirator is selected? Absolutely not. There's no way. And you say, wait a minute, where does that come from? If you go back into ANSI Z88.2 the administration of the program is charged with going back and confirming the performance of that respirator that you've selected from that

general protection factor in the application that person has put it in. So, if I can't take, say as an example, a half mask and have an effective range of say five (5) to twenty-five (25), to use that mask I might really be short in my whole respirator program. Or worse, you might be limiting the health and safety professional in the way he can use this equipment effectively to protect the worker.

And you might say, wait a minute, I can't trust them. I don't know where that fits into the certification process, because it's the responsibility to me of the professional who picks that respirator to make sure it's working within a range that the regulator people find acceptable and documented by studies to show that this equipment will perform in. And I present to you the kind of thing Barry showed us in a pretty active manual function doing lead battery activities, say, versus somebody sitting at a table assembling the plates. And all they're doing is they're sitting there in front of a table and they're lining plates up. Totally different physical demands and respiratory requirements on that person. And if we say, well, sorry gotta put him in an air line, because even though you can get that kind of a protection factor not acceptable under the guidelines that we set up, I worry about that.

The terminology that was used this morning by Dr. Bender really hit home to me as the health hazard evaluation program that NIOSH is carrying out I think is very important. But, I don't see where in many cases it should be directly tied to the

establishing of the certification protection factor, because the health hazard evaluation is essentially an arm going out and determining if the respirator administration part of the program is working. It's not necessarily a defect in the certification process of the equipment.

Now, another area that I mentioned--I asked a question this morning--that I think is important is, I think we've exhausted in defying all the problems that we can come up with, and there's probably another zillion of them out there, to take the laboratory into the field to come up with all these impactor studies and things. And I think our guest from the UK kind of brought it up--is we're really interested in the employee exposure. You see, as the industrial hygienist I don't give a rip about all these details other than that they're simple, they work, and I keep the employee safe. I've kept him below the standards. So, one of the easy ways to do it, if it's possible, is biological monitor. And you might say, yeah, that's another swamp. And in many cases there are going to be a lot of technical problems in that area. Now, what we're doing at the Lawrence Livermore Laboratory where I work, and it happens to be only because we've found a very capable staff member who's come to us as an internal dosimetry--an internal dosimetry expert, radiation internal dosimetry expert--and so we've been talking and he says, well, yeah, what does it matter if it's radioactive, we've got all these models. The radioactive community, the health physics areas, have got ICRP models that are very effective and we've got all kinds of

techniques to look at that. So we, personally, are going to look at this as a way to look at employee monitoring, not necessarily focusing on respirator protection factors, but I think it has a lot of potential.

Now another thing that we happen to have is, there is a relatively new instrument on the market called a ICP mass spectrometer. In fact, made in UK--is the company that we're buying ours from. And it has a sensitivity of around a half a part per million for most elements. And it's nice in that you just put your internal standard in, and you dilute, and you take your urine sample directly into the system for analysis. Cheap, easy way to do it. We've used it for heavier metals in a classified program that we had, but what we're now looking at is seeing what we can do, and what I'll call the classic metal fabrication element, and seeing if we can come up with some simple ways to catch that welder and say, okay, I want you to pee in the bottle at 10:30, right before lunch, right after lunch, and by the way, would you give me some samples over the weekend. And hopefully we'll be able to pick out some people and gather what I think will be some interesting information to allow us to get into another way of looking at exposure and then looking, possibly, at how respirators really perform on the individual. Because the other process that I hope you've looked at is--can you honestly tell me that these people we've seen this morning don't know somebody's watching them? And don't know, for instance, when you hang all pumps that Barry--all that stuff on them--oh, yeah,

that's the way he does his work when we're not here. And we put all that stuff in the front and you wonder how it's really effecting the fit of the respirator when you put a couple probes up there, you hang a hose that if you catch it right it pulls on the respirator. You know, we've talked and gone over a lot of these. So, those things I think have to be kept in mind. But I really look at biological sampling as something that I think we have not embraced, because we haven't had the expertise in this small community here. Or we haven't gone out and sought the expertise to look at this question of respirator performance.

So, then from a user's prospective what should we consider? I think it really--a protection factor should differentiate between different types of respirators. Remember, as the industrial hygienist do I use a disposable, do I use an elastomeric half-mask, full-face, air line? Those are the decisions that are going to be made out there. It really should--the protection factor ought to give a number under typical conditions. I don't think we should load it with all these conservative factors. That's the administrator's problem when he's running his respirator program. It is not the regulatory people to limit my tools as the industrial hygienist to do my job, and say, I don't trust your ability so I'm going to do it. See, I disagree with that. I think it ought to be an average protection factor that allows me, again, to know what that type should generally do.

I hope we can get the process to be straightforward and understandable. I mean, when you--go out and talk to an average

industrial hygienist, or an average health physicist, or, heaven, go to a construction job, and get the poor safety engineer that's trying to handle that, if he's there. Just, it needs to be simple. I don't think the certification side of the process should assume the responsibilities of the respirator user. And I see this whole idea of getting into workplace protection factor as saying certification is responsible for the administration part of the respirator program. And that's clearly, I don't think, the intent of the regulations or the standards process.

Now, you've got to have some fun. People know me, I like to have some fun, so I did some visual--I was trying to come up with a visual thought of this process of a NIOSH workplace protection factor. And if it gets included in the certification process what it's really going to do. And I had to go back a long way to pull out some old history. And I would propose to you that this is now the OSHA cowboy who has been equipped to go out and have a NIOSH workplace protection factor put together. And, note, the only two (2) things we really had to do is, we have to put the respirator on him, and then we put a non-intrusive, very small, data collection package in the system to try and bring this together. But the visual image I want to leave you with is, we don't need to complicate this process. If anything, we need to simplify it. And I think that's our biggest task, is simplification and getting it out so people can use it. That's all I have.

HARRY ETTINGER: Jim, are you saying that the--I agree with most of what you said, but do you really think that the certifi-

cation process for say a respirator has an average protection factor of a hundred (100), to pick a number, and that's all that it has to guarantee, rather than the fact that when you get the spectrum of tests on it in some reasonable fashion, it may be as low as five (5) or as high as five hundred (500)? And the high end probably isn't that important.

DR. JOHNSON: What I'd like to know as the industrial hygienist is--I go out, I do a workplace sample, or I do an estimate of the concentration; I come back and say, what factor do I need to reduce that by to get within the standard. So I need an average number because we've listened today to find out how--there's no workplace that's unique that we can say this is the only one that we should use. Some of the guys take their masks off. Well, that might tell me as the administrator I've got to train these guys more.

HARRY ETTINGER: That's a different question. I'm saying--let's say you know you have to reduce it by a factor of a hundred (100) and this respirator was certified by NIOSH for a factor of a hundred (100), but, in fact, it's really a hundred (100), but when you take a lot of the--a group of these--the protection factor ranges from five (5) to five hundred (500) which averages out to a hundred (100). That's a big impact on your deciding . . . .

DR. JOHNSON: Absolutely. And somehow . . . .

HARRY ETTINGER: You can't live with just an average.

DR. JOHNSON: Well, yeah, as long as we make sure that the

average doesn't have a big variability. In other words, we keep reducing that number so that we set some kind of an acceptable standard deviation so that I know that I'm going to get, most of the time, at least that good a number. Or at least it's a start. But the idea as to lock this in with a specific workplace to set it, I think that's going too far. In the certification process. See, that's what I'm saying. In the certification process we need standardization, we need reproducibility, we need comparability. And anybody who listened this morning has to know that isn't going to come by going out into the workplace. Nor can we afford it. I don't think we are going to be able to afford it. As Barry said, who's going to do duplicates? It's hard enough to get out and do one (1) set.

JOHN KOVAC: When you talked about calculating an average that might be difficult to do even in a laboratory context. Protection factors seem to talk about the turbulent . . . breathing gasses from the ambient to the breathing gas inside the mask. And when you do that you seem to run into a situation where--I guess it's called the physics of chaotic phenomenon--where you're talking about initial conditions playing a dominating role over the type of time averaging--the type of time signal that you get. You might not get reproducability even in the laboratory.

DR. JOHNSON: I think if you look at the data that Ed Hyatt and some of the original Los Alamos data and--remember that was applied to the nuclear area, and the nuclear area has always used internal dosimetry and whole body counting to know if there was

any problems. And as a general statement, respirators have created no problems that I know of of any consequence in the Department of Energy, or in the NRC, because of the protection factor failing. Now, maybe we over prescribed or something, but there's not an obvious defect in going back to those early '70 data and that philosophy that we used to get a rough number. And I think we're over interpreting that number or maybe we're trying to push it too far in this process.

MR. SPARKS: I've got an interest to keep it .... But if we do have some time later on that is not accounted for we can return to some of these things. We did start you five (5) minutes late so I did let you go over five (5) minutes. Next speaker. I don't want to mispronounce your name, sir, so do you want to do it for us.

ROBIN HOWIE: Robin Howie. I always get concerned when I hear scientists discussing respirators, because they tend to get hung up in numbers without ever looking at the philosophy of what the hell the numbers are for.

So what I actually want to look at is philosophy of what the previous speaker has done, because if you get a philosophy wrong, the numbers are totally and utterly irrelevant. So, could I have the slide projector on, please? Now, a fifty fifty (50/50) chance these things are the wrong way around.

All this is is a philosophy, it is not science. So, let's talk about discussing selecting a respirator to protect you. What all I tell people, none of us are ever going to have to wear

a respirator to protect our health, in earnest. We may play at being a worker for running a study, but think of the poor sot who is going to have to wear this thing day in, day out, year in, year out. He's the customer, not some ... that takes money out of NIOSH to fund a study. So let's ask ... protecting us, and let's protect us against substances present at fifty (50) times TLV. And if these substances, present separately, sodium hydroxide, xyrene and crocidolite. Any comments?

These substances all equally toxic. Yes, or no?

(Audience response: "No.")

MR. HOWIE: No, thank you. All right, let's just reinforce that. Sodium hydroxide is a mere element, xylene is a mere element, a narcotic that effects blood cell count, crocidolite is fibrogenic and carcinogenic. Let me remind you, that point two five (.25) ... is a fibrogenic health standard, it does not cover cancer. On the major ... crocidolite is not only a carcinogenic material, it's co-carcinogenic with smoking.

If I give you a respirator with a protection factor, however defined, of fifty (50), would you be equally happy wearing it against crocidolite and you would against a sodium hydroxide? I wouldn't, I tell you that right now, Allen. I want more reliability for a higher hazard, or a higher risk. So what I'm saying is that the greater the consequences of equipment failure, the greater the confidence that I require for me that that beast will actually protect me.

So, for a given device or class of devices, the greater the

risk, we should set lower APF. Because, don't forget, if you under specify the equipment your previous speakers' workers are going to wear air line equipment, but ... particulate. Now, that's damn stupid. So, if we set lower APF, then we should set lower APF for high toxicity than we set for low toxicity. That's common sense.

So you end up with a table that looks more or less like that. We'll quantify what we're talking about in a second. If you're not sure of your classification of toxicity, you assume like a good hygienist, of course, this stuff is toxic. The big problem that we have made in the past, we assumed safe until proven dangerous. That's bad philosophy. If we're wearing equipment that consequence in a high of failure, and a high concentration, that's going to be more severe than in a low concentration, because the body burden is going to be greater. So you can modify your table into that format. Higher concentration you require greater reliability because if it fails more is going to go wrong with you.

Let's look at warning properties. If it's got good warning properties and my mask doesn't fit, I'll smell it, or taste it, or be irritated by it. So that might warn me that my kit is not protecting me. If it doesn't protect me, I can hardly ask anyone else to wear it to protect them. Come on, put yourself in the position of the end user, because he's the person that pays your salary.

So, for a given device we should set lower APF if it's got a

poor warning property than if it's got a high. And you end up with a table that looks like that. Good warning property should ... to be at least a tenth of TLV, because I've got a cold just now, I can't smell perfume, I couldn't smell somebody's dirty feet if I tried. I can't smell anything. So, if you've got poor subjective detection for a given substance, set low APF. In other words, the APF is a function not only of the device, but the environment in which that device is going to be used.

What you can't see, it says on the bottom there he says he doesn't need his gas mask because he's got a bad cold and he can't smell a thing. That is true. So remember warning properties are limited. They vary by individual, they vary within the individual depending upon the condition he's in. And also don't forget olfactory fatigue. You can smell H_2 at low concentration, if it hits you at a high concentration, you don't smell it.

Let's talk about duration of wear, something else we tend to forget. If I'm going to fit a tight fitting device, and I've got to wear it for a long time, I might modify the fit to reduce the discomfort. This handsome fellow with a big nose is testing with a respirator. That's the mark ... of a half-mask, and there's the mark of the strap on the cheek. This charming young lady--look at the mark on her nose. And that's the mask work for ten (10) minutes. There's no way she can wear it as tight for as long, and we ask her to wear it for four (4) or five (5) hours. Particularly if it's a dusty, dirty environment and dust gets under that facepiece and starts rubbing. ... going to live in

the real world, not the laboratory.

So, if for a given device the consequence of failure over longer periods will be greater a normal ... appears, because the body burden is greater over the longer period of exposure. So you're going to need greater reliability over the longer period. So for a tight fitting device--and this doesn't apply to loose fitting devices which tend to be less uncomfortable--a tight fitting device; set lower APF for longer wear periods than for shorter wear periods. Come back to look at the realities of the poor sot that's gotta wear it.

Let's look at training. We know that well-trained and well-supervised wearers are likely to achieve better fit. I can quote Warren Myers who commented on one of these studies, that the WPF results that he reported and probably over optimistic because the wearers were trained and supervised by NIOSH investigators. It comes back to your comment, sir, you hang a kit on someone, they know something's happening, they modify their performance. All right, you can't quite see . . . .

This is a typical disposable respirator. Because it's uncomfortable he cut the bottom strap off. Now a supervisor will see that and say, hey, another mask on. What you really often see, also, is both straps below the ear, because it's less uncomfortable to wear it that way. The performance of the kit is not simply the kit itself, it's the interaction of the kit with the wearer. And let's not forget, it's the wearer we're trying to protect. He's the person that's most important, not us.

Any comments on this one? How often you see that out in the workplace? No supervision. Who do you go to? This is a manufacturer's sales photograph, he can't get it right. Now what chance has the user got to get it right if the fellow that makes the kit can't tell him how it should be used? So, unless the employer can demonstrate good training and good supervision set lower APF again. And you should deem him to supply good training only if he can prove that the expected penetration is achieved. In other words, assume again that it's bad unless he can prove good. Always assume that you're going to go to the fail safe situation. Never assume safe.

Now, let me comment also--I'll come back against a comment that was made this morning. Any equipment which has never been demonstrated for it's performance in the lab should ... set lower APF. How many of you would buy a car which had only ever been tested ... road? You wouldn't. You buy a car that's been tested to run as a car on the public highway. I wouldn't get a . . .

ROBIN HOWIE: (Con't) . . . so, I want the respirator to be used against my materials fifty (50) times TLV, I've no WPF or biological ... data on the ... two (2) hours. So, I go into my data. So, here's the conditions; for fifty (50) times TLV, so I've got hundred (100) of NOH, five thousand (5,000) xylene, ten ... crocidolite. I assign toxicity. So, I think it's quite clear that a simple irritant, ... soda is low, xylene is ... because it's narcotic in effect--blood cell count--crocidolite by any definition must be high; must be high.

What's the IDLH? Two hundred ..., thousand (1,000) PPM, and CA, of course, means that a carcinogen--there's none assigned. Now what that means is that my challenge concentration for sodium hydroxide is below IDLH, the xylene is above IDLH, and the crocidolite by definition is above IDLH.

By detection level I can smell a ... one (1) milligram per liter ... about TLV. Xylene on the top end ... detection level, forty (40) PPM, which is half standard, so it's about standard. Crocidolite has got no warning property at all. It is very often present with cement dust, plaster dust .... It's crocidolite we're interested in. And if I go into my ... table I can assign protection factor--the SPF .... I half it for caustic soda, eighth it for xylene, and I use my factor thirty-two (32) for crocidolite. So, it's the same device. It's the same concentration material .... But I'm wanting greater security to protect my health. If I protect my health, I'm going to protect

the person whose health I'm paid to protect.

Let's look at the duration of wear. Remember it was two (2) hours, so I'm going to half my value, because it was a long-term period of wear. I'm ... provision, so I call it one (1). From that ... I can now set my assigned protection factors remembering that my multiplying APF was times one (1), times two (2), times three (3). So, hydroxide, SPF of one four (14); xylene, sixteen (16); crocidolite, sixty-four (64). These materials are all present at the same concentration, but there is no need to buy a phenomenally expensive, uncomfortable, and complicated kit to protect against what is essentially a simple irritant.

I totally agree with Dr. Johnson's comment that we should not unnecessarily set stupid numbers when the stupid numbers are not required.

Now, let me just reverse slightly and say, right; paraphrase, thank you, sir. How do we actually, now having done that, identify the devices which we're going to use? I can say, all right, what SBF do I require NIOSH or health ... from the UK to assign to a device that I'm satisfied will protect me ... times TLV? So, I actually ... protection factor of two hundred (200) for the hydroxide, eight hundred (800) for the xylene, and three thousand (3,000) for the crocidolite. In other words, the concentration of exposure is still fifty (50) times TLV in all cases, but by taking account of all the factors I've got a simple thing that even an inspector can understand.

Thank you very much gentlemen and ladies.

ALAN HACK: Did I hear you say, Robin, that that ... IDLH-- you were suggesting ... was IDLH and not concentration?

MR. HOWIE: No, no, no, no. I was suggesting that because crocidolite has not been assigned a IDLH that any concentration ... the TLV should be regarded as being in excess of IDLH. Philosophically.

ALAN HACK: I would disagree with philosophically, because the test--my independent test ... you're running there to save a guy if you were unprotected, if he collapsed. Most of us would ... we wouldn't run it if it was oxygen deficient. So, the practical ... for IDLH, that's not IDLH for asbestos.

MR. HOWIE: All right, let me just hold that now, because that's a critical point. Obviously, you take the kind of thing like oxygen deficiency. My great concern is that many people do not regard blue asbestos, crocidolite as an acute health hazard. We know from literature that numbers of persons ... among cancers due to short term, high level exposures to crocidolite. Now I define that as acute. Acute doesn't mean to say I breath in and fall over. Acute means I breathed it in, and because I breathed it in then, there may well be a health occurrence at some point.

ALAN HACK: What respirator would you have selected?

MR. HOWIE: All right, from that table I'd probably be carefully happy with a disposable half-mask against the sodium hydroxide; probably a full facepiece negative pressure for the xylene; and certain a full face positive pressure minimum for the crocidolite.

[crescetalyte].

ALAN HACK: Well, you've got all three (3) of them, so you have to pick one (1) . . . .

MR. HOWIE: No, no, I said knowing that they'll be present on their own. ... are mixed. ... environments to show the differences that you would set in terms of the kit you ask people to wear.

DR. WARREN R. MYERS: My name is Warren Myers, and I am from West Virginia University. What I would like to do today is report to you about a study that is in progress that is being sponsored by the National Paint and Coating Association with West Virginia University. I need to let you know that this is a study in progress. We have not had opportunities to, in any detail, analyze any data, look for many relationships, or anything like that. Most of the things in the way of the data that I'll show you are primarily summary in nature. But I do want to take some time to talk to you about the protocols that we used, and some of the assumptions that we've made in the sampling we've done, and some of the problems that have arisen from them.

Briefly, what I'd first like to do is just to give you an idea of some of the things that we'd hoped to achieve. Some of our objectives were to measure performance under actual work conditions in a number of industrial operations. We wanted to collect workplace protection data on six (6) types of half-facepiece respirators, three (3) elastomerics, and three (3) disposables, all of which are currently NIOSH certified. We

wanted to collect workplace protection factor data while respirators are conscientiously worn and used, and then based on those WPF data, provide that data set to the community so that recommendations on assigning protection factors for half-facepiece respirators could be made.

The scope of the study is to collect between a hundred and fifty (150) and a hundred and eighty (180) valid workplace protection factor measurements. We are a little--on our actual samples we have approximately one hundred (100). We are actually about two-thirds (2/3) of the way through the study. We wanted to evaluate both the elastomeric and disposable respirator classes of dust, fume, mist and paint spray respirators in various use applications.

In the original protocol we envisioned evaluating the dust, fume and mist respirators in some foundries, and, in fact, we have done that. Three (3) foundries were utilized for the testing. The second application was paint spray, and there we've utilized aircraft painting, specifically. I'll talk a little bit more about that after the break, but it was at Kelly Air Force Base; a facility there that paints B-52 bombers and C-5 transports. We actually did this study while they were painting B-52 bombers. This was before Operation Desert Shield so there were bombers to paint.

The third area was in dust, and we originally visualized silica processing as one principle area we could go into. We've really been unable to find any suitable silica facilities, and so

we're looking now at other dust areas, and we hope to have this data within the next--collected within the next three (3) to four (4) months.

The respirators that we're looking at, again, elastomeric and disposable, American Optical, Mine Safety Appliances, Scott, a disposable 3-M 9920, which is a dust, fume and mist configuration, 3-M 8710, which is just the dust, and the [Gerson] 1710 is dust. And as I mentioned, the samples that we've completed to date are three (3) foundries and an aircraft paint facility.

Some of the samples that we have analyzed and taken a look at; and at this point in time I think I'm going to be slowing down a little bit here in my presentation and getting a little bit more in depth in looking at some of these different things, but in the blank samples we've looked at manufacturer blanks, laboratory blinds, working blanks, as well as samples for inside and outside the respirator, and impactor samples.

The analysis that we conducted were PIXEA and that analysis was described to you this morning by Barry in his presentation. In addition, we've done some SEM work looking at particle sizes on the filters collected from the in-facepiece sampling, and then also just to visually examine those filters. I like to see things and it's marvelous what you can figure out sometimes when you can actually see things on the filter. And so it served as a way of visually examining those filters.

Some of the key analytical points; we used point five (.5) micrometer pore polyethylene filter, the diameter was reduced

from twenty-five (25) to eighteen (18) millimeters, beam diameter fifteen (15) millimeters. Basically we were able to analyze about seventy percent (70%) of the filter surface. The cassette wash--this is the same wash procedure--in fact, I think, most of the analytical steps and points are analogous to what NIOSH has reported. The cassette wash was with [specrate] isopropanol, three (3) to five (5) mil wash. And that wash then was filtered through a one (1) micrometer pore filter.

This presents a flow of how we looked at our data, and it's important so you kind of get a feel as I go on through the data here what we're talking about. We had manufacturing blanks, which we call manufacturing blanks, were actually virgin cassettes taken from the material sent to us from the supplier; virgin filters that were analyzed. These virgin cassettes were washed and then the wash was analyzed to look at a blank for these. On the working blanks these were filters that were completely assembled and worn on the worker during the sampling period, open and closed during periods when the in-facepiece cassette was open and closed and worn during the sampling. The primary filter--what we call here the primary filter--then could be analyzed as a blank filter mask. That cassette then could be washed; that wash filter, then, providing an estimate of the wash from that blank. They were both handled with PIXEA analysis.

Just to give you an idea of some of the masses that we saw on the filters--now these are reported in actual masses--PIXEA reports to you total mass in micrograms per cubic centimeter and

to get total mass or any other kind of thing you need to work with that number. It then gives the percent of the total mass that is zinc or any of the other elements. Taking that percent, multiplying it by the total mass and correcting for the area, you can get estimate of total mass. You can see that the numbers here on the virgin filters, as well as on the manufacturer blanks, are, relatively speaking, quite clean. I've only reported here basically these five (5) elements in addition to total mass. They represented the major elements on the filter.

We also, like Barry, saw some--I guess if you would use the word contamination; I'm not so sure I would use that word. I would tend to say that there are substances there from the manufacturing process, and unless the air sample that you're collecting contains those same substances, it may or may not actually represent contamination.

On the working blank, again, we had the wash--now this is the wash from the filter cassette--the primary filter taken out of the cassette, the total masses--zinc, lead, silicone, copper--total mass on the wash filter, and the number of samples here. It's kind of interesting to see that we actually have more on the wash filter than we do on the primary filter. We're going to talk about that in a little bit.

These now are the working blanks compared to the manufacture blanks for a series of elements; the total mass reported on the filter as well as zinc, lead, silicone, copper and iron; the manufacturer filter, and the working blank filter. So this is

the filter taken from the working blank, this is the virgin manufacture filter; quite similar. This is the wash taken from the cassette--the virgin cassette--this is the wash taken from the working blank cassette. And, again, very similar. I think, though, it's important for you to note the difference here between the wash of the cassette and what you actually see on the filter.

The next series of slides will actually show you a little bit about the actual hardware that we used here. This is the actual probe housing. This is what penetrated the wall of the respirator. The green thing coming through here is actually the probe, and this is the cassette that would be attached to the end of this. Now we had a double o-ring seal in here. There's an o-ring that would seal the--basically against the end of the inlet nipple, and also an o-ring that would seal against the circumference of the inlet.

This is a--on the respirator we could change the cassette with this little hand tool that would hold the housing for us, and we could just plug the cassette into the probe housing. This is a heating bonnet. We also used a heating bonnet as NIOSH did to help control the moisture. We basically used the same kind of a technique using a wire here. This is a small bonnet that was made. You can see the wires here that lead down to a battery pack, and I'll show you that. And that bonnet just slipped over the cassette. We actually made the wire long enough that it would basically maintain a temperature in here just enough to

keep the moisture from condensing, and it would give us battery lives of about eight (8) hours of sample. All of our samples have been collected utilizing the heating bonnet. This is how it would go on, and as it's assembled--and of course without the respirator--but the sampling line attached to it.

The battery pack--we did find that to handle the moisture, we had a little moisture trap here that would collect any of the condensate and inside the moisture trap we had some absorbent material that would kind of hold on to the water so if you turned over we didn't get it running into pumps and things.

Our outside and inside raw data, basically filters and cassettes, were handled in much the same way. We have the original cassette. From that we have the primary filter which we could analyze, and we called that the outside filter mass; we have then the wash, and we called that the outside wash mass; we have on the inside the inside filter mass and the inside wash mass, so that we could keep track of these on every thing that we've done. We have collected approximately--I think about sixty-nine (69) foundry samples, and we have done washing on all of those samples.

This slide shows the major elements on the outside filter and wash. The left-hand axis is the data expressed as percent of total mass. The right-hand axis is actually the element mass. And this is for Foundry I. And the green bars represent the filter and the wash expressed as a mass, or percent total mass, and the yellow bars basically represent the same thing expressed

as the element mass. The thing that I think is important here is--now this is the outside filter and wash--for zinc we see that approximately sixty-five to seventy percent (65-70%) of the outside filter mass was zinc--and, of course, correspondingly very high element mass, almost a hundred (100) microgram--but, very small values of zinc were actually detected in the wash. Lead, kind of the same thing. Silicon is somewhat different. We--well, not on this one, maybe on another slide--this one; here, I'll show you that. But there is a difference here between what we see on the filter and in the wash. And that's going to be important as we go on here.

These are the major elements for in-facepiece filter and wash. And again, the same thing. But here again, we see that for the element of zinc we have a high percentage of the mass on the inside facepiece filter is zinc, and a very high element mass value there; very small mass on the wash of the cassette. And we can go through here for each of the foundries. Now, I'm going to focus on zinc and lead, but, again, you'll see here large amounts of mass on the primary filter, small in the wash. Filter, wash. In-facepiece, again, large amounts on the filter, very small amounts in the wash. And the third foundry. Again, the same basic thing is there.

If I could, I'd like to go ahead and get an overhead, if we could turn that off for a second. Thanks.

One of the analyses that we have had a chance to take a look at is the correlation between filter and the wash mass, and I

have two (2) data sets plotted here; primary filter mass, wash filter mass, the green points represent the data for the inside cassette, the yellow for the outside cassette, and the R squared (R^2) within the inside cassette data and the R squared (R^2) for within the set of the outside cassette. Within those individual sets we saw really no correlation between the filter and the wash data. We've not had any further--we've not had opportunity to analyze the data any further at this point in time.

If I could have the--so as we started to look at this we were seeing--go ahead and turn that off--so we were seeing large total masses on the wash filter, but when we looked for lead and zinc we were not seeing a lot of lead and zinc in the wash coming from the cassette. So we decided that we would take a look at some of these things with an SEM. This particular photomicrograph is of the wash filter. That's the filter that the wash is filtered through. This particular photomicrograph is at about four hundred (400) X. You'll see here ten (10) microns is represented by this hash. Some visual observations obviously are that there are some very large, physically large particles on this wash filter. We also took and looked at elementally what was in some of these particles. Now, we've not had an opportunity to rigorously go back and look at all of these filters and look at all the particles and that kind of thing. We've only done a limited number of these. But on this particular particle right here there's silicon, calcium, aluminum, all of those kinds of things. It's probably something from the manufacturing

process itself.

Particle two (2) here; there's a trace of silicon and copper. This particular particle right here traced to silicon and copper. This particular particle is aluminum and calcium; silicon, copper. This particular particle right here is aluminum and calcium. So, in fact, we have very large particles here contributing to the mass that we're measuring on this wash filter. And, in fact, for some of these things where we're looking at silicon and calcium and potassium and other kinds of things, they may well actually appear on the filter, but may not originate actually from leakage of the ambient environment. They may be actually something that is washed from the cassette during the washing process.

This is a sample of a wash taken from an inside cassette. This was a cassette that we used to measure inside the facepiece, and this is, again, the wash filter. This is only three hundred (300) magnification, and this is a hundred (100) micron, and you'll see again very large particles here on that filter. There are some smaller particles here. In fact, these are actually particles here that you can see at higher magnification. But what we see is that with this particular particle right here again we have traces of silicon, copper, aluminum. With this particle over here, copper, titanium, silica, all different kinds of things in here.

So, to kind of summarize here a little bit with our observations on filters and wash data, in our foundries we found that

zinc was the major element in the ambient air, and it's the major element that we found on the filter. By selecting zinc or lead there appears to be little need to do cassette washing since only small portions of these elements are lost to the cassette wall. We did not see any correlation between wash mass and filter mass, and in addition, the particles that we saw on the wash filter were very large and not what you would even considerable close respirability. So, therefore, we did not use our wash data in this initial calculation of our outside or inside concentration or attempt to make that correction in our data. And that is in contradiction to what you heard Barry mention earlier this morning. They did find this kind of thing, we did not.

When we do outside and inside calculations, with PIXEA analysis especially, there are a couple of things that you can use. You can look at mass estimates that are available. Do we look at total airborne mass? In other words, that's what PIXEA can report to us as total mass. Do we look at different elemental masses? Really, what do we look at? And in order for me to try to decide which was the appropriate thing to do, one of the things that I wanted to do was to qualitatively evaluate what we were seeing on the inside and the outside filters.

This particular slide is for Foundry I, and it shows percent of total filter mass for the inside filter cassette and the outside filter cassette--for Foundry I. Now one of the things that is real interesting here is that for chlorine we had literally no chlorine at all in the ambient environment. But yet, on

the in-facepiece filter we had close to fifteen percent (15%) of the total mass was due to chlorine. Obviously that's not arising from the ambient exposure. It's nice to kind of speculate that that might be arising from something from the respiratory tract, from sweating, from other kinds of things, and that's very possible. But at this point in time I really don't know. Lead, we saw basically the same percents inside and outside. Zinc, there is this difference between the inside and the outside, also.

Foundry II; some of the major elements that were there. And again, the thing to look at is the fact that here, again, we see this chlorine that's present on the inside, but not on the outside. And the whole purpose--again we see it with Foundry III. Chlorine is here, but it's not on the outside. Well, this chlorine is being handled in the total filter mass. It is a component of the total filter mass. So basically what we have concluded from this qualitative comparison on the inside and outside filters--we were just going to look at zinc as our element for the calculation of WPFs. We weren't going to do total mass. We weren't going to look at some of these other things, because we really didn't know, or weren't confident about where that was arising from, so we basically have focused on zinc. So all that information that we've gotten from PIXEA is basically now distilled to a single element of zinc for the calculation of WPFs.

Some of the key sampling points; our outside sample was a

respirable sample collected with a Cyclone at one point seven (1.7) liters per minute. As the protocol was developed it was actually suggested that we take this respirable sample on the outside since we were going to be in dust environments. And so that is in fact what we did. And that, by the way, is different, I believe, from what Barry reported to you this morning. Theirs were total outside. Barry did not use a Cyclone to do that. And all the earlier work that I have done is also without a Cyclone. The inside was basically a total dust sample, and we basically made an assumption that the inboard leakage all had particle size of less than ten (10) AMMD. And you've already heard enough discussion about that earlier this morning, but there is some laboratory data to suggest this from Bill Heinz's lab, ... lab, some of the things that I've done as well. And that was at two (2) liters a minute.

Sampling; we looked at first and second half of the shift. And we were sampling for greater than one (1) hour possible. I really don't have this data analyzed, so I don't have anything to report there.

Okay, some more SEM stuff. This is an outside facepiece sample. It's actually taken on a metal pourer--from a fellow who's pouring molten metal into molds. This particular photograph is taken in the center of the filter. It has a magnification here of one thousand (1,000), and you'll see a little hash mark, and that may be difficult to see in the back of the room, but there is a little hash mark there that is one (1) micrometer.

Generally, you can see that these are all physically--their physically diameters--probably much less than ten (10). Now, obviously this sample was not taken to do size analysis, so you've got a lot of loading on here, and particles laying on top of particles, and that kind of thing. But this is a pouring operation. We have fume; you can see the fume in here, this real small kind of spongy stuff. You also have particles here, several particles--again, one (1), two (2), three (3), four (4), probably five (5) particles--here, particle, particle, some kind of a fiber. But this is the outside filter. It looks like the Cyclone works. Nothing unusual here.

This is the inside facepiece sample that matches that outside sample. So, the first one was the outside sample, this is a sample collected from inside the facepiece. They're both the same length, time, that kind of thing. This magnification is a hundred (100) X, or a thousand (1,000) X, so we're not doing anything here by slight-of-hand and magnification; same magnification. Look at how clean this is compared to the outside. Just to give you a quick frame of reference, that's the outside--same magnification, now--outside; inside. And, basically this is in kind of the same area of the filter.

What would you suggest, or what would you think looking at those visually what would you think the protection factor would be on those--on that device? Come on, don't act like my class yesterday. You're not graded on this.

(Response from audience, "A hundred (100).")

WARREN MYERS: At least a hundred (100)? Two hundred (200)? We're talking dollars here? Ten (10)?

(Response from audience, "Five (5).")

WARREN MYERS: Oh, that's kind of interesting. We'll have to talk about why you said ten (10) afterwards, ...

Well, actually the particle size, or the WPF here was not a hundred (100), wasn't fifty (50), it was more like twenty-five (25) based on total mass. Well, wait a minute here. What's kind of going on? Well, one reason is particle size. Now, here's this one (1) little micron hash here, look at this particle. That particle, it's physical size, at least in this one (1) axis, is well over ten (10) microns. Up here you see another kind of a little thing we're going to take a closer look at here in a little bit. You do see some little stuff here, and there are some other areas on here where you do have little stuff, but you have this great big thing.

This is a closeup of the outside filter of just two sides previously. This is the metal pore. Now this is at five thousand (5,000) meg, and you can see again the fume that's in here, and the dust particles. The interesting thing is some of the physical texture of these things. These are kind of all round, kind of nice smooth edges. Kind of keep that in mind, because we're going to see another slide here shortly that's quite a bit different from that. But you can, again, see the fume that's in there.

Again, a little bit higher magnification this time; real

nice structure on the fume, and, of course, the particles themselves. Okay, this gomer is actually something that we found on this inside facepiece filter. When we saw that it looked so clean, we thought where's all this mass coming from. So we actually set out looking for some things on it. Well, this is one (1) of the things that we found. This hash . . .

DAY 1 - TAPE 4 - SIDE B

DR. WARREN R. MYERS: (Con't) . . . . Anybody want to speculate what they think that might be?

(Response from audience, "An insect.")

WARREN MYERS: An insect? No. What else do we have?

(Response from audience, "Off the mast." "Polymer.")

WARREN MYERS: Polymer, okay. Well, that's not bad. It's not an insect part. We actually took a look at this, again, with the SEM, and I'm no mineralogist by any means, but we do believe this is a glass fiber. There's tremendous amounts of silicon in there, and so it looks to be that it would be a glass fiber. And it's actually from a mask that has a fiberglass kind of a pre-filter on it's primary filter. So, we do believe that this is probably a glass fiber here. THis material probably is binder that's used to bind that fiberglass together. But, now, can you imagine what would happen if we used this data on silicon to calculate a WPF? It's kind of meaningless. I mean, all our silicon mass could be here in this one big particle. Another thing that we found on this particular in-facepiece sample--these things are really jewels once you start looking at them, it's really fascinating--we saw this spongy looking thing. Now this is one (1) micrometer right here, so, again, this thing physically looks very, very large. But, I'll tell you, it was so light or so easily detached from the filter that whenever you would scan the electron beam over it to actually take the photomicrograph this thing would jump around just like a tiddly wink--

around the filter. We've looked at this, there's zinc, copper, aluminum, traces of lead, all kinds of stuff in here, and I honestly don't know what this is. I originally thought that this was some kind of a dendritic structure that was on the filter and had broken loose and had come through and was sampled, but I have actually no idea what this really is, where it came from, but it has a lot of stuff that's in there.

Okay, this is a photograph of an outside filter taken at a breakout activity. So they're grind here, they're polishing things, they're taking them out of the mold, doing--actually rough grinding; not so much polishing, but rough grinding. Now, take a look at these particles. Look at how--sharp edges, things seem to be coarse and rough, and, again, this is a breakout activity. Let me very quickly go back to give you a frame of reference. This is a metal pouring activity. See the smooth edges and that kind of stuff, versus this breakout activity.

We actually got to the point where we could pretty darn near tell where the sample came from just from the physical characteristic that was available here from an SEM that, you know, when we'd go back and check the records we were right on. But this isn't a breakout activity. Now the important thing about--or one of the important things about this is this is not an activity where you would expect to see fume based on teh process that's going on there. We're just cutting, grinding, those kinds of things, breaking the molds out. But you'll see fume. This is fume here, and we'll have some closer--all of this

is fume. At least in the foundries that we were at I don't believe there was a place in there we sampled and have looked with the SEM that we don't see fume. And we see mixtures. Even on the pouring operation where you'd think that you're primarily dealing with fume we see a lot of particles.

So, that's the outside, so kind of take a look at that now, and we're going to give you another visual test here. Take that back, this is the same thing at a higher magnification where you can begin to see some of the fume a little bit better than what you could before in there.

Now, this is the in-facepiece sample taken concurrently with that outside sample. Okay, based on your visual observation, this is inside, this is outside, what do you think that protection factor would be? Anybody want to guess again? Total mass. Total mass, now, means just everything you see on the filter. Would you say fifty (50)?

(Inaudible response from audience.)

WARREN MYERS: A hundred (100) to hundred and fifty (150). Actually that's probably what I thought when I first looked at this. It was three (3). It was three (3). Why? What's going on?

Well, one of the things is that you've got very large aerosol in here, and when we're looking at mass we know that mass is a function of diameter cubed. And so one (1) very large particle like this can overshadow literally thousands and thousands of smaller particles on a mass basis. This particular--

here's ten (10) microns. You can see this particle in both axes has a physical diameter much larger than ten (10) microns. Here's some large ones and others.

This is another one--different inside sample, now, but again, here's the ten (10) micron hash right here, and I realize this is kind of dark to see in this room, but you can see a lot of aerosol here that's very large, that on a mass basis can effect these samples. And another one. And to date we've looked at about six (6) sets of these inside/outside samples. We've not looked at all of our data. In fact, if somebody wants to work on a master's project come see me after we're done here, we'll work you out something. Our observations from the SEM analysis; the in-facepiece filter; we assumed that the inboard penetration was less than ten (10) micrometers AMMD based on the laboratory work that basically involves static leaks and that kind of thing, so we collected it as a total dust sample. In reality our physical diameters of the particles that we could measure--we had numerous ones that were larger than ten (10) microns--considering the masses of the elements zinc, lead, silica and that kind of thing, we probably have in-facepiece AMMDs that are much larger than ten (10). And, of course, our outside filter was collected as a respirable sample, and so our physical diameter on the outside filters were all less than--much less than--ten (10).

Well, right away that presented a problem for us, because we're comparing burgers and fries, and we're collecting outside respirable samples; we're collecting inside total dust samples.

Our initial assumption that the aerosol penetrating the face seal does not apear to be valid given the data that we currently have from this study, and as a result we felt that we needed to look a little closer at the respirability of some of the aerosol. If I could have the overhead.

This is from a shakeout activity where we've averaged two (2) impactor samples in Foundry I. This is the distribution based on the total mass. This is the distribution based on zinc; distribution of lead, and the distribution of silicon. And, again, Barry mentioned earlier today that you see different distributions for different operations. We've seen the same thing. Some cases we see trimodal. I didn't plot the curve--the fit curve--here, but we've also looked at single mode, bimodal, trimodal curve fitting to these things to give us the best fit. We've looked at log transform curves, lots of different kinds of curves to fit these things, but generally, in this particular case, this is a trimodal. This one is probably bimodal. Some of the others--but the important thing, again, is to see that the AMMD based on teh total mass is quite different in some of these other things. In this particular case in shakeout it was the lead that was much smaller. The particular program that we used calculates a respirability factor based on the ACGIH respirability curve, and so what we've done here is to use that information to calculate the respirability fraction of this curve, and that actually should--if you'd integrate this area--be the mass that you would basically assume that you would have collected with

your Cyclone.

This is a metal pouring activity versus a shakeout activity. And, again, you'll see different distributions. This zinc distribution is quite markedly different from teh one we saw earlier. The AMMDs here in the metal pouring activity for zinc--if you recall the AMMD in the first one and shakeout was about twelve (12), this one's only three (3). The zinc--here you see one for silicon. This is the one for the lead. So, what we have attempted to do in this first cut of our data--and again I want to emphasize that we're still on the data collection process and this is just basically a report of things in progress--we've looked at trying to come up with an estimate of respirability to use here in some way to correct our outside concentration samples. And so what we've actually done here is; the program that we used will calculate this respirability based on any set of intervals that we select down here. If we select the total range for the impactor--by the way was a PIXEA impactor, the same impactor that--type of impactor that Barry showed you on the screen, so that will give you a frame of reference for that. If we do the whole distribution we see we have a respirability of point four eight five (.485), or approximately half of this aerosol mass would respirable. If we back off from the top interval which had a cut size of sixteen (16), back to the second which had a cut size of eight (8) and use just those intervals, again we get a higher estimate of respirability because we're lopping off this upper end. So, in order for this first cut to

be conservative we've actually used this estimate of respirability here to try to provide some means of correcting our outside concentrations.

So, for our computation of outside and inside values at this point in time the information that I'll subsequently report basically was calculated like this. We took the outside filter mass minus the blank filter mass, corrected that for the respirability and divided it by the sampling volume outside, and the inside was simply the filter mass minus any working blank mass and corrected for inside volume. I see my time here for this first presentation is about done. I can stop here if you'd like and we can go ahead and pick up the rest of the data when we go through with the paint spray, so that we can kind of keep on some agenda, Larry, if you'd like.

MR. SPARKS: Yeah ... people probably would like to have a break. Barry, do you have a comment?

BARRY PALLAY: Yes. Two (2) points. One is, I'd like to concur with Warren in the utility of looking at assumptions as he's showing us he's doing. In response to a question we had earlier, and it touches on this too, we too had found it useful to look at the filters after the studies. And PIXEA made it very easy to do that. About two (2) years ago we started looking with scanning electron microscope, and also optically, at the filters in the same way that Warren is showing you here. And it is very helpful.

The second point is, what Warren alluded to as an apparent

inconsistency in the deposition on the walls, I don't think that's necessarily the case. The two (2) studies we conducted that I reported on here were done without resistence wire around the cassette, so there was moisture in the cassettes. After we found that problem we came up with the procedure of using resistence wires, and in the subsequent studies we have. If you look at the percent on the wall of the ambient cassettes of ours, you'll see that the percent is much, much lower than the percent of lead inside the facepiece of those cassettes. And, so for our studies, to compare with Warren's, I think you need to make the wall correction for ours, because of the problem of moisture. And I would also--let me just mention, I concur with Warren, too, in our studies we're looking at--we're keying in on lead. There was no lead contamination from any sources that we have found when we did wall washes and so on, just a Warren has keyed in on zinc in his particular situation. So, whereas we have a lot of data on lots of different elements, you have to be careful about which ones you're going to be preparing workplace protection factor calculations on.

WARREN MYERS: Barry, did you look at your wash filters?

BARRY PALLAY: Yes, yes, we did. We followed the same procedure. We didn't see lead on any of the wash filters or any of the washing.

WARREN MYERS: No, no. Did you look at the wash filters under SEM?

BARRY PALLAY: Yes, it's been about a year or so. I just

have to--I'd have to look back at my notes.

WARREN MYERS: Did you find--did you see particles there?

BARRY PALLAY: Yes, yes.

WARREN MYERS: Large?

BARRY PALLAY: That's right, our results are fairly consistent with what you've noticed. There are all sorts of things on those filters.

WARREN MYERS: But if you have these big particles on that wash filter that are not respirable, how do you fold that into your--and that may be something we need to sit down . . .

BARRY PALLAY: Well, in the case of our analysis, I reported on lead. And none of the particles that we noticed in washes or in any other areas were showing up with any lead concentrations.

WARREN MYERS: Well, some of them had to have lead. I mean--or you wouldn't have measured any lead on the inside, right?

BARRY PALLAY: Well, the lead that we found did not appear to come from manufacturing blanks, from the walls of the cassettes, or from any other area aside from the plant.

WARREN MYERS: Oh, okay.

LARRY SPARKS: . . . get back at about ten (10) after.

(Whereupon, a break was taken for approximately ten minutes.)

DR. WARREN R. MYERS: What I'd like to do now is actually to give you a brief overview of our data, having taken you through all the description of the hardware and the information that we used to get to the point where we actually felt we could begin to

calculate some estimates of workplace protection factors.

Foundry I; this is an overview. We had thirteen (13) workers involved in that particular site. We did two (2) shifts; a day shift and an evening shift. We did seven (7) distinct tasks in the foundry. This was with the dust, fume and mist class respirators. We used three (3) elastomeric and one (1) disposable, and we actually collected thirty-four (34) WPF measurements at this site.

Foundry II; there's actually only three (3) workers. This was the first foundry we did. It's kind of a shakedown thing. Three (3) workers, one (1) shift, one (1) task; it was metal pouring only. Again, dust, fume and mist class with both the elastomeric and the dust, fume and mist disposable, and we had nine (9) WPF measurements there.

Foundry III involved nine (9) workers. Again, just one (1) shift; five (5) tasks; again, all four (4) of the dust, fume and mist class respirators were used, and we obtained twenty-six (26) WPF measurements.

What I'd like to do is to kind of show you a little bit of what the sampling trains and aparatus looked like on individuals. I'm sure most of you have seen these before, with the two (2) sampling pumps, the battery holder for the little heater, and the water trap. You can see how the heating bonnet goes over the cassette here, the electrical lines to it just were kind of mated here to the sampling line. It made a very nice compact sampling train of the outside sample.

This is Darth Vader. Actually this fellow, Lee, was one of the metal pourers--glasses for UV and that kind of thing. Again, heating bonnet here; this is with the nine nine twenty (9920) dust, fume and mist. These guys are actually preparing a crucible to pour; going through their pouring activity. And, again, the instrumentation itself really presented no problem with them accomplishing their work task. That's Son of Darth Vader. That's his buddy. Actually it looks like he has a green ear here. That's not, that's just a light back there.

This is the grinding operation. Actually in breakout the molds are taken out--castings are taken out--and rough edges ground and that kind of thing.

Just a little sidelight here, this was a facility that manufactured commemorative bronze memorials, that kind of thing, as well as grave markers for the military, so that when a Veteran would die they would send in the names and they would prepare a bronze grave marker for them. One of our guys was jagging one of these guys and so they send through a mold that had his name on it.

This is a composite slide, now, for foundries and painting operations, but what it is is, it's a plot of the in-facepiece concentration; outside concentration; for the red are the foundry operations, and green the paint spraying observations. Now, we have not had a chance yet to look to see any regression relationships here in these data sets. Just from looking at this, there may be something here. I don't know, but, again, there's nothing

real strong, at least for the foundry--if we look just at the foundry and not the paint there may be someting there, I don't know. But again, it's all over the board and there's no clear relationship there.

Modern technology is wonderful. You can do so many things with these plotting programs and everything, and you can do overheads and you can do hard copies and everything, but the thing of it is, when you want to go to make slides, see, these files have got to be compatible. Well, you know, Harvard Graphics makes [scotofiles] and they do some things nice, but if you want to do a log probability plot Harvard Graphics can't do that so you get a software package that will do log probability plots. Well, low and behold, it doesn't produce output files that coincide with most slide making programs, so you have to output them as Hewlett Packard graphics files. And they don't translate right, and so what you end up is with a mixture of slides and overheads. So that's why we're going back and forth between slides and overheads here.

This is the ambient zinc and lead concentration distributions in these foundry operations. This is for all three (3) foundries combined. We have the lead distribution, log normal distribution, sixty-nine (69) observations, the geometric mean concentration of fifty-two (52) micrograms per cubic meter, GSD of two point eight (2.8). Zinc; geometric mean of two fifty-nine (259), GSD of three point two (3.2), and, again, sixty-nine (69) observations. A nice log normal distribution.

These are the in-facepiece and outside zinc concentrations for the foundry, and, again, this is the same thing as you saw in the previous slide, as a source of reference. These are the inside concentrations, now. Again, sixty-nine (69) observations, log normal distribution, geometric mean now of two point four (2.4), GSD is six point one seven (6.17). GSD is much larger here on this.

We'll move on to the painting operation. Here we had twenty three (23) workers, all three (3) shifts were involved here. Paint spraying would start on the afternoon shift, they would go through a primer application and two (2) top coat applications that would require about a twenty-four (24) hour period. In this facility the [hepa OV] combination was required, and we were only able to evaluate the three (3) elastomeric facepieces in this particular operation. And we were able to get twenty six (26) workplace protection factor measurements.

Some of the major elements inside and outside the filters on the paint spraying operations; again, the inside and outside. This is for the primer, and the primary elements on the ambient sample were chromium and strontium chromate. We do have some titanium, a little bit of chlorine and silica. The inside, though, is quite different. Look at the chlorine here as a percent mass on that filter. Now, it was extremely hot in that hanger. We were out there one day at six o'clock (6:00) and I believe it was about a hundred and twelve (112) in the hanger. Very, very warm and a lot of sweating and that kind of thing.

So, some of this may, in fact, be due to that. With the primer we targeted either chromium or strontium as our element of choice to look at in the analysis.

This is the major elements inside and outside on filters--again, this is for the top coat, not the primer. You can see here from the red, the outside, two (2) primary ones are silicon and titanium. We keyed on titanium. Inside, again, you can see that the largest component, again, is this chlorine. So we did not use total mass or anything in the calculations--based on the total filter mass. Basically, here we've looked at titanium for top coat, chromium for primer. We did not wash the cassettes here. Once that paint sets you don't get it off, and so washing the cassettes was kind of redundant or irrelevant, so we did not wash the cassettes in this case.

Some of the airborne concentration of the primer; and we have three (3) different concentrations here that we're tracking on different activities. We've got CO calculated from teh total airborne mass as chromium or as strontium, by location on the aircraft. And as Barry has mentioned earlier today, and others that you have seen in the literature, and this is kind of--you know there's nothing new here--different operations, different activities, you see different exposure extimates. And on top of the aircraft, for the primer, at least, we saw higher concentrations than we did under the fuselage and the wing, or on the side of the fuselage either as total airborne mass, chromium or strontium. And you'll see this relationship between chromium and

strontium here between all three (3) of those.

This is the in-facepiece concentration on the primer. And, again, by location--subgrouped by location--of painting on the aircraft, again, the same three (3) elements, and total mass; chromium and strontium. We don't see that relationship between strontium and chromium now that we did on the outside, and I'm not sure why that's happening.

Here are some WPF measurements for the primer application. Again, based on which one of these we were looking at, the largest measured or calculated WPF occuring on top of the aircraft and smaller under the wing and fuselage and on the side. And, again, you see this difference between what particular thing you want to track and keep track of or use for your calculation of the WPF.

Moving on to the top coat on these aircraft. More sample numbers here, because two (2) shifts paint top coat, only one (1) shift paints primer. In this case we're looking at total airborne mass in just titanium. Top of the aircraft; again under the fuselage and wing, and to the side of the fuselage. So, total airborne mass concentrations here; thousand (1,000), three thousand (3,000), almost four thousand (4,000), two thousand (2,000) micrograms per cubic meter as paint spray.

In-facepiece concentrations, again for the top coat application; top of the aircraft, same locations, and you can see the same kind of thing that's occuring here. All the inside titanium concentration were well below one (1) microgram per cubic meter.

And the WPF measurement; here again, we get difference for different locations. Now some of this may be due to sample numbers. We don't have equal sample numbers here, and that kind of thing, but, both for total airborne mass and titanium.

Here we have some individual and worker mean workplace protection factors for paint operations. We have a number of--this data is plotted several ways. The green is actually a plot of the individual observations. The magenta is actually a plot of teh worker means. Some of the workers wore more than one (1) respirator and we just pooled that information on workers for this particular plot. The geometric means are not much different whether we used the individual observations or the worker means. The GSD changed somewhat. Of course we had different sample numbers there when we pooled some of those things. In this particular case five percent (5%) here is real high.

When we--this particular slide puts this together by operation for foundries and for paint spray. For the foundries for respirators one (1), two (2), three (3), and four (4), we see that the geometric mean workplace protection factors ranged from ninety four (94) to a hundred and sixty three (163) for respirators. With the three (3) respirators that we used for paint spray we had much, much higher WPF measurements, and I'm going to digress here just for a minute. I think part of that is more and likely due to the size of the overspray. We were not able to size that overspray. That's kind of a difficult thing to do, and we were not able to actually do that.

Another thing that I noticed in actually being in that environment wearing my respirator is that, if I was working there and I turned my head and I get a temporary leak, I could smell MEK. And if I turned my head back and I could still smell it, I adjusted my respirator. If I turned my head or looked up and got a whiff and looked back down it may reseat; I wouldn't smell anything. And you heard Robin mention something about warning properties, and in this particular case these guys are getting continuous feedback on the performance of that device; on the performance of the fit. Now, when it fit, when my device fit, I didn't smell anything. I mean nothing. There was nothing coming through. You get a little break and you could detect it. It almost gets back to classic human factors, and if you want to change someone's behavior you give them the necessary information they need to adjust that behavior. And, so the odor characteristics of the MEK in this case actually provided that. And I think in part that may have helped these individuals because in the foundry they did not get that. These folks in the foundry; there was nothing there that was unique that you could tell the respirator itself the seal had broken, or temporarilly dislodged, or whatever. They did not have that feedback. So that feedback here may have actually been pretty important in providing that level of protection.

And lastly, this particular slide just shows the distributions for the two (2) primary operations, foundry and paint spray. These were the WPF measurements, and for the foundry this

distribution, geometric mean of a hundred nineteen (119), GSD of four point four (4.4), sixty five (65) observations, the paint spray here at the five percent (5%) level, for the foundry we're looking at basically ten (10), and out here for the paint spray operation something about a thousand (1,000) or something in that area.

That takes care of the data presentation. I'll address any question you may have.

LISA BROSSEAU: I just ... question about those last two (2) slides. Are those workplace protection factors for the single elements or are they total airborne masses?

WARREN MYERS: For the single element. The foundry was just zinc and the paint spray facility was titanium for the top coat, chromium for the primer.

BOB BRENNAN: The last slide was very startling, of course. You've got virtually an average of a hundred (100) protection factor ... an average of forty thousand (40,000) protection factor. Very dramatic. Two (2) questions. Of the facepieces--I know they couldn't use the disposable in the aircraft--of the facepieces are we talking about the same models in the two (2) different environments, or completely different models?

WARREN MYERS: That particular slide?

BOB BRENNAN: Yeah.

WARREN MYERS: The average is not forty thousand (40,000). The geometric mean . . .

BOB BRENNAN: Oh, I'm sorry. I was briefly picking it up

off the mean--off the overhead. Sorry. Let me rephrase it. You have a spread, a dramatic spread, of better than order of magnitude, okay?

WARREN MYERS: Yes, between the foundry operations and paint spray.

BOB BRENNAN: What my real--I have two (2) questions--some of the things that were mentioned here this morning--are you talking similar classes of respirators or similar model respirators in the two (2) studies?

WARREN MYERS: The actual respirators that we used in the foundry equipped with dust, fume and mist filters were the exact same respirators that we used in the paint spraying operation, only they are equipped with [hepa OV] combination. So they are exactly the same respirators.

BOB BRENNAN: And the other question that goes with that is, obviously they're different people, and obviously different techniques were used to measure. The one thing that you said--made mention about--once the paint dries the cassette is gone. Do you make any kind of estimate as to just what that loss of material on the cassettes might have done to the paint study?

HARRY ETTINGER: . . . tests for workplace protection factor measurement for certification. You didn't wash the walls, he did.

WARREN MYERS: No, that's not true. We washed the walls in the foundry. We washed the walls. We got to the point that we decided that . . .

HARRY ETTINGER: It wasn't significant.

WARREN MYERS: . . . it was not significant.

HARRY ETTINGER: You found washing the walls wasn't significant. He found it was very significant. In terms of lung deposition Barry found it very important. I assume you didn't do it since you didn't mention it.

WARREN MYERS: This is just a progress report, so we've not done anything . . . .

HARRY ETTINGER: . . . we have a basis for a test method. He made a--Barry made a big point about size dependence, and you, apparently, did not worry about that at this stage.

WARREN MYERS: No, I'm very concerned about the size.

HARRY ETTINGER: In terms of the data, you did not break it down as work protection factor as a function of particle size.

WARREN MYERS: No, we did not as a function of . . .

HARRY ETTINGER: I realize you're ..., I'm just trying to put it in prospective . . . .

WARREN MYERS: The only correction that we attempted to make was to deal with the fact that we had taken a respirable sample

outside and a total inside, and we were getting apples and oranges. So at this stage . . .

HARRY ETTINGER: And you were correcting ... control it.

WARREN MYERS: So at this stage that' the only thing that we've done.

HARRY ETTINGER: And in terms of elements, he worked--you worked with very different elements. You narrow it down to using zinc, and then chromium, strontium, and titanium and [chlorodine], I assume. So that even though you started from pretty much the same point, there are at this stage fairly major differences in the way you did the experiment.

WARREN MYERS: Well, the elements are going to be dependent on where you go. I mean, he went to a place where they were manufacturing lead batteries so that was the element.

HARRY ETTINGER: But the two (2) different--the elements have an impact on the result, because of a variety of things about the solubility, the characteristics of the aerosol. But even though you both started pretty much the same point, the end product you use as an experimental protocol had significant differences.

WARREN MYERS: Yes, yes.

HARRY ETTINGER: And I do think that's the only point, because I think one of the things we're looking at here is, where do we stand in terms of having a protocol that people could use. You and Barry started very close; you live close together; I think you started together in some ways; you were originally

involved in this, and, yet, the end products only three (3) years later are fairly different.

WARREN MYERS: Yes.

HARRY HERMAN: Warren, I don't remember whether the respirators were the same under the foundry. There are four (4) different respirators. Were they all the same model, make?

WARREN MYERS: No, there are four (4) brands; three (3) elastomeric dust, fume and mist, and one (1) disposable dust, fume and mist.

HARRY HERMAN: So basic--was number two--which . . . ?

WARREN MYERS: Oh, I'm not telling you that.

HARRY HERMAN: Okay, (inaudible).

WARREN MYERS: I'm not giving away all the goodies. I cannot answer that. I don't know if those will be identified in the final report or not. That's really up to the sponsoring agencies as to how that appears.

HARRY HERMAN: . . . my question is, did the results correlate with the type of respirator as you might expect them to; the one of higher integrity having higher . . . ?

WARREN MYERS: Well, all you have to do is look at those. I mean, is there any difference there between those four (4)? I mean, one (1) of them is a disposable, and three (3) of them are elastomerics. Is there any difference there? No.

HARRY ETTINGER: Well, one's a factor of two (2) higher. The blue one is like two hundred (200), the others are like a hundred (100).

WARREN MYERS: Well, if you consider . . . .

HARRY ETTINGER: That's the numbers that Gary is talking about; a factor of one and a half (1 1/2) is his lung deposition, and he is calling that significant. So in putting the same context . . . .

WARREN MYERS: I don't see a difference there to put that in context.

HARRY ETTINGER: Well, I'm just saying that . . . .

(Inaudible discussion.)

BARRY PALLAY: Harry, are you trying to get me into a fight with Warren here?

HARRY ETTINGER: I was too late to bring up this morning that the lung deposition is only like a factor of one and a half (1 1/2). And whether ... significant as . . . .

BARRY PALLAY: Let me just comment again. Let me say it for the second time. The two (2) studies we conducted were--I did not use the resistance wire to heat the cassettes. After the problem became so obvious we did develop the resistance wire and so on. So in Warren's study, then, he incorporated that resistance wire to heat it. So that if you look at the deposition on the walls, on the ambient walls we have much less. There may be some similarity. On the in-facepiece samples for our study, since we didn't heat those walls, you really need to add the walls and the filter. So, that's the--hopefully I don't have to repeat it.

ALAN HACK: Warren, you might want to put your professor's

hat back on and ask if there's anybody in the room who thinks those four (4) numbers ... significantly different.

WARREN MYERS: Does anyone think any of those four (4) numbers are significantly different than one another? Raise your hand.

JAY PARKER: Since we only have four (4) brands there, that's one thing, but I won't argue that point. On the paint spray test I see that you used organic vapor high-efficiency. Why did you use that combination when that's not the normal paint spray configuration?

WARREN MYERS: Legitimate question. That's what the people used; that's what we were required to use if we wanted to do the study there.

JAY PARKER: Isn't that an isocyanine containing paint?

WARREN MYERS: Yes, I believe it was. Without giving any military secrets away.

MARGIE ZALESAK: On the spray paint, why do you think the impact of the loss of the solvent ... particle you originally collected impacted on your workplace protection factor?

WARREN MYERS: Very good question; I don't know. And that's one of the reasons it's very difficult to do particle sizing on that; size changes over time.

MARGIE ZALESAK: It seems to me that because of the loss of the solvent I would have expected that you lost some of your mass, and with the particles you would expect a high protection factor.

WARREN MYERS: No, no, but the mass comparison is the same, because we're comparing total filter mass outside and total filter mass inside.

MARGIE ZALESAK: That's an assumption. That's not necessarily the case.

WARREN MYERS: I would say that it is not an assumption, it is the case. The analysis is not going to detect organic vapors.

MARGIE ZALESAK: No, but the particle size going into your facepiece, where there's going to go around a curve, is going to be effected by the solid; how large of particles ... curve. And because of the difference, I would expect that to effect your outcome.

WARREN MYERS: I don't know.

HOWARD COHEN: I want to get back to what you said, Harry, in that I think that if you wanted to develop some standard methodologies you have to do like you do in toxicology. You have to develop a standard white rat. You have to have one (1) workplace, and these poor workers who are the test guinea pigs of the world, because the amount of variables in all these studies that have been published and whatever, made comparison of one study to another; almost impossible. It's almost like a learning experience. Each one you learn something about how to do a study in other workplaces. And I don't see any way to really compare these studies to each other. And since we're probably the largest brass foundry in the country, I can tell you if you do wall cassette washings for zinc oxide it would be different that

copper oxide. We've done several thousand of them. We've done that kind of work. And so each contaminant situation . . .

WARREN MYERS: Do you see a difference in wall losses?

HOWARD COHEN: . . . much different. Copper, for example, is a highly reactive compound. And when you form copper oxide it's a large particle size, which is why the copper fume standards never made a lot of sense to me; that OSHA has. Zinc oxide is not very reactive, it's a very small particle, and you'd see less of it on the sidewall than you would copper. But that's getting off to the side. The main point is that all these studies just have so many variables and key in on the substances and the way people operate, that if you really don't end up--maybe NIOSH, instead of building a test facility here, build a workplace and hire people to do nothing but simulate work, and maybe they can produce ... we sell it, and it helps pay the deficit. But basically, if you don't do that, I don't see how--you will be testing your hamburgers and french fries an awful lot in the future.

(Inaudible discussion.)

JIM JOHNSON: Are you planning in your protocol to look at the performance of the respirators with and without the sampling train on? I was just looking at your pictures seeing that one (1) disposable limited use respirator with all that gear hanging on the side. I'd sure like to just see that respirator with and without that sampling probe on the same person; you compare, say, some chamber concentrations and protection factors.

WARREN MYERS: Well, actually, we fit test these individuals with that sampling train on them.

JIM JOHNSON: (Inaudible question.)

MR. ___: Any numbers there?

WARREN MYERS: I've got my computer man that helps me back here in the back of the room, and we're busy as rats over there running all these regressions, but, no we really don't have anything on that yet.

ALAN HACK: Did you say you used the forty ... to do a quantitative fit test ... disposable media . . . .

WARREN MYERS: Oh, you know, you're right. No, I take that back. It wasn't. It was sodium chloride, and we did not do that. So, Jim, I was wrong. We only did the TSI on the three (3) elastomerics. And sodium chloride on the--saccharin--saccharin on the disposable. I'll get it right. Actually, I did run the study.

ROBIN HOWIE: I'm interested in your differences in WPFs for given devices in different environments. What's always bothered me is, if someone ... a WPF study ... used your MEK ... a non going QFT test, you get a high performance. Be very careful no one tries to apply these data to the same device, because, after all, filter penetration is zero in the workplace. Someone doesn't apply these data to the same device used in a non ... property material.

WARREN MYERS: Well, if I can dodge that question, and just wax a little philosophically here; you've all heard us mention

about the fact that classes of respirators are given assigned protection factors. Rightly, wrongly, shouldn't, should, the fact of the matter is, they are. NIOSH does it, OSHA does it. For a good number of years that number was recognized as a number that any device in that class would give against any contaminant for any worker in any job task, and on and on and on. If there's one thing that the WPF studies have shown is, that is not a good assumption. That is not the way things work. And, in fact, maybe one number is not what we can do to assign to a class of respirators. And I can't tell you I have a magical solution or formula to do that, but what all this has done to me is the fact that I realize there is a desire to make things as simple and as non-complex as we can, and that kind of thing. But the reality is, we're dealing with a complex subject, and I don't believe we're going to get to a single point--a point where we can have a single number for classes of respirators. It's just too naive.

And whether the hygienist--whether we try to have the hygienist assume more responsibility in doing that at the work site--maybe that means not doing workplace protection factor measurements. Maybe that just means doing in-facepiece sampling, so that we do an exposure assessment on the man wearing the respirator. And if he's not wearing the respirator, we take that on the lapel. If he's wearing a respirator, we ought to take it inside the respirator. Maybe that's as simple as it gets. Maybe after we've done this and four (4) or five (5) years down the road from here maybe that's where we'll be at; that routinely we

do industrial hygiene sampling on people that wear respirators inside the respirator. I don't know. See that way you'll do away with protection factors except as just a general guide as to a factor of reliability. Maybe you have half-mask respirators general guide as ten (10). Use them in your workplace. What do you see? Maybe you won't get ten (10). Well, then, that's not going to be a suitable selection, if you do in-facepiece sampling to assess exposure.

BOB BRENNAN: Warren, I didn't see--you presented a lot of data, maybe it's blurred right now--you had some fairly limited number of subjects. You must have had replications of donning the same facepiece, and yet, you didn't--I don't remember you mentioning anything about it. We're all here talking about the difficulty in taking data, and just a study before you mentioned that there was a great variability; you and I looked at the same subject with the same respirator. I'm curious of what happens if someday we run a study and we find out there's more variation between the same man and the same respirator three (3) days a week than there is between two (2) men working side-by-side. But what did you turn up ... data in your study?

WARREN MYERS: We're just not that far along yet. I would not want to comment right now about that.

BOB BRENNAN: Do you have the raw data collected?

WARREN MYERS: We have some of the raw data, but we did not do replicates in a traditional sense. We were going into this looking at getting a maximum number of data points. So that we

were looking at one (1) respirator one (1) worker combinations. That worker may wear a different brand, but that was a separate data point. So that each respirator worker data point was unique. But, obviously, one worker had a potential of wearing maybe four (4) different devices; three (3) elastomeric and one (1) of the disposable.

What happens if you take those four (4), poll them together in a mean, and plot a mean distribution? We've started to take a look at that. The only thing I can tell you is, is that it looks like we have more variance in individual observations than we do when we look at mean observations. I don't want to let someone else's information out of the bag back here, and I think you'll hear something about that later on this week.

LARRY SPARKS: Last question.

WARREN MYERS: Yeah, how come I have to answer so many questions, Larry? Is this payback time for something I did when I was with the institute, or what?

JOSEPH ZDROK: What would you estimate a study like yours would cost?

WARREN MYERS: I think that realistically if you can find sites close-by that you don't have to support extensive travel you're probably looking at somewhere around seventy five dollars ($75.00) to a hundred dollars ($100.00) a data point. And that's based on actual costs that we have had.

RON KING: Each data point is going to require analysis of a blank and inside and outside sample at thirty five (35) bucks

each, or a hundred and five dollars ($105.00) just for analysis cost per data point. I think you're way off.

WARREN MYERS: No, no. When I said data point I meant analysis, I meant filter . . . . When you look at two (2) samples for a WPF sample, you're looking at anywhere from a hundred and fifty (150) to two hundred dollars ($200.00). If you roll in a blank you've got--so I meant--yeah, I'm sorry.

MR. DONALD H. BURD: I'm real tired. I don't know about you guys, but thank God I didn't prepare anything that had any data, data points, numbers, or what have you in it. In spite of what we wrote in the--what was written in the outline which you thought I was going to talk about, the workplace protection factor study I had done, I'm not going to talk about it. I realize that with the number of people in here who have presented data, and when I heard what was going on when I saw the outline back about a week or so ago, I said what I really want to talk about is what happens with the people involved, and the problems that come up in workplace protection studies. Now, I haven't done a lot of them; I've done a few of them. We're going to publish one of the one day. And it's those who went to ISRP will see it, and those who want to look at the paper some day, I'll make some copies, if I can get Elaine to go along with me.

But, in essence, our study, just to give you a quick study of it, was a aluminum plant in Canada. We were looking at [benzoalphapyrenes]. We came up with a mean on PAPRs in the vicinity--a geometric mean of about fifteen hundred (1,500) or

so, and ninety-fifth (95th) percentile of about two hundred and seventy (270). We also did half masks at the same time, and they came out somewhat lower. I don't want to get into a commentary of best, biggest, and all that stuff.

What I was looking at, and it's kind of hard to read because my print is light, so I'll try to do it from the top of my head with the notes I've got. I don't feel that workplace protection factors have any place in the certification of respirators. You can argue it's a prejudice or an experience; I just don't think it belongs there. Not at the state-of-the-art that we're at right now. You've seen the difficulties, and in very, very experienced people, who spend a good deal of their research time doing this kind of work. They can't even get points to agree with one another. And they haven't replicated them even on the same person. The environments are going to change.

I think that we have not yet developed the techniques to effectively give us something that is reliable. And I go back to what Jim Johnson talked about, and others; reliable, reproduce-able. Workplaces change. I think you'll find once people get into the analysis of what goes on in a true workplace study versus a program study, that the expense is enormous. Now, to save lives we spend money. But the questionable results that have no relevancy to what we're trying to do, which is produce respirators or have respirators that are good for people; that protect people--it's questionable whether that's even sensible.

I just feel that we can do better things. Now, we should

continue our workplace studies, we should get together and talk about how we're going to do them, but in any way to conceive of them, even in the near future, as being part of the certification process just makes no sense to me. That's a quick summary of one (1) page.

I want to get into more specific things where we deal with people, and the problems that you have with people when you're doing a workplace study. And we're talking about doing workplace protection factor studies. There are those who can't tell the difference between a workplace protection factor study and a program study. And for those I leave someone else to teach the wisdom. Some people work without protocols. Some people who are very well respected work without protocols, and I've seen that happen, and it bothers me, because they can't reproduce that, because they don't remember what the did last time. And they do it, and they make the changes as they go, and then when you ask them for their protocol it's not available. That annoys me.

Some people carry on workplace protection factor studies with large numbers of people and small numbers of monitors. From my experience that's tough. It just can't be done. You can figure out how many you need to take care of it, I will continue on and say that you need to have--well, you figure out what you need to have. I'm just saying that I've seen protocols where there are large numbers of people for very small numbers of monitors.

Training of monitors; untrained monitors grabbed from the

facility. They work in the facility; well, we'll make them monitors, so says the facility. So they get them from the safety department, from the--just whoever will volunteer to help. The training is very poor. They don't understand the authority of the role. They don't understand what they're supposed to do. They're not sure of why they're doing it, but they do it because they're told to do it. They have no training in casualty control. Things don't always go right.

There's a lack of understanding of the purpose of the study in many cases. I shouldn't say many, let's say several. There's a dedication of monitors. Monitors stay with their people. People should not be reading magazines, doing other work, when they're monitoring. They need to be available, or they're not available, I should put it the other way, because this is what we're seeing that is a problem. They're not available to assist and rectify problems. Some don't even understand the job that's in front of them.

Now, the interesting thing is, if I understand what was suggested for workplace protection factor studies, there is an assumption in there that there is a level of competency among monitors. And I suggest to you with the number of people around who are now trained to do monitoring, they are properly limited to certain specific areas. And to try to get them again and again to do the same job in different facilities for different, let's say respirator manufacturers, or for NIOSH, you know, you need a--there's no common team available. So you are constantly

retraining and trying to grab monitors, and that is, I see, a problem, a very severe problem.

Now, the participants. The white rats, right? I don't know where you're going to find a white rat participant. There have been some studies done where you can't get agreement between today and yesterday. That's a problem. Many of the participants, because of the methodologies used in training, perhaps, are just there because they were asked to be there. They got a tape played for them, or they got a lecture. And that's not good, because participants need to understand what it is they're doing, and need to have worn the respirator before. Many have not been informed of the purpose of the study and what can be expected from the results. Some haven't even been trained and instructed in the difference between a workplace protection factor study and a program study. I'm not so sure that's that important. I wrote it down as something to think about, but I'm just not sure.

The word volunteer comes up. In some facilities they go out and the grab people to join in in these studies. You know, you have been volunteered. Some participants don't quite abide by the rules. Now, if you combine newly trained monitors with newly trained participants in different work environments, even if the respirators work the same all the time, which is probably the only constant in there, I would think you would have questionable results. Some participants join studies under the misinterpretation and were not part of the theme of the study. Now, that's

mostly with people. It's not in any one place. That's sort of a composite picture of what I've seen by doing what I call some pre-studies. That is, qualifying people for studies. And it is questionable.

The next thing, we can get away from some of the people and talk about preparation for testing. There were studies that were started in the best of form, meaning well, where the equipment was not calibrated; wasn't functional. During one study, because of failures of equipment to provide--excuse me, because of problems with equipment and the lack of proper planning, there were insufficient cassettes to continue the test, and it had to be broken off until new ones could come in Fed Exed. That's a heck of a way to go with it, isn't it?

Because of some changes in shift sometimes rehearsals and dry runs were limited to day shift leaving the night shift less trained, less prepared, and problem analysis not really covered. With extended hours to cover several consecutive shifts, the preparation and maintenance of respirators and other equipment was not done in an efficient and timely manner causing delays in getting the program started the next morning.

Cleanup and setup of facilities to the level required by the workplace protection factor studies or workplace protection factor protocols were not available, and they had to be fashioned--wait, I'm skipping lines. Let me go back again. Cleanup and setup facilities to the level required by the workplace protection factor protocols were not available, and therefore had

to be set up in a makeshift fashion in cafeterias and other places which are normally traversed by other people. Sufficient allowance for real numbers of non-usable data was not provided for in a test protocol, and the time of the study had to be extended in one case to accommodate the need for additional samples.

There's a whole pile of things that happens in the workplace once you get the study going. The equipment fails, cassettes come loose and are knocked off, people remove respiratory inlet coverings or violate sealing surfaces with their contaminated hands, cassettes fill up with contaminate and have been not watched. You question the data right there. Particulate filters fill up with contaminates, and in this case I'm talking about the filters on the respirator. And, again, we're making the assumption, of course, that this is all particulates. We didn't say the word gases, and no one knows how to do gases and vapors at this point. Pumps do not put out calibrated flow, or go out of calibration. Pumps are not charged properly. Protocol requirements on the use of the blanks are not adhered to a hundred percent (100%).

Then you get into the cleanup areas where there's a difficulty in maintaining a clean area clean. Anyone who has ever tried one of those will know what I'm talking about. No matter how you do it, you try, you clean, you clean, and they always get dirty, and then you begin to wonder what you're introducing into the study that wasn't part of the study.

Needless to say, personal hygiene and work habits play into it. Lord knows, I've made some guesses, and Warren did, it's pure conjecture that some of that stuff had to be coming from inside lungs. That was deposited there fifteen (15) years ago from cartons of Camels. I don't know, some of that stuff--you know more than I do about that, but we're finding strange things showing up. What's that going to do to a study if you happen to be looking for the particular chemical or something that looks like it or is weighed like it?

There is a need, I would say as a general rule, for a high concentration of contaminants. And now you get into available workplaces. Let others talk about it. That's my experience. I'll leave it at that, and I'm sure tomorrow with a mass of presentation by others you'll hear more about the amount of contaminant and loading of cassettes and the necessity for that.

And then you get into the comparison of the workplaces. The standardized workplace; what is that and where is it. Could people go back into the workplaces that I've done my testing and reproduce the data? And am I wrong because my data came out and yours didn't? That's a big question.

I won't bore you with analytical techniques and the losses and problems with those, because those are pretty well pinned down, but still there's always some questions in that area. What does it all mean? It means we're going to do a hell of a lot of work, spend a hell of a lot of money, and for questionable results. And I just can't help but feel for the expenditure of

funds that's going to go into this thing that we can do a better job continuing the research, seeing of we can get some sort of correlation for the future, but then going back to the standardized workplace which is the laboratory, where the contaminant is specified, to use what Jim said, the conditions are specified, the work regimen is specified, the protocol is specified, you're using the same people over and over again; they've been through the test, and therefore, they should by then have perfected it. And then I think you'll come up with something. But I really question the transferability of materials and information from one workplace to another, from one group of people to another, from workers--works to another. And I just--well, I guess I can almost just sum it up and say, that's about the substance of it.

Now there's data available, and we can sit and spit out data left and right and compare all kinds of numbers. You've seen some of it, you'll see more tomorrow. And I'm tired.

LARRY SPARKS: Do you want to entertain questions?

MR. BURD: I'll try. I have no numbers up here to play.

MR. JOHN H. KING: My name is John King; I work for the E.D. Bullard Company. I'm here to talk about a project that the Industrial Safety Equipment Association has been undertaking during the past two (2) years.

During the 1980s the ISEA had discussed at length difficulties associated with 30 CFR Part 11, and the need for upgrading. After NIOSH issued the proposed regulatory change for certification of respirators in 1987 the ISEA formed a special committee

to undertake the project of creating a performance criteria document. The committee's goal was to develop a framework for use in developing future respiratory protection performance standards aimed at testing and certifying respirators. The document we have developed incorporates many of the concepts that NIOSH has proposed.

I'll be leaving a copy of it here for the record, and I'll discuss it briefly today, and as part of another presentation tomorrow, we'll probably talk about it a little bit more.

At this point the document is in outline form and ISEA is presenting it as part of an overall program, which we will discuss tomorrow as an alternative to actual workplace testing for the certification of respirators. The criteria document calls for quantitative fit testing for all respirators as part of a pre-screening activity prior to conducting quantitative, real-time simulated workplace testing. We feel a proposed laboratory test laid out in this document, bench tests, if you will, are more rigorous and representative of real use conditions than even those recently proposed by NIOSH.

Before I get too much further into it, in talking about this I would like to digress a bit and cover some of the philosophical thinking that went into the criteria document when we formed this committee. Members of the committee had various different views and understanding of what constitutes positive pressure respirators, what terms like static pressure, demand, and pressure demand actually mean, and had different philosophical opinions as

to the significance of such things as pressure flow work rates, things like that. And so, as a collection of manufacturers, we had to reach some common ground ourselves.

We began the undertaking by creating a set of terms and definitions which we all understood and agreed upon. Terms like category, class, style, group, type, mode, efficiency, capacity, tight fitting, loose fitting, hood, mask, filter, cartridge, etcetera, were defined as having very specific meanings and often different from heretofore commonly accepted terminology. Terms like disposable, demand, and pressure demand we dropped from discussion, because they were so already confused by a lot of people, and in many instances created new terms.

What we did was established a format--we established a set of parameters common to all kinds of respirators, and these formed the format for each of the performance sections that we drafted. We drafted individual performance sections for negative pressure air purifying respirators, positive pressure air purifying respirators, or PAPRs, airlines, open circuit SCBAs, closed circuit SCBAs, and we're currently working on, and will be continuing work on escape units and combination respirators. But for each of those types or categories of respirators, we wrote up an outline that dealt with these twelve (12) or thirteen (13) items.

We began drafting the methods of performance testing with the philosophy that all respirators must be tested using breathing machines, or metabolic simulators under various conditions

before simulated work or man tests are performed. And that respirators be tested as complete units as opposed to testing components separately. For example, testing just an exhalation valve, or just a filter element. We're proposing in this document that they be tested on breathing machines as complete respirators. I'll come back to this slide in a minute and cover the points one by one. In the meantime . . . .

I only have these two (2) slides to show. We start off with considering what a breathing machines does. We discussed what it should do, what measurement parameters should be evaluated, and why. For example, we considered physiological parameters such as breathing resistance, and the effect of excessive pressure swings inside of a hood on the ears, for example; the effects of positive and negative pressure adjacent to the respiratory inlet coverings primary sealing flange, or where it interfaces with the body with regard to contaminant intrusion or exclusion.

We came up with these various parameters; BP being breathing pressure. That would be measured in the throat of a head form. The IP being internal pressure. That would be measured next to a primary sealing flange. For example, in a full-facepiece mask where you have your own nasal cup, we would propose measuring the pressure associated with breathing in the throat of the head form, or basically inside the oral nasal cup; the pressure associated with the potential for contaminant exclusion being outside the oral nasal cup right next to a primary sealing flange, and considering both of those concepts, rather than

trying to integrate them into one (1) pressure.

We concluded, for example, that specifying a flow rate for PAPRs or air lines was not only unnecessary, but design restrictive. Breathing machine testing to assure and maintain positive pressure along with CO_2 monitoring to address contaminant exclusion and adequate gas exchange characteristics is a more appropriate way of specifying it than it is to set an arbitrary flow rate.

Requirement that PAPRs have real time pressure flow monitors serves as a better way to address issues such as clogged filters, low batteries, overbreathing, and so on, due to heart work rates. WE feel that's better than specifying some arbitrary service time. The committee, then, extended that concept to other respirators such as air line respirators. And I'll talk about that in a little bit, as far as the alarms are concerned.

NIOSH's concept of stratifying or rating particulate filters at various efficiencies was extended to other areas such as performance at different work rate levels. Characteristics of respirators which experience has indicated has caused confusion for the users, that we're aware of as manufacturers, were sometimes dealt with in unique ways. For example, many users wonder why thirty (30) minute SCBA units don't last thirty (30) minutes. In this case the committee decided to stratify or rate SCBAs based on the volume of gas available for consumption as measured on a breathing machines as opposed to service time.

Concept of treating all respirators uniformly was always in

the forefront of our thinking. For example, we felt applying sound level requirements to only hoods was a design restrictive thing, and we are proposing it be applied across the board to all respirators. The requirements for respiratory inlet covering lens impact protection was upgraded in our thinking in terms of using the latest ANSI Z87 impact requirements. And we're proposing adding requirements for optics in field of vision into lenses. SCBA . . .

JOHN H. KING: (Con't) . . . also applied to all SCBAs. Much time and consideration was given to concepts of fit testing and workplace testing. We reviewed and discussed results of known studies and tests. Like NIOSH, we chose the Los Alamos Fit Test Grid to address required size range of respirator fit. The work performed by [Skaggs] at Los Alamos also served as a prototype for our simulated workplace testing proposals and thinking. What I thought I would do is, since it's a pretty long document, it's about sixty (60) pages long, I would pick one of the sections. I chose PAPRs as a section to pick on just to detail out a little bit more for you to get a better flavor for some of the criteria that we're proposing. I chose PAPRs because they involve air purifying elements, they involve or deal with the concept of different work rates that I mentioned, as air lines would be, for example.

Going back to my original slide, under general description--it's very short, I'm going to read you what we have written down here for items one, two and three. Under general description we have, "Provides protection by purifying air through the use of air purifying elements. The air is forced through the air purifying elements by a motive force other than the wearer's lungs. The motive force shall be sufficient to maintain internal pressure above ambient pressure at specified work rate levels." Respirators are rated according to work rate levels. For example, level one, two and three. A level one would be something

like what NIOSH uses now in their breathing machine testing, with basically a forty (40) liter per minute volume. A level three would be what NFPA is using for SCBAs. Level two would be somewhere in between.

Styles and classes; respiratory inlet coverings are provided as half-mask, full-facepiece or hoods, and maybe the loose fitting or tight fitting. Style is the term that we associated with basically the type of respiratory inlet covering. Class is something we associated with negative pressure or positive pressure. And these types of respirators would be classified as only positive pressure respirators, PAPRs.

Modes of operation. Since air is forced through the air purifying elements by motive force other than the wearer's lungs, and we're not necessarily saying it has to be a battery powered device, the air can be regulated to flow variably or continuously. A variable flow device as we have it defined in terms of mode of operation would be something like a demand valve driven device where the flow, as if flows into the respiratory inlet covering, changes substantially in terms of flow rates as opposed to a continuous flow, which would be like a continuous flow air line. In a PAPR, depending on the breathing cycle, and whatnot, it could theoretically be a continuous flow, or it could be a variable flow, or it could be a combination of both.

Under general requirements we've, like I said, added high mass and high speed impact test requirements for teh lenses in respiratory inlet coverings. We've added optical requirements

for prism imbalance and optical definition. We've put a requirement in that we're still working on refining the methodology of doing this, but a requirement for shelf life. A statement in there with regard to intrinsic safety--this is all under number four of general requirements--and a requiement that all PAPRs have a pressure flow monitor.

There is still a lot of work we have to do here. There are a lot of issues to be addressed like enviromental stability of the monitor, the accuracy of the resolution, the rules of automatic integration, for example. People who make PAPRs now, there's at least one (1) on the market that measures pressure inside the respirator inlet covering and sounds an alarm if the pressure approaches ambient or negative. There's another type, one (1) or more types of PAPRs on teh market that measure flow and integrates that flow over several breathing cycles, for example. There's a lot of ways it can be done, and we're just trying to go through the logic of what we should do there in terms of the stability of the device. We've added field of vision requirement to the respiratory inlet covering, and that covers what we've done for general requirements.

Under number five, what we're proposing here is that the respirator be put on a breathing machine and the--as I indicated, there are two (2) different types of pressure measurements we could be taking, one (1) in the throat of the head form, one (1) elsewhere--the breathing machine would be operated at a work rate level that's appropriate to that respirator. In other words, the

manufacturer would say this respirator is designed for this work rate level, and it would be tested at that work rate level.

Number six, we would also operate the PAPR on a breathing machine, except in this case it would exhale carbon dioxide, and we would measure the steady state CO_2 buildup in the respirator to assure that there is an adequate amount of flow through the respiratory inlet covering to provide a gas exchange.

Under the simulated work what we're proposing is a ten (10) man test panel with one (1) person representing each of the ten (10) Los Alamos fit test panel boxes. Each subject would don and wear the respirator according to teh manufacturer's instructions in a quantitative fit test environment, and have to obtain a fit factor, if you will, of at least ten (10) times that assigned value for that respirator. After conducting that, at least nine (9) of those ten (10) people would have to obtain acceptable fit factors for that model of respirator. Having passed that threshold in qualifying then the respirator and the test subject, to go further, we would then propose the simulation of work in a relatively large chamber.

It would--the type of contaminant in the chamber might vary depending on what's appropriate to the respirator, but typically it would either be a solid or a liquid aerosol. Something like equipment that ATI manufactures for generation detection where both inside and outside concentrations can be measured in real time continuously. The chamber would be big enough to simulate work. We're proposing five (5) different work regimes, some of

which performed under high wind conditions where we have fans in the chamber.

The chamber shall also have the capability of elevated temperature and humidity. Each test subject would simulate work for one (1) hour, or for the service life of the particular respirator if it's less than an hour.

During the simulation and work the test subjects would be continuously monitored for total inward leakage. Total inward leakage would be compared to teh chamber concentration to provide a percent penetration which is integrated over the entire one (1) hour period. Those nine (9) or ten (10) integrated averages then would be analyzed and the ninety-fifth (95th) percentile of the individual average penetration values should be equal to or less than the applicable penetration value listed in section twelve, which would be where we have inward leakage values listed.

In the case of rough handling, and we're still developing some of the protocols here, but we have proposed packaging respirators and components to be tested according to Mill Standard 8-10D. We're proposing a shaker table test for complete respirators and air purifying elements similar to CEN standards, and that this be done, as far as on air purifying elements, prior to the breathing gas quality requirements, which is next.

In the case of particulate air purifying respirators, they could be either liquid aerosol or solid aerosol, basically like what NIOSH has proposed, with stratification at various efficiency levels. What we would propose is that a point one (.1) to

point three (.3) micron count median diameter particle be used with a geometric standard deviation less than one point eight (1.8) micron at a concentration of fifty (50) to a hundred and fifty (150) milligrams per cubic meter. The respirator would be operated on a breathing machine that is in the environment of this concentration, for whatever period is needed for that respirator to have been challenged with two hundred (200) milligrams of contaminant, at whatever work rate the manufacturer is specifying that respirator capable of sustaining. And throughout that entire the instantaneous penetration shall not exceed the values for that particular filter. We have similar requirements for vapor gas cartridges. But, again, the point being that for the most part we're talking about testing complete respirators on breathing machines.

Under miscellaneous requirements we have requirements for sound levels and end of service life indicators. Under labeling, marking and instructions we're saying that each respirator needs to marked with the appropriate work rate level that that respirator can function under and still maintain a positive pressure. Air purifying elements would be labeled wiht the group, the type, the work rate level that they work, as well as an applicable agency limitations and the estimated shelf life and expiration date. Each respirator incorporating a tight fitting respiratory inlet covering would bear the following limitation: "approved use of this respirator is limited to respirator wearers having successfully completed an acceptible fit test as recommended by

the manufacturer."

In item twelve--of course this is the hard part, trying to come up with what total inward leakage values would be acceptable for a given class, type, category, style of respirator. You know, in the case of PAPRs obviously a type three or four filter, four being a high efficiency filter, would have a lower allowable penetration value than a type one, being basically a dust filter. We have not come up with those values yet. It's part of the ongoing work that ISCA is doing. And that's kind of just to give you a flavor for some of the requirements that we have in the document. And, as I said earlier, this is just part of an overall proposal that ISCA will be making tomorrow as an alternative to workplace testing. Thank you. Any questions?

HARRY HERMAN: If we could switch over to supplied air, how do you envision that this would fit in a case, which I'm sure you're very familiar with, where you have an abrasive blasting helmet inside a confined space doing abrasive blasting? How would you try to synthesize that for testing?

JOHN KING: Well, I think the simulated work test chamber that I described where we have fans to create high wind conditions would be somewhat of a simulation of the type of wind currents and whatnot that can get developed in a sandblasting operation in a confined space, or relative tight space that you're talking about.

HARRY HERMAN: That's the question. You have an added element, and that is the velocity of the . . . .

JOHN KING: Absolutely, you're right. And that's why we're considering the wind blow around in there too, inside that chamber, as part of one of the regimes.

NANCY BOLLINGER: Have you performed any studies to determine if your new procedures are any better predictors of respirator performance than those procedures, say, currently required in certification?

JOHN KING: Not studies in terms of actual laboratory tests where we did one next to the other and compared results and tried to relate it to anything, no, we have not.

NANCY BOLLINGER: Have you done any studies that might compare it's relevancy to workplace performance?

JOHN KING: No, ISCA as an organization has not done that yet. Some of us manufacturers have done things separately. I've done simulated sandblast testing, for example, and compared it to certain simulated work regimes in a quantitative fit test chamber as an individual manufacturer. And there are still, to be quite honest with you, some disagreements on certain issues and philosophies amongst the manufacturers. I mean, I might have my own ideas or my own correlations between what I've done and Don [Birgbecter] might have different values, and we're still trying to sort those out.

ROBIN HOWIE: A few minor points, if I may. Are you going to look at the ... performance of these equipments, because ... is quite common. Are you going to insist that the equipment meets a minimum level of performance ... and you have ...?

JOHN KING: I'm sorry, would you repeat the question? I don't know if I understood it.

ROBIN HOWIE: If you're ... and you're wearing a PAPR, battery powered, and your battery fails, ... have the problems of battery charging, so it's no longer being forced into the face-piece, the wearer is now driving it through the filters, are you going to specify a ... of performance or not?

JOHN KING: Well, we're specifying that the device have an alarm, and if it's not delivering a positive pressure inside the respiratory inlet covering that alarm sounds and will warn the user that it is no longer working.

ROBIN HOWIE: Yeah, sorry, but with all due respect, a warning device is not going to provide ... protection.

JOHN KING: That's true.

ROBIN HOWIE: So what do you have to do ... a device which you get a high level, a high nominal level of performance? It has to fail to some level of performance, which may reduced compared to the power on, if you're going to prevent exposure to materials which may have acute health effects.

JOHN KING: Well, I'll be honest with you, we really haven't considered that. Certainly in the case of a PAPR that works with a hood or a loose fitting respiratory inlet covering, that's, right off hand, a tough challenge.

ROBIN HOWIE: Right. ... of course for that kind of device. If you lose power there a high buildup of CO_2 in the breathing zone.

JOHN KING: Yes, that's right.

ROBIN HOWIE: So, it's then--also, it's very ... it is very similar ... to what you have in Europe, ... what we call the CEN....

JOHN KING: Right, we looked CN extensively.

MR. ____: Are there going to be copies of that document available?

JOHN KING: Yes, yes.

MR. ____: From where?

JOHN KING: From ISCA.

MR. ____: Is it something that you would want us to duplicate ... presentation ... duplicate it overnight and make some available in the morning.

JOHN KING: Sure. I will give you a copy right now.

LARRY SPARKS: A couple of administrative things. First of all I want to offer appreciation to all the presentors today. As most of you may have figured out I am not a technical person, which is why I'm up here and the technical people are there listening. But I found it very stimulating, and I really appreciated the positive nature of the people who were presenting their work and sincerely helped philosophies and beliefs and so forth. We have back there some photocopies of some maps of the area and a list of some restaurants in the area. We're here to--if you want to take a look at it--to get you started on what you might want to do for those of you who are staying over this evening. I'll remind you we begin again tomorrow, here in this

room, at nine (9) a.m. We look forward to you all being here.

(Whereupon, the meeting was adjouned.)

DAY 2 - TAPE 1 - SIDE A

January 10, 1991

LARRY SPARKS: Two (2) presentations this morning from two (2) different people from 3M Company. They are related, as I understand it, so we're not going to worry about the precise timing of the two (2) presentations. We'll just try to keep the whole package within the basic time allotted, and we'll call a break probably at the end of the first one, or whatever, to try to keep some continuity for the speaker. So we'll ask Mr. Craig Colton to come forward and address us.

CRAIG COLTON: Thank you. I am Craig Colton. I am with 3M, and on behalf of the Industrial Safety Equipment Association will be presenting summaries of research of respirator performance studies which we feel will address questions which were raised by NIOSH in their federal register notice announcing this meeting; including things like standardizing of nomenclature for workplace performance and measurements, feasibility and practicality of developing a detailed protocol, available techniques and procedures for doing these type of studies, and some of the limitations of assigning performance values to respirators.

The first place to start is with the terminology. The studies that we're going to report are workplace protection factor studies as they were defined by the American Industrial Hygiene Association. Prior to that the Los Alamos National Laboratory, I believe in '82, and then NIOSH in 1983, proposed and published definitions of respirator performance terminology.

The AHI terminology was prepared in consultation with the principals from Los Alamos and NIOSH, so I think that represents hopefully some type of consensus.

The workplace protection factor study, then, is, we think, the best measurement for respirator performance. It's the measure of protection that's provided by the respirator in the workplace by a properly selected, fit tested, functioning respirator when it's correctly worn and used. And as you heard yesterday, it's defined as the concentration which the user would inhale if they were not wearing the respirator divided by that concentration of the contaminant that's inside the respirator facepiece. These two (2) concentrations, then, are measured simultaneously while the respirator is being worn. And that makes it very different from some of the other performance terminologies that we could use. In fact, upon--in looking at the inside concentrations, it's during the workplace protection factor measurement in which the variables are controlled to evaluate respirator performance. So we see that the measurement's going to be made only while the respirator is worn. To sample it any other time you're not going to be sampling respirator performance. You're maybe going to introduce use practices into it.

Training of the workers is going to be important. By using experienced workers, you eliminate that worker related factor of how comfortable they are with being able to put on the respirator and don it, or at least try to reduce that. There's been studies

that have shown that in people who were fit tested in comparing who wee respirator wearers and people who were non-respirator wearers, they achieved--the respirator wearers achieved better fits than the non-wearers.

Fit testing is important. First of all you want to eliminate the poor-fitting respirator subject combinations because you're trying to assess, again, respirator performance the way it's supposed to be used. Fit testing is one of the things that is required. So we eliminate that, or try to eliminate that variable. Also we want to try to provide some consistent level of fit, at least for the duration of the study.

Respirator condition is going to be important. One of the things is a properly functioning respirator, so that means respirators without leaks or other defects are to be used. And then proper respirator selection, and that means that the respirator needs to be appropriate for the contaminant that we're going to be measuring in the workplace.

To date we've done nine (9) studies that have been completed, and that's what will be reported here. The reports as we're going to list them are in chronological order. In fact, as more studies were performed we've refined the test protocol, so that's why I think it makes more sense to look at them chronologically as we move along here. We refined them according to what our experience or the previous studies--as we conduct these studies, what we think they've told us. Now, one of the reasons we've been involved with doing workplace studies is, we were concerned

that we wanted to be able to check the performance of the respirators to make sure that that performance wasn't inconsistent with the current assigned protection factors.

The first study we did was some time ago, back in 1984. It was in a brake shoe manufacturing. The contaminant was asbestos dust, and I might just remind you this was prior to the current OSHA standard, which I believe came out about June of '86. Anyway, it was prior to the current standard. The product that was manufactured was somewhere between twenty (20) and sixty percent (60%) asbestos, and various tasks in this facility were sampled. The respirators tested were mostly half masks, at least the first ones you see there. The first two (2) that are listed were disposable dust, mist respirators. The third one a disposable dust, mist, fume respirator. Then the next two (2); both are elastomeric facepieces, but one had dust, mist filters, and one was tested with a high efficiency filter combination. Then there was a powered air purifying respirator with high efficiency filters which, if we look at brand name Air Hat, but if we looked at the proposed ANSI revision Z88.2 this is what they would call loose fitting facepiece.

The test protocol consisted of worker preparation and along with that included explanation of the purpose of the study as well as receiving fitting instructions. In order to be consistent with the fitting instructions that we provided these workers, sound on sound slide presentations for accomplishing the fitting was used. Qualitative fit testing was done using saccha-

rin. It was done according to pretty much what is now published in the lead standard protocol. The test subjects only wore respirators in the study that they had demonstrated that they were capable of getting a fit with. Also the workers in this particular facility were experienced respirator users, I guess, to the extent that prior to the study they had been using the 3M 8710, which is one of the test respirators. The subjects were asked to remain relatively clean-shaven and they voluntarily cooperated with us during the study.

Once this was accomplished then the respirators were donned according to the instructions which they had received, which were also consistent with those published on the instruction package of the respirator. The sampling equipment was--at least the test person was assisted by the test supervisor with all the sampling equipment in putting that on. They donned their respirators, but then for hooking up the collection cassette to the probe and putting on the pump and that, then the test supervisors, or observers as I'll probably refer to them later on, helped with that.

And then the observers--the reason I use that term anyway--they would go to the workplace to observe the sampling. What they were there for was to make sure that the samples being collected were consistent with the protocol that had been agreed upon for this particular study. In other words, we were interested in making sure that the studies were going to be workplace protection factor samples that were collected. Twelve (12)

workers ended up being qualified for the study and that participated pretty regularly.

This shows the sample collection equipment. The things that are probably important here is, if you look at the cassettes, what was used for the sampling was twenty five (25) ... closed faced cassette; three (3) piece extent, where the extender was a half (1/2) inch extender. This was used not only for the inside sample, because that's what it took in order to be connected to the probe of the respirator, but it was also used on the outside sample, or the breathing zone sample. And then on that sample, also, was placed the similar probe that was used in the respirator. That way we would be--what particle loses would occur due to the sampling set up, and the probe, hopefully, would be the same. We'd be comparing apples with apples, or maybe a little closer, burgers with burgers, Warren.

The sampling probe was used was one designed by Dr. Lou at the University of Minnesota, and you've heard a little bit about that probe already. Sampling time ranged from a half an hour to one (1) hour, and the sampling rates ranged from a half a liter per minute for the outside sample, or the breathing zone or lapel sample, and then two (2) liters per minute for the in-facepiece sample. In selecting these flow rates we wanted flow rates that would, one, collect enough on the outside without overloading the outside sample, but yet we didn't want to underload the inside sample.

This shows the probe that was used in the study. When it's

into the facepiece end, there's a part of it that projects into the facepiece by about three (3) millimeters, just a little bit off of the surface of the respirator. This shows the position of the probe. We tried to be consistent with that in mounting about midway between the nose and the mouth. And this shows one respirator with that probe location.

The analysis was performed by Clayton Environmental Services. They were using face contrast microscopy. The NIOSH method seventy four hundred (7400) set a counting rules at this time. They identified the asbestos to be chrysotile. In addition, which I'll talk about later on, some of the these samples were also submitted for scanning electron microscopy.

This shows the asbestos concentrations in the various areas with compounding having the highest average concentration in this particular study. Many of the inside samples that we collected were below the detection limits. Detection limits in this particular study were a thousand (1,000) fibers per filter. And when I say many, we're talking about twenty-five percent (25%) of the inside facepiece samples. So, we've got the result here for all the individual results that were collected, and for these samples that were undetected, the one thousand (1,000) fibers was used for the calculations. Even though the laboratory reported it as less than one thousand (1,000), we used those--we used that value as what was found. One of the things is you've gone and spent this time collecting these samples, you'd like to be able to use those, but when they come back undetected that causes

problems. We could talk about the ability to do this, or whether this is correct or not, because, in fact, as one person has put it, at least the one value we know it's not is the detection limit. So hopefully that may enter some conservative nature into the measurements.

While we would have preferred longer sample times for the study, or maybe higher flow rates, still ten percent (10%) of the outside samples were lost due to overloading. Also, tests were done to determine if the closed face probe cassette sampling results that we were using for the outside sample were different than open faced cassettes sampling. We also did studies to determine whether or not the lower flow rate, half (1/2) liter per minute versus two (2) liter per minute, if that would cause any effect on the sampling results. And we found that no significant difference was caused by these changes at a ninety-five percent (95%) confidence level.

We got sixty-one (61) respirator sample sets out of the study, and the sample set is an outside and inside sample. Ten (10) sets were invalidated due to overloading. There are also things like interference with filter and bacterial--interference on the filter such as bacterial growth--test equipment problems such as sample pump failure, collection cassettes that get knocked off the probes. Then, as I said, this shows all the sample sets, and we calculated the geometric mean. The geometric standard deviation, the fifth percentile, is up here.

This shows the face contrast microscopy, and you see the

results. And for the half-masks they were greater than the ten (10) at the fifth percentile. Now in this slide you see the asbestos concentrations by face contrast method, and then you also see the scanning electron microscope method, and then you can see the workplace protection factors. The workplace protection factors are running about five (5) to ten (10) times higher where the SEM was used. And this is due to the higher fiber concentration that was detected in the outside sample with this method. And it's got greater sensitivity for smaller fibers, so that it counted more. It's also interesting if you look at the inside concentrations, though, that by using this method they didn't change much. They're approximately the same by both methods for the inside.

This perhaps maybe shows a little bit about what was going on with fiber loading. We had a lot of the inside samples that were at or below the minimum detection limit, and so the inside fiber amount concentration was relatively constant through the study, and then we did have places where some of the outside samples had a lot higher fiber loadings and higher fiber counts, and so forth.

So some of the conclusions from this study is that if you looked at all those individual samples, or even the best estimates to the fifth percentile, all the WPFs were in excess of ten (10) in this particular study. Workplace protection factor reporters reported here are perhaps conservative due to the limited sensitivity of the face contrast counting method. Also a

little bit of variability in product performance was compounded with variability in sampling and analytical method.

One of the things that we could find out in this study is with regard to the performance of the respirators with elastomeric facepieces. The respirator with the high efficiency filter and the one with the dust, mist filters appeared to be equivalent performance.

Well, that's the first study. The second study that we did was a little bit different. This was a powered air purifying respirator with a loose fitting facepiece. The environment was in a roofing granule production plant. The contaminant would be silica--it was a silica dust environment. Due to the analytical method what we measured was silicon dust. They were cleaning up the silicon dust, so the tasks that were sampled were sweeping, brushing walls and shoveling.

The product tested, as mentioned, was specifically the 3M air hat with the loose fitting facepiece. We tested it with either dust, mist filters or high efficiency filters. It was also tested without a shroud, which is as it's shown here, and with a tyvek shroud as shown in this study.

The protocol consisted of evaluating five (5) workers, or testing five (5) workers who had been trained in the use and donning of the respirator. No fit testing was performed in this study because this was a loose fitting powered air purifying respirator. Each worker was equipped with the sample pumps, tubing, and filters. Sampling period ranged from thirty (30)

minutes to one (1) hour over a duration of four (4) days. The pumps were calibrated three (3) times a day, at the morning, noon, and then at the end of the workshift. Again, continuous observation, and the analytical method was PIXEA, proton induced x-ray emission analysis, which you've heard a lot about already.

As far as the sample setup, respirable dust samples were taken for the outside sample, the inside sample was also collected, of course, at the face shield, and then, in addition, in some instances a total dust sample was collected. This shows the sample setup, and you can see the in-facepiece sample connected to the probe, and then on the lapel there the Cyclone for taking the respirable dust sample.

The workplace protection factor calculations were done by determining the PIXEA levels--or determining the blank levels using the PIXEA analytical method. And once the average blank value was determined that was subtracted from the inside and outside samples. Then all the outside--or concentrations were calculated and workplace protection factors calculated. All the outside samples in the calculations had mass loadings that were greater than twenty-five (25) times the blank level. The reason I point out the twenty-five (25) times, or how we agreed upon that is, by this time one of the things that had been done is NIOSH had suggested a protection factor of twenty-five (25) for this type of device. So in order to go out and test that performance, then in order for our samples to have an equal chance of being able to prove or disprove whether or not the respirator

would provide a protection factor of twenty-five (25) we had to have at least that much mass on the outside sample.

If we look at the results compiled here; first of all, you can look at the total dust, mist samples and the total Hepa filters. And I might add here that the total dust, mist samples consist of taking all the dust, mist samples without the shroud and those with the shroud and adding them up, and that really comes out to forty-five (45), not twenty-five (25). Your math is correct. But there you can see the geometric means, the standard deviations, and then the fifth percentiles that were found in this particular instance.

We also looked at the data a little bit differently here, for now we went and looked at samples that had at least one hundred (100) times the blank level. And the reason we did that is because in the current ANSI Z88.2 powered air purifying respirators with dust, mist filters are assigned a protection factor one hundred (100). And so this was in order to ... to make sure that the samples would have an equal chance to show or dis-show a protection factor of one hundred (100). The sample that--there were about three (3) samples or so that were eliminated in this situation from dust, mist, and I guess one (1) from the high efficiency filter because their mass loadings were not up to one hundred (100) times. But those samples, no matter how good they are, will not be able to determine whether or not a protection factor of one hundred (100) is possible because the mass loading just wasn't sufficient enough.

Another difference that you can also see here is in testing the version with the shroud and without the shroud. In fact that's probably quite evident, and that there does seem to be a difference between those two (2) particular versions of the respirator. One of the things of the one with the shroud, it tends to take on more the configuration of a helmet or hood that I'll show you later on here.

The third study we conducted involved a supplied air respirator. It was an air line respirator, the environment was on a flattop barge where they were using sandgrit to blast the paint, so it was an abrasive blasting version of the respirator. Again, it was silica dust, and what was being measured was silicon due to the analytical method. This shows the respirator that was being tested. Here we have a hood or a helmet respirator, the shroud, the breathing tube; it has a vortex air regulating valve on it, and then fifty (50) feet of compressed air hose was used in the study. All these were the parts that make up the approved NIOSH assembly.

The protocol consisted of training the workers. There were five (5) workers involved with the study. Again, a positive pressure respirator, loose fitting, no fit tests were performed.

A little bit about the sample setup. The workers in this particular study wore three (3) sampling pumps, and then all the other equipment for the sampling train. And as total dust samples were taken, a respirable dust sample was taken in the breathing zone, and then we have the inside the facepiece sample.

Sampling pumps, again, were calibrated daily, checked for their proper flow three (3) times a day.

This shows the sample setup on this particular worker. Here we have the total dust, the respirable dust sample, then the in-facepiece sample. One of the things that this environment necessitated, which was one of the problems, perhaps, that can sometimes occur, is that due to the abrasive atmosphere here the cassettes would get extremely damaged by the abrasive blasting materials, so a shield was placed over the cassette just to protect that, so it would be intact when the study was over.

The sampling procedure, then; the workers were assisted with donning the helmet and placement of the sampling equipment, like before. Workers carry out their normal scheduled routine, at least as best we could determine. We told them we weren't there to see how they did the job, but just there for sampling problems with the equipment; make sure that the sample was collected properly. Sampling periods ranged from thirty (30) minutes to one (1) hour over a duration of three (3) days. Each worker was observed at all times. The samples were obtained at minimum and maximum flows into the helmet by adjustment of the control valve, so we had set those and took samples at both air flows.

(Inaudible question from audience.)

We had then calibrated so that when we set the flow rates at the particular know we knew what it was, so, yes.

Here shows at least one (1) of the workers in performing their normal routine. I've done a lot of fit testing and never

had any worker do this in a fit test environment. You can also see the three (3) pumps that are on the particular worker.

The calculations, analytical method and all that was the same as I mentioned in the powered air purifying study previous to this. In this particular study it pointed out some concerns for sample loading. We talked about it a little bit where we looked at the concerns of twenty five (25) times and one hundred (100) times, but here we definitely started to see a relationship; becomes especially important for whatever that minimum workplace protection factor is one is trying to show.

Here we have the outside filter weight versus the workplace protection factor. And the outside filter weight is a multiple of the--expresses a multiple of the blank--the working blanks that were collected. And so if we look at the samples there we had thirty-seven (37) sample sets in which the masses were all greater than ten (10) times the blank level there, and then we can see what the geometric mean workplace protection factor was in this particular situation.

Then you'll notice that with an increasing mass loading--in other words, as we collect more and more material on the filters--we see an increase in the workplace protection factor. Those samples that only have ten (10) times the mass on there, there's no way those samples can ever verify whether or not the respirator is going to have a protection factor of a thousand (1,000) or not, since that was a minimum protection--or the APF that was assigned to this particular device. So if we look at those

samples in which mass loadings were a thousand (1,000) times or greater, then we see we only ended up with seventeen (17) sample sets from this particular study, and the geometric mean is a lot higher than it was when all the samples were collected. This shows just the fifth percentile, and the geometric standard deviation. And, again, we see the same relationship.

Now we reported--you'll see a lot of the slides either prior to this, and then after this, in which we've used fifth percentile. Fifth percentile was one of those measurements that investigators prior to us started using in reporting, so we've done so. Here, if we look at the one thousand (1,000) time line, then, the fifth percentile is greater than one thousand (1,000).

This is the graph of the relationship between the outside mass loadings and the workplace protection factor that was found. We'll have a little bit more to say about that. At least Alan will talk a little bit about that, but I'll go on to the next study.

Chronologically the next air line study that we performed was this one. It was done in a foundry environment, and I guess I had one of those things that--in this particular environment it was difficult to get pictures because of the lighting levels, and so I apologize for that particular filter. But it was in a foundry application. The task was grinding. The contaminant involved iron, silica, and aluminum dust.

A supplied air respirator, but maybe what we call general purpose. In fact, if we look at the respirator here, you'll

notice that this is very similar to the abrasive blasting respirator that was tested earlier. In fact the only difference is in the abrasive blasting provisions for the helmet and that particular part of the respirator. The vortex valve, breathing tube, compressed breathing hose; the same for this particular study.

Six (6) workers were trained in donning and the use of the respirator, and were used for the study. They used this respirator in their job. Again, no fit testing was done. They were instructed into the purpose of the study. The equipment and protocol was identical to that of the previous air line study.

When it comes to results, the calculations were performed as previously stated, except in this particular study one of the things that was very noticeable are the low concentrations of the dusts that were found there. This shows the outside samples and inside samples for iron on the top there, and then for the silica dust--silicon dust--on the bottom. See, the range is somewhere between a hundred (100) and twenty-eight hundred (2,800) micrograms per cubit meter for the iron outside, and then on the inside it was point two (.2) to eight (8) micrograms per cubic meter. And sort of similar ranges for the silicon dust.

When we got to looking at the results we noticed again a mass loading relationship was found. This one shows what it was for iron, so when this one was identified--you'll notice that the loadings by using multiples of the field blank are much lower than in the previous study. Here the highest level we get up to for iron is seven hundred and fifty (750) times the multiple of

the field blank. We started out with thirty-nine (39) samples that were all above twenty-five (25) times, and then after the four (4) days that we're here only eight (8) samples that were greater than seven hundred and fifty (750) times.

And you can see the workplace protection factors. Again, they're increasing with mass loadings, but they're much lower than they were in the previous study. Look at silicon. That was an anolyte that was looked at in the previous study. Here we see even the mass loadings are even much lower. Here the highest mass loading was three hundred (300) times the field blank here. Again, increasing loadings, increasing protection factors, but much lower protection factors here. Now this relationship is going to be discussed in a lot more detail when Allen Johnson gets up here and continues with the information here.

The next study we performed was in a metal fabricating facility where they manufactured aircraft components, and so we've got airborne metal dusts that were used. The sampling locations; primarily it was the polishing and grinding department, but there a couple samples taken in the blasting department and also the spray coating department. In the polishing and grinding area silica dust from the abrasive wheels was of concern, and then titanium and aluminum from the metal parts. In the coating there was, like I said, a limited amount of sampling. There they had a lead containing material that was sprayed onto parts. In the blasting department they did blasting with aluminum oxide and zirconium silicate abrasives.

This shows the respirator that was being tested and one of the grinding stations. There were several grinding stations in this particular area, and workers all performed the same job. A disposable dust, mist respirator that was being tested; you can see the outside sample, inside sample. One of the things that is perhaps a little bit more clear here is you can see the probe that was attached to the outside cassette which is identical to that used to attach the cassette to the respirator.

Here, perhaps a little bit better view of being able to see the respirator that was being tested and the hookup there. Again, we were still trying to have a consistent probe location, and also a probing technique there midway between the nose and mouth, and using gaskets, making sure we don't get fibers on the threads of the probe so that that would result in leakage.

The sampling equipment was the same except we started to make one change here. First of all twenty-five (25) millimeter cassettes were used in both the inside and outside sample here. The other thing that had come up by this time we thought maybe we needed to adjust for was that since PIXEA only reads a portion of the filter and doesn't read the entire filter, maybe we should try to focus the material that was collected into a smaller area so that the beam would cover more of the collection area.

So what we tried--we went to--some people talked about using rings, we went and got some rings also that we could place on the inside of the cassette and the filter so that we would direct the material here. By visually looking at it we thought we saw some

things that may be indicated that when it lie flat we lose some sample there, so we used some colored aerosol here so that we could visually see what was perhaps going on, and loaded some filters. In the handling we've busted part of the dust here in the center, but if you look here, instead of getting the nice sharp ring, we started getting little fingers of the material where it was like starring out to the sides.

So in order to take our measurement, but then to be able to correct for the area that was made up by the stars, since each of them appeared to be a little bit different, we thought it became a better practice just to eliminate the ring and then just use our correction factor for the area of the filter for the size of filter we used. That seemed a harder problem to control than using a consistent factor for the area of the filter.

Test subject screening was very similar. Fit testing was doing, again using the saccharin ... lead standard protocol. Education and training was conducted to make sure the workers knew how to wear the respirator properly. Also, the purpose of the study was included; why we were doing this study, and then also a check of the assessment to make sure that they understood what was going to be expected of them by us.

The sampling procedure consisted again, calibration three (3) times per day, the flow rates were around one and a half (1 1/2) to two (2) liters per minute. I mentioned the probe location and technique. Also we wanted to handle the samples so that we could avoid contamination which presented a problem in this

particular study. The concentrations here were lower than what we expected, and this resulted in longer sampling times in order to get meaningful analytical results. The samples times ranged from thirty-five (35) to two hundred and thirty-five (235) minutes of actual time. In fact, the concentrations were low enough that for the observers in this particular study, as they stood back and away from the grinding operations, there wasn't a requirement to wear respiratory protection. So this was perhaps a little bit unusual for most of the workplaces that we've gone to in that the observers didn't have to wear respiratory protection.

Also, I mentioned--I'll show you the continuous observation in a minute. Also another problem with handling to avoid contamination; since we had to sample for longer periods of time that meant the workers were having to take off the sampling equipment, stop their job, and so forth several times. So maybe on the longer samples we'd have sample removal and hookup maybe three (3) to four (4) times for that one (1) sample. Also, we were not able to go to what we would identify as a clean area so we had to do some sample change out in the work area, in which we'd do it and then remove from the work stations, but still, it posed a problem for contamination of the sample. The blank samples that were collected hopefully control this variable.

Continuous observation, as I mentioned earlier; that shows one of the observers in the background there, and as I mentioned the levels were quite low so the individual didn't have to wear a

respirator. And, like anybody else, if they don't have to wear a respirator, they'd prefer not to.

Sample analysis was done the same as before; PIXEA. The detection limits for the three (3) elements ranged from nine (9) to thirty-five (35) nanograms per sample. The analytical ... expressed at least as a coefficient of--as CV for the mean outside filter weights was around plus or minus seven percent (7%) for the three elements. While we had nanogram sensitivities they were not specifically beneficial to this particular study due to the contamination problems that we had. The field blanks were significantly above the stated analytical detection limits which is probably due to the multiple handling that occurred of the samples.

Now we had done enough studies that it was possible to start to formalize, at least we thought, our rules for the data interpretation. So, as we've alluded to earlier, we defined the mean field blank values, we would reject sets with outside samples that were less than, in this particular study, eleven (11) times the blank. But the eleven (11) times blank here, since this was a half-mask respirator, the protection factor we were trying to verify was that of a ten (10). The reason eleven (11) times is there is since we're subtracting the blank value from all the samples then, we've got eleven (11) times minus the blank value gives us a number of ten (10), so that's how that number was cited.

Now, for the upcoming studies that number will change

depending upon the type--or may change because of the respirator that's being tested. Reject inside samples. Reject sets with inside samples which the value was less than the blank, because by the time you subtract the blank value I don't know what to do with a negative number. I mentioned the blanks were subtracted; calculated outside and inside concentrations; the WPFs were then calculated, and then the statistical analysis could be performed.

This shows the results. The mean outside concentrations in this study were from one hundred (100) to three hundred (300) micrograms per cubic meter. The inside concentrations ranged from a half (1/2) to two (2) micrograms per cubic meter. So we had very low inside concentrations. The workplace protection factors were checked for outliers as well as generating the statistics that you see presented here.

For the titanium sample four (4) of the samples were outliers. If those outliers were added back into the data the workplace protection factor would go from the fifty-nine (59) to the forty-five (45).

For the silicon four (4) sample sets were rejected. Three (3) were due to non-detectable inside filter weights, and one (1) was due to an outlier. When that outlier is added back in the mean of one seventy-two (172) goes to one thirty-seven (137).

I might also add that on that study you notice that for the three (3) different elements here they also have three (3) different workplace protection factors. These were all done in the same environment, at the same wearing, the same worker, it's

just that a different element was measured. The question here is which one describes the respirator performance. I really don't know.

We also did some sampling in the blasting area. Two (2) samples were collected there. When we looked at the WPFs for the zirconium material in the spraying area, or the coating area, lead mist was the contaminant. You evaluate there and we see the workplace protection factor. Since only three (3) samples were there, those are just the values that were collected.

From this particular study, then, we're also starting to get a better handle of some of the errors and problems that were arising in the study. You see some of them here; sampling pump reliability. In fact, we found that probably the inside samples are pretty tough on the sample pumps. We talked about calibration procedures and so forth, and a lot of these particular problems can be controlled by good industrial hygiene practice, good observations, good record keeping and so forth.

The next set of errors get into things like probe design; perhaps a little bit more difficult to control, but we can experimentally verify things like probe design. Probe leakage can be done by performing leak tests. Probe placement, and you'll hear a little bit later on, plus it's been alluded to earlier, about problems with that. While I don't think we could solve it, at least we could try to be consistent with our probe location and technique.

Analytical methods are important, sensitive and specific

ambient methods for ambient air contaminants should be used. You heard a little bit about maybe stuff coming from workers for inside so that makes . . .

CRAIG COLTON: . . . the fit testing that needs to be done also needs to be meaningful for the respirator used. You can't do quantitative fit testing on a respirator that only has a dust, mist filter and no way of interchanging that filter.

Good training can be accomplished. Hopefully you're repeatable with the instructions that you provide to the worker and their degree of experience is also something you can record and relate to. Hopefully good sample handling so that you avoid contamination, because it's easy to contaminate these inside samples to the nanogram levels.

Another possible source of error are the ones that are listed here when it comes to data analysis technique. We talked about eleven (11) times the field blank value so our samples would have a equal chance of proving and disproving our protection factor ten (10).

Also, you'd like to have confidence in the analytical technique, which happens to be related to the filter loading, not the concentration, but how much material you have on that filter when you send it to the lab. And the closer you are to the blank value, of course, the less confidence one has. Also, due to the many sources of errors, I think you have more confidence--the confidence in individual protection factors is less than what you have in mean protection factors.

This is about where the--if I digress a minute. Some concerns were raised about one of the things that we haven't done

here is looked at particle size yet, so it was suggested that we look at particle size and that became a concern. So we returned to the work site. Now this was about a year after the study was done that we went back to do the particle sizing. So these particle sampling results were not collected at the same time that the study was going on, but we attempted to verify that a lot of the conditions of the work environment, the wheels that were being used, the speed at which they were being operated, the parts they were working on, in fact in some cases many of the workers and temperature were at least the same as when we were there. So hopefully our thought is that these are at least representative particle sampling of what was there. Maybe not exactly what was there, but representative.

Some interesting things about the sampling here. We used Cascade impactors to do the sampling. Sampled at about two point two (2.2) and two point four (2.4) liters per minute. Sampled for five (5) to seven (7) hours on two (2) consecutive days. The mylar filters that were used were coated with vaseline. The analysis was done by ICP and so silicon was not analyzed. So you see just information for aluminum and titanium here. One of the things that's interesting, you notice a large percent of the material here, less than the point five (.5) micron, is in the most penetrating size for the filter which was of concern. Some concern that the protection factors might have been due to not having small particles there, but there was a fair amount of small particles there. And that may be responsible for some of

the differences between titanium and aluminum as we tried to look at the differences in the WPFs there. In fact, if you look up to the five (5) micron size particle, a large percentage of the masses are there.

Also the relationship on outside filter weight versus protection factor was also of concern here; investigated and found that the higher the outside filter weight the greater the workplace protection factor. This shows you at least the information from titanium. One of the things that we started to find with this particular study is that here we have an area where at least there is increasing--with increasing filter weight we have an increasing workplace protection factor. And then it's not until we get out here into this area where we don't--we see the workplace protection factor is not related or effected so much by the mass loading that's on the particular outside filter. And perhaps at this point, now, we've got a proportionate amount of collection on the inside filter as with the outside filter. So it's at least proportional. Perhaps that's where the workplace protection factor should be measured, because that, perhaps, defines the performance of that respirator.

If I look at the next study, we move off of a half-mask respirator and now move on to a full-facepiece respirator. The environment was a secondary lead smelter. The tasks involved were furnace loaders and operators, people in the casting area, warehouse, and also baghouse workers. The contaminant was lead in this particular workplace. Air sampling was conducted on four

(4) days in basically the four (4) areas; the furnace areas, casting, warehouse and also baghouse areas. The product tested, as I mentioned, was a full-facepiece respirator equipped with high efficiency filters. Of course, NIOSH approved. One of the things that I want to point out on this particular full-facepiece respirator, which I'll come back to later on is, notice the presence of the nose cup. When we talk about the probe location that's going to be important.

The test equipment was very similar as in the past studies using the twenty-five (25) millimeter cassettes, still three (3) piece cassettes, so on. We have changed the sample pumps from what we had used earlier. We basically had worn them out so there is some tough duty for pumps doing inside sampling.

Another change that we made, probably the biggest change, to the sampling equipment that was used, you notice here. This was our water trap or moisture collector here, because there is a large amount of moisture we'd find would come to the inside filter, and we put that in there to protect the pump.

Test subject screening, the same. These people normally wore full-facepiece respirators; informed about the purpose of the test; education and training on the respirator. Again, used slides, but instead of using the sound on sound slides, it was narrated by one of the people conducting the test. And then quantitative fit testing was done here, and the reason is that since they were using full-facepiece respirators the OSHA standard required this person to do quantitative fit testing. So the

method we used was quantitative fit testing using the TSI Porta-count. Care was taken by the observers, while it looks somewhat questionable here, to make sure that the things like the hair bonnets are not projecting through the face seal.

Another step we added after the workers were subjected to the quantitative fit testing, the exercises, I might add, that they did, were those that were in the lead standard protocol for qualitative fit testing. So we kept the exercises the same as in the qualitative protocol. The pass/fail criterion was five hundred (500) for the workers, and thirteen (13) workers were qualified for this particular study. Once they were qualified based on passing the fit test then face measurements were also taken.

This shows the probe that was used in this particular study. This probe is a little different than the ones we see, but the specifications for it were still the same as the Lou to minimize particle entry loss. So the entry characteristics were the same as the probes we'd used in the past. Then a probe was also placed on the outside filter with those entry characteristics.

This shows then the probe location was in--we placed it where the speaking diaphragm normally was put to get a gas tight fit. Also put it inside the nose cup rather than outside the nose cup, because we felt that would be the best location. It also provided for a consistent and reliable probe location. The other thing on this particular study on the probe is then we have a sleeve here to allow hooking up the cassette to that particular

probe. That shows at least how the cassette, then, would be attached, and, of course, then sample line to the cassette. However, we thought that if we sampled from the facepiece on the outside of the nose cup, then we would be mixing--we wouldn't be getting--where air would be mixing hopefully, so that's why we thought it was better on the inside the nose cup, and it was also closer to the breathing orifices.

Sampling procedure; very similar, except here on the outside sample you see we went down as far as a half (1/2) liter per minute in some samples. Again, with PIXEA you're still concerned about problems with overloading the filter, so sometimes a half (1/2) liter per minute was used to avoid overloading of the outside filter. So one of the problems it becomes is an analytical technique that can withstand very larger orders of magnitude difference in measurements from the inside sample to the outside sample. You can see the sample times there. They're getting considerably longer in order to collect more mass onto the filters.

Sample analysis was the same. Also prior to the study, then, reasons for sample set and validation were also established. And these would be things that would make the sample not fit the protocol or the definition of what we were trying to measure. Things like the inside sample comes off the probe. In one case we had a probe break. In some cases where the respirator is totally removed before the sampling period is ended--they'd get anxious when they think it's done; they're ready to

go. Sample pump failure. Also we preestablished that the outside filter weight needed to be at least fifty-one (51) times the blanks since in the lead standard OSHA's assigned a protection factor of fifty (50) to full-facepieces, and if the inside filter weight is less than the blank we're reject that.

Calculation procedures are the same as the rules we established. We also did particle size sampling here, again, with personal Cascade impactors. We used graphite furnace AA for the analytical method and sampled at two (2) liters per minute. That shows our cut points.

This shows the particle size results. Lead dust plus there's some material there in the smaller particle sizes as well. One of the things is when you look at the outside concentrations when we look at the percent mass you'll see that while we're looking at maybe a few percent there in the fume size range that it represents a significant amount of mass.

The next tray is not a full tray, if that's some hope for the finish. This shows the results from the full-facepiece study. Outside samples ranged from a hundred and fifty (150) to almost thirty-four hundred (3,400) micrograms per cubic meter. Inside samples ranged from point 0 three (.03) to three (3) micrograms per cubic meter. So those are the results of the ranges of the samples that we collected here. So, one of the things here is that by looking at the inside samples, no worker was overexposed to lead in this particular study. In fact, as we go through this, and as I'll finish, you'll see that that is a

consistent theme throughout the whole--throughout all the studies.

We look at the workplace protection factor studies; we collected--we ended up going here for four (4) days, as I believe I mentioned earlier. We sampled basically about ten (10) hours or so during the day. In other words, after the first shift we carried it over into the second shift due to some using force for the other observers that are along to get more workers into the study, and hopefully more data points. What we came back with when you look at the ones we lost--a lot of them fell off of the probe, and other mechanic problems, and we're now down to twenty (20) sample sets. Based upon those twenty (20) sample sets, the geometric mean is a little over thirty-nine hundred (3,900). We have a fifth percentile of about ninety-five (95) and a lot of variability.

We looked at the mass loading relationship here since we started to see this in so many places again. One of the things you'll notice there is all twenty (20) samples are greater than one thousand (1,000) times the blank, so that fifty-one (51) times criteria was never a thing to be concerned about in this particular study. However, if you look at, again, increased mass loadings, we're seeing increased workplace protection factor. Although the rate, perhaps, maybe is not as different. In fact, in this particular study maybe we started to get close to the plateau for this environment and this respirator. Getting down to quite various small sample sizes, though, down at the end.

This shows the same thing for the fifth percentile, and it also shows you the geometric standard deviations for these studies. One of the other things was since we had done quantitative fit testing we thought maybe that could predict the workplace protection factor, and we found no correlation. I don't know if we need to examine that more.

Conclusions from this particular study is that the assigned protection factor of the full-facepiece respirator is about--if you use the fifth percentile--is about one hundred (100) against lead dust and lead fumes. That was the challenge in this particular environment. All lead concentrations measured inside the respirator were less than the OSHA PEL, and the quantitative fit factors did not predict workplace protection factors.

This is the next study. If you look at that, some of the slides at least as I started off in the beginning study, they should look very similar. It's a secondary lead smelter. It's the same secondary lead smelter except this is about a year, year and a half later, and this particular employer had changed from using full-facepiece respirators to going to powered air purifying respirators. So, since by this time they had been using them for over a year, thought they were somewhat experienced with them, we went to sample in the blast furnace, reverb furnace, casting area, and the baghouse area. The warehouse area was not sampled in this study, because those workers there did not use powered air purifying respirators; the concentrations were lower there. So that part was eliminated.

The sampling was during five (5) eight (8)-hour shifts. We were there for four (4) days, but we sampled over five (5) eight (8)-hour shifts. Again, to get more workers into the study and increase that--the number of workers. This shows the respirator that was being tested; powered air purifying respirator, full-facepiece, tight fitting device. It's the same facepiece that was used in the full-facepiece study, so we got one testing it in positive pressure mode, and one in the negative pressure mode.

The test equipment was the same as in the previous study so there were no changes there. The sampling procedure was the same. In some cases we were able to sample for a little bit longer time period, one (1) to four (4) hours perhaps. That's because that's how the work shift worked in this particular--this time around.

Test subject screening was pretty similar. These people by this time normally wore powered air purifying respirators with this full-facepiece. Again, they are informed about the purpose of the test. The training on the respirator donning was done. By this time and in some other studies, it was becoming difficult to always find room for a slide projector when you go. While it's nice to make sure you always cover the same material in the training part of it, it became difficult to always find electricity; place to set it up; place to project it and that. So by this time the donning and respirator instruction was done by not only verbally from one of the observers, but then they also demonstrated it.

Quantitative fit testing was performed as before using the Portacount and so forth. Since this was a tight fitting powered air purifying respirator and that's been suggested--so we did that. The workers were assisted by the observers with the sample setup; hooking the sample to the probe and so forth. And this is in the clean area before they've gone out to the sample site.

I might also add that I started--I guess I forgot to mention it in the full-facepiece study, but by this time we mentioned about the concern with the moisture and we've put a moisture trap on the sampling line to protect the pump, which you can in fact see it there on that slide. Also the moisture caused problems for the particular filter, and we had a cellulose--or a typical back up pad--and when that would get wet we'd also lose samples because then your sample would implode and you'd end up then pulling away from the walls of the cassette and you'd have a lost sample, because you were sampling around it. So that was another reason for invalidating samples. Again, that's due to the moisture. That can effect flow rate, so we changed how often we were calibrating. And now we were calibrating back in the full-facepiece study before and after each sample set. So if we took three (3) samples sets we calibrated six (6) times. Also we moved by this study to a plastic porous backup pad to allow the moisture to move on through. So there was some equipment change.

Reasons for sample set invalidation are very similar here. We had lost a lot of sample sets coming off of the probe so we changed that sleeve arrangement a little bit, because these

workers were quite physical in the tasks that they performed. In fact, when we went to this particular study we were ready to estimate the work loads--we thought that would be important--so using the ACGIH classification in the TLV booklet, in fact, we estimated at heavy workload. This was quite a hustling bunch of workers here. They didn't just step down off of the powered equipment, they jumped off of it and run over, pick up the sledge hammer, and all in the same movement start attacking their work. They attacked it and hopefully the observers weren't in the way.

We seemed to take care of the probes falling off the cassette this time around, but we still had several other things. The only thing different is we've increased the outside filter loading requirement since we're looking at a powered air purifying respirator, and APF of one thousand (1,000) has been assigned to it. And we also, since air flow was going to be important, it had an alarm. We would use the alarm as indication that the flow had fallen and the respirator wasn't operating in it's proper condition. So we tested the alarm before the workers went out into the workplace. In no cases did the alarm ever sound during the test.

Sample analysis was the same. Particle size sampling was done. There were area samples, but it was done in putting it in areas near--we tried to get as close to the worker as possible, tried to get it about breathing zone height. The results indicated that the distribution was pretty similar to what it had been there before.

Calculation procedures were the same. We look at the outside samples, the concentrations ranged from a hundred and sixty-two (162) to a little over four hundred (400) micrograms per cubic meter, so somewhat pretty much similar. Inside samples, it was different. They ranged from non-detectable levels to one point four five (1.45) micrograms per cubic meter.

So if we go and we look at all of the studies and those that we can blank correct--of course non-detectables it's hard to blank correct, because you've got--and we ended up with twenty (20) samples in this particular study. In fact, maybe I guess what I should--out of fifty five (55) samples that were collected thirty four (34) of them were below the detection limit, so over half our data--the inside samples were less than that, so hence no workers were overexposed to lead as indicated by the inside samples here. One sample was an outlier, and that's how we get down to the twenty (20) samples. The means, somewhere around forty-two hundred (4200), and you see the fifth percentile there.

One of the things, since this was the same environment this is probably as close as we've ever come to keeping the variables similar from one study to the other. And so I've put both the full-facepiece and the PAPA results up here. And you see their means are very similar. There's not much difference in this particular situation. However, when we tested the fifth percentiles we did find that those were different.

Now the question is, though, one of the things is, remember, we've got these thirty-four (34) samples sets that were non-

detected. While it makes it hard to do math on those numbers, that represents good information, because here we've got--what that's telling me is we've got good, consistent level of performance that was being provided by the respirator. So, then, the way to handle that, we went back to say, okay, we'll use a detection for something--for lack of a better idea, which perhaps doesn't make much sense. But it gave us a number.

On the inside blanks, or the field blanks, I should say, we did not find any lead so we did not blank correct, so these data were not blank corrected. We have our fifty-five (55) sample sets, we now look at--using the detection limit as the inside sample value--we look at the geometric mean and the fifth percentile and it's greater than one thousand (1,000).

What's another way to look at it? Well, time weighted averages. This is lead, that's what maybe makes more sense. So another way to look at that is go back to the original samples, the twenty (20) samples we have, and combine all the masses and then the volumes and divide the mass by the volume and use those numbers to calculate time weighted average workplace protection factors. You see the results better there.

Well, there's one more version we can do of this. We can go and take--we only had twenty (20) samples to work with from fifteen (15) workers. What about those other samples? So we can go back and take that detection limit amount, add that in and call that the mass that was found on those, now combine the total masses, total volume of the air volume, and calculate the time

weighted average workplace protection factor there and the fifth percentile. And you see the results there.

One of the things is, look at mass loading relationship again, all fifty-five (55) samples the mass loadings were greater than one thousand (1,000) times, so we met what we set out to do in this particular study. It shows you the mean and the fifth percentile, which you had seen earlier. You also notice, though, that with increasing mass loadings, increasing workplace protection factor.

This shows the graph here, the correlation coefficient was point nine seven (.97) in this particular study. So we still probably hadn't gotten to the plateau area perhaps in this particular study, to really measure the true performance.

Some of the things we did conclude from this study is a full-facepiece PAPR provides good protection under workplace conditions. The PAPR provides a higher degree protection than its negative pressure counterpart. The PFs were different when we looked at the fifth percentiles specifically. We think PAPRs with full-facepieces should be fit tested in the negative pressure mode, and that the data supports ANSI Z80.2 recommendation of assigned protection factors of a thousand (1,000) for tight fitting PAPRs. Also, the workers were not overexposed as indicated by the inside measurements.

The next study was on a half-mask dust, mist respirator. It's a disposable dust, mist respirator done in an aluminum smelter with pre-bake anodes. The contaminant was aluminum dust,

and we sampled for the respirable fraction. It said--about this time people were saying, well, maybe in order to make studies more comparable and avoid large particle size effect on the outside is to use a Cyclone sample as your outside sample. The workers sampled were carbon changers. It shows some of the tasks that they performed. There you can perhaps see the inside sample probe a little bit more clear. In fact, this is really--the probe location is very similar--showing hookup of the particular sample. Again, trying to get midway between the nose and mouth.

This shows the sample setup on this particular worker. Of course, her inside sample; here's our Cyclone sample, and then we have our field blank that was collected. It was treated just like all the other samples except no air was drawn through that sample.

We looked at the workload. One of the things about these workers is that the task, the carbon changing task, was perhaps not that long. It wasn't a full eight (8) hours. In fact, the task was broken down into three (3) parts, and the sample times ranged from sixty-seven (67) to a hundred and thirty-five (135) minutes. But when they worked to do the change, they worked hard. In fact, again, by rating it, we rated it as heavy work, because as soon as they got done they got to go sit down and play cards. So that was their motivation to get away from the heat. And you can see it was quite warm and working at a high rate there.

This shows the sample results here. Again, in this particular case we had respirable dust samples. That was the outside concentration, and this shows the twenty-three (23) full shift samples that we were able to collect from this particular study. Fit testing and all that was the same. The protocols were very similar. We see the geometric mean was from twenty-seven (27), the fifth percentile, thirteen (13) in this particular study.

Non detectable levels were found on the field blanks so there were no corrections found for the--no corrections made for the blanks. Also, there was one (1) outlier found. It's protection factor was at the high end. It was a hundred and sixty (160). One of the assumptions that this made is that--the reason we put the Cyclone here, too, another reason, is that the assumption is made that all the particles on the inside sample were respirable particles. And that may or may not be appropriate. In fact, fortunately we never verified that.

It shows another operation which brings me back to being able to talk about the task. The task was performed in three (3) different--three (3) distinct--segments. They'd have their opening up the cells, and then they'd change the carbon, and then they'd come back and cover up the anodes here. One of the things that--we got to looking, and since we talked about this mass loading relationship is what if we had just looked at the area at which we thought we could get the greatest mass loadings. Not the area that had the highest concentrations; we're not looking at where we got highest concentrations, but where we could get

the highest mass loading. In other words, the procedure lasted long enough; either longer, maybe the concentration a little bit higher, but the combination gave us higher mass loadings. And it was pretty easy to identify, or somewhat easy to identify that there was one (1) task that provided us with the greatest mass loadings. So, we decided, well, what if we only looked at that particular operation, and this shows, then, for the twenty (20) samples that were collected during cover up; the geometric mean workplace protection factor in the fifth percentile that was found. Again, this is using a respirable dust as the total dust--or as the outside concentration--so we didn't change that part, but the chance in the workplace protection factor, then, appears to be due to the mass loading.

Particle sizing was important since we were using this Cyclone. We did do particle size sampling. Again, area samples that were done. In addition to the particle size sampling with Cascade impactors we also did optically where the looked at the samples collected on the Cyclones, and we found that in those particular samples in the wet--on days that we had some rain there, which perhaps the humidity was a little bit higher, the geometric mean was one point four nine (1.49), and on the 'dryer' days where it wasn't raining the geometric mean on the Cyclone--the dust we'd find on the Cyclone--count median--was two point six one (2.61).

This shows Cascade impactor information that's on the--that's presented here on this slide. And this shows the particle

size distribution. A lot of stuff at the ten (10) micron state there. If we go down smaller to point two five (.25) we also see a fairly large percentage of the mass fraction in that area. In fact, it looks like we've got a bimodal distribution here.

The other thing we were concerned about is, what's this doing with regards to our outside sample. Of course, I think many of you are familiar with this. This is the collection curve for the Cyclone when it's operated one point seven (1.7) liters per minute, as we sampled here, and what percentage of the size fraction we would sample. If I take those two (2) graphs and superimpose, perhaps it gives you a better look at what we've excluded--what percentages of the aerosol we excluded. So we were looking at just the smaller stuff there.

We looked at the mass loading relationship, again, of the filter weight and the workplace protection factor studies, where it's taking all of the data that we had, plotting it, then we see that particular relationship. So conclusions here, the half-mask dust, mist respirator that was tested provided workplace protection factors of ten (10). No worker was overexposed to aluminum. There's the inside concentrations. We also believe that these workplace protection factors represent conservatives estimates of protection. We didn't test again where we could measure the true performance of the respirator, and the data tends to support, then, the proposal that Z88.2 is working on an AFP of ten (10) for this particular respirator.

The last study. I'm as happy as you are. This is almost

like doing a workplace study except I dress nicer. The next place was a brass foundry that we went to. Air sampling was done in five (5) days in the core making area, molding making, pouring area, and then the cleaning area or grinding area of this particular workplace.

The workload here was estimated to be moderate to heavy. I think we'll see a worker that was working at a heavier rate. Temperature was between twenty (20) and twenty-nine (29) degrees Celsius, so roughly sixty-eight (68) to eighty-four (84) degrees Fahrenheit. The produce tested was disposable high efficiency respirator. This shows the worker there sweating while he's not--the one in the front wasn't tested on the day this picture was taken. He was tested earlier. The respirator, as I mentioned, disposable, HEPA filter. It's available in two (2) sizes, NIOSH approved. Test equipment of the study was very similar as to the last study in that we're now--again we used a ten (10) millimeter nylon Cyclone for the outside cassette--for the outside sample.

Probe location was slightly different. Since we have an exhalation valve in this particular respirator, the probe and then mounting of the cassette was going to be to the side. We're still trying to get between the mouth and the nose, but we had to be a little bit to the side of the exhalation valve in this particular study. The workers were fit tested using saccharin following the fit test protocol in the lead standard.

The workers were, as in all the studies here--we stressed that the workers were to be clean shaven. I mentioned that at

the beginning. I might make a comment about clean shaven. They're clean shaven by, I guess, what would be worker criteria. First of all, many of the workers, what they tell you is--they come in there and you ask the clean shaven; there's some you look at the stubble, and you really question it. But there's differences, of course, between workers that way. But when the worker is many times bigger than you, the question is how far you say you're lying. And what they usually tell us, I shave at the end of the shift, and then I come back and work, which was pretty common. So at least the best situation was, when we got them the beards were at least sixteen (16) hours old. In some of those, some of them really have a healthy growth after sixteen (16) hours. But that's one of the variables that becomes perhaps difficult to do. So in all these studies they were 'clean shaven', but not like I am today.

Seventeen (17) workers were qualified for the study using the saccharin and fit test protocol. And again, training--by this time we're doing it totally verbal and demonstrations by one of the test observers. The protocol was the same; half-mask respirators, so our criteria is eleven (11) times that we're looking for. Again, told of the purpose of the test, and so forth.

The sampling procedure you see is very similar. The outside flow rate's different because it's the Cyclone. It was the same as in the past in the previous study with the Cyclone. I don't think we need to say much about that.

Here's the concentrations for the lead and zinc that we found. Outside concentrations for lead ranging from thirty-four (34) or three point four (3.4) to seven hundred and eight (708) micrograms per cubic meter. So, not as high of concentrations as in some other work sites. The inside concentrations for lead ranged form non-detectable to four point three (4.3) micrograms per cubic meter. Again, less than the OSHA PEL. You also see information on zinc, and again, no worker overexposed to zinc. And used the fume PEL there.

This shows the results, then, that we came back with on this particular study. We had a large number of the lead samples--of lead inside samples--that were less than the detection limit. In fact, about one third (1/3) of the total samples. This shows that. In the case of the zinc, I guess there was perhaps one outlier so we had sixty-two (62) sample sets there. Also, I'll mention that for zinc it's sort of interesting, because the sensitivity--the level of sensitivity to detection limit here for zinc was lower than it was for lead, so we didn't have this problem. We didn't find any of the samples non-detectible for zinc. Which, maybe that's the explanation for that. Although one of the things is, then what do we do about those lead samples, and, again, revert back to what we've done before; take the detection limit, add that amount to the inside filter and use that to calculate workplace protection factors. And that's what you see on the line indicated Lead DL, for use of the detection limit. Again, a large fraction of the data, though, is non-

detectible. I think that information tells us something.

Particle size sampling; this shows you just a combination of everything, the respirable dust sample, then the particle size distribution.

This is the grinding area. Notice a fair amount of stuff there; ten (10) micron, then some other peaks as we proceed. We didn't calculate a mean particle size because I don't think it really represents the data we collected here, so we're just showing it this way.

You notice in the casting area--the pouring--it's still somewhat similar as it was in the grinding area, but when we get to the molding area it's different. There we've got a lot higher percentage of the mass down at the small end of it. I don't know if I have any explanations. The one thing I can tell you about how this building was set up is that you had a grinding area, the pouring and then the molding, pretty much in a straight line through the building, and one of the things that you noticed was that at the end of the molding area there was a door that evacuated out, and you could at least notice the breeze that went through the building. So it might be that the drift, especially like fume from the pouring area, might be drifting down to the molding area. That's just about the only explanation I have for that.

We looked at mass loading. Again, I'll just show you the information for zinc. It was similar for lead. We're finding the same thing. We have--eleven (11) times wasn't particularly a

problem in this case for zinc. But, again, we're still finding that relationship which makes us somewhat concerned that, you know, I don't know if we've ever measured the true performance of the particular respirator.

The results of this study support the use of a half-mask respirator for particular concentrations up to ten (10) times PEL. We think there's a good reason to look at the protection factor and filter weight relationship. Also, by this time, while we didn't have any information to indicate that the inside sample was not a respirable dust sample, it started not to make sense, though, to go out and do a respirable dust sample for lead when the standard calls for total dust, for a couple of reasons. One, if you still do particle size sampling then I can maybe get at the respirable--the Cyclone traction, and look at it that way. So I still have that information, perhaps.

The other thing is that you go in here to the workplace and try to get these people to go along; we found--we've had nine (9) studies, that means we've had to find nine (9) people that were willing to allow us in. We disrupt their work for a week, and you tell them you're going to get something out of it. I mean, we're going to benefit, but you're going to, too. And to go in there and just do sample for something like lead where they're looking at total dust samples, and then to do respirable dust sampling doesn't make much sense as a benefit to that particular person. So I suggest we need to consider that if we're going into a lot of workplace sites and want to get their cooperation.

Particle size sampling is important, as I mentioned earlier. And, again, what we found in this study, and in all the studies that we report here, none of the workers were overexposed to any of the contaminants that were sampled there. So the question is, can we do workplace protection factor studies. Well, we just presented nine (9) of them. We think we came pretty close to meeting that definition. Now, did we measure the level of the true performance of the respirator? I don't think so. We really haven't gone out and tested them where we can really show what that level of performance is. What we have been able to show, though, is that the performance is not inconsistent with the assigned protection factors of them at this particular time, and the protection that they're providing the workers is appropriate.

This information also had some impact on what we think makes up the protocol for this. For that particular information Allen is going to present that.

. . . presentation on the work that they have been that they have been doing.

ALLEN JOHNSTON: Good morning. I'm Allen Johnston from 3M. I'm going to be speaking on behalf of the ISEA this morning, taking a more broad opinion that we might have as a specific manufacturer.

I'm going to start by telling you what our basic or overall interpretation is of the information that you just saw. There was a lot of information there, a lot of studies we've done, and it might look like we know a lot of things, but I think basically that we know that we don't know a lot of things. We know that we don't know how to test respirators like this, and we know a lot of things are problems. So basically, when we look at--we're talking about the performance capabilities of respirators we know they have traditionally been evaluated by testing filter efficiency, fit, total inward leakage, or other measures of performance under well-defined and well-controlled laboratory conditions. That's our history.

In recent years increasing emphasis has been placed on development of test methods for evaluating the respirators in the workplace, and the goal here has been to define the level of protection achieved by persons wearing respirator protection in work environments. Now workplace protection factor testing, we think, does show promise as a tool for increasing knowledge about capabilities of respirator protection, but a number of technical

issues need to be resolved before optimal test protocols and data analysis methods can be defined.

At this point there are still too many uncontrolled variables and too many unknowns associated with workplace protection factor testing to allow standardized reproducible test methods to be defined. As a result, although we would encourage continued research on workplace protection factor testing, such testing is not currently suitable for incorporating into certification standards. We know too few things about what we're doing. We just cannot understand what we're actually measuring yet.

You might say we know how to do such testing because you've seen many tests, but we don't know what they mean. I think it's basically that simple.

To give you a little bit of background and information of why we feel that way, in situations where respirators are relied up on for worker protection, it is important that respirator programs include a means for assuring the quality and effectiveness of respirators in use. I think we all agree with that. The common starting point for this process of looking for safe effective respirators has been the selection of approved respirators. We've relied a lot on NIOSH laboratory type testing. In fact, the certification testing using the defined laboratory methods, the filter efficiency, cartridge service life, breathing resistance and looking at these other properties of respirators under well-controlled conditions where we can assure important variables such as temperature are controlled, humidity is con-

trolled, test agent concentration is controlled, air flow is controlled, all these types of variables are well-controlled and maintained; in those cases we feel confident that we can assure predictable and reproducible equitable results regardless of the respirator type and regardless of the manufacturer.

Researchers who have been looking at performance of respirators have frequently used these same types of laboratory tests, because of the fact that they feel able to get reproducible results. However, the ability of laboratory data to predict performance of respirators in specific workplaces is not always clear. So that question arises, how do we extrapolate or can we extrapolate.

Well, when you look at the workplace, conditions in the workplace have extremely variable temperatures, humidities, air contaminant concentrations, particle size distributions, and on and on and on it goes. This has resulted in the interest in going to the workplace to start looking at some of these variables. So interest in doing testing in the workplace and discussion about workplace testing of respirators has increased significantly especially since NIOSH issued the proposal regarding workplace protection factor testing, or simulated workplace protection factor testing in the certification process.

So much of our discussion with respect to ISEA has centered around the basic question. What workplace protection factor test procedures, if any, would be suitable for incorporation into certification standards? A basic answer to the question is that

incorporation of workplace protection factor test requirements into certification standards would only make sense if it was possible to define standardized test methods which have the ability to ensure collection or generation of meaningful and reproducible protection factor results for all types of respirators. It would be very nice if we had enough knowledge to do that and could control workplace protection factor testing well enough to define test methods which would meet the criteria of being objective and reproducible, but unfortunately it is not yet technically feasible to do that. We simply cannot achieve that goal at this time.

Workplace protection factor testing is still best classified as research activity. Despite the significant progress we've made and all the information that you've seen today and yesterday, we still need to make a lot more progress in understanding the variables that are associated with this type of testing. So a number of very, very key technical issues need to be resolved.

As you saw this morning, 3M has conducted a lot of studies. We didn't, by the way, report all of them to you. We could talk on some more, but I don't think we'll do that. We have also very thoroughly reviewed the work done by other researchers, by Warren Myers and by Barry Pallay, and by other people that have been involved in workplace protection factor testing. We're very interested to see what other people are doing. And through this work of our own and the review of the work that other people have done a number of key issues related to technical feasibility of

conducting workplace protection factor studies have been identified. And put into broad categories we can classify these perhaps as study objectives, site selection, subject selection and preparation, sampling procedures, analytical methods, and data analysis procedures. Within each of these categories there are several potential sources of variability which are not yet and may not ever be controllable to the extent necessary for ensuring a fair and equitable certification test.

We'll start by looking at the test objectives. You've heard a little about that--heard a little bit from Craig and a little bit yesterday. The objective of testing respirators in the workplace must be clearly defined before suitable test protocol can be developed. The term protection factor as you've heard has several very different meanings depending on the context in which it is used. The American Industrial Hygiene Association with input from NIOSH and other organizations has suggested definitions including a definition for workplace protection factor. Unfortunately, despite these definitions, official recognition, acceptance or use of these terms has been very slow. As you look at studies reported even today, and they call them workplace protection factor tests or test results, they really are not. So it's a very big problem for us. The lack of universally accepted protection factor definitions has lead to inconsistent use of protection terminology which, in turn, has resulted in significantly different approaches to respirator testing in the workplace. And according them to the current definitions, the

goal of the workplace protection factor study should be to determine the protection capabilities of a respirator. That's the protection factor provided by a respirator which has been properly selected, properly fit tested, included in a properly defined and operating respirator program, tested while it's being properly worn and used, and on it goes.

And in fact, if you look at the definition; I'm going to read that to you even though you've heard a little bit. This is the actual AIHA definition for a workplace protection factor. It says, "workplace protection factor is a measure of the protection provided in the workplace under the conditions of that workplace by a properly selected, fit tested, and functioning respirator when correctly worn and used. It is defined as the workplace contaminant concentration which the user would inhale if he were not wearing the respirator divided by the workplace contaminant concentration inside the respirator facepiece. So both the concentration outside and the concentration inside are determined from samples taken simultaneously only while the respirator is properly worn and used during normal work activities."

Now, if you look at all those inclusions in that statement, and you go back and look at the research and look at the studies that have been reported on and try to see if those two (2) match up, I think you'll find that although there are a large number of protection factor studies that have been conducted in various workplaces, most of them have not provided data that would meet this definition of a workplace protection factor. Many have

resulted in estimates of effective protection factors; still more have provided estimates of program protection factors, and just so you understand the differentiation there, an effective protection factor study, would be evaluated performance of respirators which were properly selected, fit tested, fitted, and used, but the sampling may have been conducted during periods of respirator use as well as periods of non-wear time. A program protection factor study might evaluate respirators which may not have been fit tested at all, or may not be properly worn or stored. So there may be other elements that are coming in there. So results from the effective program protection factor studies and the program protection factor studies have the ability to provide estimates of how well a respirator program is set up or functioning. They do not have the ability to measure respirator performance capability.

They also do not have the ability to provide information about the added difficulties encountered when attempting to run true workplace protection factor tests. So as a result, the actual experience we have with workplace protection factor testing per se is much more limited than might be assumed from a review of the studies that have been reported and published in the literature. And this makes it difficult, because agreement on and improved use of protection factor terminology is still very slow. It's a very important first step for us to achieve before we can ever have any hopes of developing standardized methodology. And we have not even reached that phase yet, in my

opinion. We need to work better together to make sure we're talking in the same language. And once we do that, perhaps we can move forward somewhere and start addressing some of the other technical obstacles. But this very basic fundamental difference in terminology we're using is a stumbling block before we even get into technical issues.

Take a look at some site selection considerations, another one of the major areas of concern, and here, if you take--look at--the techniques used for sampling inside of respirator face-pieces, they might reasonably be used in virtually any workplace if your goal is to estimate worker exposures while they're wearing respirators. But if you're trying to estimate a work-place protection factor test or workplace protection factor for a respirator, this is not any longer true. Valid workplace protec-tion factors depend on the researcher's ability to control and/or identify and understand the impact of multiple variables. Important site selection considerations include all of these that you see here. They type of operation, the number of workers wearing respirators, the physical layout of the facility, the accessibility to the work areas, logistics of having several observers in that same area with the workers, the distance between the work areas and the mobility needed to get between the work areas, and the availability of clean areas to set up sample removal--sample setup and the sample removal--the variability of the work processes and the work cycles, and type of ventilation and variability that might have, the duration and frequency of

respirator use, the work rates and the movements of the workers. The amount of interruption of the work task that can be tolerated differs significantly. The impact of our interference as observers with the workers varies significantly. The safety rules in effect vary significantly. The type of respirators routinely used in the plant will vary. Other protective equipment in use will vary, and that may effect how the respirators are used. The types of air contaminants present obviously vary. The availability of air sampling data varies considerably. Completeness of the respirator program or existence of the respirator program varies. Compliance with fit testing and training elements and other elements of the respirator program vary. And management interest and commitment to a study vary. And probably there would be several other variables, and you could keep going on and on an on listing the variables related to site selection. And most of these we simply cannot control. They're not reproducible, even in the same workplace. So in looking at something we're trying to standardize, this is a very, very major concern. I don't know how we would address that issue in looking at trying to standardize testing in workplaces per se.

Also, if you look at screening and going through these types of criteria, the available sites for conducting meaningful workplace protection factor tests quickly become very limited when you go through this process; you run out of places that you can find that are suitable for conducting studies. A good study will require at least twenty-five (25) suitable workers, all

wearing respirators, fairly continuously. You need normally significant concentrations of air contaminants so your analytical methods will be suitable in their sensitivity and specificity to conduct a sample--conduct an evaluation--over the time periods that workers normally work; maybe one (1) to two (2) hours maximum at a time. The work sites need to be accessible. They need to be safe for your observers. You saw some of those slides in that secondary smelter, and we had some concerns about that for our own people. Do we want to go in there and get run over by a pot of molten lead. That's no exactly my idea of having a good day.

And management willingness to commit the worker time away from the job is important. If they do piecework they don't want to see you. They want--they might want to see you if they don't have to work a full eight (8) hours, but if they're busy and they're getting paid on how much they put out, they don't want you to interfere with them. So there are a lot of problems like that that have to be considered related to the site.

In addition, you can get into things like how much training do they do in house. Do they have respirator programs. Each of these factors varies significantly within workplaces and between workplaces. So it's extremely difficult to envision any means of defining achievable workplace test conditions which would approach the level of standardization and control necessary for a reasonable quality assurance test, or a reasonable respirator certification test. I just don't think it's really possible to

do in a workplace situation.

The next general area of concern would be related to the test subjects themselves. If your goal of testing respirators in the workplace once again might be to evaluate the workers' exposure, that would be basically an industrial hygiene evaluation as Warren Myers mentioned yesterday. That might be the best thing to do with in-facepiece testing. Just look at worker exposures. And if you're doing that, again, you can test any worker in any workplace, it doesn't really matter. But if you want to generate a workplace protection factor, again, you can't just pick just any worker. You've got some very critical needs with respect to which workers you can use in order to do this type of testing. And those needs include things like willingness to participate in the study; level of education and training and experience with the respirator that you want to test; the fit capability and the fit test experience that the worker has; the physical characteristics that they have such as beard growth, or dentures, or any other characteristics that might effect fit or use of the respirators; the level of exposure to the air contaminant of interest; the job task they're doing; the mobility they have are all very important factors.

If you look strictly at those criteria we can say some of the elements have to be met. We know that we cannot possibly generate a workplace protection factor unless a test subject is familiar with the respirator, is performing a job for which that respirator is appropriate, trained in fitting and use, is capable

of getting a good fit, willing to follow the established respirator use policy, and willing to volunteer for the study. The worker's level of experience needs to be identified since it may also have a significant impact, and that will, again, vary significantly in the workplace and between workplaces. And the other things like work rates, and facial hair, and facial size, and eyeglass requirements, medical and job restrictions, work locations, many, many variables which really are not controllable by the researchers going in.

In some cases we have found it necessary, as you heard Craig talk about, to conduct education and training programs or to perform fit tests prior to initiating protection factor testing. The fit tests must be suitable for the type of respirator involved. Now several attempts at workplace protection factor testing have been invalidated for this reason, including at least one (1) that's been published by NIOSH. They did not use proper fit testing terminology. They did not use proper fit test methods, excuse me.

When we look at this issue where you use qualitative fit testing, you've got to use those with validated test protocols. Where you use quantitative fit tests, you've got to use methods that are either recommended by the manufacturer, that are consistent with recent work on test variability and fit test design conditions, are consistent with recent OSHA or ANSI guidelines on fit testing. Those are all important to reference and incorporate into your test protocol. As an example on methodology, if

you wanted to use the TSI Portacount, which you saw in a couple of our slides earlier, or if you wanted to do quantitative fit testing with a standard small particle oil-mist system; if that's your goal, you need to have respirators fit tested that are equipped with high-efficiency filters. Any other respirators tested with a Portacount or tested with a quantitative fit test system would be giving you invalid results. You would be misrepresenting the data. You would be misrepresenting the information to other people, and you would be following guidelines inconsistent with both OSHA standards and the manufacturer's recommendations.

If you're able to control or document all of these many subject related variables, there is some possibility of generating meaningful workplace protection factor data for a test site. You can use that to show that your protection is adequate for the assigned protection factors of the device. Unfortunately, because of the extreme amount of variability that's possible with the test subjects and their jobs, it may be difficult or impossible to extrapolate the results even to other operations or different conditions in this same factory. An extrapolation of the results to other workers or other locations introduces even more uncertainty. You simply do not know how to go from point A to point B, there are too many other variables that will interfere with that.

It's difficult to conceive of any possible certification protocol for workplace testing which could incorporate different

respirators, different test subjects, different test locations, and different operating conditions, yet still come up with results that assure fair and equitable treatment of all respirators and all manufacturers. Certification tests must be reproducible and must assure equitable testing to gain safe, effective respirators across the board. The state-of-the-art, if you want to call it that, workplace protection factor test methodology that we have does not come anywhere close to meeting this type of criteria, and therefore, the methods that we have now are not suitable for certification testing.

Getting onto the next general area; sampling concerns or sampling procedures. The current in-facepiece sampling procedures do not yet assure reproducible results in the laboratory, let alone in the workplace. Respirators must be fitted with probes for this type of testing as you've seen. The various probe locations have been evaluated and reported on, versus different face seal leak sites, and different breathing patterns have shown inconsistent results. We've got sampling bias related to probe location, probe depth in the facepiece, sampling methods, meaning do we sample continuously or do we use a pulse/flow sampling method or some other means of sampling. We found that there are problems here; potential problems. I don't think we know how to address those problems yet.

We also have a problem with, we call it random air sometimes; variables perhaps that we cannot precisely identify. That's also been noted in several studies. Laboratory research

on sampling bias has concentrated on vapors. More work is needed to evaluate sampling bias with particulate test agents to better define what the sources now being called random air might be; to determine how laboratory testing--how laboratory research relates to workplace testing, if at all; and to identify and validate improved sampling methods that can be incorporated into workplace studies. All of these are critical needs for improving our methodology. We cannot adequately address any one of these areas right now.

It's clear that without that optimal sampling methods can't be defined. All we can do now is take information we've learned in the past and do the best we can. But each time we do a study we're still learning very rapidly how to improve things and how to change things.

So even a fairly simple decision such as where do we put the probe in the respirator; that has not been fully resolved. It's know that it's critical, but we do not have a consensus on where to put the probe, how to put it in the respirator, how to use it, in all situations. And we may not be able to standardize that because we have different configurations and different respirators. So it introduces a very significant problem with respect to standardization of test methodology. So as we look at that; well, you've seen that in the most recent studies we've developed a pattern of putting it in the breathing zone of the test subject between the nose and the mouth. And that's perhaps been reproducible from the standpoint the location has been the same in

basically all the testing, but it doesn't mean that your biases are the same. It doesn't mean that your test results are the same. It doesn't mean you have any control over the results. So from that standpoint, yes, we've been reproducible from putting it in the same location, we have not been reproducible in the data that we've generated.

Other concerns related to the probe might include the design--there have been different probes used in different studies--integrity of the probe, the tightness, the seal, and a lot of other factors related to the sampling train and to the sampling method. You look at the sampling pumps that have been used; the commonly available air sampling pumps seem to be quite sufficient. They do break down after time. We have worn some out. The air flow rates we've used have normally been one (1) to two (2) liters per minute; certainly acceptable or seem to be acceptable without increasing or decreasing pressure within the facepiece significantly. So we don't really seem to have a problem with identifying sampling pumps.

When we get to the sampling devices, the collection devices we want to use, that's a different story. We still have several concerns in that area. Moisture buildup you've heard about being one concern that can substantially increase the pressure drop across filters, and can collapse filter backup pads. Imploding, the fact that you heard about, was a problem. And that collapse, obviously, invalidates the samples you're collecting. You heard about the stiff--the plastic backup pads, the porous pads that

have been used to reduce that problem, but they have not eliminated the problem. It still exists in some sampling even though we have used porous sampling pads. Heated coils wrapped around the filter cassettes have been suggested as another option to help reduce the humidity. That seems to be quite effective in some cases, but it may be only partially effective in other cases. We still do not know that that's applicable to all situations and can always solve the problem. And so I don't think we've solved that problem of moisture buildup. Yes, we've made a lot of progress, no, we haven't solved it, so we cannot adequately address that issue yet.

Moisture from exhaled breath is a concern from another standpoint if you look at gas and vapor sampling. All the studies we've heard about have been particulate. Where's the information on gas and vapor sampling? We don't have any. A large percentage of the respirators in the workplace are gas and vapor respirators. We do not know how to test those respirators at all. We're just starting to look at methodology for gas and vapor respirators, so we have no information on how to test gas and vapor respirators in the workplace.

One hundred percent (100%) relative humidity has potential to significantly change the anolyte absorption characteristics and recovery from absorbent materials. So if you're talking charcoal tubes or silica gel tubes, quite likely they're not going to work. They don't work well at a hundred percent (100%) humidity.

There may be some other problems with gas and vapor testing. If you talk about the metabolic fate of your analyte may be a concern here. Possible effects of concurrent skin exposure to the liquid form of the material is a problem. The lung absorption and retention from prior exposures is a problem. Odor thresholds, you heard mentioned yesterday, as the important variable and a concern, and how that effects the results of gas and vapor testing versus particulate testing. So we've got a lot of work to do here, and we really have not started to look at gas and vapor respirators. So we need to do a lot more research is a basic position there. We have a very severe lack of information, especially with gas and vapor respirators, and also with non-metallic particulate. And that really means this creates a major limitation on our ability to even start developing standardized test methods. We cannot do that until we answer a lot more questions.

Our sampling strategies also have to be considered. In-facepiece sampling procedures recommended in Europe for determining total inward leakage have sometimes recommended inhalation sampling only, or sample during the inhalation portion of the breathing cycle only, and the theory here has been that this will more accurately measure the contaminant concentration leaking into the respirator. It won't involve the dilution effect from the exhaled breath. However, this in theory sounds good, in practice may not hold true. And that relates back to some of the sampling bias work and the probe placement work that was done by

Warren Myers and others that showed inadequate mixing and problems with inhalation only sampling. In fact, inhalation only sampling might significantly increase sampling bias instead of reduce sampling bias. We simply do not know. We do not have enough information there yet. We have a lot of information out there, we don't know what it means. We don't know how to fix the concern, we don't know how to resolve the concern.

Exhalation only sampling has been suggested by some as a method for decreasing the sampling bias, and that, again, was related to gas and vapor testing in the laboratory. We don't know how that relates to particulate. We don't know how that relates to the workplace. So that's a major area of concern.

Another important requirement we have is a collection of a sufficient number of samples to allow meaningful statistical analysis. If plans are to complete all of your sampling--if you want to go out and do a study and you want to collect all of your samples before you go back to the laboratory and initiate your data analysis, you're going to need probably a minimum of two (2) to three (3) times the number of samples you think are necessary. You've got to plan that you're going to lose sixty-seven percent (67%) of your samples probably--are going to be thrown away and invalidated before you get done analyzing the results. At least that many, sometimes--we have come back--in one case we came back from a study and we ended up with zero (0) data points. Kind of the same situation of the SCBA study you heard about yesterday. From one standpoint you ended up with a lot of hope but not much

data; we've done the same thing. We've had the same experience. It's very expensive, very frustrating, but there's nothing you can do about it. The data is not valid; the data aren't valid. That's a problem.

Validity of samples collected on test subjects will vary depending on whether or not an appropriate level of observation of test subjects was provided. And Don Burd mentioned a little bit about that yesterday. In our experience in our testing it's not possible to generate a valid workplace protection factor without one (1) observer for each test subject; is not possible.

Some of the work you heard about being able to track the pressure in the facepiece; that's an excellent idea. I think that will help tell you if that wearer keeps that respirator on. That still is not going to invalidate the need for one (1) observer per test subject, because you cannot possibly know if you met the definition of a workplace protection factor unless you have one (1) observer per test subject. If you go back and read that definition I think it will be quite clear to you why that is.

And even then, if you've got one (1) observer per test subject, the attention and the care paid to the test protocol by the observer is very critical for generation of meaningful results. This I know has been a problem in talking to some of the people involved in past studies--has been a problem in some of the workplace protection factors that have been reported. The observers were not necessarily well-trained, and then you get

into a situation where you don't really know how valid the data might be. This issue also relates back, then, to the terminology issues. That's a very significant concern, which is not technical in nature, but it's a very significant concern from the standpoint of being able to run a study in a workplace situation.

The next general area is analytical methods. And here the selection of an analytical method for a workplace protection factor study is complicated by a need for extremely good sensitivity per samples collected inside the respirator, coupled with an ability to handle very high concentrations--high sample loadings--orders of magnitudes higher than the inside samples when you get to the lapel samples. Other potential complicating factors here include high moisture content, which I've already mentioned; the limited sampling times you have which are restricted by the duration of the jobs you're trying to cover, and the presence of gases or vapors from previous exposures that you may be exhaling ... lungs, or the presence of smoke or particles coming out of your lungs that you've had from other exposures. We don't really know how or if we can control for those types of variables in exhaled breath.

The benefits of limitations of analytical methods need to be carefully considered. And a number of methods have been used; a number have been evaluated for particulate contaminates. The best methods will be very specific and very sensitive. Methods such as gravimetric analysis are easy to do and they are less expensive sometime to perform, but they have very poor sensitivi-

ty and they cannot distinguish workplace contaminants which leaked into the respirator from other contaminants not related to the workplace such as cigarette smoke, or such as spit or sputum or sweat that the worker generates on his or her own.

Microscopy methods have been used. Sometimes they have good sensitivity and specificity. Sometimes they have neither. They always present a filter overloading concern. Proton induced x-ray emission you've heard a lot about. It's got excellent sensitivity, also has filter overloading concerns. Inductively coupled plasma analysis, graphite furnace atomic absorption, radio amino assay, all those techniques have also been used with some success with particulate. But, again, they all have benefits, they all have limitations. There really is, unfortunately, no single best method for evaluating a respirator study or evaluating a respirator in a workplace. And, unfortunately, each of these different applications, each of these different methods that you use for the different workplaces has a different level of analytical variabilities. So, again, you're talking more and more variables as you go from work site to work site and change your test protocols.

In the potential sampling and analytical methods for sampling gases and vapors in the workplace are not well defined at all. I mentioned problems with charcoal tubes and silica gel tubes. We've done some work recently with thermal desorption; it looks like that may be promising, but again, we've just started and we really do not know where that's going. So we really

cannot report any successes to you or any usable information on gas and vapor sampling of inside of respirators.

More work is needed to address potential sampling and analytical problems. For example, you heard about deposition of particles on the walls of filter cassettes raised yesterday, and you heard two (2) different sides to that. Barry had a situation in his study where he found it was a significant problem. Warren, in his study, had a situation where he found that it wasn't a concern. Methodologies were different in the way the samples were collected. The air contaminants were different. We have also looked at that issue. We've looked at deposition on the sidewalls of cassettes and we have not found it to be something anywhere as high as what Barry saw. We did see some deposition on cassette walls, mostly not significant. So, Warren's got a position that he didn't find it significant at all, Barry found it very significant, we found it someplace in the middle, maybe not very significant; someplace over here, but there's some continuum there probably, where we don't know what we're talking about is the basic situation. There may be a problem, there may not be, we simply do not know. We need to do, again, more research to find out what's happening. Until we do that, we can't answer that question, we can't proceed to develop a better method.

Getting beyond that, you heard about some general rules for the sensitivity of an analytical method during Craig's presentation. As he mentioned, a goal of many of our studies or most of

our studies, has been to determine whether or not our respirators have the ability to achieve their assigned protection factor in the workplace. And the sample acceptance criteria that he outlined were similar to these.

If you want to have a capability to find out if you achieve a certain number and a certain assigned protection factor, you've got to collect enough material on your outside filters to be able to find out if that is ten (10) times your inside sample, or a hundred (100) times your inside sample, or a thousand (1,000) times your inside sample. So you take your assigned protection factor, whatever that might be, multiply that by your mean field blank analyte, and if you don't have at least that much material on your outside samples, you might as well throw all the data away and not even analyze. It's worthless.

If you take that one (1) step further and you think about that and you say, well, if you talk about analytical confidence levels, and you look at inside samples, you're almost always right at or very near your detection limit. And when you're at or near your detection limit, your analytical errors are immense. Your confidence levels are very poor. So you don't really want to be anywhere near your detection limit. You want to be well above your detection limit. So if you're sampling in a half-mask respirator which has an assigned protection factor of ten (10), that means your minimum sample acceptance criteria here on the top line would only be ten (10) times your blank. That's probably not good enough. You probably want to be at least ten (10)

times higher than that, and some people would say a hundred (100) times higher than that before you really want to start looking at the data. And I think that's a reasonable way to approach sample acceptance.

Now, unfortunately, the only way to do this is after the fact. So what it ends up being is, you collect a lot of samples, you come back, you have them analyzed, you pay the money, you throw them away. It's frustrating, but we don't know how to do it any differently in order to get anything that might be usable information. So it's not a good approach, it's not a good way to do it, but we can't define methodology now that would allow us to follow any different rules.

You've heard a lot about sample loading. If the detection limit of your analytical method is found incapable of meeting some of the sample acceptance criteria, maybe you can find another analytical method to fix that problem. Or maybe you can increase the sampling time to get better loading. It's important that we look at this, and it's a sample loading phenomena that relates to the confidence level. It's not air contaminant concentration, it's the amount of material that you're collecting on your filters, which gets back to your ability to put confidence levels in what you're finding. So if you increase your sample loading, you can obviously achieve better analytical results, or hopefully achieve better analytical results. That relates sometimes to concentration, because you can take shorter samples in higher concentrations, but it's not necessarily a

concentration phenomena.

Analytical precision is another concern. If we look at the standard approach that industrial hygienists use for accepting samples we would say that our analytical precision must be at least plus or minus twenty-five percent (25%) or better to accept that as a valid sample. Well, if we look at an inside sample from a workplace protection factor test what we typically see would be the best achievable confidence levels are probably plus or minus thirty-five percent (35%) to plus or minus fifty percent (50%), so that one sample alone is well beyond our typical acceptance levels. Consider the fact, also, we're adding another sample to that, we've got a second sample with it's own confidence levels and we're looking at a situation where we can start out the study by saying we're predicting as we go into this study that in one component of variability alone we will have at least plus or minus fifty percent (50%) error capability. And we're talking one component alone, which is analytical confidence levels. Nothing to do with all the other variables we already talked about. It's a very, very big concern when we talk about trying to set up anything that might be validated and reproducible in a workplace site.

Our last area that we talk about is the data analysis procedures. With all the variability inherent in sampling strategies and sampling methods and analytical methods and overall study designs, I think you'll agree it's not very surprising that we see a variety of opinions on how to analyze the

data, and how to interpret the data from workplace tests. We've done a considerable amount of research to try to identify and control variables, understand those variables, and we want to do a better job of defining incompletely defined variables, but we're still not able to do that. This does not mean that the workplace data we've generated is not valuable. It is valuable from the standpoint of what we wanted to achieve with it. We wanted to find out--to make sure that our respirators were, in fact, able to achieve some sorts of assigned protection factor levels. We did not ever intend to have this type of testing developed to the stage that it could become a certification tool or that it could become a quality assurance tool for us to use. We do not think that is achievable.

Another point to mention from that; if you talk about the individual data points that we collect on these studies, a lot of people tend to over interpret what the value of those data points might be. The basic situation we have is that each individual data point as a number standing alone by itself is not worth anything, really. The variability is too high. We just don't have enough confidence in any individual number to use that as a meaningful number. We can only make sense out of it if we put it into some sort of a data population.

We have used some basic rules for that, and our basic rules boil down to these: before you analyze samples you invalidate samples sets that are effected by sampling problems; probes fall off, you have leaks, you have malfunctioning pumps, that sort of

thing. After you analyze the samples, you reject samples sets with insufficient inside or outside sample loading or unacceptable analytical precision. Now that's a difficult rule because we don't know what is acceptable. What precision is acceptable? That means already our rules aren't working too well, because we haven't defined what acceptability is. We have said, well, let's do the best we can.

Outside sample loading must be at least a hundred (100) to a thousand (1,000) times the mean field blank level before we'll consider it to be meaningful information. Inside samples loadings should be greater than the field blank. A place to start; not necessarily the best rule. It's a place to start. We also use the mean value of field blanks to correct inside and outside sample loadings. Again, that's a place to start. We don't know if that's the best method to use. That's a standard method to use, but if your variability of your blanks is very wide maybe that's not so good. If it's very narrow, maybe that's a good method. You've got some questions. Is this an acceptable method or not? I don't know. That's essentially the best we can do right now.

We then use corrected sample loadings for concentration and protection factor calculations. If you do blank corrections on inside samples you can sometimes end up with minuscule numbers. If you have a blank of one (1) and you have a sample of one point 00 one (1.001) and you subtract the blank, you end up with point 00 one (.001) inside and your protection factor goes sky high,

which Harry, is why you get numbers that go way above a hundred (100) if you have a hundred (100) times the blank rule, because of the fact that you can be dividing by an extremely small number after you subtract the blank.

That probably doesn't make good sense. Well, how do you solve that problem? I don't know. That's a difficult problem to solve. We don't know the best way to do that, so, again, we follow a rule which we think is the best we can do at the present time. We're not into making a lot of corrections. We don't think that's going to solve any major problems that we've identified.

You need to consider whether or not some sort of corrections are desirable with respect to relative humidity sampling in particular. As we get into gas and vapor sampling we may want to look at that very carefully. How does that humidity effect our collection efficiencies on our inside samples? How does lung retention effect things? I have mixed feelings on that. The information you heard yesterday, I could debate that for a long time. There are very, very many issues in here that are really not resolved.

We also, then, calculate appropriate measures of distribution such as geometric means and geometric standard deviations and fifth percentiles, and again we find that typically these studies look like they're log normally distributed. Maybe in some situations they're not. And what methodology you use is obviously going to be dependent on what your distribution is and

that, again, can vary significantly from test location to test location, and by statistician that you use, and recommendations that you hear. So we have not reached any consensus on that issue. We, again, try to do the best that we can based on what our experiences are.

We identify potential outliers, and it's very important to do that, I think, and to investigate reasons why they exist. Now, one way, if you've got a . . .

DAY 2 - TAPE 2 - SIDE B

ALLEN JOHNSON: . . . doesn't look like that's valid. That may be one way to get rid of data points like that, but that doesn't always work. Sometimes your distribution--your standard deviation--is so high that everything stays in anyway. And so you don't necessarily have enough control over that issue of outliers. What do you do with the outliers? How do you define where they came from? How do you know whether it's a valid number or not? You really don't at this point. We don't have enough information.

You need to examine the data to determine if protection factors generated are independent of outside sample loading. Craig has shown some of that. If you don't find it independent, I think you need to reevaluate the amount of mass that you actually collected on your outside sample.

Your test for differences among respirators, differences between test subjects, differences among observers, days of the week, other appropriate variables in your study should be conducted to find out whether or not these are affecting your results. There are things other than the respirators themselves that may be contributing a lot of the variability to the study, or most of the variability of the study in some cases. You need to define any problems you encountered with the data analysis, and lay that out and explain it to people. You may not know what it means, but maybe somebody else who is looking at the data can look at that and say, well I understand what they did. They may

or may not agree with it, but at least they will know what you did. And I don't think we can reach any conclusions now on what is right and what is wrong, but I think we can explain for each other better what we're doing so we can look at that and we can realize what you did versus what I did versus what Craig did versus what Barry did or Warren did. I think we need to do that more. We don't, or can't I think at this point, agree totally on the methodology. There are too many variables and we have too many concerns that we don't necessarily see eye-to-eye on at this point. So there's a lot of room for debate, and I think because of that it would be virtually impossible to generate workplace protection factor data, especially for respirators of higher performance capabilities, that would really today be considered representative of the respirators. So if that was the goal, to find out how well does this respirator really perform, I don't think we can do that. We're not to the stage yet of being able to generate information that really shows you how well the respirators work.

Examination of the data with respect to outside sample loading you've heard about. And that relates, as I mentioned, to the analytical confidence levels. It also relates to concerns raised about the relationship between outside sample loading and resulting workplace protection factors. Now, it's often assumed that a respirator being worn by an individual has a protection capability which should be measurable in terms of a single number. You've got somebody out there working in a test environ-

ment, we're making the assumption that we can measure that individual's protection and come up with some sort of a meaningful number. I don't know if that assumption is really true, but that's what we're trying to start with as a basis. That's our goal.

Some often further assume that if the fit of the respirator or the function of the respirator is not altered, and aspects such as particle size distribution in the workplace are not changed, then that protection that the respirator is actually providing should be fairly or relatively constant over a range of environmental conditions. That's another assumption that is made. Again, I don't know if that is true or not true. This appears to be the basis for assigned protection factors for classes of respirators, and Warren got into that or alluded to that a little bit yesterday, and Robin certainly talked about that yesterday.

Significant correlation, in our work anyway, is known to exist between sample loading, or the mass on the filters, and analytical precision. I think that's--that issue is not really in debate. The closer the sample loading is the analytical detection limit, the less confidence there is in the numbers that are reported to you. And conversely, at least within a certain range, your ability to believe you data, to trust your data, increases as your sample loads. At least to a certain point, anyway.

So, if you carry this relationship a step further and you

look at what it means in a situation where you're comparing two (2) samples, one (1) outside sample to one (1) inside sample, we know it would be beneficial to optimize the sample loadings to make sure our analytical confidence levels are optimized. But as we've mentioned already, we know it's not possible to optimize sample loading inside of respirators. It's hard to get anything in there, let alone optimize sample loading. In fact, we don't want anything to go inside the respirator, so that's--from that side we know the respirators work. But from the standpoint of trying to give you a number, we can't do it, because we don't see enough leakage. So we can't optimize sample loading inside respirators.

Maybe we can outside. That's the only place where we have some capability to optimize sample loading. And that's what we've been working on. That's some of the information that Craig showed you, all the slides and information, and we've reported on that previously. We're trying to look at ways where we might be able to find some rules to optimize outside sample loading.

The correlation observed--I might mention also, we have not used--and I think this is a common misunderstanding, two (2) common misunderstandings--we have not used concentration. We have never reported the correlation to be concentrations. It's sample loading mass, not concentration. The other thing is that we are not talking about individual data points. We're not saying workplace protection factor one has a workplace protection factor of ten (10) and outside sample loading of one (1) or

whatever it is, and plotting each individual data point. We're looking at populations of data. So all the variability that's inherent in one individual data point I would predict would never show you the correlation between outside sample loading and workplace protection factor. There are too many variables there. You wouldn't see it. But if you look at the populations, and what happens to the populations, you get a little bit different story.

I'll give you an example here, and these are the only numbers I'm going to show you, and I'm not going to talk about them a whole lot. Craig already showed you these, anyway. These were the results from the two (2) supplied air respirator studies that he talked about earlier this morning. And we had basically the same equipment, the same test method, same contaminant, but we had vastly different amount of loading on our outside samples based on the fact that these contaminant conditions in the workplaces were drastically different. As we looked at that we did see that trend, an apparent trend, between how much loading we had and what the protection factor was.

Now, if you get back to what I mentioned about not using individual data points, I want to make sure you understand what we did here. Study number one says there were a total of thirty-seven (37) data points. Those were all greater than--had mass loadings on the outside filter--greater than ten (10) times the field blank value. For those thirty-seven (37) sample sets the geometric mean workplace protection factor was two thousand one

hundred forty-three (2,143). You go down to the last one there, it says fifteen (15). Those fifteen (15) data points are part of that total population, so they were included in that thirty-seven (37) up on top. But those fifteen (15), if you look at those only, they had mass loadings, all of them, that were greater than one thousand (1,000), two hundred (200) times the blank. And if you look at those data points you find that the geometric mean is four thousand and twenty-three (4,023). That's the methodology that we have used to look at that.

If you want to look at what happens we have plotted that and showed those two (2) on a single graph. Now, again, I don't know if this is a valid technique or not. I'm showing you this only for comparison purposes. What happens if you do this. Interestingly here, if we looked at the data from the low mass loading data there, we could have predicted the data in the second study, up to a certain point. And actually, it looked like--now that's--that line is drawn for graphical presentation, this is not a statistical presentation of the data that would probably show you a straight line all the way through. I'll make that as a statement. Up in the top end of that second set of data we think we probably started reaching a stage were maybe we were measuring some of the performance characteristics of the respirator. Maybe or maybe not. We were probably getting close anyway. So we think that that relationship maybe would start to taper off there, and then you would start seeing increasing amounts of material inside the respirator as the concentration outside the

respirator went up. That's what you would expect to see if you believe the assumptions we make about the way respirators work in the workplace. So we've got a situation to resolve here. I don't know how to resolve that. The best we can do now is say, we think we need to pay a lot of attention to this issue. We think you need to emphasize collection of a lot of material on the outside samples to make sure you get something that starts being representative of what the respirator is actually doing. But, again, we need to do a lot more research on this issue. We do not know what the true relationship is.

If you look at this plot here there's--on that first study there, the one on the low end, we say a correlation coefficient of point nine seven (.97)--actually point nine nine seven (.997)--for that study. On the other study we showed a correlation coefficient between the mass loading and the workplace protection factor as point nine seven two (.972), so there are very strong correlations in the way we analyzed the data. And you can take this to your statisticians and I'm sure they would find some things to argue about it, which ours have, and we've argued around this issue a lot. But what we're trying to find is a way where we can find out. How do we set up methodology where we start looking at evaluations of respirators rather than staying in areas where we have so much confusion and so much variability and so much inability to measure things accurately that we can't possibly ever reach consensus on how to do this type of testing?

Beyond the statistical considerations, and I'm not a statistician, you can get into some other debates that are a lot more simple than that. You don't need to get into the statistics to start talking about some of the major observations that we see in workplace testing.

All the studies that we've conducted to date have had significant ranges of outside concentrations. And significant ranges of workplace protection factors. The outside concentrations in many, many cases have been well above TLVs. And we've seen in each study many high workplace protection factors and low workplace protection factors, but we've not seen a single case in our studies, or in fact in anybody's workplace protection factor studies where a worker was overexposed or even close to being exposed at a concentration above a TLV inside the respirator.

So the situation is that where a high protection factor was needed in the workplace the respirator was measured and shown to have a high protection factor. But on the other hand, if you look at the situations where you've got a low protection factor, well that's all that was really needed. Now somewhere in there that logic leaves me. If you're going to be doing a study and you're going to be identifying what's really happening out there, you would expect that sooner or later you'd get the guy that had the low protection factor and the high concentration and you'd have an overexposure. You'd think that would happen sooner or later. It's never happened, which tells me we're not measuring what's going on in the respirator. Beyond these statistics,

that's my conclusion. So I would say we do not know what these results mean. All we're doing right now is working on methodology and doing research. We do not know what the test results really mean.

So in conclusion, workplace protection factor testing, we think, can be useful for evaluating performance of respirators in the workplace, but the accuracy and reproducability needed for a valid certification test is not currently achievable with this type of testing. Whether or not it's ever achievable is a question you might ask, and I would think from what we know now I would say chances are it will not be achievable. It's not yet possible for us to standardize test protocols, to standardize sample collection, sample analysis, data analyses, data interpretation, in a manner that would adequately address the unresolved technical issues. And I think, in fact, at this point in time it would be detrimental to our progress to do that. If we standardize on what we know now and start locking into things that may or may not be true, it would probably hinder our progress more than help. I think we need to continue to do things in different ways to find out more about what we're doing before we start standardizing protocols. We need to do a lot more research is the basic position. It's important. We agree it needs to be done, but it's got to be looked on for what it is. It's research, it's really not appropriate for certification testing.

I think at this point if you have any questions of myself or Craig we'll be glad to entertain a couple.

HARRY HERMAN: One point that you kept alluding to, but I think it need reemphasizing is that, in order to do this Craig had to find some pretty dirty places to work in, and that isn't true with the whole real world.

ALLEN JOHNSON: If you try to find situations or factories where you've got the right conditions to do an efficient study it's very, very difficult. And if you want to do replicate testing, and go back and do multiple testing, you're going to have an awful hard time even getting people to talk to you, let alone let you come in their factories. It's difficult to do; very, very difficult, and that point deserves a lot of attention. It is not an easy thing to do, and we've only done--it looks like we had a lot of information here, we've done a lot of testing, that's nothing compared to what we would have to do if was a certification test. And we have a very difficult time even doing the limited amount of testing that we have done, getting cooperation and finding suitable places for workplace testing.

HOWARD COHEN: I think one of your studies you examined lead as the contaminant. I'm sorry Craig, I took notes up to about six (6) and then I kind of got lost. I think lead is one of them. Did you look at a program protection factor? I know you wouldn't have done the data per se, but perhaps the facility that they were wearing respirators were in a lead program and you could evaluate the program protection factor. Did you look at that at all?

ALLEN JOHNSON: We didn't get involved with the biological

monitoring aspect or any other aspects of the facility's program, so, no, we did not do that.

CRAIG COLTON: I don't know which study it was, but in the one when we went to the secondary lead smelter to do the study, we didn't look at their program protection factor, but one of the things that they did do there at that place is they had, even before we came in and told them anything, a high period of wear time for that respirator. And we know that their blood leads; they were meeting OSHA standard in that, because they had relayed that to us, but we never really related it. They had sufficiently motivated the workers to keep the respirators on when they were in the workplace, and it was amazing even when we went down there for the first look, how well they kept them on.

HOWARD COHEN: The reason I mentioned it is, it seems to me that one of the things that your work shows real well is that you can't do studies to determine accurate workplace protection factors. On the other hand, from a certification--one of the purposes of certification would be to determine if a device performs properly, is it failing in the workplace. It seems like a program protection factor might do a good job of determining respirator failure. In other words, we've got a high exposure situation, we do many things, but through the use of that respirator, if it were not being worn and people's blood leads are low, you could probably do some calculations to show that. If they're high you're not going to be able to direct that solely at the respirator.

ALLEN JOHNSON: I think you could generate a lot of meaningful information in that direction, Howard, but you wouldn't be able to relate it to the performance of the respirator. You'd be relating it to the performance of the management of the respirator program, or the performance of the employees, or the performance of the program itself would be what you were measuring.

HOWARD COHEN: If the program works, the respirator works. If the program works, the respirator works. If it doesn't work, that's only one possible . . . .

ALLEN JOHNSON: In essence, that's right. If you are maintaining your blood lead levels at a very low level, you know your respirator works, and you know you don't have a big concern, you know your program is working.

HOWARD COHEN: . . . lot of these workplaces all over the country that we could look at where people are wearing respirators and there are biological contaminants that--in fact they're being regulated by OSHA if they do that kind of . . . .

ALLEN JOHNSON: And I think we, from the standpoint of biological monitoring, if that's a reasonable and feasible method for the workplace, I think we certainly encourage people to follow that because it is a very good tool to use to make sure your respirator program is effectively working. Our goal is safe and effective use of respirators and that's a very good way to achieve that goal. And I think that makes a lot of sense to follow that type of testing. But again, that doesn't necessarily relate to respirator performance per se, and that, again, if you

get back into the certification process I think you're one step removed from that when you start getting into the workplace and talking about those issues.

JERRY SHERWOOD: I've got a question relating to the five (5) percentile group, who I think are the group we should be concerned with. Does your data give any evidence this is related to individual--consistent individual--loss, or is it spread out through the whole population?

ALLEN JOHNSTON: That's somewhat difficult for us to address. We don't have a lot of replication samples for individuals, so we have done some testing of that sort. I think yesterday Barry mentioned that he had seen higher intra-subject variability than he did inter-subject variability. And we have some indication in one of our tests that we've looked at that that may be our same finding, that we higher intra-subject variability than inter-subject variability. I don't necessarily know how to explain that to you. I think ... a situation where we'd have to look at that very seriously and try to look at all the variables associated with both sides and go out and start working on those variables and identifying and controlling those variables and doing some more work to look at them individually. Design a study where we actually looked at those variables rather than just saw them showing up someplace.

BILL NEWCOMB: I would like to comment on a hypothesis that the reason that the protection factor might vary is because it actually is varying. What you're measuring is total inward

leakage and as the loading up the efficiency of the filter goes up and therefore there is less that goes . . . .

ALLEN JOHNSTON: In some cases I think that may be true. I think a lot of that has to do with our particle size distribution and uniformity of that distribution, does it change up and down. And filter efficiency probably does increase a little bit, but if you look at a half-mask respirator you talk about how much your filter efficiency changes from times zero (0) to time ninety (90) minutes. I think you'd find it was not significant with respect to total inward leakage. The highest percentage of total inward leakage in a half-mask is normally from the face seal leakage, so if you're looking at changes in filter efficiency, I don't think you'd find that as a problem. Robin, maybe you could comment on that.

CRAIG COLTON: And it doesn't explain air line.

ALLEN JOHNSTON: It doesn't explain air line, no. If you look at the air line I think the basic problem there--remember that slide, one of the first slides that Craig showed that was on asbestos. It showed samples inside and almost all of them were zero (0), and it showed outside samples and they went up like this. I think that's what we're seeing. We're not finding anything inside the respirator. So the reason they're going up is the fact that they're going to keep going up until we start seeing something inside the respirator. And that seems to be not happening until a much higher level than maybe we thought it was going to happen at. So our respirators are working, I guess, is

the point. I don't know how much we need to beat that to death. Alan Hack made a very reasonable comment, I think, yesterday. I think we're beating a dead horse by trying to overemphasize the need to go out and validate some of these things.

HARRY ETTINGER: Suppose you had a workplace protection certification program which instead of worrying about the actual workplace protection factors, simply said you want to show statistically that its above ten (10) for half-mask, fifty (50) or a hundred (100) for a full-face, whatever magic numbers people come up with. How much would that simplify matters? Because most of your data was well above numbers that are assigned protection factors. Suppose you just said you have to show it's higher, say, ten (10) for a half-mask. Let's focus on half-mask particulate only.

ALLEN JOHNSTON: Okay, I guess we have talked about that at quite great length, and we have not reached any consensus on that. We've had a lot of debates about what the meaning really is for information we generate. I think that's a basic critical problem if you look at it from a scientific point of view in that do you want to generate information that would be scientifically pure, if you want to put it that way--maybe that's not a good term--valid information . . . .

HARRY ETTINGER: That's answering a different question. The question is let's not worry about having a precise workplace protection factor, let's just say that--let's NIOSH and OSHA decided that all half-masks--particulate half-masks--must be at

least ten (10) X in a workplace study somehow defined and all you have to do is show that it's ten (10) X or greater.

ALLEN JOHNSTON: I don't think we could do that in the context of the workplace because of the fact that we cannot agree on what would be the best situation to do that in. Now, if you take that one step further, and it was mentioned yesterday the possibility of doing a simulated workplace protection factor test. If you take that concept and you start applying controlled variables, the things that are controlled better, if you control the test, if you control the concentration, if you control the work movements, if you control the temperature and the humidity, if you control those variables to the extent that we in typical laboratory bench tests, in those situations I think you are approaching a situation that might be reasonable. But, on the other hand, we still do have a lot of concerns and questions about protection factors, assigned protection factors, and how we relate test methodologies to assigned protection factors. I think there's a lot of debate ongoing there where it would be difficult to come up with a consensus on that point, but I think if you move towards simulated testing that had some sort of a universal or semi-consensus agreement on it, I think you would find people dropping off a lot of these arguments about well what happens if this, and what happens if this happens, and try to control a lot more of the variables. We can't control enough variables in workplace sites to do a meaningful test, I don't think.

SAM TERRY: In your supplied air testing you have a very high flow regime inside the mask--high velocity--I would suspect that sample flow velocity becomes much more critical than flow volume in that situation. In other words, did you ... for and the sample isokinetically?

ALLEN JOHNSTON: We did not necessarily sample isokinetically. We did not attempt to make corrections for the velocity of air inside the helmet, no. And again, that's another example of a variable. You may want to look at that and say, what does that do. We cannot tell you, we did not correct for that.

SAM TERRY: . . . quite significant flow concentration. One particle was . . .

ALLEN JOHNSTON: That's possible. I really don't know.

BOB BRENNAN: Early in your talk you made mention of one of the limitations; is that virtually all the published work is on particulate. That was in the . . . . As soon as we get into the discussion everybody falls into the mode that all you've got to do is arrange for some sort of particulate measurement and you've got this whole problem licked. I'd like to call attention to your own words ... didn't know where to start with gas leakage. And it may not--we made a basic assumption as a industry, as a governmental body, about ten (10) years ago that you can substitute little ... of oil, or little particles ... for a gas and get an idea what's happening. I haven't seen real studies that verify that anywhere.

ALLEN JOHNSTON: I certainly don't disagree with you since

they already mentioned that in my report. I think that is a very significant concern. We need to know more about that issue, yes.

BOB BRENNAN: The discussion the last couple of minutes has just drifted back into let's find a particle that will make this okay.

ALLEN JOHNSTON: And that's very common. Discussions almost always do that because we always end up going back to what we already know, and that's what we know about, is some of the particulate testing. We don't know anything about gas and vapor testing, so it becomes a very short question and answer period.

HARRY HERMAN: If you could comment; you've said that you don't feel that workplace protection factor studies are meaningful.

ALLEN JOHNSTON: No, I didn't say that, Harry. I didn't say were weren't meaningful, I said they were meaningful. I think they are meaningful from the standpoint of what we had intended them to do which is make sure that we are achieving some sort of an assigned protection factor level. We want those to be able to show us that, yes, in fact if we have a half-mask respirator, it does have capability to provide and assigned protection factor of at least ten (10) in the workplace. That's the goal we have. How successful we are in achieving that goal still depends a lot on the methodology we use. So I think from that standpoint, yes, the results are very meaningful, they're not reproducible from the standpoint of what we need to look at quality assurance, or what we need to look at for certification.

ROBIN HOWIE: . . . following up Harry Ettinger's comments about a quality control test. Plumbing has always concerned me. If you're trying to quantify the performance of a piece of equipment, accepting all your comments of ... variability, obviously, then if you're looking for the actual performance, you want a heck of a lot of data. If you ... mask into getting 'a WPF' of forty-five (45) and you're assigning ten (10) to it, it would require relatively few data points statistically to demonstrate that forty-five (45) is greater than ten (10). If your mask is fifteen (15) and you might require one heck of a lot of points then to show that fifteen (15) is more than ten (10). So I'm quite sure that you could apply standard routine quality control analysis techniques to WPF data to assess do I or do I not get at least the minimum level of protection assigned.

ALLEN JOHNSTON: I think you can--there are a lot of things you can do, and I agree with you that if you've got higher numbers obviously you need fewer samples. I think one of the problems that we keep coming back to with respect to any place we start statistics is, we still don't know if the numbers we start with are valid. And that's a problem.

HOWARD COHEN: I was just going to add onto that. What Harry said is--I think when you looked at your studies, if I were a respirator manufacturer the first place I'd do is go into very, very--make sure I have tremendous filter load. I'd look at high concentrations, high errors, and my respirator performs well ... so I get my ten (10) without a problem. If I find a workplace

location that was low filter loadings I may have a very good respirator and I may have a heck of a time showing a ten (10).

ALLEN JOHNSTON: You're absolutely right.

HOWARD COHEN: So I think one of the problems is, first of all, what are you measuring. You're really measuring respirator performance; that's really what you're measuring. And if you're not, then you still have to test no matter whether it's ten (10) or anything else to do--you know, you don't have the test . . . .

ALLEN JOHNSTON: I think we have addressed that issue, and the fact of the matter, we agree with you totally, Howard. If we're in a situation where there's very light dust loading we know the respirator works and we know the worker's not overexposed, but we also know that we have not evaluated the full potential of our respirator. And we're very confident that that has not happened. That's a difficult situation, but trying to optimize the sample loading, again, that would be nice to be able to do that, but we have not found a way to be able to do that yet in the workplace. In a controlled simulated test booth it might be possible to do that. In the workplace we don't think that's possible.

LARRY SPARKS: A couple of announcements. Starting with this afternoon's session, Gwen Strickland-Cid, who is--Gwen, why don't you hold your hand up here--from our General Council Office, will sit in the Facilitator chair for the rest of the time. Let's try to remind ourselves to identify ourselves when we speak up. We are probably progressing toward a transcript

plus the documents that people have given us, like the last two (2) presentations they have given us written documents and so forth; approaching maybe a thousand (1,000) pages when we get done. So it will be a while before the transcript is available, but those who, in fact, present us with written backups or present us with written copies of your audiovisuals and so forth, we will try to make those a part of the record, and put them as attachments, or something like that. So it will take a little while for us to get that together, but it is our intention to make this information as available as we can make it, and for those who weren't here to be able to access these presentations and opinions and so forth.

Let's reconvene at one thirty (1:30). Thank you.

(Whereupon, a lunch break was taken for approximately one (1) hour.)

DAY 2 - TAPE 2 - SIDE A

GWEN STRICKLAND-CID: Good afternoon, I'm Gwen Strickland-Cid. I'm one of the attorneys for NIOSH, and I'm merely acting as a facilitator for this technical conference here today. So, basically what I'm here to do is to keep track of the time and keep us on scheduled and introduce the groups of presenters.

This afternoon from one fifteen (1:15) to two fifteen (2:15) we will have a panel discussion discussing--actually we will have several presentations--discussing the feasibility of workplace testing and alternatives, and it will be coordinated by Mr. Donald Wilmes of the 3M Company.

I'm sure Larry Sparks reminded you yesterday that you need to identify yourself when you ask a question or you speak, and to please speak up for purposes of the transcript. Hopefully you will keep track of your time so that I don't have to do anything other than listen today. So I give you Mr. Wilmes now.

DON WILMES: Thank you. I hope our time goes from one thirty (1:30) to two thirty (2:30).

MS. STRICKLAND-CID: Oh, I'm sorry.

DON WILMES: No problem. Today there will be five (5) presentations from the Industrial Safety Equipment Association. First will be Don Burd discussing the infeasibility of conducting workplace testing, then Rich Grunberg will be talking about the concept of individually assigned protection factors, or a rating system. Then Ron King from 3M will discuss the economics of conducting workplace testing. I'll briefly mention the alterna-

tives of assigning performance levels to respirators, and then John King will continue with his performance criteria document of yesterday. I guess first is Don Burd.

DON BURD: ISEA believes workplace testing of respirators would provide the best information on the actual performance of respirators if practical, reliable, and reproducible tests could be conducted. Unfortunately, insufficient information exists to understand how to conduct these tests to meaning measure respirator performance. The purpose of this presentation is to explore the feasibility of performing tests in the workplace to determine workplace protection factors as part of respirator certification.

Workplace testing studies have shown properly fitted respirators adequately protect workers from workplace contaminants. They also verify the reliability and utility of laboratory performance tests of respirators to assure actual performance at the levels of exposure for which the respirators are certified. Precisely quantifying performance of individual models of respirators beyond the level for which they are approved, however, is not technically possible today.

Certification of respirators by NIOSH must be done in an equitable and impartial way and provide credible assurance that the respirator will provide the anticipated protection. Complete understanding of and confidence in the methods used in the certification is necessary to assure results. It appears that today we have more questions than answers concerning the methods to be used in workplace testing.

Workplace contaminants--most of the workplace studies that have been conducted wee done in workplaces where the contaminant of concern has been a metal. These work sites and contaminants were chosen because analytical methods with sufficiently high sensitivity exist to make them useful for this application. Even so, many data points are lost because the contaminant level inside the respirator is below the level that even the best analytical methods can detect. When this happens one cannot quantify the level of protection that a respirator is giving. From a practical standpoint, the analytical sensitivity should be at least one thousand (1,000) times greater than the anticipated concentration in order to minimize the number of non-quantifiable test results.

It is extremely difficult to find workplaces with sufficiently high concentrations or continual respirator usage, especially when testing the higher performance classes of respirators. Most employers have installed engineering controls to greatly reduce the level of contaminant present. Likewise, when the tests are run in these atmospheres containing metals it is common to find vastly different protection factors for each of the different metals present. Logically this does not make sense.

Particle size may be a partial answer, but work needs to be done to determine whether this is an artifact of the methods used or if this is a real phenomenon. If the numbers are real, which number should be used? The analytical methods that have been

identified are mainly suitable for metals. What about all the other contaminants where there are no suitable methods?

In the past, several investigators attempted to use gravimetric methods. Recent work indicates that the body generates much of the total mass of the particulates present inside the respirator, and therefore this method is not suitable. In the smelter studies Warren Myers found as much chlorine inside the respirator as he did lead, even though there was no chlorine outside the respirator. One must assume that the chlorine came from body-generated fluids. Much more work needs to be done in this area.

For particulate contaminants much work needs to be done to determine the effect of particle size on the performance of the respirator in the workplace. Recent work indicates that collecting only respirable dust on the outside of the respirator while collecting total dust on the inside may be inappropriate because some amount of large non-respirable dust can be present inside the respirator inlet covering. This would indicate that the face seal leakage holes are not of the filtering size. More work is needed to determine the physical nature of the particulates that are found in the facepiece.

ISEA is not aware of any reliable facepiece sampling methods suitable for sampling any of the many gases and vapors present in the workplace. To date there have been no credible studies performed to determine the workplace protection factor for gas and vapor respirators. The high humidity and insensitivity of

the analytical methods so far have precluded gas and vapor contaminant workplace testing. It is well known and reported in the literature that the human body accumulates many gases from previous exposures and eliminates them subsequently through exhalation. This makes it very difficult to determine if the contaminant present in the facepiece came from respirator leakage or came from test subjects' exhaled breath. Test method development in this area has barely begun with very much work remaining.

Now as to test sites; finding the proper workplace test site is a very difficult task. Briefly I would like to describe several factors that must be present in order to constitute a suitable test. One, it must contain high enough concentrations of a suitable contaminant. Two, the site must contain a large number of workers exposed to the suitable level of the contaminant. Three, the operations at the site must be such that workers remain in the contaminated area for a suitable length of time. Four, the management of the site and the workers themselves must be willing to participate in the study. To find a work site as described is extremely difficult. Most employers have been installing engineering controls to reduce the airborne hazards in the workplace. The majority of workplaces have jobs where the workers are only exposed to very low levels of the contaminant for long periods of time, or alternatively, for very short times if the contaminant levels are high. Typical of the higher exposures are the maintenance type jobs that only occur occasionally and are not scheduled, and thus are not suitable as

test sites.

Another major problem that is encountered is obtaining management approval to test in their workplace. The testing imposes a considerable burden on the operation. Productivity is greatly reduced as the workers' jobs are interrupted with the necessary additional training, fit testing, and sampling required for the study. It is not only a burden on the employers, but also the employees. Often where workers are on productivity incentive plans, they will lose money. In addition, workers frequently do not want to be inconvenienced by the burden of the sampling pumps and tubing.

Suitable workplace testing sites can be found occasionally. The problem of finding suitable sites would become extremely serious if workplace testing were to become a certification requirement. There simply would not be enough available sites for testing.

Some other problems; much work still needs to be done on data analysis and interpretation. Some researchers are suggesting that correction factors be added to account for lung loss, particle size, analytical error, and sample probe bias. These corrections add much error in calculating respirator performance. The corrections are usually the man or average of a highly variable number. Additional research is needed to control these variables rather than to try to correct for them. These correction factors add much variability to the measured values.

After these problems are solved we will have to test proto-

cols that can be used with the various contaminants and types of respirators that will be tested. A unified protocol will be necessary for reproducible results.

In summary, workplace testing of respirators as part of certification is technically not possible and inadvisable as a regulatory policy. While ISEA wholeheartedly agrees with the concept of determining performance of respirators in the workplace, years of research remain before the many problems and remaining questions on how to do it are resolved. ISEA continues to support the continued research in this area.

RICH GRUNBERG: My name's Rich Grunberg from MSA. In item number six (6) of the Federal Register Notice of this conference NIOSH solicits information and recommendations regarding the approaches for and benefits and limitations of assigning performance values to individual respirator models. With the current state of technology to measure respirator performance and the lack of understanding of the variables that affect respirator performance, ISEA does not believe that a meaningful rating system can be developed.

Now, there is precedence for government imposed individual performance ratings for products. EPA has implemented a rating system for automobile gas mileage. There is also a rating system for wear, traction, and noise for automobile tires. EPA also rates hearing protector performance by the use of noise reduction ratings, or NRRs. The mileage and tire ratings are obtained from a very controlled objective laboratory test using specified

equipment and very rigid test protocols. Consequently, they are considered reproducible. Similar results will be obtained when the same products are retested or when the same products are tested in different laboratories.

Even though the mileage ratings are reproducible, they can be very misleading. When the EPA mileage ratings were first posted on new car windows consumers assumed that this was the mileage they would obtain when they drove the vehicle. The public eventually recognized, with much help from the media, that the rated mileage was only a relative number and not necessarily the mileage that they could expect to get. The EPA ratings were found to be merely a means to compare the gas mileage performance of various makes and models of automobiles. The actual mileage varies considerably due to driving habits, geography, weather, fuels, etcetera.

While EPA's mileage rating systems rely on objective test methods, the EPA NRR does not. The test method for obtaining the NRR is highly variable because it uses human beings as test subjects. Consequently, the ratings are not reproducible with data obtained from one test subject to the next, from one laboratory to the next, or even for the same test subject and same hearing protector from one test to the next.

Since hearing protectors are safety devices, a large safety factor is included in the equation used to calculate the published NRR number to account for the large error possible from the highly variable test methods. The EPA requires manufactur-

ers to mark all hearing protector packaging with instructions for calculating the theoretical noise level to which the wearer would be exposed while using the hearing protectors considering the ambient noise level in the environment.

Now recent studies have demonstrated that the NRR number on the product is not reliable. In fact OSHA has advised it's inspectors to use one half (1/2) the NRR number to calculate the expected noise level reduction because of the large error involved in the generation of this NRR number. In spite of this variability, users continue to rely on the actual NRR ratings to determine which hearing protectors should be used. All attempts to find more objective methods to test hearing protectors have failed.

Furthermore, the perceived benefit of the NRR rating which was to enhance the state-of-the-art in hearing protectors has not occurred. In fact, the NRR ratings have stifled hearing protector research. For example, a dynamic hearing protector cannot be tested by the current test protocol, yet the product is extremely innovative. We believe that this type of rating system will lead some manufacturers to become innovative in finding test labs which yield the best test results rather than developing better hearing protectors.

Measuring respirator performance is much more complicated than measuring hearing protector performance. There are many more factors that could effect the total performance of a respirator. It is interesting to note how the experts' understanding

has evolved over the past couple of decades. Ten (10) to fifteen (15) years ago it was though that respirator performance could be measured by a quantitative fit test. The results of those tests were termed protection factors. In fact, the ANSI Z88.2 1980 standard even allowed the minimum fit factor found from three (3) quantitative fit tests to be given to the individual as his assigned protection factor.

Today it's broadly recognized that many more factors must be accounted for in addition to fit factor or total inward leakage factor to attempt to asses respirator performance. The actual performance of a respirator will depend on the type of contaminant present, the mechanism the respirator uses to eliminate the contaminant, the environment in which the respirator is used, the work being performed, and most importantly, the wearer themselves.

Our ability to measure or rate the performance of a respirator is limited to just a few substances for which we have analytical methods. Most contaminants occur in the facepiece in concentrations below that which can be measured. If we were to modify the respirators, for example, going from a chemical cartridge to a particulate filter, in order to test the respirator in a contaminant for which we have identified analytical methods, we believe the results would not be the same. With a surrogate filter the weight and balance of the respirator and the resistance of the respirator would have changed, probably yielding different performance results than if the cartridge was used.

Additionally, little information exists as to how the contaminant enters the respirator. Therefore, it would not be valid to assume that a gas or vapor would behave similar to a particulate. Rating a respirator by its fit factor, which is a ratio of the test agent outside the respirator to that inside a respirator, would also result in a meaningless system. All the research done to date has shown no correlation between the fit factor obtained from a fit test and the amount of protection the respirator will provide in the workplace. Therefore, any rating system using fit factors would be meaningless to the user in terms of the actual protection the respirator would provide in the workplace.

The results of fit testing are highly variable. A respirator with a fit factor of fifteen (15) is, in reality, no different than a respirator with a fit factor of twenty (20). Nor is there any different between respirator with a fit factor of twenty thousand (20,000) to one with a fit factor of twenty-five thousand (25,000). Studies have shown that because of the great variability of the quantitative fit test differences in fit factors of this magnitude are not statistically significant.

It is also quite likely that the use of such a rating system would encourage respirator users to use these ratings as assigned protection factors as was done in the 1980 ANSI standard. ISEA, again, believes this would result in unsafe use of respirators. We believe that the respirator fit requirements for the respirator user contained in what will be the new 1991 ANSI Z88.2

standard is a good, conservative, but workable system. The concept contained in this standard of requiring a fit factor through the use of either a qualitative or quantitative fit test of ten (10) times the assigned protection factor for the respirator user is a good one.

Respirator fit, through the use of new designs and materials has improved greatly over the past decade. This improvement came not as a result of a rating system, but because the employer are now fit testing respirator users before assignment and during periodic training. In 1980 I would estimate less than five percent (5%) of the respirator users ever had any fit test performed on them. Today I'd estimate in excess of seventy-five percent (75%) of respirator users are fit tested in one manner or another.

Poor fitting respirators are being rejected by the marketplace through a proper selection process by knowledgeable industrial hygienists, safety engineers, health physicists, and other professional trained people. If NIOSH wishes to improve respirator fit the best way would be to further encourage fit testing of all certified respirators on all users during the selection process and during periodic training.

In conclusion, a successful respirator program relies on the worker wearing his respirator. Although respirators should meet minimum performance requirements, too much emphasis should not be placed on individual fit factors or any other single rating system. Other factors such as comfort, ease of use, and ease of

maintenance must be considered. The market currently considers these factors and will continue to do so. They'll drive the progress toward respirators with better overall performance, not just higher fit factor ratings. Thank you.

RON KING: I'm Ron King, 3M Company, representing ISEA this afternoon. My presentation is going to be dealing with the costs for performing workplace analysis based on our experiences. Before I start I should point out that the cost of studies that I'll be talking about are based basically on a number of the studies that Craig Colton talked about this morning, and the fashion in which they were done. Most certainly, the very long-term more research oriented studies that were reported by Gary Noonan, Barry Pallay, and Warren Myers yesterday would certainly come up with costs or resulting costs that are much higher that what I'll be talking about.

A major element of workplace protection factor testing is, in fact, cost. This total cost is made up of both labor hours required and the direct out-of-pocket costs. The requirements for a good test consist of a number of steps; preparation, a pre-test visit, on-site testing, sample analysis, data analysis, and report rating.

Preparation includes locating a potential test site. This done through the sales representatives, distributors or other professional contacts. The object is to find a site that uses the appropriate respirator in the workplace with a contaminant that can be measured with good sensitivity and will cooperate

with the testing program. Locating such a site will take approximately three (3) man weeks with preparing equipment and samples requiring an additional three (3) weeks.

After the tentative site has been determined the next step is a pre-test visit. Our experience has shown that this step, though costly, will save money in the long run. During this visit the contaminant can be determined. Is it one that offers good analytical sensitivity? The concentration can be determined by taking area and personal samples in the representative operations. Other questions to be answered at this time include the number of workers wearing respirators, is it a representative population, is the respirator usage long enough for adequate sampling time?

Logistics will cover things like a relative clean area to train workers, fit test and change sample cassettes. Other considerations will include accessibility to the work area and safety concerns and equipment required for the test observers. It is also good to review the respirator program at the site. Since the object of the test is to test the capability of the respirator, tests should not be conducted, as explained earlier, under conditions of misuse. Test site cooperation is very important as the actual testing will require a number of outsiders in the work area and some disruption is unavoidable. The cost of the pre-test visit will be about three (3) people days plus a direct out-of-pocket cost of about fifteen seventy-five (1575). That includes travel, samples, and sample analysis.

Now assuming that the results of the pre-test visit were satisfactory, the next step is the actual on-site test. In most of the tests completed and reported at this time we attempted to gain or to gather fifty (50) to a hundred (100) data points. We generally planned to take one (1) sample set per worker before the lunch break and one (1) after the lunch break. Therefore, two (2) samples per day per worker and observer requires five (5) observers for five (5) days to gather fifty (50) data sets. If the contaminant concentrations allow shorter sample time the same group may gather up to a hundred (100) sample sets. Each sample set consists of an inside sample, outside sample, and a blank so we were handling, just for worker sampling, up to three hundred (300) cassettes. In addition, more recent tests have added sampling such as Cascade impactors for particle size distribution.

One person is assigned full-time to keep records and to organize and to keep track of the three to four hundred (300-400) cassettes being used. Again, experience has shown this to be the best way to assure that data is reliable. The cost of the on-site testing will then require thirty (30) people days and over nine thousand dollars ($9,000.00) direct cost as shown. The cost for sample analysis shown is for proton induced x-ray emission. That has been used for most of the particulate contamination because of it's excellent sensitivity.

This cost does not include the cost of analysis if we were doing cassette washing. If we were going to do cassette washing

this figure would at least double. If we knew how to do gases and vapors more costly analysis methods may be required that would again significantly increase the ten thousand dollar ($10,000.00) figure as shown.

Finishing the test will require about four (4) people weeks to tabulate and analyze the data, and another four (4) weeks to prepare the reports for presentation, publication and archival filing.

Totaling the labor required for a typical study results in eight hundred and twenty-four (824) people hours. While people cost will vary, professional personnel will conservatively cost ninety dollars ($90.00) an hour where salary, benefits, and overhead are included. So the people cost is then seventy four thousand one sixty (74,160). Adding this to the direct cost as shown results in a total study cost exceeding ninety-six thousand dollars ($96,000.00).

Analyzing this cost for a typical full line manufacturer, the fifty (50) samples sets taken will probably yield only twenty-five (25) good data points. This reduction is caused, as has been talked about in other presentations, by a number of uncontrollable variables such as inside concentrations below the detection limit, overloaded outside samples, pump or equipment failure during the test, human error, or accidental sample contamination. Therefore, at ninety-six thousand dollars ($96,000.00) for twenty-five (25) points yields a cost of over thirty-eight hundred dollars ($3,800.00) per good data point.

If we were attempt to gather a hundred and twenty-six (126) good points, as suggested in the NIOSH draft, the cost of the study would exceed four hundred and eighty thousand dollars ($480,000.00). This is for one (1) respirator, one (1) contaminant. If each NIOSH submission carried this requirement the cost starts to multiply rapidly. A full line manufacturer with a steady stream of new products and product improvement may make as many as twenty (20) submissions to NIOSH for approval each year. The workplace testing costs would exceed nine (9) million dollars. To backfill or to update earlier approvals would require another thirty (30) submissions based on the NIOSH suggested three (3) contaminants per approval. The total cost, then, to one (1) full line manufacturer then exceeds twenty-four (24) million dollars.

While many of the costs used in this analysis are certainly approximations, most are based on our actual testing experience. But no matter how you analyze these numbers the cost is huge.

DON WILMES: My name is Don Wilmes from 3M Company. Before I start my official presentation I would like to wish our distinguished from UK a happy forty-sixth (46th) birthday.

ROBIN HOWIE: Thank you very much.

DON WILMES: You notice that box sitting by you?

ROBIN HOWIE: I saw it ... realize ....

DON WILMES: It's a gift from the group. It's a box of correction factors you can take back to the UK with you.

ROBIN HOWIE: Thank you very much.

DON WILMES: They're just small ones, we didn't want you to have to carry too much back with you.

I'm going to talk about the alternatives for assigning respirator performance levels. If we had the technical understanding to perform workplace testing in a feasible and reproducible manner it would be the best method for assigning protection factors. Our understanding of how to perform a meaningful reproducible workplace performance test, however, is only in the early development states, and much more research is still needed. At the same time it appears NIOSH is seeking to add more confidence that a certified respirator exceeds it's assigned protection factor.

ISEA believe that positive interim actions can be taken. First, research needs to continue on workplace testing methods to solve the many technical problems that exist. The research should from both a theoretical basis in the laboratory and in the actual workplace. Many problems still exist with both the technical and practical aspects of the testing. For example, no one has identified any proven methods for sampling and analyzing gases and vapors inside a respirator. This clearly would be research that should be carried out in a laboratory.

Testing of respirators in the workplace should continue. It appears that each time such testing is done more knowledge is gained that someday will lead to a better understanding of all the variables encountered during workplace testing. ISEA believes that while workplace testing cannot be done today or in

the near foreseeable future in a feasible and reproducible manner, steps can be taken today to enhance confidence through the certification process that certified respirators will perform adequately.

I will briefly summarize those steps now. First, to test respirators in the laboratory using upgraded bench tests. Two, perform fit tests on a ten (10) person anthropometric panel. Conduct simulated workplace testing using the members of the above panel. And fourth, conduct field evaluations of all certified respirators.

Upgraded lab tests; upgraded laboratory tests can be used to evaluate many of the problems that are being found in the workplace. In fact, NIOSH has incorporated many changes in the first proposed revision to the certification standard that we believe address many of the concerns about workplace performance of respirators. For example, in the proposed regulation NIOSH has significantly upgraded the certification requirements for particulate respirators. These proposed test methods used test aerosols considered to be the most penetrating size, and thus, the most difficult to filter. This improvement will ensure that the respirator filter will perform in the workplace at least as well as it did in the laboratory. This will provide greater assurance than exists today. There are many other changes in laboratory testing that can and should be done. John King will discuss a few of these later.

Fit testing. A necessary part of a simulated workplace

testing is the qualification of the subject through the use of a quantitative fit test. The test subject should be selected from an anthropometric panel. The panel would consist of one (1) person in each of the boxes of the Los Alamos grid. John will discuss this in more detail later, but this will give assurance that certified respirators will fit a wide variety of people. Only subjects that have passed the test will be qualified to wear the respirator in a simulated work test. This would be typical of real use requirements.

The quantitative fit prior to the simulated workplace test would be the only fit test used in certification. ISEA believes the only real meaningful fit test is the fit test that will be performed on the actual wearer of the respirator. NIOSH should make fit testing of the respirator on the actual wearer a condition of certification. ISEA believes this is the best way to improve respirator fit. ISEA believes a statement should be placed in the NIOSH limitations that the respirator wearer be initially and periodically retested as a condition of certified respirator use.

Simulated workplace testing. A practical simulated use test in the laboratory should be incorporated in the certification process. The test should incorporate those factors that have been identified as being pertinent to the performance of a respirator in the workplace. Some of these variables could be work rates, wind velocities, work regimes, which have been currently identified as effecting respirator performance. As

workplace testing research continues to identify factors effecting performance these findings should be incorporated in the simulation tests to assure that these factors are adequately addressed in the respirator design and performance.

We recognize the need of researchers to correlate the results of simulated workplace testing or various laboratory testing to workplace testing. Such correlation will enhance the confidence that can be placed on non-workplace testing. While direct correlations is desirable and understandable, it is apparent that researchers have not yet developed workplace tests to the point where this would be possible. Correlations are only possible when all the variables affecting the result are known and controlled or are factored in the predictive equation. Today our level of knowledge barely scratches the surface of all the information necessary for this understanding. Correlating one workplace study to another is not well understood, let alone correlating any workplace study to any testing that we have done in the laboratory.

Workplace evaluation. NIOSH should require a workplace evaluation of respirators in a manner similar to that done in the UK. In this evaluation respirators are put into appropriate use in the workplace for a period of time, then brought back into the laboratory where appropriate laboratory performance tests are performed. Design weaknesses and defects can be found after a period of use when performance is checked. For example, filter efficiency should be checked to assure that they are not degrad-

ing during use; cartridges checked to assure channeling has not occurred; exhalation valve checked to assure they do not leak. ISEA believe that this type of evaluation is not only valuable for discovering problems, but also very feasible.

In conclusion, ISEA believes that NIOSH has already proposed many steps to add greater confidence to the respirator certification system. The additional steps that we have recommended, plus what you have heard yesterday from John King, and will hear later, will add even much more confidence. With these recommendations ISEA believes certification system in this country will exceed that of any other country in this world. Research must continue on the methods and problems associated with workplace testing of respirators. ISEA and it's members will continue to support research endeavors to find the answers to the many problems and questions currently shrouding our ability to perform meaningful workplace evaluation of respirators. Thank you.

JOHN KING: John King with E.D. Bullard, representing ISEA. I'll be the last one in the panel here, and when I'm done I'll ask Don Wilmes to come back up here and field any questions you might have about ISEA's approach and beliefs with regard to testing and certifying respirators.

To just go back to the criteria document that I talked about yesterday a little bit, I want to try to address the question, why is the criteria document more rigorous than what NIOSH has proposed and how will it improve the performance of respirators in the future. I don't know how to do this. I could take one

(1)--I think I'll take one (1) section at a time, starting with negative pressure air purifying respirators.

The particulate and vapor gas penetration tests that are specified in this document are done on complete respirators as opposed to just filter elements, and, therefore, addresses all aspects of the respirator with regard to filter, facepiece interface, gaskets, exhalation valve leakage, and so on and so forth. This is done on a breathing machine where cyclic breathing takes place. It is done at relative high rate of cyclic breathing and a very low rate of cyclic breathing. The low rate would be, for example, to address any sort of contaminant being sucked back into an exhalation valve, for example. Many of these issues aren't really addressed in the current criteria that NIOSH uses for testing.

CO_2 accumulation tests; again, to verify that dead air space is kept to a reasonable level. Don talked a lot about the quantitative fit testing and the simulated work--the quantitative fit testing, as we envision it would essentially be done in the simulated work test chamber or one very similar to it. The simulated work test chamber would be something like what I indicated yesterday with regard to the work that Skaggs did at Los Alamos where various work regimes can be set up with regard to moving blocks and climbing stairs and running on a treadmill, etcetera.

Rough handling requirements that we're suggesting would also improve, we thing, the efficacy of respirators when actually

shipped and received by users. The required limitation that the user do a--pass a--fit test that would be acceptable we think is also an enhancement and should be part of the certification process. With PAPRs, for example, in addition to what I just talked about the feature of mandating and the use of an alarm we think is a significant improvement, as well as applying that to air lines.

The use of breathing machines at various work rates and rating respirators at various work rates to give the user a little better feel for, well, I can work harder in this respirator maybe than I can this one because it's rated at a higher breathing rate, we think is a significant improvement. But right now, for example, the term pressure demand is, we feel, somewhat confusing to people, users in particular, whereby in the past pressure demand respirators were viewed as those types which had a demand valve where relatively high rates of flow under cyclic breathing conditions were possible and available. We now have air line respirators approved as pressure demand respirators that don't use demand valves. They are, in fact, continuous flow respirators and they did not provide protection with regard to very high work rates and high flow rates, and yet they're called pressure demand. So rating respirators on the basis of a work rate we feel is a significant improvement.

In the SCBA area we feel that the NFPA organization has done an excellent job of creating tests and standards for SCBAs that exceed those found in the NIOSH regulations. Tests for corrosion

resistance and dust resistance and thermal resistance, and communication and rough handling, and lens abrasion, etcetera. In the area of SCBAs used for fire fighting, for example, the flame tests that are being . . .

JOHN KING: . . . of the device in terms of where that can be used then a failure mode analysis should be required for all SCBAs.

The question was raised yesterday as to what we have done to validate or correlate the test we've proposed. I need to, I think, at this point go back to the original goal that I said we set before us when we started to develop this document. And our intention was not to write a proposed standard with exact wording where all the Ts are crossed and the Is dotted. Our task was to develop a document that set forth a philosophy and guidelines for the test and not put in all the numbers and that sort of thing. In fact, we have previous drafts of this document where we have numbers in the tables that you see in that document. I took those numbers out for this particular presentation today, because we feel that the regulatory agency--that NIOSH--should put these numbers in. What we're trying to present is a philosophy and a scheme of things. And this is what the document represents.

You know yesterday and today I haven't really heard anything or seen anything that shows that respirators fail to protect. I think that they apparently do work. Studies can be mounted at considerable cost which you just heard which attempt to measure workplace protection factors. These studies may have some value in terms of basic research, but no means has emerged to link workplace protection factor results with decision criteria for testing and certifying respirators. I don't think we should

allow our collective frustration with poor respiratory protection programs to lead us into a public policy which places an expensive burden on respirator manufacturers which will have no or little benefit to the respirator wearer. ISEA's criteria document represents an approach to testing and certification that is scientifically more rigorous and more performance related than what has been proposed in the past in terms of laboratory tests. This greater rigor emphasis on performance represents a significant improvement in respirator quality assurance and efficacy which can only serve to benefit the respirator wearer. Thank you.

DON WILMES: I guess we'll field any questions.

CHING-TSEN BIEN: I have a question that ... direct with ..., but we're talking about testing respirators, the ANSI Z88.8 subcommittee ... testing as for air purifying respirators. I guess we have a lot respirators manufacture participate. I take a rough look, compare the ... seems have a lot similar things to the ... document. I just asking since I have all the manufacture here, is ISEA willing to ... to vary ... test methods ... standards? We just want to make sure the ... work.

DON WILMES: Well, I'm sure, speaking for ISEA, before any test method is adopted it would be validated, and I am hesitant to use that word 'validated', because it's a nice motherhood catch-all word, but what does it really mean. If you test a filter efficiency and you get a number you assume that that is filter efficiency. I don't know why you need to validate a test

because I don't know what it relates to. There's--I assure that before any tests would be done we would participate in any round robin sort of testing or any testing of this sort to make sure that the test methods were reproducible and reliable. But I'm not sure what you mean by validating.

CHING-TSEN BIEN: What I'm saying, yes, we have method here, from my ... committee, it you propose any test method you always have ... to make sure the method work. So I'm just saying is ISEA willing to participate ... round robin tests?

DON WILMES: Certainly.

BOB DA ROZA: I agree pretty much with what all you presented. There's one area I'd like to comment on a little bit, and that's on the anthropometric panel for face sizing. The anthropometric panel just requires a couple of facial dimensions to find a person in a box, but the actual face shape of people who ... that box can vary considerably. So if you're going to certify that a respirator has, like on a size or like shape, by any person just because they happen to fit in that box, you're going to have different shaped faces every time you get a new panel. And what I think would be better would be to make up a series of mannequin heads, one that fits each of the boxes, so that you always fit the respirator that's going to be certified on the same exact face, as opposed to on a person, and then use the breathing machine test to do a face . . . .

DON WILMES: I would tend to agree with you in that it's often--the anthropometric panel is often--thought about wrong.

It's meant to represent ninety-five percent (95%) of the work force with those two facial dimensions. It's not meant to represent ninety-five percent (95%) of all the people in the workplace, just those two (2) dimensions.

Unfortunately, I appreciate your concern, but I'm afraid if you went to a mannequin method that the goal would then be to design respirators to fit mannequins rather than people, and I would be very--I would be reluctant to proceed in that direction. But, I appreciate your concern there. You have a definite real concern.

ALAN HACK: Speaking of the panel, I think it's probably been interpreted more rigidly than we ever intended it to be. It was just an attempt to get a wide variation of faces by picking people from all the extremes. But face ... face which appear to be useful measurements. The boxes themselves have no significance at all, it's just dividing ... everybody from the middle. And twenty (20) years later I hate to see it so rigidly enforced, that if you miss a person from one box your test is invalid. That's not really important.

And back to what Bob said, I don't think you can do any fit evaluations on a mannequin. A mannequin is not a face, and I don't think any data you get fitting a respirator to a mannequin has any validity at all in terms of comparing it to people's faces for purposes of fitting.

DON WILMES: I'd just like to comment on what Alan said. I agree with him. In light of that, the only thing using the

anthropometric panel forces you do to--to get a wide variety of faces. It doesn't do any more than that. You can't relate a certain portion of the panel to a small respirator. It may work out that way, but there's no guarantees. It just--we're proposing it simply because I think it's the best way to best assure that respirators will fit a wider variety of people. That's the best way we know how today.

HARRY ETTINGER: I don't know if you or Rich can answer. If a manufacturer wants to bring a new, let's say, full-face respirator on line, what's typically the order of--without getting proprietary--the budget would look to take care of design, testing, development, preparing molds, marketing, etcetera, the whole bit? What sort of number are you talking about?

DON WILMES: I would say millions.

HARRY ETTINGER: In the millions. So, let's say five (5) million dollars. I just want to put into prospective that compared to the four hundred and eighty five thousand dollars ($485,000.00) which was the cost of one test. It would bring out the ... alarm. We're all talking big money, and it's not totally astronomical compared to the cost of bringing a new model on, if you're saying this is the cost of marketing.

DON WILMES: Realize, Harry, though, that bringing this one (1) model on--when you bring one (1) model of respirator, you don't bring one (1) model of respirator on, you bring fourteen (14) models of respirator along that will need testing. You'll have a particulate air purifying, a gas and vapor, canister

version, a pressure demand, a powered air purifier version of that respirator, all of which will require workplace testing. So we're not talking about a simple four hundred and fifty thousand dollars ($450,000.00) or whatever that number was, but we're talking multiples of that, because when you introduce one (1) new facepiece the figure we were giving, I assume, I was responding to one (1) new facepiece. There are many respirators associated with each facepiece, and these will all require testing, so that number becomes pretty higher. A lot higher than the development costs by the time you're done. You understand what I'm saying?

HARRY ETTINGER: Yeah. A lot of models come out and are used just as a half-mask facepiece and it doesn't have a pressure demand, it doesn't have a PAPR . . . .

DON WILMES: Yes, but it has--everything has a whole multitude of filters and cartridges. Any other questions? Thank you.

MS. STRICKLAND-CID: As you all know we started about fifteen (15) minutes late. We've added a couple of minutes to our agenda. We will next have a discussion my Ms. Susan Tannahill from the Environmental Health Division of the University of Strathclyde. Her discussion will center on workplace protection factor studies of negative pressure full-facepiece dust respirators using asbestos removal. And I move that after Ms. Tannahill speaks that we take a very short stretch break so that we might be able to get back on schedule.

SUSAN TANNAHILL: Good afternoon everybody. The work which I'm going to discuss describes a study which was carried out to

evaluate the workplace performance of health and safety executive approved negative pressure full-facepiece dust respirators during asbestos removal.

The main objective of my work was to investigate the intra-subject variability and the inter-subject variability. Just to remind you, intra is the within worker variability, and inter is the between worker variability. As we all know the purpose of respirator ... equipment is to protect the worker against a variety of potential hazardous substances in the atmosphere, and it's essential to know what sort of protection we're likely to get from these respirators.

So, in the United Kingdom the overall performance of any respirator can be assessed using either approval standards which are issued by the Health and Safety Executive or British Standards, or we can turn and look at workplace protection factor studies which have been carried out. Nominal protection factors based purely upon laboratory data have been assigned to all the different categories of respirator. It's generally assumed that if a respirator is properly and maintained then we're likely to achieve this protection factor, but looking at studies which have been carried out, this is not always the case.

Most of the studies have been carried out in the States and a great deal of them look at the positive pressure respirators and, in the case of negative pressure respirators, they're looking at the half-masks and the single use respirators, but very limited data in fact exists dealing with the full-facepiece

negative pressure dust respirators. And that's what I'm going to look at. They are approved in the United Kingdom, incidentally, and the have a nominal protection factor of nine hundred (900). Over here NIOSH assigned protection factor, I think you call it, which os fifty (50). ... which should be one (1) step ahead is even increasing this, so it doesn't really make sense.

The sparse workplace protection factor data--one study carried out by [Cundi] has shown a geometric mean workplace protection factor of sixty-six (66). Now this was against asbestos, and work by [Shackelton] showed that geometric mean of twenty-three (23); even lower, and this morning we heard from Craig Colton, and I'll fill your--his work protection factor--the geometric mean was relatively high, about four thousand (4,000) I think. The ninety fifth percentile was very low, I assume because of the wide variation in the results from the different workers.

The concern clearly arises from the results which are available and when designing a workplace protection factor study we can approach it in two (2) ways. We can either say what level of protection are we likely to achieve, which is just looking for these magic figures, or we can say are we going to get a protection factor greater than or less than the assigned protection factor. so we don't really need as many data points as we would if we were just looking for this magic number. In this study we are just trying to find out are they working as well as HEC or NIOSH or ... are saying they will, and also looking at the intra

and inter-subject variabilities, as well as looking at the influence caused by the various variables which were identified which have known to affect the workplace performance.

In order to calculate the workplace protection factors concurrent lapel and in-mask samples were collected during asbestos removal. Further, the method used in this study deviated from the recommended method which is similar to your NIOSH method--what's the number--I can't remember, but it's the ... in-filter method that we use in the UK. Where it deviated from the recommended method, full scale laboratory and in some cases workplace based experiments were carried out to ensure that this method did not, in fact, distort the results.

The challenge concentration was evaluated by drawing air at point five (.5) liters per minute through a twenty-five (25) millimeter diameter point eight (.8) micron pore size sampling filter. And this was held in a ... sampling head which was fitted on the wearer's lapel facing downwards. The in-mask concentration was evaluated by drawing air at two (2) liters per minute through a thirteen (13) millimeter diameter, one point two (1.2) micron pore size sampling filter, which was held in this adopted ... holder. And I think some of you will recognize that. How it was adopted, the outer lips were removed and the nozzle at the end was in fact reduced in size. This was placed into th_ brass nozzle and that was attached onto the visor just inside t_ full-facepiece. There we have it there.

Now the main advantages of positioning the filter holder

here were that the vision of the wearer was not obstructed, which is an important safety factor, and the filter holder did not distort the respirator--the mask--in any way, and fibers which were likely to be inhaled, i.e., those near the ... valve in a cup were more likely to be sampled. And also the sampling filter wouldn't be subjected to high relative humidities as would be the case if it was placed inside in a cup. And finally, ... position effects wouldn't have to be considered because of it's location. Here's a diagrammatic sketch of that. And there you have it there.

Initially the in-mask samples were evaluated by drawing air onto a twenty-five (25) millimeter diameter sampling filter, but the preliminary results showed that there were very few fibers inside the mask, so in order to improve the sensitivity we reduced the filter size down to thirteen (13) millimeters. But because of the smaller size the flow rates had to be reduced, so instead of quadrupling the fiber density, what we did was actually double it. So these modified respirators were tested at the Institute of Occupational Medicine in Edinburgh to ensure that the modification didn't in fact cause any problems and that they continued to meet the British standards; the ones that they would have to meet if they were going forward for approval.

Asbestos workers were selected at random from two (2) companies, and an attempt was made to issue the workers with the same respirator with what they used normally, but taking the time scale of this project into consideration, this turned out to be

impractical. Parameters which could potentially influence the work performance of the respirator were identified, and these are listed in the next slide. No, that's the twenty-five (25) millimeter diameter sampling filter in the .... If we can just look at the next slide you'll see that inside there. So there's not a great difference apart from the size of the sampling filter.

These are the parameters which were identified and two (2) questionnaires were filled out. One (1) was filled out for each worker to take records of his personal details, and another questionnaire was filled out for each workplace sample, noting exertion, sweating rates, and things like that. In about ninety percent (90%) of the samples the workers were observed, but it wasn't always practical in places like ... attics. In order to quantify the inter and intra-subject variability between one (1) and six (6) samples were collected from each worker.

Now the range of workplace protection factors which were calculated were vast. In fact, it ranged from as low as eleven (11) up to over eight thousand (8,000), although I think eight thousand (8,000) was just one of those freak results.

There we have for respirator A the range from eleven (11) to over three thousand (3,000); for B from twenty-six (26) to over eight thousand (8,000), and limited data has been collected for respirator C so I'll just concentrate on the other two (2) respirators for just now. When analysis of the ... is carried out it actually shows that there is a significant difference

between the performance of respirator A and respirator B. They're both very similar respirators, just different brands, but the workers seem to prefer using respirator B, so if they have a comfortable respirator maybe they're not adjusting it so much in their face. That's the only reason I can think of just now why these results were like that.

From a look at the pooled results of the workplace protection factors we get geometric means of two hundred sixty-four (264) for respirator A and seven hundred and twenty (720) for respirator B. Both were geometric standard deviations, which are in line with the other studies which have been carried out. We see very low fifth percentiles, ... for respirator B, but almost at the nine hundred (900) and well over the NIOSH standard, were quite a bit below when we look at the ninety-fifth percentile where we should be directing ourselves towards. Now that's for the pooled results.

Looking at the individual workers, the top--two hundred and sixty four (264) relates to all the workplace protection factors from all the workers, but when we break that down into worker one, two, three, four, where they had three (3) or more measurements taken, we can see that their geometric means vary from worker to worker as does the standard deviation. So some workers are experiencing a greater variation in performance that is achieved. The results are very similar for respirator B, but taking the geometric means of the geometric mean--the top one is the geometric mean of the pooled results, and below that is the

geometric mean for the individual workers. And when we calculate the geometric mean of the workers' geometric means, we come up with the figure at the bottom, and we can actually see that the standard deviation decreases considerably from the individual standard deviations from the workers. So what that's showing is that the intra-subject variability is much greater than the inter-subject variability, and this emphasizes the need for multiple measurements collected from individual workers.

We'll look at respirator B--the results for respirator B. We're seeing the same pattern ... here. The fifth percentile is in fact up a bit, but it's just much the same as respirator A. Now I'm going to move on now and take a look at the other possible sources of variation. The preliminary results showed a correlation between the challenged concentration and the workplace protection factor. And this phenomenon has been reported by a number of other workers, and it's often attributed to as a behavioral effect, i.e., if they think that they're going to experience high concentrations then they'll wear the respirator more tightly ... and as Robin said yesterday, if they smell, then that would happen too. But with asbestos fibers you can't see it, so I was very dubious about the behavioral effect, but with this increased data set, this relationship is non significant and critics of workplace protection factors have often said, we're only seeing low workplace protection factor at low ... concentrations. So I think evidence for this argument does not exist with this data. And also the question of facial hair is a lot of

different schools of thought, but in my study I found that facial hair didn't make a significant difference. When I'm talking about facial hair, I'm not talking about beards--which moustaches aren't too important in terms of these measurements, but a beard would obviously effect the results. Facial hair here, I mean one (1) to four (4) days growth.

So, in summing up, the protection factors measured here back up previous findings and we can conclude that they did not meet the assigned protection factors by the HEC. The important finding from this study is this large intra-subject variation. These findings emphasize multiple measurements are required in order to have a valid experiment. If anyone has any questions.

MR. _____: Your test subjects were not fit tested at all?

SUSAN TANNAHILL: No, it's not a requirement in the United Kingdom.

ROBERT DA ROZA: I was very interested to hear, again, in your paper as was presented in some of the other papers, that intra variability--the variability of the fit factor that one person gets from repeated donnings is greater than--the variation of that is greater than the variation between subjects. This is one of the reasons, I believe, that why the ANSI standard Z88.2 1980 required three (3) fit tests for determining what fit factor for what protection factor to give to a worker--required you do three (3) and do some kind of averaging or taking .... When Z8.2 1980 was going to be revised we wondered whether we should still require three (3) fit factors. And checking around we found that

hardly anybody in the country does three (3) replicate fit factors when determining what fit factor to give to a person. What I've heard here today and yesterday is that we're rediscovering that there's a great variability between fits, and if you're going to say how well a respirator fits a person, only do a measurement--making a measurement once--doesn't really do much good. Then you're saying you really should do it a number of times. And yet nobody has practiced this. Almost nobody. OSHA's practiced it. Almost nobody has practiced it over the last ten (10) years in the United States.

SUSAN TANNAHILL: Well, I think no experiment has been designed to actually look at inter and inter-subject variability apart from the study yesterday, but I think--was that actually in the design stage? Was it designed to look at inter and intra or was that--you were able to analyze the data?

BARRY PALLAY: I chose replicates on individuals so I could get data on inter and intra-subject variability.

SUSAN TANNAHILL: Well, I think you study is the only study that actually did that. Most just use . . . .

BARRY PALLAY: I think there may be some others, too, but not very many.

BOB BRENNAN: I understand that you didn't do fit testing on the workers, but let me ask whether it is the worker's normal practice in donning their respirators to do a negative or positive ... themselves when they don, or what is the practice in this plant?

SUSAN TANNAHILL: It varies from worker to worker. Some did negative pressure fit tests.

BOB BRENNAN: Some?

SUSAN TANNAHILL: Just, yes, some.

BOB BRENNAN: Covered the exhalation valve and inhaled?

SUSAN TANNAHILL: Yes.

HOWARD COHEN: Would--you loaded your cassette quite differently from some of the others we've seen. Yours was actually--the filter was inside the facepiece itself, which is quite different. Did you have some of the problems with humidity still within that filter--the filter getting very wet inside the respirator--that the same people have had which are just hooked right to the outside of the respirator?

SUSAN TANNAHILL: No, no. There was no moisture problems, because it would be very--you would see that when you went to clear the sampling filter with acetone. Under the microscope, it would be very dull, and this wasn't the case.

JERRY SHERWOOD: That also--that type of measurement is measuring the inhalation only, isn't it, because you have trap valves on the inner mask . . .

SUSAN TANNAHILL: Yes.

JERRY SHERWOOD: . . . to stop exhalation?

SUSAN TANNAHILL: Yes.

JERRY SHERWOOD: So you were in fact getting a better measure?

SUSAN TANNAHILL: Yes.

ALAN HACK: We were discussing the lack of ... and it might be because of the nose cup. We noticed you were collecting it between the visor and the nose cup so that was fresh air entering the mask through the filters, not mixed with exhaled breath that's very humid. So if the ambient air wasn't terribly humid you wouldn't have the hundred percent (100%) humidity you find normally in a mask. Now, all the full-facepieces in Europe come with nose cups, and we haven't required that here. Maybe we should. It would surely make this type testing easier.

BOB BRENNAN: Yes, I understand the comment about the nose cup, and I understand what it would do for the moisture. However, I would propose that you be careful with them, or talk to Warren at great length--Warren Myers at great length--because without the turbulence you get from the exhale some of the variability you saw may have been the result of streamlining between leak and mouth and bypassing your filter inlet, and no real way of telling at this point, I don't think.

SUSAN TANNAHILL: What we can see is these workplace protection factors could in fact be over estimates.

BOB BRENNAN: Or ... some of your data--what Warren seemed to find was depending upon where the leak was if there was no turbulence in the mask you may or may not detect it at any particular probe location.

ALLEN JOHNSTON: I think we're back to the terminology issue we discussed earlier with respect to what's a workplace protection factor and what isn't. In our definition your study would

not be a workplace protection study because it didn't include fit testing and it didn't include a uniform worker training and it didn't include a lot of the things that we otherwise do, so I think people trying to compare this study with other studies are going to be quickly confused about what it all means. That doesn't mean your study is wrong or our studies are right, or ours are wrong and yours are right, it just means that we have to look at them differently because they're very different studies and they mean different things. And I think in both cases we don't know what it means.

SUSAN TANNAHILL: Yes, that's--non-uniformity between USC and the UK data, and I appreciate that.

ALAN HACK: I agree with you and I disagree. It's true, you can't compare the two (2), but if they don't normally do fit testing in Europe than that is workplace protection factor study.

ALLEN JOHNSTON: ... normally does there, you just can't compare with ours ....

SUSAN TANNAHILL: A lot of publications actually show that there's no correlation between fit tests and WPFs, so we're back to, is the fit test really necessary when doing your workplace protection factor study for valid results.

Are there any more questions. No? Okay, thank you very much.

GWEN STRICKLAND-CID: I think we've stopped on a fairly provocative note. We are--depending on how you look at it, five (5) minutes late, so if you want to just take a ten (10) minute

break, we will be back on schedule. So if you'll just come back at three o'clock (3:00) we'll get back on schedule.

(Whereupon, a ten minute break was taken.)

DR. CLIFTON CRUTCHFIELD: I think the basic message I bring this afternoon is fairly simple. I don't think the emperor is wearing any clothes.

You may ask what does a paper on quantitative respirator fit testing have to do in this particular session when we're looking at workplace respirator evaluation protocols. I think it's important to perhaps sit back and look at the fundamental protocol that's being used to assess respirator performance in the workplace.

Let me show you ... that I have not seen presented nor have I seen published, any information that convinces me that aerosols can tell us what we want to know about respirator performance in the workplace. So, in a way, I'm asking you to take a quick look at the vehicle that we're utilizing and try to asses with me whether or not that vehicle can get us where we want to go. And I don't think that it can. We've heard a tremendous amount of information about variation and all the parameters that we don't know much about that effect the kinds of data that we're generating. And I look back and see the data and I say, well, some things I can tell you based on what has been presented; that workplace protection factors are strongly dependent on filter loading, concentrations, the contaminant that we used to make the assessment between the in-facepiece levels versus ambient levels,

and the numbers are sort of driven around by a whole host of factors, most of which we don't have control over. We've had some rather discouraging sessions when we talk about those factors and how little we understand or how little control we seem to have over them. So the question is where do we go from here?

A quick analogy. This workshop in a way--by analogy it's as if we've been asked to go out and do a survey of the American population for body weight, and we get together, and in talking about our survey protocol we say, we need to decide whether we should have our tape measures graduated in centimeters or in inches. But if we take that tape measure out, I think we can probably arrive somewhere in the general area, but it's going to take a tremendous amount of strapping and a whole lot of extrapolating to get there. One wonders if perhaps it wouldn't be better to take a bathroom scale rather than a tape measure out to get at the data that we're looking for.

I'd like to review with you during the next forty-five (45) minutes--quickly review--some of the studies that have led me to the conclusion when I say that I don't think aerosols can necessarily get us where we want to go. I'd like to leave some time afterwards, though, after looking at the studies that I've conducted to try to make some sense of what does it really mean. Where do we go if we can't use aerosols? And I'm not convinced, like I say, that aerosols can get us there. What are the options? We don't have any information on gas and vapor. I submit

to you that we can use air.

Air is pretty universal. How do we use air in the form of pressure? Pressure is very fast, so what I'm going to describe first of all is my version of the bathroom scale that maybe we should take out on our survey, and that's a technique that I called the controlled negative pressure technique for respirator fit testing.

How does it all work? This is a version of the initial protocol, and this thing has gone through some rather elaborate enhancements, but the basic concept is still the same. In order to do a negative pressure fit test the first thing we do is seal the air purifying pass into the respirator. We do that by replacing the filter cartridges with manifolds--airtight manifolds. The manifolds have several ports. There's a breathing port, there's an air exhaust port basically, and there's also a pressure port.

With those modifications made to the worker's actual respirator, because you notice we're not probing the respirator, so you can, in fact, do the test on a worker's actual respirator, if you're ready to do the test you basically do so by--you conduct the test by having the worker seal off the back part of the respirator, they hold their breath. At that point then you start exhausting air from the respirator to establish and then maintain a constant negative pressure or pre-selected negative pressure inside the respirator, which we're monitoring through the pressure port.

The pressure is pre-selected to, in fact, replicate the average inspiratory ... inside the respirator as it's used in the workplace. Now what we've got is the air purifying path are sealed so that the only path or avenue for air flow into the respirator is through a leakage path. With the pressure held constant the exhaust rate equals the air leakage into the respirator. So it's a fairly simple procedure. And you're talking about ten (10) seconds to do a test. Essentially five (5) seconds to establish the pressure and currently we're using five (5) seconds to in fact measure the exhaust flow rate. It's a static measure of air flow leakage into the respirator.

Now we're used to using a ratio of inside/outside to infer leakage. The ratio of the fit factor is what we used to impute leakage into the respirator. We call it penetration. Here we sort of got the reverse in that we directly measure leakage or penetration of air into the respirator. In order to translate that into a fit factor basically you'd take the ratio of leakage air--first of all total air flow into the respirator, divide that by leakage air and that gives you a fit factor if you want to follow along with fit factors, which is more classic.

So here was a new way of coming up with measuring leakage into a respirator. Leakage of what? Leakage of air. It's a very rigorous, but also a very conservative approach in that if air leaks into the respirator any contaminant that you may be concerned about may leak into the respirator. If you tell me that ambient aerosol leaks into the respirator, what does that

tell you about what you find at one point or another point in any foundry or any other process or industrial operation that you went to visit. And I'm not sure how you translate information based on a particular particle size to any other particular particle size or workplace environment. Air, though, is a fairly standard universal testation.

Anyway, there's a fairly simple rapid way of getting an idea of how well the respirator fits the face. A bit later on I want to talk about what does that number mean and what are some of the variables that I think we need to be looking at. But first of all, here's a new method, what do you do with a new method? Well, you obviously need to some kind of comparison against the standard method, and the standard method is still generated aerosol.

It was a bit troubling, though, when you look at the standard method and nowhere could I find validation of the standard method. We have a huge assumption that, in fact, if we measure concentration outside, if we measure concentration inside, that tells us how much leakage we're actually seeing into the respirator. It's a very large assumption, had not been validated, so we essentially--when we did our comparative study--tried to take a look at--we took a crack at doing a validation study.

We started by using leak needles. No human subjects, no respirators, just could each of the two (2) systems, the controlled negative pressure system and the--this was a computerized Dynatech ... system. Could they in fact measure leaks through

various sizes of needles? We used fixed leak assemblies. For the negative pressure system it was a small airtight canister that had the various probes on it, and also it had a septum into which we could put our leak needles. In terms of the aerosol system we used a Y. On one arm of the Y was a hepa filter, on the other arm of the Y was a septum into which we put the leak needle. The base of the Y was then plugged directly into the mass sampling line on the Dynatech system. And that's an important point. It was plugged directly into the mass sampling line. And what did we see?

Using the four (4) leak needles we found very good correlation between measuring the leak with both systems. The fit factors--and these are equivalent fit factors--basically we said, okay so I have a leak measure through a needle, what does that mean? In a way we took our negative pressure canister and said that's our surrogate person for now. And our surrogate person normally at rest has a breathing rate and expiratory flow rate of approximately twenty-six (26) liters a minute. So that gives me a basis. And that's a standard number that's used throughout both phases of the study that I'll report. A respiratory flow rate of twenty-six (26) liters a minute, and that then gave us an equivalent fit factor.

We looked at fit factors and said, okay, the two (2) systems seem to agree quite well. Aerosol is reporting a higher fit factor. Well, either that's--we don't have the right number, or possibly we're getting some aerosol loss.

CLIFTON CRUTCHFIELD: . . . are in fact re-showing the known or the measured flow rate through the mass sampling line and the known flow rate through the leak needle at the measured pressure differential that we had at the base of the Y. So we knew the driving force through the leak needle, we knew the flow through the leak, consequently, and we knew the total flow into the mask sampling line. So that gave us a predicted fit factor. We compared that to the actual fit factor and found that, in fact, the actual measured fit factors were higher, an indication that we were loosing some aerosol in the leak needles.

We concluded the fixed leak portion, needles only, by taking a look at how well did the two (2) systems stack up and the answer was very well. The controlled negative pressure system could measure leaks very effectively. The aerosol system also measured leaks very effectively. On most of the slides you've seen so far the error bars have been too small on the log scales to be visible. So variation has not been a problem. Both systems measure with good consistency and with good reproducability. Typically, five (5) or six (6) tests represented by each data point. And that was the fixed leak system.

Now the next step in this quasi validation study, if you will, was to say, okay, what happens if, in fact, we take the leak--now let's put the respirator on a subject and let's do multiple tests of a respirator on a single subject--respirator only--and then let's introduce our leak needles to the respirator

so that we have some measure of known leak and let's see what happens.

First of all, data for the negative pressure system. Here we have data--the circles are respirator on the subject and the other data are leak needles without the subject. You notice that when we pout the respirator and the needle together on the subject that we've introduced a second leakage path into the respirator. So we have more leak now and the negative pressure system picked that up. It also--you can see from the data that when the needle is large the needle becomes the major source of leak, and when the needles are small it's the respirator face seal that in fact is the major source of leak. The negative pressure had enough--the system had enough--sensitivity to point that out.

Now take a look at what happened when we put the needle on the respirator on the subject and did the aerosol system. And this aerosol test was immediately after the negative pressure test without removing the respirator. Now we still have the two (2) sources of leak. Compared to the single needle leak that we'd seen before, that without subject--just the needle data that we've already seen, and you notice that instead of now finding lower fit factors with the two (2) sources of leak, when we actually go to the respirator on the subject the fit factors increase dramatically. The needle leakage is still there, the driving force through the needle is still there during inhalation, but the aerosol system is no longer seeing the leak.

And the question is why. And the answer is--my answer is--we are no longer directly plugged into the mass sampling line with our leak needles. We are now having the leakage go into the respirator and the leakage is not going into the mass sampling probe. Evidence, in my opinion, of significant in-mask sampling problems. Am I the first person to say that? Absolutely not. It's one of the many factors, one of the many variables that have been identified. I find it--I think it is a very significant problem. The result is that we're going the wrong direction. We are under sampling inside the mask, we're overstating measures of fit as a consequence.

Now, this is a simple comparison between the data that we saw with the negative pressure system and the aerosol system when we had the leakage needle on the respirator. Again, only one (1) subject, but you notice that there's a very large difference between the measured fit factors--the measured leakage--that we saw with the two (2) systems. With the aerosol system generally overstating fit by an approximate order of magnitude.

That was on one (1) subject with multiple tests--repeated tests. We followed another subject through the course of this particular phase and basically tested the subject with both systems back to back without removing the respirator, taking care to try and not shift the basic fit of the respirator. This is one (1) subject over a number of days wearing both half-mask and full-face respirators, and not trying to maintain consistent fit. What we were trying to do is look at an array of fits. Does the

system track over good fits versus bad fits, and the tracking between the two (2) systems was very consistent. But something else that was very consistent is the relationship that aerosol systems are overstating measured fit by an approximate order of magnitude.

Another part of this--well, what have we done? This slide is an attempt to depict what we've done. In a way we've measured leakage through needles. Both systems saw the leakage very well; very consistent. We measured on the subject leakage with just the mask itself, and we also measured the mask and the needle combined. And with the negative pressure system up here for the three (3) needles that we used, you notice that when we combined or added the measured leakage through, first of all the respirator itself and the needle, it added up to what we saw when we put the two (2) together again on the same subject. And that was consistent across all three (3) leak needles. That pattern was not consistent when we used the aerosol system. We saw a lot of variations, and, as a matter of fact, we saw leakage that we felt was there not being seen basically by the aerosol system.

The last part of this particular study was an assessment of--we looked at a hundred and twenty five (125) Air Force personnel; did back to back negative pressure and aerosol or aerosol negative pressure--randomized the order of the tests--and did a fit test. We didn't replicate fit tests among the population, but we had a large number, and what do we see? Two (2) things, I think. One is this overestimation or overstatement of fit

relative to what controlled negative pressure we're seeing by an order of magnitude. Aerosols were an order of magnitude higher. If you look at one hundred (100) as a passing fit factor, the negative pressure system had a lot more failures than did the aerosol system. Negative pressure numbers that we've seen are typically much lower than aerosol numbers. And that was a comparison study we did between the controlled negative pressure system and the aerosol system. But that was based on--first of all, what was the challenge pressure throughout this particular phase of the study? It was a half inch of negative pressure, and that was consistent throughout. What inspiratory flow rate did we use? Almost twenty-six (26) liters per minute. That was a number that we derived from the literature. Ah, but what if you used a much higher inspiratory flow rate, you'd get much higher negative pressure fit factors, and this was true. What we needed to have is a better understanding of what goes on inside the respirator as a person wears it. And perhaps as the person works. And so we didn't put together a study where we try to come up with the inspiratory pressure and inspiratory flow rates that are associated with a number of the parameters that we thought had major effect on those factors. And that was basically a work rate study that we did using thirty (30) subjects divided into females wearing half-mask respirators, and the males wearing both half-mask and full-face respirators so that we could look at gender effects, we could look at mask effects, we had each subject work at four (4) different work rates on a cycle

ergometer and we had each subject wear three (3) different respirator cartridges, low, medium and high filter resistance. Basically, used a dust respirator for low resistance, the hepa filter for medium resistance and a combination organic vapor hepa filter cartridge for high resistance.

We had the subject work on the cycle ergometer; spent a period of time stabilizing, basically, the work rate, and then spent a minute measuring their inspiratory pressure and inspiratory flow rate. Inspiratory flow rate was measured by using the pressure signal from the probed respirator to--we had inspiratory period from the pressure trace; we had to tap onto the exhalation valve in order to get expiratory flow. We used expiratory flow plus inspiratory period to compute inspiratory flow rates.

First of all the pressure data. What we found was pressure data for the three (3) cartridges, low, medium and high cartridges, for our subjects, and this is just an example of one of the data sets that we got. We found that inspiratory pressure was strongly determined by work rate--we used four (4) different work rates--and also strongly determined by cartridge resistance. And that's nothing really new there, but now we're able to in fact quantify that relationship quite well.

When we looked at the difference in inspiratory pressure between male and female we found that at the lower work rates we found a significant difference between male and female as far as inspiratory pressure inside the mask, but that difference tended to disappear as work rates increased.

We found a more significant difference when we looked at the difference between half-mask and full-face respirators. And I think that what you're seeing are dead space effects. You work harder with the full-face respirator because you're overcoming the dead space. And so then we were able to predict what the inspiratory pressure would be for either half-mask or full-face respirator equipped with low, medium or high filtering element resistances for males and females. And that's pretty much what we saw in the pressure data.

Our next slide will review what we found with the inspiratory flow rate. We found that it was not as dependent on cartridge resistance, but was, again, strongly dependent on work rate.

We found no difference between the--related to gender, at least, the differences were not statistically significant on inspiratory flow rate, but they were significantly different when you looked at half-mask versus full-face respirators.

So what do we have at this point. We've got a technique--the controlled negative pressure technique--that can in fact give us a number to start with. ... discuss with you perhaps how meaningful is that number in just a moment. But we also have a method of now controlling the fit test to make it more than just a fit test conducted at rest while the worker wears a respirator and goes through an exercise protocol. We can make it more work rate dependent, and we can control some of the factors. The basic test, again, is, we determine how much air leaks in a respirator is a function of the driving force for leakage into

the respirator which is in fact the pressure that exists in the respirator.

Now, let's take a moment, if you will, to think about the typical quantitative respirator fit test and how it's conducted and what we learn, and perhaps what we don't learn, when we do that. We have a well-established exercise protocol that's designed to make the fit test more representative of what happens in the workplace. How do we make it more representative? Well, we know that workers, in fact, don't stand around and stare straight ahead as they do in the normal breathing ..., that they move around and they do work. How does our standard fit test become more representative? We do have movement. We move the head side to side. As a matter of fact, most of the exercise protocol is aimed at movement of respirators; movement of the face. What we haven't done or paid any attention to is the fact that the driving force for a leak is the pressure inside the respirator, and we don't much about it. We do the deep breathing, but we haven't standardized deep breathing in that your deep breathing is different from my deep breathing is different from anyone else's.

What are we trying to determine? And I think if I could look at the next slide--what I think we need to learn from our fit test are first of all, and the most important parameter is some measure of fundamental fit. How well does this respirator fit that person? And that is, I think, the primary reason for doing quantitative fit testings. So the first parameter we want

to see is fundamental fit. That's what normal breathing presumably tells us. Does a small or a large mask of this brand or that brand fit you better, you the individual worker? And if we can't answer that question very well, then I think we are basically wasting our time doing quantitative respirator fit testing.

But we want to go beyond fundamental fit, because, like I say, we all know that the worker, in fact, doesn't just stand there and look straight ahead out in the workplace. We also know the workers don't hold their breath out in the workplace. So how can we take a number that's derived by asking a worker to hold his breath and make any sense out of it?

Well, let's look at what happens beyond fundamental fit, because the controlled negative pressure system can give you that measure very rapidly just as well, or much better than, the aerosol system can give you, with a lot less variation. But we need to go beyond. And how do we go beyond? We ask the worker now to do exercises. Because what happens when we do exercises? We're going to break the seal of the respirator, we're going to induce more leak, presumably. But if you look at all the data that I've been able to scrape up that's been published that actually give specific fit factors for specific exercises, you find that there's no significant difference between the exercises and normal breathing.

The conclusion is, then, that the exercises are not in fact compromising the seal of the respirator or at least if they are, we're not able to measure that with our current technology. What

happens when you turn your face? Beyond the fundamental fit of the respirator if, in fact, you compromise the seal, how is that done? And we'll take it side to side. As you turn your head to the side presumably then you open not a leak in the respirator, but you open a break in the seal. Why is that not a leak? That is not a leak unless you are in fact inhaling. Unless there is a driving force for the contaminant to go across the seal barrier and into the respirator it is not a leak.

A modification, as I understand it, in the ANSI standard is, in fact, we should not do our side to side test this way. Why not? Because we don't know what is happening. When is the worker inhaling during that test? And it's only during inhalation that he actually has a leak, and that's, at rest, about forty percent (40%) of the time. So ANSI says, no, let's now turn the head to the right, pause, conduct a full respiratory cycle, and then turn the head to the left. Now, we've compromised the seal, we've opened a break in the seal with the head to the right; we do our inhalation, we've got both components of a leak. We've got a break in the seal and we've got a driving force when we inhale. So, in fact, we should see the leak.

Modified negative pressure fit test, or side to side is, in fact, the same thing. Now you know what the fundamental fit is, you just measured that. And now you take basically a snapshot of--did you open the seal, and in five (5) seconds or ten (10) seconds you know whether you opened the seal and significantly changed your fundamental fit with side to side. Modified is up

to down. You can't do this in the negative pressure system because you're changing the volume--the internal volume--of the respirator and pressure is very, very fast. You're basically ... at sonic velocity inside the respirator so you know immediately--if you change the volume you know immediately if the worker is not holding their breath. Now that addresses this second question of are we opening significant breaks in the face seal during the course of face movement.

A third factor that I think is important is, as we move in the workplace do we in fact significantly and permanently shift the respirator on the face so that in fact it does not return to its original sealing configuration? Is there a shift in fundamental fit? And the way I can assess that is say, you've got a measure of your fundamental fit, now do whatever you want to do. Stand on your head, do a cartwheel, shake your head vigorously, try to dislodge the respirator, and look at fundamental fit, and you know--you have enough sensitivity now to know--whether you've had a significant shift in the fundamental fit.

But there's one (1) other factor that I think is vitally important that we have not assessed, and that is when we do a fit test on a person for the purpose of assigning a respirator to them or for purposes of checking the fit at some subsequent point, we've asked the worker to don the respirator. Now how much change will you see if in fact you took the respirator off and put it back on again, and took it off and put it back on? Do we have any confidence that in fact when the worker exits our

laboratory--quasi laboratory setting--and goes out into the workplace that they will in fact put the respirator on the same way they put it on when we just did our fit test? Using the negative pressure system--this was just one (1) subject--a chance to look at this--I haven't had a chance to do it with a population yet.

Can we see the effect of donning the respirator? Can you put a respirator on? What's the source of this intra-subject variation that we've been plagued with the aerosol system? On one (1) subject with a good fit--what we're looking at, each bar represents five (5) normal breathing or fundamental fit measurements of the respirator on the face, the respirator is removed, it's put back on, and that's the next bar. Again, the mean of five (5).

A couple of things we've picked out here. One is the respirator on this particular subject fit very well. You're looking at a fit factor of around two thousand (2,000) if you want to think in fit factors. We're measuring leak rates, so about twelve (12) to fourteen (14) milliliters per minute. Equivalent to a fit factor again of about two thousand (2,000). It depends on what your estimated work rate is.

That is an excellent fit. In my opinion, an excellent fit; two thousand (2,000). And you're seeing a great deal of repeatability. This particular person could put this particular mask on very repeatably, not only over five (5) donnings on a given day, but over five (5) days. And you see that there's one (1)

donning where it wasn't on the same way. So I have very good confidence that when this worker takes the respirator off and puts it on again they do put the respirator on pretty much the same way every time. And I don't think you could show that kind of data with the aerosol system. And I think mass donning is a very important component of how much protection you ultimately get.

Some of the conclusions about--why do I say that I don't think aerosols can get us where we want to go? What have I learned out of the studies that we've conducted so far? What do I think I've learned? One of the things is that--I don't know--when you say aerosols I don't know what you're talking about, because every aerosol situation is different. Every particle size distribution tends to be different, and so we have this moving target. And we have nothing to substantially or fundamentally tie to. And I don't know how to accurately translate, well, we've got this fit when we use this size challenge agent, now you're going to see this presumed size in your workplace and so that fit means that. So why don't we go to something that doesn't change, something that is absolutely universal, and that's air. It doesn't change, and I go back to the statement that if air leaks in contaminant may leak in. So we're at the conservative end of it. We're at the most rigorous test end of it in my opinion.

Secondly, I think in-mask sampling problems are significant. I don't think we've resolved them, we've done a lot of work.

Most of the work that's been published though highlights the problems with in-mask sampling, and yet our fundamental assumptions right now for both respirator fit testing and for workplace protection factor testing is that this ratio that we strive so hard to get, these very valuable numbers, are based on an assumption that is still an assumption. And I don't think that the in-mask sampling data that we're getting is what we think it is. We have significant problems.

A third point. I think we need to take a look at what we do with a fit test, and try to come up with something that's more meaningful rather than standing around shaking our head side to side, moving our head up and down, and reading the rainbow passage. Let me talk about the rainbow passage for a moment, because if you talk to users, if you talk to people who do respirator fit testing, the rainbow passage is synonymous with quantitative respirator fit testing. And one of the big complaints, criticisms, of the negative pressure system is that, wait a minute, you can't hold your breath and read the rainbow passage so how can you do a fit test. It's very true that you cannot use a negative pressure system and read the rainbow passage, and so maybe--how can you do a quantitative respirator fit test?

Let's examine that. We've got an assumption, and the assumption is that talking, in fact, flexes the face seal. And if we look at the data that's available which exercise do you think, if any of them prove to be significantly different from

normal breathing, which exercise is it? It's talking. In which direction? It's lower. You see lower fit factors--significantly lower fit factors--for the talking exercise. And so obviously talking is compromising the face seal.

But now I want you to talk to me, but the condition is of course, you've got to be inhaling when you talk to me. So if you're not inhaling--if in fact during the course of talking I put a respirator on with a probe, hook the probe to a pressure transducer, and I read the rainbow passage. What do I see when I read the rainbow passage connected to a pressure transducer? What pressure do I have in the respirator? The answer was the average pressure with a lot of variation, but not many of those instantaneous spikes going low. During the actual talking it was about a tenth of an inch positive pressure in the respirator.

So where is the driving force for the leakage that we're seeing with our quantitative--with the aerosol test? How is the stuff getting in the respirator, because that's the only one that's showing a significant difference. And my answer to that is, it was already there. What do you see when you're talking? You see better modulation in the mask, you see an extended exhalation period. I'm a proponent of--I think streamlining is a significant problem only in inhalation cycle for respirators. If you look at the flow rate--one (1) liter a minute or two (2) liters a minute depending on the system that you're using--that you're pulling out of the mask sample probe, and you look at the flow rate going down into the lungs, the overwhelming flow rate,

the overwhelming pattern for air flow during inhalation is into the lungs. So how is this particle which is now going to leak through this site here, or this site here, or this site here going to get to the mass sample probe? And I think my conclusion is, it doesn't very often. We help it get there when we exhale. We help it get there more when we extend the exhalation and modulate the exhalation by talking. And so what we see and interpret as more leak because of the talking exercise is a better measure of leak that was already there, and the leak didn't occur while we were talking. So more meaningful exercise protocols.

The last point--it has to do with Bob da Roza's comment about maybe we need to go back because the variation--especially the intra-subject variation that we're seeing--maybe we need to go back to doing three (3) fit tests instead of one (1) fit test. But what are we taking about? Pull a subject in and--don't be like a lot of people who do fit testing. Do spend some time talking about and doing a little training with the respirator. Quantitative fit testing; two (2) basic reasons for doing it. One is to select the best respirator and the other is it's an incredibly useful training tool. It should be used that way. Spend some time with the worker.

But now you're going to spend five (5) minutes wearing the respirator to get it warmed up so that it actually fits more closely what it is going to do in the workplace. And then go through--you need at least one (1) minute for each exercise to

get an average value, and I think I can get better information in my five (5) second than I get in that one (1) minute. But now let's do that for six (6) exercises. That's another six (6) minutes, plus five (5) minutes for training, plus five (5) minutes for warm up--maybe we can combine some of that--suddenly you're looking at thirty (30) to forty-five (45) minutes or more for each fit test for each worker. And what is that an invitation to do? In a lot of programs that's an invitation to forget fit testing and forget trying to utilize what can be an incredibly valuable training instrument. And so I don't know that going to three (3) fit tests to try to solve the variation problems that I think are more fundamentally related not to the respirator, not to the worker, but to our measurement tool, is the answer. And that's the end of my comments. Are there any questions?

ROBIN HOWIE: Just some minor comments. If you are actually showing leak ... from aerosol or in-mask sampling ... the UK, a lot of respirator use and marginal use conditions. In other words, we tend to overestimate the performance of the mask. So the question is, do we observe the health effect, because a mask with protection factor of ten (10) ... under performing that factor of ten (10) giving the protection. We would expect to see ... of whatever it happens to be. Do we ...? Question number one.

Question number two. It ... lovely to do this type of ... experiment in ... used ... of carbon monoxide, sample inside the

mask with the normal techniques and--pretend it's an aerosol for the shear hell of it--do your negative pressure, and pick up ... and tell us fundamentally which is the test.

CLIFTON CRUTCHFIELD: I'm going to tell you that in the next presentation.

ROBIN HOWIE: Thank you very much. I'll shut-up and go away then.

CLIFTON CRUTCHFIELD: We've done that sort of, and that's what I'm going to present in a half an hour.

ROBIN HOWIE: ... activities I've experienced in the UK is that if you have activity which involved work you'd delegate three (3) to five (5) minutes to run ... so the body stabilizes ... activity. In other words, if I make you walk at four (4) miles an hour before you--for the first few moments you live off an oxygen deficit, you do not increase your ... volume until that deficit has been used up. So if you're going to ... you're test is now a half hour to forty-five (45) minutes per replicate, not per set of replicates. ... in the UK are more intelligent, we're ... replicate test and high quality data.

CLIFTON CRUTCHFIELD: Let me answer that. The second answer, I hope I'll shed some light on later on. The first question was if we're overstating fit by an order of magnitude--now I didn't say overstating protection factor--overstating fit factors by an order of magnitude, and I think we are--how many people have seen fit factors of fifty thousand (50,000) in any fit testing that you've ever done? Physically impossible.

There's no way, based on the data that I think Bob Heinz has produced about the quality of the exhalation valve--if you look at flow--if you look at air flow into the mask and how good the exhalation valves are with a perfect seal--and typically it's very hard to get that perfect seal using glue on a mannequin, much less a worker just putting it on--you're talking about minimum leakage rates of around three (3) to four (4) milliliters per minute. ... says a maximum possible with a half-mask respirator fit factor of maybe seven thousand (7,000). So where does this fifty thousand (50,000)--well, where does the million come from? We've seen those thrown in once in awhile. Numbers that are totally unbelievable. Well, they have no meaning anyway. A fit factor of fifty thousand (50,000) has no meaning. In my opinion a fit factor of ten thousand (10,000) has no meaning, and yet we are very enamored with trying to measure fit factors to a hundred thousand (100,000). We're at the wrong end of the scale. And I can't remember your third question.

ROBIN HOWIE: I'll try and remember myself. Just a comment on the time it takes ... activities.

CLIFTON CRUTCHFIELD: Oh, okay, but realize that we simulate--by setting the pressure you can simulate the in-mask environment for any activity in as long as it takes to punch a number. So you don't need the forty-five (45) minutes. We used, not forty-five (45) minutes, but we used a five (5) minute period on the test cycle to stabilize and then moved up in increments that are work rates.

ROBIN HOWIE: ... I presume you're looking ... volume with activity, and the subject ... will not change fast.

(Inaudible statement from Ms. Strickland-Cid.)

CLIFTON CRUTCHFIELD: That may be similar to what we saw when we looked at using the expiratory volume with the period, and not seeing significant different with the inspiratory flow.

GWEN STRICKLAND-CID: One more question.

RICK [HORNING]: [Of NIOSH.] I take it from looking at your graph that you had up there that the intra-subject variability using your method is considerably lower than the intra-subject variability using the aerosol method. I was just wondering, did you actually calculate the GSD for your method?

CLIFTON CRUTCHFIELD: No. On the subjects themselves I didn't go to the geometric standard deviation with the one subject where we had ... six (6) tests. I did that arithmetically, and I'm not sure that in fact you need to go to a geometric distribution. I fundamentally can't see why that explains what I expect to see. But on the arithmetic basis, if you look at coefficients of variation they were substantially lower with the negative pressure system.

RICK [HORNING]: Ten percent (10%)?

CLIFTON CRUTCHFIELD: No more of this fifty percent (50%), a hundred percent (100%). My assessment of the measurement capability of the negative pressure system as it exists today it's at worse case a five percent (5%) device. It's probably a two percent (2%) device. It's a fundamental way of measuring leak-

age. Now the question is, how do you equate that measure of leakage into what you anticipate, and I'll cover a little bit of that a little bit later on.

GWEN STRICKLAND-CID: As you can see, Dr. Crutchfield's coming back at four thirty (4:30). Next we have Dr. Ching Bien of OSHA; the Directorate of Technical Support. He will discuss limitations of current WPF studies and OSHA's experience with simulated worker protection factor studies. I just want to remind those of you who are interested in getting a transcript there will be an instruction sheet on the table in the back about how to make a request.

CHING-TSEN BIEN: Thank you. I would like to discuss this subject from the bureaucrat's point of view. Purely low tech.

The OSHA health standards prescribe the use limit for each class of respirator. These express the maximum use concentration, MUC, which is a product of protection factor, PF, and the permissible exposure limit, PL. For example, if the PF for the half-mask negative pressure respirator is ten (10) and the PL is ten (10) parts per million, then the MUC for this air contaminant is one hundred (100) PPF. Since respirators are a ... class such as an active pressure or PAPR. ... that the health of the workers is protected assign MUC for each ... is based on the worse performance rather than the best performance in each class.

The PF listed in many OSHA standards were based on the results of quantitative fit testing conducted at Los Alamos Scientific Laboratory in the early '70s. The measured deficiency

of their data was that exercise used for the ... was sedentary ... only slight facial movement, which does not correlate well with the dynamic movement that occurs in the workplace which may involve different movements.

In the last few years many investigators has conducted studies to determine the performance of respirators in the workplace. These studies are useful for regulating agencies such as OSHA to establish or to revise MUCs for respirators. Three (3) investigates, the NIOSH, respirator user, and the respirator manufacturer conduct workplace protection studies for a disposable dust-mist respirator. Different WPF values were reported.

NIOSH reported the lowest WPF and the respirator manufacturer reported the highest WPF. But looking at the variables which may effect the results, it was found that factors such as ambient concentration, particle size, work rate, work time, and analytical method were all different. The NIOSH study reported the highest ambient concentration. The ambient concentration for the ... for the other two (2) studies were much lower than their respective PLs. In other words, the latter studies were performed in workplaces where respirator protection were not even required.

The sampling time for the NIOSH study was about four (4) hours, while the time for the other two (2) studies were not reported. Analytical method used by NIOSH were much less sensitive than the other two (2). With low ambient concentration the presence of large particles, short sampling time, and utilizing a

very sensitive analytical method, a WPF of a thousand (1,000) or more could easily be obtained from a low performance respirator such as the negative pressure half-mask air purifying respirator.

Since there's no definition of what constitutes a workplace testing, what are the conditions that should exist in the work-place, how the respirator should be tested, and how ... results should be reported. It is necessary to standardize the test protocol. We believe that with uniform test protocol it would be easy for the respirator manufacturer to conduct the test, for NIOSH to evaluate the test results, and for the regulator agency to determine whether a WPF study is acceptable for consideration rule making.

The workplace should be a place where test conditions are representative of other workplace in the country. In order to determine whether a workplace is representative the following factor should be considered when developing a standard testing protocol. I will go over after each of this.

Site survey. A site survey should be required for each WPF study. The site survey should include observing the activity of the worker, calculating respirator wearing time and the work rate, performing personnel monitoring to measure the exposure of each prospective test subject, measuring particle size at the prospective work station, and other factors which determine whether this site is suitable for conducting that WPF study. It is important the workplace have a respirator program which is in full compliance with the OSHA respirator protection program.

The next is physical qualifications. Physical qualifications for respirators wearers is only required for a few ... OSHA standard health standards such as lead or benzene. There is no specific physical examination protocol in the OSHA respirator protection standard. Since WPF studies are performed at the high contaminant concentration level with physical physiological stress imposed to the respirator wearers, to ensure that the health of the test subject is protected there should be an exam qualified in accordance with the guidelines established by proper authorities such as the Department of Health and Human Service, or the American National Standards Institute ... physical qualification for respirator wearers ANSI Z88.6.

It should be noted that all test subjects in OSHA sponsored environmental chamber studies were required to meet physical qualification requirements as ... by the National Lab that conduct the test.

Contaminant concentration. The WPF is usually expressed as the ratio of the ambient and in-mask concentration of the challenge. A WPF of ten (10) means that the respirator would provide a ten (10) ... reduction ambient concentration under the prescribed test conditions. A PF of ten (10) means that the respirator wearer would be exposed to the air contaminant at the PL level for an ambient concentration up to ten (10) times the PL. By definition the PF and the WP are not the same. The WPF is equal to PF only when the WPF study is conduct the ten (10) times the PL concentration of the .... If a WPF study was conducted in

a workplace with a contaminant concentration only three (3) times the PL, and the WPF of ten (10) was obtained for the respirator, by OSHA definition of MUC this respirator should be certified as having a PF of three (3) instead of ten (10).

Particle size. Quite often the total ambient particulate concentration is used to calculate WPF values. This tends to exaggerate the WPF value especially when the ambient aerosol contains a significant fraction of large particles. Since the respirator facepiece is a ... device, non-respirable particles should not be present inside the facepiece unless the particles penetrate through the gaps in the facepiece seal. Such ... is any indication that the facepiece will not don or fit properly. The test subject was over-breathing or the respirator is defective. Determining such things are accepted purpose of a WPF study.

Another consideration is that the gas or vapor molecules are always respirable. Using a WPF based on total particulate may not be directly applicable to gas or vapor exposure. Since sampling for gases or vapors for WPF determination is still being developed we have to rely on the result of WPF studies based on respirable particulates for gas or vapor applications.

Since the Cyclone has been used widely to collect respirable aerosol, the respirable fraction of the ambient aerosol ... Cyclone should be used to calculate CO.

Work time. Except as specified in the OSHA lead standard, there is no requirement specified how long a respirator--how long

a worker is required to wear a respirator. It is quite common that respirators are worn for most of the shift. OSHA even issued variances to allow employer to required employees to wear respirator for the full shift during the lead exposure. Since wearing a respirator may cause physiological as well as psychological stress performance of the respirator ... with an increase in wearing time. In order to assess the time on respirator performance the minimum accepted time for respirator wearing should be at least five (5) hours during each shift in a WPF study.

Environmental concentrations. I just want to brief you a little bit about Los Alamos . . .

DAY 2 - TAPE 4 - SIDE B

CHING-TSEN BIEN: . . . describe the test conditions. We're using different temperature and humidity. The most stressful condition is a high temperature and humidity at thirty-two degrees (32°) Celsius, and eighty-five percent (85%) relative humidity. Actually, we want to go higher. However, the doctors at the lab said, "No, it's the highest you can go." And the ... of concentrations twenty (20) milligram per cubic meter, the particle size of point six (.6) micrometers.

Then is the respirator use for study. We have two (2) negative pressure respirators, MSA ... 2 half-mask, ... full-facepiece MSA half-mask PAPR ... loose fitting facepiece PAPR ... ... loose fitting facepiece PAPR. Survivair full-face pressure demand supplied air respirator and ... continuous flow supply hood.

Thus the exercises. We used similar to work exercise. We have a different task ... exercise regime. The first one is step and back down for ladder for five (5) minutes continuous, and rest for five (5) minutes. And move gravel with a shovel for ten (10) minutes from one pile to another place for ten (10) minutes, rest five (5) minutes. Pounding nails above the head for five (5) minutes, and pick up cinder block for ten (10) minutes. I believe I maybe missed a rest period between the pounding nails and the pick up cinder block. There's five (5) minute rest of time. Then pounding with sledge hammer for five (5) minutes, rest five (5) minutes. The total time is sixty-five (65) min-

utes. And the user, if you're working a stressful area you are recovering in air-conditioned room, or reduced stress. For this case, no. The test is just sitting in the chamber to rest.

It is understandable that adverse environmental conditions such as the high temperature and the humidity impose additional stress to the respirator wearer. This has been demonstrated from Los Alamos study. The test that you perform inside the chamber are moderate heavy to heavy work rate, and the high temperature and humidity. The test results indicate for negative pressure half-mask air purifying respirator there was twenty (20) times reduction in the protection factor when the test subject performed heavy exercise inside the environmental chamber. It was observed that the facepiece slipped due to moisture accumulation on the face. This may not have occurred if the respirator were tested under normal environmental conditions. Since summer is often hot and humid in most parts of the country, it is necessary to perform the WPF study under high temperature and humidity in order to represent many workplaces.

Work rate. When OSHA sponsored environmental chamber study was to measure the performance of positive pressure respirators, such as powered air purifying respirator--go back to last slide please. The tested worker on a treadmill at the work rate which is eighty percent (80%) of the maximum cardiac capacity for that individual. The results indicate after thirty-five (35) air flow rate of hundred fifteen (115) liters per minute a tight fitting PAPR does not ... impulse pressure inside the facepiece until the

air flow has been increased to a hundred seventy (170) liters per minute.

Another treadmill study on the performance escape self contained breathing apparatus conducted by the Lawrence Livermore National Lab indicate that at the rated air flow of forty (40) liters per minute the concentration of oxygen and carbon dioxide inside the hood of the escape SCB reached a dangerous level a few minutes after the donning. This situation could be correct by increasing the air flow to at least sixty-five (65) liters per minute. This example illustrates that work rate is critical to the performance of a respirator, especially for the commonly used negative pressure air purifying respirator. It is important that the tests performed by the test ... in the WPF study should be high enough to impose considerable physiological stress of the respirator wearer.

Sampling and analytical methods. The selection of the sampling and analytical methods could have a significant outcome on the results of a WPF study. The sampling method should have a high collection efficiency and it should be commonly used. The analytical method should yield reproducible results. For example, asbestos counting is subject to many errors such as variation between counters, the field to be counted, and the distribution of fibers on the field. For these reasons, asbestos counting should not be used in the WPF study. Furthermore, the method being used in a WPF study should be validated. For a validated method variables such as ... position and the recovery rate have

been validated through round robin tests. All errors associated with this method would have been identified and their magnitude determined. Since many industrial hygiene methods have been validated and the are quite sensitive, there is no need to use a non-validated method in a WPF study. A non-validated method could be used only when it has been validated by NIOSH, OSHA, National Institute for Standard and Technology, or other national recognized independent laboratory. So round robin test with at least three (3) laboratories.

Sensitivity of analytical method. The sensitivity of ... detection limit ... analytical method should be appropriate for the protection factor being determined. Since carbon monoxide is a major source contaminant during a fire it may be used to measure the performance of the SCBA in a fire environment. Infrared spectrophotometry can detect CO at the concentration of five (5) PPM. It is generally recognized pulse pressure SCBA would provide the PF at least twenty thousand (20,000) or higher even at the high work rate. If the infrared method is used in the WPF study to measure CO, no WPFs higher than a thousand (1,000) would be measured when the CO concentration in the ambient is less than five thousand (5,000) PPM.

On the other hand, a low detection limit tends to boost WPFs of respirator with low assigned protection factor. One example is WPF study on asbestos abatement. Water spray was applied to the asbestos insulation before removed. The asbestos containing water droplets had increased the size of asbestos from respirable

to non-respirable, and very little of the wet fiber penetrated through the respirator facepiece. The NIOSH method of asbestos measurement requires that counting be terminated at hundred (100) fields or hundred (100) fibers, whichever occur first. Since there was very few fibers found in the in-mask samples, counting fields were increased to five hundred (500) in order to search for fibers. The increased counting fields artificially boost WP values for many samples, especially for those report a WPF in excess of a thousand (1,000). For example, a WPF of seventy eight hundred sixty (7,860) was reported in one sample. However, only one (1) fiber was found in in-mask sample. If two (2) more fibers were counted the WPF would be reduced from seventy eight sixty (7860) to twenty six twenty (2620).

Just another example of two (2) different studies. If we look odd, it's all different, it's for lead. They are using the different methods. They have a different concentration, different detection limit. However, the strangest thing here, the one has a high ambient concentration report lower results. And, unfortunately, I don't know what the particle size. But, if we look this, the study be report much higher concentrations.

Now we can look at most such reporting high concentrations, they all under the detection limit. So that's a question now. If you not collect too many samples then you have a artificial very high concentration ... detection non-detectable limit. ... including this you will get a much higher result. Second slide show the same thing.

A photometer using quantitative fit testing is considered to be a very sensitive method. For a challenge concentration of twenty (20) milligram per cubic meter a fit test of twenty thousand (20,000) is the limit of detecting which correspond to a concentration one (1) microgram per cubic meter. Recently more sensitive instrument have been developed. Several non-validated methods have sensitivity in the nanogram to the [picogram] range. It may be justifiable to use a very sensitive method in a WPF study for pulse pressure respirator with APF of a thousand (1,000) or more. However, very sensitive methods have been used in WPF study for half-mask negative pressure respirator. Since these studies were performed at very low ambient concentration with ... large particle, very particle penetrate through the respirator facepiece. The WPF then become a function of sensitivity of analytical method. The lower the detection limit of the analytical method the higher the WPF that would be achieved. APF as high as fifteen thousand (15,000) have been reported for negative pressure half-mask respirators. However, fit factor of three thousand (3,000) was report on that respirator. In order to report realistic WPF value the detection limit should be reported as one hundredths of the PL value of the challenge. For example, if the ambient concentration is twenty (20) milligram per cubic meter, the in-mask concentration is point 0 five (.05) microgram per cubic ... and the PL is fifty (50) microgram per cubic liter. The reported WPF is larger than forty (40) rather than four thousand (4,000).

Method of reporting. Except for the WPF study conducted by NIOSH most studies give very little details concerning variables such as ambient concentration, particle size, environmental conditions, work rate and the sampling time. Since these factors are important in judging whether the WPF is representative to most workplaces details of test conditions should be reported. Some studies made very generalized conclusions, such as the current OSHA assigned protection factor is too low for this class of respirator. However, this study was performed with only one (1) respirator with one (1) type air contaminant in one (1) workplace, and under test conditions that could not be considered to be representative. Since the study was very limited in scope, it's conclusions should be confined to the test condition only.

Not all workplaces have all represented test conditions described above. In order to determine whether a workplace should be selected for conducting a WP study a rating system has been devised to aid selection.

Ending concentration, the first one. A point is given for each ten percent (10%) of MUC of the contaminant in question. If the MUC is five hundred (500) milligram per cubic meter and ambient concentration of twenty (20) milligram per cubic meter, would be assigned a rating of four (4).

Particle size. A point is given for each ten percent (10%) of respirable portion of aerosols in the ambient samples. If the sample is fifty percent (50%) respirable a rating of five (5) would be assigned.

Work time. Ten (10) points would be assigned for sampling time of five (5) hours or more. A sampling time of thirty (30) minutes would be assigned a rating of one (1).

Environmental conditions. A point would be assigned for each five degrees (5°) of Celsius in excess of twenty eight degrees (28°), and a point would be assigned for every ten percent (10%) increase in relative humidity in excess of fifty eight percent (58%). For example, if the study was done at a temperature of thirty degrees (30°) Celsius and eighty percent (80%) relative humidity, it would be assigned five (5) points.

Work rate. Ten (10) points would be assigned for work rate at eight percent (80%) of maximum cardiac capacity. A worker at forty percent (40%) of maximum work rate would be assigned a rating of five (5).

Analytical method. Ten (10) points would be assigned to a fully validated method with a round robin test consist of three (3) national recognized independent labs. Three (3) points would be assigned when the method is validated by only one (1) independent lab.

Physical qualifications. Ten (10) points would be assigned if hundred percent (100%) of the test subject had been qualified physically by DHHS or the ANSI guidelines. Eight (8) points would be assigned for a workforce with eighty percent (80%) qualified test subjects.

Workplace survey. Five (5) points would be assigned to a complete workplace survey mentioned above. Five (5) additional

points would be assigned for a respirator protection program which is in full compliance with 1910.134. A representative WPF study is when they have obtained fifty (50) or more points from above evaluations.

Conclusion. In order for the results of the WPF study to be applicable to any workplace the test conditions should be representative of most workplaces. The above mentioned the fact that should be considered in developing test protocol for the WPF study and for evaluating the acceptability of a WPF study for constructing the maximum use concentration table for respirators in the OSHA health standard. Thank you.

GWEN STRICKLAND-CID: Any questions?

BOB BRENNAN: Back at the beginning of your talk you had mentioned that the purpose of all this was to find the worst respirator in the class and assign that to a class with--was that in there, or--maybe I didn't get that quite right.

CHING-TSEN BIEN: Well, we consider MUC, the PF ten (10) is, we said, the worse performer. That means we assign--we classify by respirator class, right? We have a half-mask, full-facepiece. If we say--that means, should be every respirator approved ... in that class you achieve a PF of ten (10). Not the best one, not the average one. Because we have to protect every user.

BOB BRENNAN: When look at the scope of what you've asked, and look at the goal--and maybe there's some realignment that might possibly be needed between the goal and the scope--that's a tremendous scope you laid out for the goal of being assigned a

number that you're going to use that's developed from the very worst piece of gear that you can find.

CHING-TSEN BIEN: No, we just said that your test condition you select should be representative to most workplace. That means you did a study in the foundry that result can be applied to other foundries or maybe other workplace. That's my point.

BOB BRENNAN: Okay, my point is, look at the goal or look at the result that you are getting for that tremendous amount of work that you're ... to be done, and perhaps that scope of work should have a different goal.

HARRY ETTINGER: Two (2) questions, Ching. Do you really believe that any two (2) or three (3) work sites in the United States are representative of all workplaces in the United States? It seems like an impossible request.

CHING-TSEN BIEN: I never believe in workplace study anyway. That's why we did all the work on chamber study.

HARRY ETTINGER: Second question, is there a rationale you have for the different weightings you put--you have ten (10) points if this component, two (2) points for so many degrees or so much humidity. Was that just sort of a professional judgment on your part, or was there a rationale and decision logic used to come to those weighting factors, and did you decide whether any of the workplace protection factors by Pallay or Myers or industry people or whomever, whether any of those will pass your passing grade of fifty five (55)?

CHING-TSEN BIEN: My work is as arbitrary as anybody else

setting his--in his ... study. Everybody sets a boundary limit. I set mine. So I just say--I'm not really speaking for the agency, I just say--I want to say how I validate WPF study.

BOB BRENNAN: I wonder if you had a decision logic you went through to come to those different numbers?

CHING-TSEN BIEN: No, I just think--just arbitrary thinking. Maybe you have to refine when the time goes on.

JERRY SHERWOOD: Could I possibly make a comment. I'm a little concerned with your paper, and with some other ones, when we consider the sensitivity of analytical methods, particularly when applied inside facepieces. We're talking about nanogram quantities of material. Now that represents a unit density sphere of ten (10) microns diameter. So we may be collecting a single particle inside the mask and saying this represents a sample of the air that the wearer is breathing. The only thing we know about that is that that one (1) particle has not been breathed by the man. It tells us nothing at all. We're faced with the same problem as we have with radioactive particles in the past, where we would have to throw out half our air samples because they were not representative. They contained one (1) discreet particle. I give a word of warning that we may be getting into this range as well now with non-radioactive substances due to the sensitivity of our analytical methods.

CHING-TSEN BIEN: That's the problem. We just hit a moving target. Maybe after a few years we have a test to measure molecules. We're not measuring anything. Based on the WPF we

can ... three (3) ... based on how many molecules inside you can find in the facepiece. So that's the problem. You can not just keep--really the problem you find--place has a high lead concentration, however it's difficult to find. Instead, we just try to find more sensitive methods to get a wide range number, which is a problem.

ROBERT SHERWOOD: One (1) smaller particle instead of one (1) larger particle.

CHING-TSEN BIEN: Yes. The applicability for those studies ... various method to some other workplace which have very high concentration. Right now I don't see any correlations. If you conduct study at very low concentration, can the result be applied to the place with very high concentration? We don't have any data available to correlate.

GWEN STRICKLAND-CID: It seems like we do have a lot of discussion and questions. We do have a block of time tomorrow afternoon. Hopefully everyone will be around and you'll have an opportunity to think over some of these presentations and have a more extended discussion tomorrow. We have our last presentation scheduled right now. Actually we're about ten (10) minutes late. Dr. Clifton Crutchfield again, speaking on the feasibility of a new method to determine respirator protection factors by breath analysis.

CLIFTON CRUTCHFIELD: Thank you. I'd like to quickly present the results of a pilot study we did. Some of the thinking that went into designing this particular study--I obviously

have a bias against aerosols, so I didn't want to use aerosols to try to measure how well a mask is performing. Also, I don't have a lot of faith in in-mask sampling. Suddenly I'm running out of a lot of options. If I want to say--can I get any correlation at all between measured fit factors with the controlled negative pressure system which uses air as a challenge agent and some other method of assessing respirator performance? So that's what drove us to look at biological sampling. The idea was, okay, let's us a vapor. It's going to be as rigorous as air from a standpoint of challenging any leak in the respirator.

I don't have good confidence that we--I didn't have very much confidence--that we could successfully measure from the mask, though, the concentration of the vapor inside the mask. The [sesabi] I think is very shaky. So, therefore, why don't we look at the possibility of measuring [sesabells]; what gets into the lung, what does the body see? That's what we're really interested in after all.

So let's look at breath analysis. It's an invitation into a swamp unless you give a lot of thought to what you're doing. What do you need? First of all you need a challenge agent of vapor or a gas that is not very toxic so that you can generate a fairly high concentration as a challenge agent without over exposing your subject. You also have to be very careful about the characteristics of your challenge agent and what happens once it gets into the body. If it significantly metabolized you're not going to see it, and that's another correction factor. If

it's very soluble then when are you going to get a good snapshot of what's happening. How much variability is there with breath analysis? A whole lot from subject to subject.

This is the result of only one (1) pilot study, but here's the basic protocol. One was to find an acceptable challenge agent. The second one was to say, given that challenge agent, can we, in fact, calibrate a subject, expose them to a range of low concentrations, and then peg those exposure concentrations to a breath concentration, and at what point do you pull the breath concentration, and what part of the breath, and basically we wound up taking in valvular air samples, or [inexpiratory] air. And we took them at thirty (30) minutes post-exposure. Let me show you some of the data that we came up with.

Again, this is a pilot study of one (1) subject. We settled on freon 113 as our challenge agent. We played around with a lot of freons initially because freon has a high threshold limit value--it's fine if you take a thousand (1,000) as a TLV--and it's fine if you want to say, well, let's not have a possible exposure above an action level of five hundred (500). Freon fit into that category so we looked at the freons.

Another consideration, though, is what kind of analytical sensitivity do you have, how much can you get? So what was our analytical sensitivity? In using GC electron capture detector we were able to see freon in the breath with pretty good statistics down to about five (5) parts per billion. So that gave us a working range.

When do we take our sample? Here's one of the first things we did. First of all we exposed the subject for thirty (30) minutes in the chamber at various concentrations, and then we looked at the decay of the concentration. What you see here is a thirty (30) minute, six (6) part per million exposure concentration. We were able to achieve very good real time control of the actual chamber concentrations using infrared. Our challenges were high enough.

And here you see the breath decay curve. We did all of our numbers--all of our procedures--in triplicate. So what you're seeing are standard deviations of three (3) trials. But, here's the breath decay curve for a thirty (30) minute, six (6) part per million challenge to freon 113. And you see that you get very rapid elimination during the first portion--the first few minutes--after the end of exposure, followed by a flattening out, an exponential decay. There's a technique called feathering which you can try to fit the data to, in this case, a two (2) compartment modeling--a two (2) compartment model--saying that in a way we assume two (2) compartments and that first of all you're seeing very rapid elimination primarily from what's in the blood. Then you're seeing a kick-in of the tissues which has a longer half-life for uptake and also elimination, and this technique of feathering where you break the curve we just saw--we've now expressed it in log--and we've basically broken it into the two (2) linear components for a two (2) compartment model. We were able to estimate half-lives. First of all, out of the blood,

half-life of about four and a half (4 1/2) minutes is our estimate using this feathering technique. And out of the second compartment which we assumed one of the fatty tissues--the organs--a half-life of about fifty one (51) minutes.

Based on this we came up with, our pilot study is going to be based on taking a thirty (30) minute post-exposure breath sample. Why thirty (30) minutes? At that point we're out in the range where, especially on this first ..., where you don't get a great deal of variation. And what do you see coming out? We actually--our thirty (30) minute samples are the average of twenty five (25), thirty (30) and thirty five (35) minute samples. So now we've got a challenge agent and we've made a decision on how long we're going to expose and when we're going to take our post-exposure samples from the breath.

The next step was to say if we're going to calibrate our individual, basically, we've got to expose them to a range that we anticipate may in fact be in a respirator as the respirator is worn. And so this is basically our calibration curve for this particular individual. Each point, again, accomplished in triplicate. And we got pretty good reproducability on what we saw coming out of the breath. And our calibration exposure concentrations which are sort of hard to pick up off the scale were a half a part per million, one point five (1.5) parts per million, six (6), twelve (12), thirty (30), fifty (50) and sixty (60) parts per million. Each point we did in triplicate. That gave us a working range for this calibration curve of protection

factors from eight (8) up to a thousand (1,000), using a five hundred (500) parts per million challenge concentration with the respirator being worn.

So once we had developed our calibration curve for this particular single individual now the idea is we can put a respirator on the individual, send them into a five hundred (500) part per million challenge--this curve was based on the challenges--the concentrations--that I just read out, that series of concentrations--and then we see what comes out of the breath. The assumption is if that's what got into the respirator, now we've got our calibration curve so we can put the person in the respirator, put them in the chamber, measure what we get out of the breath thirty (30) minutes post-exposure and make a determination of what their average in-mask concentration or exposure was. And that was the whole idea.

When we went to the chamber study we did fit testing with the controlled negative pressure technique, immediately put the person into the exposure chamber. They were in different rooms, but we tried not to move the respirator at all. We also had looked at breath to see if there was any residual contamination inside the breath prior to each study. This is what we saw when we compared--now this is with half-mask and full-face respirators, and an attempt, again, not to have the same data point, but we induced leaks so that we could look at a range of fits. This is the relationship we saw between the controlled negative pressure system on the X axis and the biological system on the

right.

A higher correlation than I've seen anywhere else, but also we were overstating protection with our controlled negative pressure system by about two and a half (2 1/2) if you look at the regression equation. Now the negative pressure systems is already--we've been overstating fit by an order of magnitude with the aerosol system, and now we're finding that the biological system is still overstating fit some, but still in this quite a bit of scatter but we were pretty encouraged at this point thinking that maybe we do have a mechanism in the gas vapor more rigorous challenge realm with looking at how well that respirator actually provided protection to the worker.

The limitations. We did do replicates, triplicates, in our samples, but we did not look at some very important parameters such as elevated work rates. And that's now been proposed as a study to NIOSH and we're hopeful it may be funded, because we want to look at a lot of the parameters such as elevated work rates and temperature and humidity. The things that will in fact, we think, effect the performance of a respirator. Now here's a way of looking--of bypassing aerosols and all the variabilities, bypassing in-mask sampling and all the variabilities. I think there's a way of basically calibrating our subjects, doing our studies, and getting a clearer picture of how much protection is actually being afforded the worker.

Some of the things we did. We used new organic vapor cartridges for each test. After several of the tests we looked

at the cartridge and then pulled a high rate of air through the cartridge to see if we could get breakthrough, and saw none. So breakthrough through the cartridge itself was not deemed to be a significant exposure rep for this thirty (30) minute exposure at the concentrations we looked at.

One other thing that we saw and worried about--there were several things, and this led to quite a discussion about are we getting any skin exposure, because that's a possible route of exposure. And there was another, because we had such extremely low amounts coming out of the breath when we took our breath--collected our breath samples--our inexpiratory volumes in glass tubes. Is there a possibility that there is what we referred to as an aura around the subject because they've been absorbing the vapor and now, are the still outgassing to the point that you might put a few molecules into your tube, and because of the sensitivity issue is it possible that we're seeing that? So we went to an emergency response team and borrowed--pretty low budget operation--borrowed an SCBA just to take a look at this issue very quickly. Put the subject into the chamber with the assumption that at five hundred (500) parts per million and an SCBA we shouldn't see very much of anything in the subject in the breath after a thirty (30) minute exposure for a worker who is only sitting there. They're not exercising.

And we saw something. Oh, okay, now what we're seeing is that aura or is that skin--and this is sort of an added--you know, we hadn't actually planned this--how can we determine what

it means. Well, if we reduce the exposure time to half and this aura, we probably should be able to see the same level. Someone has an idea here. If we reduce the exposure time to half and we see a decrease in what's in the breath, maybe it's more due to another route such as skin. And as a matter of fact, we did reduce exposure to half and we saw half as much in the breath. It was a very low amount, but in fact, these data have been corrected for the amount we saw after the SCBA. Our assumption was SCBA gave us perfect protection, no. But again, it was a very low challenge environment.

One other thing we did, though, is for a series of the tests we said, okay, let's pull--during the thirty (30) minute exposure period let's pull an in-mask sample, collect it in a bag and see what the bag shows us as far as what the average exposure concentration was and see what kind of correlation we get.

And here is the relationship between the bag samples and the biological method. Not very exciting data. And we also said, well, what do the bag samples look like relative to the fit factors that we had measured with the controlled negative pressure system, and again, not very exciting. Either the biological system doesn't work and the bag system is really great, but if that's the case then the controlled negative pressure didn't measure leakage into the mast. I have lot more faith in that than I did in in-mask samples that we pulled in through the bag.

That's the pilot study that we did. I think it's a way, though, of doing a heck of a lot in a controlled, perhaps simu-

lated, work environment, because you can simulate a tremendous amount now, totally independent from any kind of mask sampling requirements. The worker goes into the chamber wearing a respirator and does whatever you want to do. Presumably the most representative protocol of movement and work rate that we can come up with that can be translated then to a wide array of environments. And here's a way of challenging very rigorously, because molecules can go where particles can't, and here's a way of saying this respirator gave this level of protection to this worker's lungs. So I'm pretty encouraged by what we saw as preliminary data in a first cut pilot study as another way of bypassing two (2) of what I think are the major sources of variation that are absolutely driving us nuts right now. And that's the aerosol variation and the mask sampling variation.

And I'd like to open it up to any questions, comments or shots.

HARRY ETTINGER: You've eliminated the sampling the aerosol variability, but now you've introduced the biological variation, which between myself and yourself should be fairly significant.

CLIFTON CRUTCHFIELD: It could well be.

HARRY ETTINGER: Well, it's very difficult to put a handle on how well you exhale or absorb within the lung, and then even the variation among an individual day after day depending on a variety of factors on their biological systems.

CLIFTON CRUTCHFIELD: I think we have at least a shot on the intra-subject variability in that we saw a pretty good replica-

tion with the one (1) subject over time day after day, with three (3) samples at each data point.

HARRY ETTINGER: You have a shot at the intra, but the inter I think would be impossible.

CLIFTON CRUTCHFIELD: That's why I say the requirement, I think, is there to actually calibrate each specific individual. So you're not being--you can't to out and test a thousand (1,000) people, but you can qualify a given panel and I think extract a tremendous amount of information about a wide range of respirators, as far as challenging them with a gas and vapor, which is more rigorous than challenging with an aerosol. But I don't think you can take the results from one (1) worker and say, hey, this is the way things are. That would take a serious validation step, and I think that's going to involve each worker initially--we've proposed to, in fact, calibrate--do the same calibration step--in triplicate for each worker or each subject that we want to test. In a way you're not only bypassing the aerosol, but you're bypassing a lot of the variation that--by the calibration step--then it becomes a relative thing for each worker rather than--because I don't think you can handle it in absolute terms based on our knowledge right now.

BOB BRENNAN: There's a classic experiment that you might want to review if you're going to do this. I believe that DuPont did it first where they take the arm of subject and expose it to the gas and breath it in the mouth, and while you're calibrating the subject it sounds like you're going to have to do that to

each subject, also.

CLIFTON CRUTCHFIELD: I thought of the back instead of the arm, but the arm makes--it's a lot easier with the arm.

BOB BRENNAN: I think it's easier to seal off.

CLIFTON CRUTCHFIELD: I appreciate that comment. I think it's a valid thing to look at.

ROBERT SHERWOOD: Presuming you control the metabolic rate following the exposure before you take the sample, because washout will depend on the metabolic rate during that period, how then will you overcome the situation where if you have hard work during the exposure the person will still be metabolizing fast for the period immediately after the exposure period? Which would be different from a sedentary.

CLIFTON CRUTCHFIELD: And sort of different from each agent, and that's why you get one that doesn't--you don't metabolize.

JERRY SHERWOOD: Yes, and washout time still varies with metabolic rate.

CLIFTON CRUTCHFIELD: And I think that--our protocol now calls for the calibration to be done at each proposed work rate that we're going to use. But the other thing that we did relative to being very cautious about having a low overall exposure during the thirty (30) minutes and then suddenly having possibility of a significant exposure, because of outgassing from clothing and such, was that the subject exited the chamber, kept the mask on, went outside and did not remove the mask until five (5) minutes after they were outside. So the dilution could help us

as much as possible.

ROBIN HOWIE: Are those the same data points physically as the one you showed previously on your previous ... graph?

CLIFTON CRUTCHFIELD: Yes, they are. The same.

ROBIN HOWIE: . . . side by side ... they are the same.

CLIFTON CRUTCHFIELD: The data points, yeah, and the correlation between the points.

HASKELL MULLINS: Did you do any breakthrough curves on your respirators? You are using a freon. Most carbon beds do not absorb freon very well. You'll have a breakthrough curve in a short period of time. Did you continue to use the same respirator over and over, or did you change it out every test, or what?

CLIFTON CRUTCHFIELD: We used the same respirator, we changed cartridges after every test, and we also looked at the cartridge after the test and in several instances we took that cartridge that had already been used in a test, pulled as I recall twenty five (25) liters a minute through the cartridge and then sampled and looked at the downstream concentration, and found it to be very, very low. So breakthrough did not look like a significant problem to us.

KEITH SIMPSON: Did you look at absorption of the freon on the rubber mask?

CLIFTON CRUTCHFIELD: No we did not.

KEITH SIMPSON: And the second part . . . .

CLIFTON CRUTCHFIELD: To follow that up. The mask itself could absorb the freon, and that could have continued--I'm trying

to say where that would go. Would that continue the exposure for the five (5) minute period post-exposure?

(Response from audience, "I don't know.")

CLIFTON CRUTCHFIELD: I'm not sure what the significance of the mask absorption would be, but that's a possibility we've not looked at yet.

BOB DA ROZA: When we used freon 12 we checked with DuPont's freon experts, and they basically told us in sampling freon 12 and other freons that they stick to almost anything except metals, and they will absorb and desorb as you're taking samples. They just continually sort of hang around. So you really need to watch out for the freon on the clothes, and the desorbing later, and everything.

CLIFTON CRUTCHFIELD: A primary check during this particular study was to look at breath immediately before each test. We were worried about outgassing from clothing and such. We had a relative idea of--well we were using a [moran] in the exposure chamber and we knew what it's lower limit and--we knew there was not a large residual component in the chamber, but when you get down to parts per billion levels you're right, it does tend to hang around.

We did look at sample stability in the breath tubes and found that we had to heat the tubes . . .

DAY 3 - TAPE 1 - SIDE A

January 11, 1991

GWEN STRICKLAND-CID: Could we gather in the room to get started, please. This is the third day of our technical conference. I'm Gwen Strickland-Cid, for those of you who were not here yesterday. I'm facilitating this session for you.

We have a few housekeeping matters before we get started. First, I would like to encourage you again to identify yourselves when you speak so that our record will be complete. Once you get this thousand (1,000) page transcript you may want to know who was making certain comments. And also to speak loudly for those of you in the back.

The second thing is to make sure that you pick up your handouts at the back. Particularly the one instruction sheet tell you how to make a request for the transcript. They're on the table outside the door.

The third is what we'd like to suggest is a change in the schedule on the recommendation of Mr. Shoub, and also seconded by Mr. Tom Nelson of DuPont. We would like to move his presentation up before lunch from twelve (12) to twelve thirty (12:30) and then do lunch from twelve thirty (12:30) to one thirty (1:30) and then have the open discussion for those of you who are anxious to get back to Pittsburgh because of weather concerns.

The open discussion will merely be an opportunity for you to make statements, raise questions, there's no formal presentation scheduled for that time. So if you want to make a statement or

comment, just feel free. Dr. Don Campbell will facilitate that.

At this time we'd like to start with Mr. Robert Da Roza of the Lawrence Livermore National Laboratory talking about validation of a simulate workplace protection factor measurements protocol.

ROBERT DA ROZA: Good morning. This is a better turnout that I thought for this time of morning on the last day. That's great. Everybody looks awake, too.

First, before I start into formal talk, I wanted to go on the record as saying that I don't think--rather I think--that actually certifying respirators by doing some type of workplace protection factor study on the individual respirator would be a mistake, that it is too uncertain, too variable from one workplace to another, and that it would be no way to inter compare one respirator with another, and that would be very poor in the certification process. I do think that respirators need to be certified by a laboratory simulated workplace protection factor study of some type--protocol of some type--but not by actually going out in the workplace with each respirator.

My talk this morning is on the validation of an experimental strategy for respirator testing of a simulate workplace protection factor study. It was done by myself and Carol Sackett, and sponsored by DuPont Company with help there from Tom Nelson and Steve Dixon.

Our purpose is to validate the methods to be used in a simulator workplace protection factor study. What do we have to

do to do this. Three (3) main factors; we want to confirm the reproducability and accuracy of quantitative fit testing--our particular quantitative fit testing--system up to about twenty thousand (20,000) fit factor. We want to determine if an aerosol and a gas give the same fit factor. We also want to determine if an exhalation valve sample is representative of the air breathed.

First, to confirm the reproducability and accuracy of the quantitative fit test, we need to do several. One is measure the linearity of the photometer; as we measure the challenge concentration in our test chamber with the photometer and we measure the concentration of aerosol inside the respirator with the same photometer, and this can be over four (4) or five (5) decades on the instrument. There's always been an uncertainty as to whether that instrument--the photometer--is linear over that whole range, and are you really getting--is a ratio really correct.

Another thing, when you're using a large changer you have sample lines about ten (10) feet long, and we want to know are we loosing any of our sample in that line, and if we are can we do something to correct for that. Our concern, when you're looking at very high protection factors, where we'd be measuring subject generated aerosols, when a person talks, breaths hard, even doesn't breath hard, they are exhaling some aerosols. Are those of a concentration high enough that it would effect the fit factors measured?

We also want to look at effective moisture CO super 2--I don't know what happened to that--as released carbon dioxide, and

other emissions. In other words, are there some subject generated things that may effect our photometer reading? Also, we planned on using chlorofluorocarbon 12 as the gas, and we're concerned how much of that is absorbed into lungs and what kind of lung correction might we have with it.

In determining if an aerosol and a gas have the same fit factor, we needed to develop an analysis method for the gas. I'll go into that later. We need to measure the aerosol mass concentration to characterize our aerosol, and also to measure the aerosol particle size distribution to, again, characterize our aerosol.

In the last part, which is sampling, and that has become such a big question since Warren Myers' studies on streamlining in ..., we just took the attitude that was mentioned the other day, that if you take your sample of exhaled air that at least it's more mixed than if you try to sample right inside the mask as a person is inhaling. This is not just exhaled air, but it is air that goes out the exhalation valve, which is a mixture of what the person is exhaling plus what was in the facepiece before he started exhaling. We decided to do that on four (4) configurations of the MSA Ultaview full-facepiece. That comes in these four (4) configurations; the gas mask with dual cartridges, pressure demand air line, constant flow air line at four (4) cubic feet per minute, or you could boost it on up to six (6) cubic feet per minute. The NIOSH certification is for four (4) cubic feet per minute, however, MSA knows that's not enough and

you can't even crank it down to four (4) cubic feet per minute, you have to do some other things to reduce it that much. They normally give you more than four (4).

We're going to look at three (3) artificial leak sites. We need to get some leakage. First we're going to do this validation test on a mannequin head in a breathing machine. So to get leakage we'll put a hypodermic needle through the rubber part of the mask to allow some aerosol to leak in. And we want to get a fit factor that's kind of reasonable somewhere between a hundred (100) and a thousand (1,000). We'll apply three (3) leak sites, forehead, temple and cheek, and we'll try two (2) breathing rates, twenty (20) liters a minute which is what most of you are doing right now, and a hundred (100) liters a minute which is about your--close to your maximum breathing rate. And we'll do duplicate runs.

Continuing on with the exhalation valve sampling, we'll make measurement with both the aerosol and the gas, and we're going to make measurements at four (4) different locations in our setup, which is the test chamber, a respirator on a mannequin head that goes through a hose from the mannequin head to a breathing machine. In the throat of the mannequin head we have a little mixing disk that causes turbulence so that any streamlining is eliminated.

So we will sample after the mixing disk between the mannequin head and the breathing machine. That is to simulate in a person what they would really get into their lungs. We'll sample

just inside the mouth of the mannequin head. The mouth is about a three-quarter (3/4) inch diameter pipe. We'll sample in a tube attached to the exhalation valve, and I'll show you that later, and we'll sample in the standard lens position, which is between nose and mouth right in the lens. We'll, of course, determine the concentration in the chamber between all these.

Other measurements we'll make, when applicable; we'll measure the [delta p] in the mask on the pressure demand on the pressure apparatus, the flow rate of air through the exhalation valve--put a flow meter on it--and the flow rate into the mask, and the pressure into the supplied air line--monitor all those things.

To confirm the accuracy of the quantitative fit test we're looking at the linearity, we decided that a gravimetric method would be the standard. However, to collect enough aerosol over that range and reasonable length and accurately is not really possible. So what we have to do is to enhance our gravimetric technique. We used a polyethylene glycol molecular weight four hundred (400) aerosol--has the same kind of properties as DOP in corn oil, except it's not toxic and doesn't grow bacteria or anything. We spiked it with fluorescein. And after some calibrations using a volumetric dilution method we calibrated a fluorescent spectrophotometer. So what we would do then, we'd create the aerosol concentration, look at it with a photometer, and also collect a sample over the same time period on point two (.2) micrometer hole size [nuclear port filter]. We would then

put the [nuclear port filter] in some solvent to dissolve off all of the fluorescein spiked peg, and then look at it under the spectrophotometer. This allowed us to get this large ... range. And the results are that this particular photometer, which is a Phoenix 7000, is linear over all five (5) decades.

We have since inter compared this photometer with another Phoenix photometer and they don't agree. So, I would say that just because this one is linear does not mean that yours or any others are linear, because the other of mine doesn't agree with it.

We looked at particle loss in the sampling line, and we used a flow rate of a liter per minute and about twenty (20) feet of line. We wanted to see what the particle loss was as a function of particle size. So what we have here are two (2) particle size distributions. One with twenty (20) feet of line added, and one without any line added. You see that they're almost identical so that the loss was only, we figured, one point four percent (1.4%). With a three-sixteenths (3/16) inch diameter ID it was only that. With a smaller--a one eighth (1/8) inch--we had a higher loss so we didn't want to use that.

We decided there was no effect on photometer from subject generate carbon dioxide or moisture. We looked over old data with subjects wearing SCBA, and from these hundred and ten (110) tests on human subjects working at a high work rate, we found that at least forty (40) of them had fit factors greater than forty thousand (40,000), and nine (9) out of our ten (10) sub-

jects had at least one (1) fit factor over forty thousand (-40,000). So we figured that if there was an effect of carbon dioxide or moisture it would have shown up; we would have never gotten fit factors that high.

We measured the absorption of chlorofluorocarbon 12--freon 12--into the lung. We exposed two (2) subjects to seventeen (17) parts per million of it, and we found those small--seven percent (7%) and four percent (4%)--lung loss. Basically the way you measure lung loss is you have them in a chamber on the air line and measure the concentration of chlorofluorocarbon in the chamber. You then have them unplug the inlet line from their air source and they're breathing in chamber air and you measure the chlorofluorocarbon concentration in the exhaled air coming out the exhalation valve. And the comparison of those two (2) is--the difference is whatever is lost in the lungs on in the sampling system.

We hadn't used a gas before. Well, actually we had used a gas before. We had used freon 12 in gas chromatography, but you can only take a sample with the gas chromatograph every couple minutes. And also, it has become apparent that chlorofluorocarbons were destroying the ozone layer and we really didn't want to contribute to that.

So we looked for something else that would have a high sensitivity and would be innocuous and hit upon sulphur hexofluoride. TLV for sulphur hexofluoride is a thousand (1,000). Studying all the literature I couldn't find anything wrong with

it. People have used it and mix it with--they replace nitrogen in breathing air in doing the lung operations. I apparently is very innocuous, and our high atmosphere chemists say it doesn't destroy the ozone layer.

To detect it we used an instrument called a Leak Meter II by ITI Industries. It had the capabilities of detecting the halogens at high sensitivity in air. Normally you think of electron ... detectors being very sensitive for halogens, when it's associated with a gas chromatograph. And that's true because the gas chromatograph separates it from oxygen. This detector also detects oxygen. However, they came up with a scheme to decrease its sensitivity to oxygen so you could still see the halogen. Now that's great for the low concentrations. For the chamber challenge concentration we wanted to do it continuously with the [Moran] 1A--the infrared. So we used two (2) instruments, one for the chamber, one for inside the mask, and intercalibrated the two (2). So this gave us a large enough dynamic range.

The exhalation valve sampler shows little bias for the gas mask configuration. We'll go into that in a second. Let me show you what sampler looks like. We added a little thin stainless tube over the exhalation valve cover, put a couple sampling fittings on it--one (1) for aerosol, one (1) for gas--and then put a aluminized mylar tube on the end of it. This is about three (3) feet long. The need for the tube was that when a person is not exhaling there is no air going down here, but you're sampling at like a liter a minute, so you would be drawing

chamber air back up the tube. So the tube is long enough so the chamber air never gets up more than about half way.

A little bit better picture showing how we attached to the exhalation valve. The yellow cover is the exhalation valve cover on the pressure demand exhalation valve on this mask. We made a little coupler arrangement--this shiny part--that fit around it. IT's sealed on the top part and our stainless steel tube will go around this shiny part here.

We had originally planned to use two (2) work rates, twenty (20) liters a minute and a hundred (100) liters a minute, so I told my helper to find out what needle size she needed to get a leak rate somewhere between--fit factor--between a hundred (100) and a thousand (1,000). She kept adding needles and larger needles and said, "It won't leak, it won't leak," so finally I took a corkboard and cut a three-eighths (3/8) inch diameter hole right in the rubber above the lens and it still wouldn't leak. So we started thinking, well maybe positive pressure really is good after all, and so let's look at what's going on here.

So we increased the breathing rate--cranked up the breathing machine--and I'll just give you three (3) points right here with this big hole. With these three (3) breathing rates the minimum delta P during the breathing cycle is given here, and the fit factor which were well above ten thousand (10,000) at lower breathing rates now dropped to around seven thousand (7,000), a hundred (100), and then down to ten (10). Right over this change from fifty five (55) to sixty five (65) liters a minute breathing

rate we had a dramatic change in fit factor. Some lights lit up, we said, hey, this is probably the most important thing we really should know about this respirator. As a user or someone that's going to give it to other people to use we really ought to tell them that if you're working at low rates you'll get real high protection factors, but if you're working fairly high--this may be eighty percent (80%) or so--you're not going to get fit factors worth a darn.

This is--we did a lot of work with ten (10) subjects; a lot of replicates, and I measured their various things; breathing rate minute volume, and let's look at the minute volume line. Subject five here has a minute volume when he's working at eighty percent (80%) of his cardiac reserve of almost a hundred and six (106) liters a minute he would really be getting no protection from that respirator. Whereas subject four or seven would be right in the range where they would be getting around a fit factor of a hundred (100). If they weren't working quite this hard they'd be getting a great protection factor. So even with a bunch of people working at the same rate with this respirator some would be getting good fit factors, some not. If you got a different group of people in here you may end up with a quite different number of them getting good fit factors. I think you really need to understand basically what the respirator does before throwing it on a bunch of people.

This is just showing we have a range of people, range of ages, range of weights and heights.

So what we actually decided to use then for the pressure demand respirator was to use a copper tube with a one eighth (1/8) inch ID a half inch long, and with that leak we changed the breathing rate and looked at the delta P and it doesn't go negative until you get to a hundred (100) liters a minute. And it's negative then, about six and a half percent (6 1/2%) of the time. So we decided to use a breathing rate in our test of a hundred (100) liters a minute so we would get some moderate leakage.

I'll give you some examples of what our data looked like. First for the basic configuration, the gas mask configuration, the leak location was at the forehead. Here we have the fit factor along here, and this is for twenty (20) liters a minute data with the gas mask. This if for our different sample locations. Two (2) replicates, the green being the first replicate. This is--we started the run by sampling between the mannequin head and the breathing machine, then we switched over and sampled just inside the mouth, standard lens position, exhalation valve, then we went back to the breathing machine. That consists of one (1) run. We then would switch to a different leak position and then later on come back and do our second replicate. And you see here that what we're saying now is that the breathing machine samples are what is equivalent to the lung. So our best standard sample position was going to be the one that agrees best with the breathing machine.

Sampling at the temple, the same kind of thing. We're

seeing here we're apparently having some bad streamlining for sampling at the lens, but the exhalation valve sample is agreeing pretty well with the breathing machine. We obviously don't have lung loss in this experiment because it's a mechanical breathing machine.

Again, at the cheek, we have a lot of streamlining so the lens sample is almost a factor of two (2) off. Not that a factor of two (2) is that bad, but it . . . . Okay, at the higher work rate what this is showing here is that at a hundred (100) liters a minute we're getting poor fit factors, and--the scale changed on you--this shows the comparisons between the different sites. For some reason or other the mouth is showing abnormally poor here. We thought maybe mouth would be a good sampling place, but it doesn't always agree either.

Again, a hundred (100) liter a minute at the temple. This is just to show you the variation we've been getting. And our third location at the cheek, and all these--the higher breathing rate--the mouth sample was always giving us a low fit factor and the others weren't too bad.

This is with the same facepiece but we've put it into the pressure demand mode. Actually it's not physically the same facepiece but it's essentially the--it has the same shape and all, but they make it for pressure demand mode. We'll have the leak location there near the forehead, and this is using this ITI leak meter, so this is using sulphur hexofluoride gas. And we get our protection factors here. Replication wasn't quite as

good on this one. The lens is the worse, the exhalation valve is a little high.

I think this is--yeah, this is the photometer, so it's the same test as the other one only this is the photometer. So one of them is--you can see the pattern is the same, there just is a little offset in the actual numbers that we're getting. I think the reason for the difference in the actual fit factors between the gas and the aerosol is that the Leak Meter II is intended to be a survey instrument and we were using it as a laboratory instrument instead. So it was a little hard to do a good calibration on it. And I think that our calibration was a little bit off on that. But you see the patterns follow the same--there's just a slight difference in the magnitude.

Both our photometer and the Leak Meter II give real time results, and time starts down here. One of these is the leak meter and one is the photometer. I, frankly, don't remember which one is which. It doesn't really matter here. But what you can see--well, this is a dual pin chart recorder, so the pins don't match up perfectly. This time here is the same as that time there, but on the chart, of course, they're offset a little bit. And what you'll see is that when you have a little peak on the one or valley on the one, you have the same pattern on the other. Looking at the lens sample, about the same. Looking at the exhalation valve sample, this peak, peak, peak, dip, dip. What was happening is that as your leak changed due to the breathing cycle--the leak changes some all the time--what you

picked up with aerosol you also picked up with gas. So it was a fantastic example to me of how the gas and aerosol leaks follow each other. And we don't have a different leakage from one versus the other.

Now we want to do the constant flow configuration. And we decided we would try it at both four (4) CFM and six (6) CFM. We needed to choose the breathing rate to do the test, so we ran through a bunch of different breathing rates, and at four (4) CFM going into the constant flow mass we watched the delta P and here at forty eight (48) liters a minute we start going a little bit negative. So that looked like, okay, we're getting a little leakage here. We wouldn't get any leakage up in here, and we'd get a lot of leakage down here where it's really going negative over four (4) inches. With a higher flow rate we had to go up to like seventy eight (78) liters a minute before we started over breathing the respirator and getting a negative pressure. So we then decided, okay, we know that with these input flow rates the respirators are going to be great up to those flow rates and then--so we do our test at that point.

That is just showing that we did it with a leak meter and then--this is at six (6) CFM. Four (4) CFM was the same scale so we're having a little poorer protection factors with four (4) CFM than we had with six (6) CFM with the same leak location.

With those constant flow data there was a big discrepancy between the breathing machine results and the exhalation valve results. So we looked here, okay, what is the percent bias from

the breathing machine result? Sampling at the mouth, and this is our summary--one of our summary slides--showing for these different configurations here, constant flow four (4) and six (6), gas mask with a nose cup--we did a couple--and then gas mask, twenty (20) liters a minute, a hundred (100) liters a minute, and pressure demand.

This shows the bias. Well, you just get a horrible bias on this constant flow, and that's because you're continuously having clean air go out the exhalation valve and it is a not very good place to sample there. We tried to correct that data for the flow through. Notice this is about five hundred (500). On this one after doing the correction, which was a logical type of dilution correction, we got our bias down to a little less than two hundred (200). But it still has a high bias.

In summary, the photometer aerosol measuring system is capable of accurately measuring ratios of aerosol concentration over range of one (1) to at least ten thousand (10,000). The aerosol and gas concentrations correlate very well, but we have a small bias probably due to our calibration error.

The exhalation valve samples are representative of the air breathed for some mask configurations. It's very good for the gas mask. The pressure demand configuration is--it's better to use the exhalation valve sample than the lens, but there's still a little bias. On the constant flow there's a large bias, and we may be able to correct that, but we haven't yet. And the positive pressure configurations did not leak until they were over

breathed. And I guess that was an important conclusion. The final conclusion is that the photometer system and exhalation valve sampler described should produce accurate measurement of simulated workplace fit factors for gas mask and air supplied pressure demand respirators. And we probably can get accurate fit factors for the constant flow by working out some way to correct for the dilation due to the flow in the constant flow respirators. And that is the end of that. Are there any questions.

GWEN STRICKLAND-CID: ... take a couple because we are ....

HARRY ETTINGER: Bob, if I look at your data it suggests that the error by sampling what you call the lens, which is sort of typical of what we do in the field, is much bigger than the corrections we're worrying about in great depth on lung deposition, which was a factor of one point five (1.5) or even whether you wash or don't wash the filter. That lens versus the truth--the breathing machine--is a bigger error than any of those other things that we're spending an enormous amount of effort on to fine tune. Is that a fair statement?

ROBERT DA ROZA: That's true. For this particular configuration we had that was certainly true. What other work has shown is that sometimes the lens sample may be low, may be high, may be low, and may be off by as much as maybe two hundred percent (200%). In our particular configuration, yes, it was a major--was a larger factor. I agree with you.

JEFF BIRTON: Bob, where you correlate gas versus aerosol,

what was the size of the aerosol?

ROBERT DA ROZA: It has a mass medium aerodynamic diameter of about point seven (.7), and then it had that distribution that I showed in the one slide. Pretty much the standard aerosol generator.

JOHN KING: Have you thought about how you would sample in a loose fitting device like a hood--loose fitting hood--and, you know, your work seems to be geared toward taking a sample from the exhalation valve. If you had a loose fitting hood have you thought about how you would deal with that?

ROBERT DA ROZA: No, only when we've done loose fitting hoods we're just tapped into them at someplace towards the front, and didn't try to collect any exhaled area.

DEBORAH NELSON: When you have that sleeve on the exhalation valve, if you had leakage back through that exhalation valve you wouldn't see that because on each exhaled breath you'd be putting clean air into that sleeve and then as the valve closed and you pulled in air through the exhalation valve you'd be bringing that clean exhaled air back in.

ROBERT DA ROZA: . . . expert on exhalation valve leakage and I'm glad you picked that up, right. You're absolutely right, yeah. If it was dirty or leaked--faulty--you would not pick it up. Very good point, Debbie.

GWEN STRICKLAND-CID: I think this should be the last.

CLIFF CARTYLE: Did you leak test the mask prior to insertion of the fixed leak?

ROBERT DA ROZA: Right. Yeah, we could cap off the leaks and we would actually leak check it fairly often. We'd cap off all the leaks and do a fit factor and find out we didn't have any leakage.

CLIFF CARTYLE: Would it be possible with a breathing machine, with the same configuration, to actually--after you run a test with the gas and with the aerosol--to connect your leak--a fairly large leak--to a spirometer for example, run the same experiment, and then get a direct readout of air leakage into the system during that dynamic phase ... by tracing on the spirometer so that you didn't have an absolute--this is what leaked in. You've got two (2) measures ....

ROBERT DA ROZA: ... our proper tube didn't cause the leak. We could put a air flow device on it.

CLIFF CARTYLE: Exactly, and then you would have an absolute comparison standard perhaps.

ROBERT DA ROZA: That would be interesting to do. Okay, thank you.

GWEN STRICKLAND-CID: At this time Mr. Barry J. White from The Jefferson Group will talk about the concept of simulated workplace testing of respirators.

BARRY WHITE: This is another low tech presentation. In fact, it's so low tech I don't even have a slide that says it's low tech.

My name is Barry White. I am Vice President of The Jefferson Group, a government affairs consulting firm located in

Washington, D.C. The Jefferson Group represents clients that both manufacture respirators and use them in the workplace. I'm here today on behalf of the Industrial Safety Equipment Association. Prior to assuming this position I was for eight (8) years the director of Safety Standards for the Occupational Safety and Health Administration. I was also for nearly a year the acting Director of Health Standards. In both capacities I was directly involved in considering the regulation and use of respirators in the workplace. In addition I served as a regional administrator at OSHA and saw first-hand the application of OSHA respirator policy in practice in the workplace.

I might add whenever we wrote a standard at OSHA we always had NIOSH show up to make comments on the standard. I find it much more enjoyable to be here to comment on the NIOSH standard than the other way around.

During the opening session on Wednesday Dr. Campbell remarked that the total NIOSH revision of standards addressing respirators will encompass four (4) versions. Version one was published as a proposed rule by NIOSH in August, 1987. There was significant disagreement with many provisions, particularly those that would have required workplace testing or validated simulated workplace testing of industrial respirators as part of the certification process. To it's credit--to it's very great credit--NIOSH has removed those provisions from it's second proposed rule which is currently being rewritten. That document without those initial provisions Dr. Campbell referred to as

version two. Now we may see that second proposed rule this year.

Version three will be a proposed rule that addresses those removed issues of workplace testing or simulated workplace testing. Input from this technical conference will help NIOSH determine the content of that proposed rule. Version four, the one that will answer all of the technical questions that we've raised, is probably down the road a few years. In fact, our children may be here addressing some of those technical problems.

I would like to make some recommendations this morning on both version number two and version number three. First, regarding version number two, the second proposed rule, I urge NIOSH to adopt the appropriate language of the new ANSI Z88.2 for the determination of protection factors. OSHA is required to use consensus standards as the basis for regulation when such standards are available, unless it can show a good reason why it should not do so. In practice OSHA seldom references ANSI standards in their entirety anymore, preferring to place similar language in the body of the regulation. The ANSI standard language is usually not picked up word for word because of economic reasons enforced by the Office of Management and Budget.

However, many recent OSHA safety standards are closely based on the appropriate ANSI standard. OSHA and other agencies take this action not only because it must, but because has found that ANSI standards are produced after a consensus is reached that the agency often finds difficult to obtain on its own via the public rule making process. NIOSH has already experience this difficul-

ty.

Most of the differences of opinion in a consensus standard have already been ironed out through discussion and resolution by experts. Some argue this consensus process may not produce as far reaching a standard as would otherwise be the case. On the other hand, it produces a regulation that may not have to be fought through the courts. And if an agency is taken to court reliance on a consensus standard is an important factor in its favor.

In the new ANSI standard the term protection factor has been exchanged for the term assigned protection factor, APF. The APF is defined as the expected workplace level of respirator protection that would be provided by a properly functioning respirator or class of respirator to a properly fitted and trained user. ANSI would appear, properly I think, to place more real world emphasis on the proper fit of the respirator and the training of the user, than the more respirator orientation NIOSH would appear to prefer.

Addressing the issue of fit testing the ANSI standard would provide a safety factor of ten (10) to account for the difference found between fit factors obtained in a non-work setting and workplace protection factors found under actual working conditions. This safety factor should help alleviate NIOSH's concern about non-workplace or non-simulated workplace data.

Let me now address the issue of workplace testing. In Item No. 1 of the Federal Register Notice of this conference NIOSH

solicits information and recommendations concerning the feasibility and practicality of developing a detailed protocol for conducting workplace protection factor tests that would apply to all workplace settings, all contaminants and all respirator types. If there is one clear message we have heard at this conference, it is that it is not possible at this time to develop such a detailed protocol.

I would like to echo Dr. Da Roza, it would be inadvisable for NIOSH to propose workplace testing as a regulatory policy. If not actual workplace testing, what about simulated workplace testing? Simulated workplace testing is valid only if the results of such testing can be correlated with actual workplace testing. We're not to that point yet. Too many variables are unknown and are uncontrolled to permit a predictive equation.

However, the path of simulated workplace testing is a much more useful one for NIOSH to explore than actual workplace testing. If NIOSH will focus on simulated workplace testing, commentors can focus their comments on how to perform valid simulated workplace testing rather than concentrating on why actual workplace testing cannot be done. NIOSH should not be in a rush to propose a regulation. This is not a crisis situation we are facing.

The testing reported on here at this conference, whatever else its limitations, verified the currently certified respirators properly fitted and properly used protect workers that use them. They meet the performance factors currently established.

What NIOSH needs to do is to develop criteria to assure that those respirators in use continue to meet those already established performance factors.

The primary problem with respiratory protection in the workplace today is not with the respirator, but with the poorly managed respirator programs. I urge NIOSH to take the time to prepare a proposed rule that will present suitable protocols for simulate workplace testing. I urge them to consider carefully the preliminary work being done by ANSI in Z88.8 and Z88.9. Thank you for the opportunity to speak here today.

GWEN STRICKLAND-CID: Comments or questions?

We've had another change in the program. At this time Mr. Tom Nelson of DuPont will come to discuss the process of assigning protection factors used by the ANSI Z88.2 committee. Mr. Alan Hack will not make a presentation at this time, but I hope his presentation will be a part of the record. I'm assuming he will do so. I'm not sure he's here.

DAY 3 - TAPE 1 - SIDE B

THOMAS NELSON: As you heard the ANSI Z88.2 committee recently reviewed the 1980 standard and as part of that process arrived at new set of assigned protection factors. The process took over five (5) years and we met about three (3) times a year, and we spent at least one (1) day each week that we're meeting discussion assigned protection factors. And near the end, I think, we spend two (2) straight days doing nothing but discussing the assigned protection factors.

I wish to review with you the process and decisions made by that committee. At first I think I'd like to point out that in the notice of this meeting several points were listed as being desirable to discuss. These included the available techniques and procedures for measuring assigned protection factors for respirator types that offer very high levels of worker protection, the approaches for and benefits and limitations of assigning performance values to individual respirator models, and with a goal to encourage better performing respirators to be developed, since NIOSH be measuring the performance of these individual respirators and discimining that information to the public. The process is and experiences we had as a committee I think will provide some insight on the answer to these specific questions. Namely that the assigned protection factors are not determined based on individual study results but rather are the results of an analysis of the data from several studies.

Secondly, assigning performance levels to individual respi-

rators is not a wise goal. Examining the data from several studies there is a range of performance seen. This performance is due in part fo the variability oft he study protocols, but also due to teh program in which the respirator is used. It would be a mistake to assume a particular model of respirator is better than another without knowing more about the tests being performed and teh variables that affect results.

Finally, I believe in the goal to encourage better performing respirators, but disagree that this should be encouraged by providing assessment of performance which implies that one respirator is performing better than another. The assignment of respirator protection factors should be one of a scientific analysis of the data and information, not one of a political decision making process.

Let me go now and talk about the procedures that the committee used to assign the protection factors. The considerations invovled that we're doing this. The heirarchy of data that we were going to interpret was primarilly we were going to put reliance on workplace studies. If there was no information on a workplace study we agreed that we'd look at simulated workplace studies. If not any data at that level we'd go to fit test studies, and if we did not have fit test studies, then we'd use any other data that we could find. The studies that were available in the literature were gathered and the relevance of the data was judged by the committee.

For most of the data where there was workplace studies we

interpreted that data by reviewing the fifth percentile of the distribution within a study. For half-mask respirators here is the list of studies that we reviewed. When we were doing this review of the studies was a time period of about nineteen--the data was mainly from the period--we were discussing this and the period of time here we were doing this discussion was 1984, 1986. So studies that were being done or came out in 1985, '86 or past that time were not part of this decision process.

You can see there are a number of different studies. And the type of things we were looking at were the type of studies that are involved. The type of material that we're looking at--these are all particulates. And I think the important thing we're looking at is, if you take a look down near the botton, is the fifth percentile. From these studies the fifth percentiles varied from approximately eleven (11) to approximately a hundred and sixty (160). There was also one (1) study that was a program protection factor study--some people asked some questions about that earlier--which had a mean factor of about twenty six (26). From this analysis of these studies the committee concluded that the assigned protection factor of ten (10) that was listed in teh current standard seemed reasonable.

For full-facepiece negative pressure respirators we could find no new data. All the data that was available was the fit test data that was done by Los Alamos in the early '70s. The committee at that point decided that we were no smarter than the previous committee and there was really no reason to change that

value from a hundred (100), and we kept that value.

For powered air purifying respirators, this again is a very busy chart and you're not going to be able to see it all at once, but to give you an--this is really to give you an idea of the studies that we looked at. There wwere a number of studies and this chart lists for the loose fitting facepiece, the helmeted visor type respirators, half-mask powered air purifying respirators, and full-facepiece respirators. If you look--if you can find in there--I'll just tell you what it is, it's much easier--there were five (5) workplace protection factor studies for the loose fitting facepieces. These had fifth percentiles that ranged from twenty (20) to fifty (50), a rather narrow range compared to the half-mask. From that--those five (5) studies--the committee concluded that an assigned protection factor of twenty five (25) was appropriate.

For the half-mask and full-face power air purifying units much less data was available. There was no workplace studies available for a hooded type powered air purifying respirator. For the half-facepiece powered purifying respirators the studies had fifth percentiles of eighteen (18) and seventy nine (79). We had some discussions on the committee of whether or not those studies were actually valid studies because the equipment had gone through changes over time. There was a full-facepiece simulated lab study that found the fifth percentile of five hundred (500). And from here the story gets even a little bit more complicated.

And this is why I think we probably spend five (5) years and I don't know how many days having discussions. But when you look at a powered air purifying respirator you can attain the same type of respirator--the configuration--in an air supplied mode. The flow requirements are the same and the committee thought that there could be--we need to have consistent data--consistent numbers between a powered air purifying unit and air supplied unit.

Then as we got to talking--you know, there was a difference already assigned between continuous flow respirator and pressure demand type respirators. And we had a hard time understanding why there would be a difference in performance between those types of units. Not to mention the difference in assigned protection factor that was given for a full-face pressure demand respirator and a full-face pressure demand respirator with an escape bottle. That seemed a little bit different as far as what the numbers would be.

There were some information--you heard some of this earlier in the week--that there is a lab study taht was done by Los Alamos for a air supplied hood found the fifth percentile that was from three hundred (300) to a thousand (1,000). The field study 3M did with the sand blasting hood had a fit factor of--a fifth percentile--of a thousand (1,000). There were some other lab studies--Bob da Roza's study on SCBAs--where we found that there were people who had fit factors under work conditions that were well below ten thousand (10,000), the current value.

When we got to this point, as I said, we proposed assigned protection factors and those changed meeting to meeting. I think the easiest way is to go to the next chart and we'll just go through and tell you what the results were. The process, I don't think, is that clear. For negative pressure half-mask air purifying respirators we both--we had not changed from the '80 standard--and have a ten (10). There is a difference, though, that the other standard did allow and gave credit for quantitative fit testing, and would allow a fit factor of up to a hundred (100). If you had a quantitative fit factor up to a hundred (100) you could use that as assigned protection factor up to a hundred (100). I think as Bob said the other day, nobody was doing three (3) fit tests that he could find and I'm not sure if people were using this assigned--this higher assigned--protection factor. I think it was a good thing.

The full-facepiece respirators, we both agree, with a hundred (100)--two (2) committees--except that the other committee was trying to allow quantitative fit testing and was going to allow higher fit factors up to a thousand (1,000) for full-facepiece respirators. For demand type respirators we looked at that as a committee as basically the mode of actions pretty much the same. They're both negative pressure, the only different is you air is coming from an air supply. So we just have no difference in fit factors between the two (2) modes.

For powered air purifying respirators the committee, as I said--the loose fitting, we came up with a twenty five (25). For

half-facepiece we selected fifty (50) based on those two (2) data points, eighteen (18) and seventy nine (79). For full-face we decided that a thousand (1,000) was an appropriate number. I think the logic that developed that number correlates more with the work that was done with the lab studies on full-facepiece air line respirators being very similar type data. The hooded helmet would be a thousand (1,000) for a PAPR.

There was a little difference when you went to dust-mist filters and you have to lower that. For atmosphere supplying pressure demand without escape provisions this group is saying fifty (50) is the limit, and a thousand (1,000) for full-face versus a limit of anything less than IDLH in the '80 standard. With escape the other standard would say you could use it up to ten thousand (10,000). I think we're saying that a thousand (1,000) is still the limit for a full-face with pressure demand with escape, but you could go into IDLH environments if it was less than a thousand (1,000) times the PEL.

Air line continuous flow, fifty (50) for a half-mask, a thousand (1,000) for a full helmet, and hood a thousand (1,000) which agrees, and twenty five (25) for the loose fitting type, which agrees with PAPRs. For self-contained breathing apparatus originally the committee came out with a recommendation of a thousand (1,000), but when the standard went forward to the full parent committee for voting that wasn't accepted, and we didn't like to do it, but we are compromised position. I think the concensus we finally came up with was no value in the table, but

a footnote that addressed some of the concerns the committee had that there is data that shows you do not get necessarily ten thousand (10,000). But we had to provide some kind of guidance, so for calculation purposes use ten thousand (10,000).

Not all may agree with the numbers that we came up with, but I feel they are the best available with the amount of information that we had at the time. Where does this lead us now? Based on my experience I can recommend the following research needs.

The studies that we looked at for the half-mask negative pressure respirator were not conducted with the sampling probes that minimize sampling bias--the work that Warren's been doing. More data is needed to confirm the assigned protection factor, as more data is needed for just about all types of equipment.

We need to understand the variables that give us the wide range in assigned protection factors we have seen. One aspect of these studies is that it is different from most science in that we are starting a piece of equipment as it is used in the work-place. The performance we see is affected by teh program that is in place in the study site. Before workplace studies can be used in a certification process that portion of the data collected that is due to the person and the work location needs to be quantified.

For air supplied and powered air purifying types of respirators we need to understand how to collect valid data. Little work has been done on the collection of samples from inside the facepiece with this type of equipment. The question that needs

to be answered is whether the probing screen used for negative pressure respirators is valid for this type of equipment. The process to arrive at assigned protection factors from studies in the lab or workplace needs to be accepted by the professionals of industrial hygiene. Not many groups have wrestled with the data and limitations of the information to arrive at safe use limits. And having gone through this with the ANSI committee I think that there is a great need to get the professionals, groups like the AIHA respirator committee involved in discussing how do you take data from studies and apply that to safe use limits.

The last point I think is important is that the process should be one of the science and not get involved in the political process. I think two (2) of the major areas that change with the ANSI standard involved decisions that were made for reasons other than science; the assigned protection factor for loose fitting PAPRs and the protection factors for pressure demand respirators with escape provisions. For the PAPRs the notion at the time of their introduction was that a higher use number was needed to be given to encourage their use. You wouldn't want to pay the extra money for equipment and not get anything back in the way of use conditions. This is what I heard stated by several people. This led to very high assigned protection factors being given which turned out to be unwise. I worry because I see the same pitfall occuring today with the notion that we'll get better equipment if we provide data and attribute that better performance to specific equipment without understand-

ing the tests that led to this data.

In a similar fashion, the higher assigned protection factors were assigned to pressure demand respirators to encourage their use. Again, I worry that we try to provide incentive to go towards specific equipment without real reasons or specific benefits. Thank you for the time and being allowed to give this presentation. If there are any questions I'll try to answer them. I don't know if I can answer on any of the specific studies we used in getting the assigned protection factors, but I'll try.

MR. ___: Is there a write-up on your reviews of the various articles and is there documentation on this decision-making process?

THOMAS NELSON: Documentation exists only from the standpoint of minutes over five (5) years. There is a brief write-up that we did at one point. Bob, I think I gave you one (1). Bob da Roza has written a little bit on that. It's not that clear a process. When you have very little data, it's hard to write down your decision logic. It's called professional judgment. We had a heavy dose of it.

HARRY ETTINGER: Tom, in your opinion, should we--are we worrying about some of the subtleties--worrying about variations of ten (10), twenty (20), thirty (30), fifty percent (50%), when there are bigger variations which we should focus on? You show tests where there are variations of almost ten (10)-fold. It's nice to science on lung deposition, that's kind of fun, and you

get a factor of fifty percent (50%), and you get up and you say, that's a significant difference. In your opinion, looking at the variations you dealt with, what level of difference is significant? That's almost semi-science.

THOMAS NELSON: Yes, I guess to answer it a little bit differently, is, I've got confidence in these numbers that people are being protected. And from hygiene viewpoint--one of the first discussions we had as a committee, were we going to have an assigned protection factor table. And we spent a little bit of time arguing about that and decided we needed to do that. As a committee we have to give guidance to hygiene people. People need to use this equipment. And so I think is--do the certification tests give the equipment that can be used in a program that will give you protection.

Now, with the half-mask I think we have quite a bit of data. I'm very comfortable with that piece of equipment and it's use. when you get to other pieces of equipment I still feel comfortable because of the way I think the equipment is used. Air supplied respirators, if that assigned protection factor was two thousand five hundred (2,500), maybe even two hundred (200), I don't think it would change my selection on the ... piece of equipment, because of the way they are used. I don't know if I answered you directly or not, but tried to.

GWEN STRICKLAND-CID: We're a bit ahead of schedule here. We have a break scheduled for ten fifteen (10:15), so I'd like to ask if anybody has any questions that they would like to enter-

tain between now and ten fifteen (10:15). If not, we will break until ten thirty (10:30) and then resume and go from ten thirty (10:30) to twelve (12:00) noon. We'll be back on schedule and we will have our lunch from twelve (12:00) to one (1:00) and then we'll have our open discussion from--well actually, we're really ahead. We'll have our lunch from twelve (12:00) to one (1:00) and then we'll resume again at one o'clock (1:00) for the open discussion.

So, if you have any questions if you would just raise them now.

(No response).

GWEN STRICKLAND-CID: Okay, break until ten thirty (10:30)

(Whereupon a break was taken.)

GWEN STRICKLAND-CID: I'm sorry about the delay, but when you have clients in the building sometimes you have to do a little consultation. It's ten thirty two (10:32) and at this time Ms. Suzanne Pinette of TRI/Environmental, Inc. will discuss a simple test method for respirator cartridge/canister effectiveness against specific chemical challenges and work conditions.

SUZANNE PINETTE: Each workplace presents a unique combination of chemical challenges and environmental conditions. Hopefully some day we'll be able to choose appropriate cartridges using predictive models on workplace protection factors. The one message that again we keep hearing at this meeting is that we're not ready to do that just yet. The technology is just not available, and what is available is prohibitively expensive and time consuming. It's clear that progress is being made and we're learning a great deal about these studies, but what can we take home to the user as far as what can be done to improve the safety of a respirator cartridge user in the workplace now given what we know? Perhaps the best thing we can do is to improve what we can and go with our experiments until we have something more reliable.

As a user of chemical cartridge respirators myself, and as a safety officer who recommends respirator cartridges for use by others, I want to have as much information about cartridge effectiveness as I can before making those recommendations. Respirator cartridges are currently supplied with NIOSH/MSHA

approval, but I find that this isn't sufficiently reassuring to my needs.

NIOSH and MSHA approval involves testing and necessarily limited protocol. Cartridges are tested against a thousand (1,000) parts per million challenge of carbon tetrachloride for fifty (50) minutes and ... supposed to achieve a critical ...penetration of point five percent (.5%). The canisters are similarly tested with five thousand (5,000) parts per million challenge of carbon tetrachloride. They need to go for twelve (12) minutes, and the critical penetration rate is 0 point one percent (0.1%) of the chemical challenge.

This has some limitations for somebody who's trying to do an application that doesn't include carbon disulfide. How can I infer the effectiveness of a particular cartridge in my specific application using this information? This is kind of non-specific testing. There's one (1) chemical involved, one (1) humidity condition, one (1) temperature condition, one (1) flow rate, and does this apply to all organic vapors under all conditions? My applications and most people's applications often involve more than one (1) chemical species and they're almost always different from carbon tetrachloride.

Humidity conditions in the laboratory--or in the workplace--are often higher, and the temperature can often be higher as they certainly are in Texas in the summer. So I think that my reservations about making decisions based simply on NIOSH approval are shared by many other users. This is the information that we

have, but there are ways to get more information easily, and we need to move in those directions.

Respirator cartridges can be tested against specific chemical challenges. The technology is available. The time required to do the testing is minimal, it doesn't take five (5) years of study, and also the cost if affordable. You don't need to come up with a million dollars to test a cartridge.

First, let's look at some of the parameters we would want to control in this type of respirator cartridge testing. People have published chemical cartridge service life studies. This one was published in 1973 by Friedman in the AIHA Journal. It shows that with a homologous series the absorbance of chemicals on the cartridge decreases with---the service life will increase as the molecular weight increases. And then when you add a moiety to the alkane you find that there are some changes there, and how could you make a prediction. Then with miscellaneous compounds like benzine ... you find that there is even less predictability if you are using just one (1) chemical. How would you know how benzene was going through, say from carbon tetrachloride tests?

Some of the difference in service life are a little disturbing for someone who is going to actually be wearing the respirator. Look at the ethylene oxide; it's less than a half a minute as opposed to acidic acid which goes for a hundred and five (105) minutes. Of course these lives are at five (5) part per million levels. I'm just showing that different chemicals are absorbed differently by the same cartridge.

Lots of people have said this, but Jerry ... did--said that up to a ten percent (10%) decrease in service life can be seen when there is a ten degree (10°) rise in temperature in the workplace. Humidity is an important factor. If you have a wet cartridge water soluble compounds tend to be differentially absorbed, and you'll have the opposite effect with a non-polar compound. This is something that we've observed, and I'm sure almost everyone in this room has seen studies that have shown this.

Flow rate is also an important factor. It's been shown in lots of studies that flow rate affects the performance of the cartridge. Obviously if you're challenging a cartridge with a larger volume of air charged with the same concentration of chemical that there is going to be more chemical on the cartridge and it's going to take--it's going to last--a shorter period of time.

So the most important respirator cartridge testing are temperature--I mean organic vapor cartridge testing. I have to remember to say. I'm a little more specialized than that ya'll. Temperature, humidity, air flow, the nature of the chemical challenge, and the concentration of the chemical, and, of course, the cartridge design. Now we can do tests that choose a specific cartridge and then control those other four (4) parameters.

I'd like to propose that chemical cartridge respirator testing methods be validated by round robin testing and published as a standard for evaluating chemical cartridge performance. TRI

would be happy to participate in that type of study, and I think that the standard would be of use to people in the field who need to know this information. Workplace protection factors are not prepared to give people specific information at this time.

The need for this kind of study is perhaps indicated by the fact that several laboratories have already built respirator cartridge testers and are putting them to use. And our customers have been asking for these tests, and the information is something that they need and is probably increasing the safety of their employees using these cartridges.

This is a drawing of the respirator cartridge testing system that we build at TRI. Let me describe how it works. I guess part of my point is that it's easy to build, and it's something that is inexpensive to run.

The input air comes into the system via a ... house supplied compressed air, and goes through a humidity trap and then through a charcoal bed to remove the contaminants that might be in that air. The sample is tested by GC to be sure that there is no interfering contaminants present. The air then goes through a flow/temperature/humidity controller--Miller Nelson--the choice of temperature and humidity is chosen by the customer depending on the intended use of the cartridge or canister. The temperature of the entire system--this whole thing--including the sample chambers and the air delivery system, is enclosed in a glove box which is temperature controlled.

The choice of flow rate is also made by the customer. The

flow controller is set to deliver three (3) times the flow for each cartridge because there are three (3) cartridges being tested in parallel. The balance of flow through the three (3) cartridges is checked with a flow meter at the distal end of the chamber. Adjustment valves are positioned at the inlet. They are not drawn on here, but we have valves at this position to adjust the flow if necessary. The humidity can be checked at the pre-test exhaust port which is down here before the test to be sure that the desired humidity is not compromised by condensation within the system despite the temperature controls we've attempted to put in.

The sample test chambers are made of glass process pipe and have teflon gaskets against stainless steel end plates on both sides in here. The sample holders are stainless steel with neoprene o-rings both inside where the cartridge is sitting inside of the holder, and against the glass wall of the chamber. Both the holders and the sample chambers can be replaced to accommodate different size cartridges.

A sampling port with a silicon septum for syringe insertion is position on the sample chamber downstream from the cartridge position. The effluent from the tests is conducted through plastic tubing to an exhaust hood.

The chemical challenge may be either gaseous or liquid or both at the same time. A syringe pump can be calibrated to deliver the required concentration of the liquid chemical. The compressed gas cylinder of the challenge chemical with a regula-

tor can be set up to deliver the required concentration of the gaseous challenge chosen.

There is a sampling port located downstream of a three (3)-way valve where samples of the challenge chemical mixture can be taken and analyzed before the test is begun to be sure that the delivery rate is correct. These measurements should, of course, be taken before the test is begun and at the end of the test to ensure continuity. A sample should also be taken from each sample chamber before beginning the test to ensure that there is no interference from pre-test contamination of the test chamber.

There is a mixing chamber here to ensure the uniform distribution of the chemical challenge in the challenge air. The desired concentration and the nature of the chemical challenge is determined by the customer. The test is begun by turning a three (3)-way valve so that the challenge chemical mixture flows through the sample chambers. Samples can be taken at five (5) minute intervals, fifteen (15) minute intervals, your choice, for the duration of the test period, which is also determined by the customer.

Samples are taken with an airtight sampling syringe equipped with a shut-off through the sample ports in the challenge chamber. The syringe is inserted into the septum and the plunger is withdrawn and pushed down several times to be sure that a representative sample is taken. The syringe is then taken to a gas chromatograph for analysis using the NIOSH air sampling methods for analysis.

It's basically a simple system and it has a lot of flexibility at this point. You can choose whatever type of detection system you'd like, and it works. It gives us repeatable data, and usable data.

The reporting should include some of the following. It should of course be test ... and some sort of QC done on the procedure. The cartridge type should be reported, and any prior conditioning of the cartridge needs to be reported. Some of our customers have requested that we pre-condition the cartridges against specific humidities before starting the test. The chemical challenge and concentration needs to be recorded. The test temperature and humidity, and the detection limit achieved by the chemical analysis. We also need to tell the customer the breakthrough time for each cartridge at that detection limit so that they can see how much variability there is, and also to judge when the chemical first goes through.

Then, also, a penetration curve should be provided that is set up in parts per million versus time after the initial challenge. This is the form that would be most useful to customers who are trying to meet PELs or decide, at least, what level of exposure their people are going to be seeing.

This system allows us to test a particular model of respirator cartridge against a specific chemical challenge while controlling the temperature, the humidity and the air flow. There are some problems, of course. The highest humidity condition that we've been able to achieve with this system without getting

condensation is ninety percent (90%). We can conceive of workplaces that go all the way up to a hundred (100). We'd like to automate the sample analysis and data acquisition so that the sample interval can be reduced, and then we would have a more complete set of data. We're on the verge of doing that.

However, we're achieving already useful and repeatable results at this time, and some of our results would have been impossible to predict just using the NIOSH approval. The value of this test is that it's simple, it gives results in units of parts per million and time which are usable by the unsophisticated respirator user. It's affordable and the results can be obtained in a reasonable amount of time. The user can stipulate worse case test conditions and use the results to make critical decisions about actual workplace applicability of a particular chemical cartridge against specifically tailored chemical atmospheres and environmental conditions. They can decide between different cartridges or they may decide that a cartridge really isn't appropriate in this case and we need supplied air, an SCBA, or something else. Thank you very much.

GWEN STRICKLAND-CID: Any questions?

DEBORAH NELSON: Have you been able to test this against any mixtures like you might find in paints or lacquer thinner compounds?

SUZANNE PINETTE: Not that. We have done other mixtures and there have been very interesting results. I'm not able to present most of my results because they've been done for custom-

ers, but we'd like to do some studies and I think we're going to write some proposals to try to get this a little bit more well defined for the public.

JERRY SHERWOOD: Your diagram of the test rig shows a very narrow bore tube inlet into the test chambers. Do you have a defuser to assure a fairly uniform flow rate through the cartridge?

SUZANNE PINETTE: That drawing was done by one of my technicians and it's really not very accurate. I think the tubing is about seven eights (7/8) of an inch or something. No, I don't have a defuser in there.

JERRY SHERWOOD: Then you might not get uniform velocities through the cartridge itself?

SUZANNE PINETTE: That's possible. I'd like to talk with you about it.

JAY PARKER: Are you testing three (3) cartridges at the same time?

SUZANNE PINETTE: Uh-huh.

JAY PARKER: Why three (3)?

SUZANNE PINETTE: Well, it gets you some--it gives you three (3) replicates under the same conditions and you eliminate doing them in series--the problems that doing them in series--we find that the cartridges are very consistent one to the other.

JAY PARKER: So you are testing really one (1) at a time, but you have three (3) going at the same time. You're measuring the breakthrough to each--you're not combining the three (3)

cartridges, you're measuring individual ... for each cartridge?

SUZANNE PINETTE: Yeah, that's right.

JAY PARKER: But cartridges are normally used in pairs, so what do you do with your data, do you adjust it for that?

SUZANNE PINETTE: The thing with this is--and the beauty for me really--I don't make any decisions about application. I'm just telling them this is how this cartridge behaves under these conditions, and what you want to do is make some inferences about how it's going to work when you put two (2) or three (3) of them together. You know, some cartridges and canisters get used in triplicate--in threes (3s). I'm trying to keep it simple and give them some information about the cartridge itself and how it behaves.

GWEN STRICKLAND-CID: Just so the record is correct, Mr. Hack's paper will not be a part of the transcript for this conference. We're now moving into our last presentation by Trenton Niemeyer of FILCON Corporation to discuss the reinstallation and justification for using lab face fit testing as the principal means for respirator selection.

TRENTON NIEMEYER: Good morning. My name is Trenton Niemeyer. I represent FILCON Corporation. As it has already been stated the topic of my presentation is reinstallation and justification for using laboratory face fit testing as the prior means for respirator selection.

Three (3) years ago NIOSH held public hearings to obtain comment on its proposed rule making 42 CRF Part 84. At the time

of the meetings conversations with different manufacturers and other interested parties revealed that a great deal of confusion existed regarding why the industry was making its proposal. Speculation abounded and the majority of comments voiced were mainly objections over procedural issues.

As the weeks passed following the hearings the story unfolded. Workplace testing by Myers, Nelson, Dick and Campbell and others clearly showed that protection factors generated by laboratory face fit testing were artificially high, and in many instances did not correlate with workplace fit testing. Laboratory fit testing, therefore, was to be discarded. NIOSH went further and proposed that manufacturers conduct workplace testing to determine acceptable protection factor which could be assigned to each individual respirator style. This protection factor would then be a guideline which respirator users could use in selecting an appropriate respirator.

FILCON analyzed the scenario not only from the standpoint of what was the best way to design and present our respirators, but also from the viewpoint of product liability. We, as a manufacturer, do not only have to comply with NIOSH test procedures where there's at least some definition, but we must also safeguard against liability lawsuits which is an entirely great area. Any statement regarding an assigned protection factor which might appear on our labeling must, therefore, have a solid empirical basis and be fully supported.

After a lengthy analysis FILCON came to some conclusions

which I'll share with you up front. These were collectively defined--these issues collectively defined--a direction which we believe the respirator industry should pursue.

One, first any attempt by NIOSH to assign a generalized protection factor to a specific respirator is inherently dangerous. It could create a false sense of confidence in the user and foster misuse. To a certain degree this seems to echo previous comments made at this conference that face fit testing, at least for this purpose, does not belong in a certification process.

Two, the state of the art in face fit testing is still in its infancy, and considering the differences in opinion which have been expressed again at this conference, there seems to be some support for that statement.

Three, due to the first two (2) conclusions the only current way to ensure that respirator wearers receive adequate face fit protection would be through individual testing.

Four, the principal means of testing should be laboratory face fit testing, because with potential modifications in the protocol it will represent a completely controlled environment. This recommendation assumes that a final reconciliation between laboratory and workplace face fit testing occurs, and the elimination of the polarization which currently exists.

Five, laboratory face fit testing will correlate positively with workplace testing if a margin of safety of twenty five (25) times the fit factor--twenty five (25) times between the fit factor and the assigned protection factor--is incorporated into

the laboratory face fit test results. Now this twenty five (25) times level right now is an approximation on our part. That we can see information in the literature which suggests that this level could be downgraded to in the neighborhood of seventeen (17) to eighteen (18) it could also be upgraded to the neighborhood of thirty one (31) to thirty two (32).

In making these conclusions we realize that there are several major issues with which to contend, and we would like to address these presently. Probably the most important issue is the reconciliation between workplace and laboratory face fit testing.

In attempting to sort out this mess one fact hit us almost immediately. Neither NIOSH nor anyone else appears to have attempted a reconciliation of the two (2) methodologies. At least we cannot find any information to the contrary. Laboratory testing appears to have been discarded without proof that the methodology was inherently defective. The only justification appears to be a lack of correlation between the two (2) test methods. We believe this effort was premature. The only thing that was proven that one particular form from amongst a whole series of possible protocols was shown to be defective. No consideration seems to have been given to the possible repairing or modifying of key parameters in laboratory face fit testing to make the method a better evaluator of actual worker face fit.

Furthermore, there has been no proof that workplace testing is the definitive methodology. Workplace testing seems to have

been given a preference solely because it yielded a more conservative data and more conservative data was a safe haven in the face of uncertainty. The situation left open the possibility of whether laboratory face fit testing could be modified to make it consistent or at least correlate with workplace testing.

We looked at Warren Myers' work on the use of PAPRs. There was a correlation to a degree that workplace tests were consistently lower than those generated with laboratory testing. The correlation was low but at least it was positive. This gave NIOSH the basis for downgrading the assigned protection factors from one thousand (1,000) to two twenty five (225).

In the case of negative pressure respirators the situation had completely gone askew. A study by Lenhart and Campbell show absolutely no correlation between the two (2) methods when the sample was viewed as a whole. Variance in individual test results showed an apparent negative--put negative in quotes--correlation in some cases, and a positive though very weak, correlation in others. Workplace testing levels ranged from ten (10) to over forty thousand (40,000). ... the assumptions in the study show that the laboratory testing was used to pre-screen the test subjects. Minimum acceptance criteria for inclusion in the study was two hundred and fifty (250). The only approach with such divergence in this information was to break down the results further and analyze them separately. We arbitrarily separated the results in two (2) cases and decided to deal with the negative correlation as a worse case scenario. This case showed a

twenty five to one (24:1) ratio between laboratory and workplace testing. The only significance we assigned to this value was that it was a point for comparison.

Why the difference? To answer this question we started to compare individual parameters common to both methods, and without going into a lot of detail, we discovered two (2) possible errors in one (1) area which if applied laboratory testing would provide a basis for correlating the two (2) test procedures. One of these areas was the absence of any means to measure and/or control the user level of inhalation. How much air, for example, was inhaled in the deep breathing exercise of the NIOSH quantitative protocol? Did the deep breathing truly represent the maximum amount of air that a test subject might inhale under any circumstances? There was no way to tell, and furthermore, there was a real likelihood that the answer would be no.

For example, West, in his Essentials of Respirator Physiology reports existence of two (2) independently functional compensatory drives which can trigger hyperventilatory responses, but which are both dormant when the subject is at rest. Foster, et al. in The Lung indicate that at maximum expansion the diaphragm is inhibited if a test subject is sitting. Dr. ... Wassermann, a leader in respiratory exercise testing has reported increases in vital capacity to levels of in the eighty five (85) to ninety percent (90%) range--which is considerably higher than the normal seventy percent (70%) which has been assumed in the past--of the total lung capacity by well-conditioned athletes. All this

information forced us to consider the upper boundary of tidal volume as the only way to begin quantifying the importance of an inhalation rate.

Specifically, we began looking at the ratio of the mean tidal volume that anaerobic threshold to the mean tidal volume at rest. ... a mean tidal volume at anaerobic threshold which is the same as vital capacity ranged from forty eight hundred (4,800) to six thousand (6,000) milliliters. A few extreme cases even showed values as high as eight thousand (8,000) milliliters. Major variables contributing to this high upper boundary included age and body surface area. Males in the twenty (20) to thirty (30) year old age bracket, for example, showed a significantly higher maximum intake capacity. Vital capacity, however, decreased rapidly with age. The wide range of this variable, therefore, could be a major contributor to the inter-subject variability of generated individual protection factors. Total body surface was also shown to be significant and had a similar wide range of values.

We then began to hypothesize. If a tidal volume of four hundred (400) milliliters was used as the measure of air intake for a subject at rest, and a mean tidal volume at anaerobic threshold of six thousand (6,000) milliliters, the ratio between these values is fifteen to one (15:1) and explains, at least in part, the twenty five to one (25:1) ratio between laboratory and workplace face fit testing in our worse case scenario.

If we chose the upper boundary of the tidal volume distribu-

tion at anaerobic threshold to be certain that all test subjects are included, the ratio grows to twenty to one (20:1). Another error contributing to the difference in the twenty five to one (25:1) ratio, we believe, is the present composition of the face fit formula used to compute a protection factor based on the five (5) exercises of the NIOSH protocol. Four (4) of the five (5) exercises are performed at rest. This creates a weighted average which favors a higher protection factor. If the formula were restructured to provide a weighted average evenly distributed between the protection factor recorded at rest and the protection factor at 'maximum deep breathing' the increase in weighting would cut previously generated laboratory protection factors in the neighborhood of fifty percent (50%). This situation alone could help explain some of the remaining difference between that twenty five to one (25:1) ratio.

Our hypothesis continued to grow, but did not explain why there was such a wide variation in the workplace protection factors. Judging from the data we reviewed, however, we believe that the wide range workplace protection factor shown in the Lenhart and Campbell study is partially a reflection of the wide range of possible inhalation rates in humans.

FILCON is the first to admit that a formal study is necessary to prove this belief. All that we are doing here is exploring some possibilities. This, I believe, is one of the purposes of this conference. One of these possibilities is that exercising is a permanent set of variables that has been, in fact,

previously excluded from face fit testing and could be a key factor in reconciling the two (2) test methodologies. Our work to date has been focused on that area and has been limited to a literature review. However there is enough information in the literature to form a valid hypothesis and give direction for future research.

FILCON recommends that NIOSH re-examine this dimension and keep open the possibility of using laboratory face fit testing. As I listen to what has been said at this conference I am becoming more convinced that the only way to really attack this problem and reconcile the two (2) methodologies is to do a parameter by parameter study between the two (2) methods. Part of the study should require that the parameters are duplicated in each method so that the number of different parameters can be narrowed and analyzed for relevance.

Moreover, we recommend that NIOSH consider collecting physiological data during workplace face fit testing. Until this is done, collected data that excludes a quantification of physiological variables will be applicable only to the specific test subject in his or her specific work environment for a specific job function. Any generalization of this information beyond this level would be dangerous. The fact remains, the same problem that adversely affected laboratory generated test data also affects workplace generated test data. There are no means to measure and/or control the level at which air is inhaled into the face mask. From a practical standpoint there is a question of

how to do this. We recently saw an ad for a portable exercise tester which straps to the users chest and which is made by an Italian firm whose name--and I have to apologize for this--I don't have right now, because the brochure that was sent walked off from my desk. I promise however, I'll be able to get a duplicate copy and sent it to NIOSH at a future date. The tester contains a sample pump, a micro analyzer, and a transmitter which broadcasts continuously to a receiver and data storage holder located nearby.

The tester is intended to monitor physiological parameters of athletes. A quick review of the brochure, however, suggested that it would be easy to modify the unit for face fit testing procedures. Also, while on the subject of equipment, we suggest that NIOSH take a look at the totally automated cardiopulmonary analyzer manufactured by Medical Graphics Corporation of ... Heights, Minnesota. Different models ... but most provide a real time breath by breath analysis of all pulmonary parameters. One unit goes so far as to provide real time competition feedback from a hundred and forty four (144) parameters.

Two (2) final thoughts on laboratory face fit testing. One is that even if laboratory and workplace face fit testing are eventually correlated, laboratory testing should be given preference as the primary face fitting procedure. The preference is purely practical. We believe that reconciliation would acquire stress testing an anaerobic threshold to yield comparative results. Stress testing of the average plant worker could cause

unexpected adverse consequences and open the door to potential liability. Modification of the current NIOSH protocol to include a twenty five (25) times margin of safety may be the only practical way to dealing with this problem.

The other thought has to do with obtaining acceptance by employers of the idea of doing individual face fit testing. Conversations with Nelson Lydell, he expressed a concern that employers would simply ignore this requirement. After reflecting on this I submit that the issue in one partly of our own attitudes. If we, as respirator professionals, don't take ourselves seriously about individual testing, who will? A quick comparison between face fit testing and eye examinations indicates that the issue may be one of expectation. No one thinks twice about conducting individual eye exams. Why shouldn't respirator face fit testing eventually be given the same status. Think about it.

The next issue I would like to address is the limitation of the U.S. Air Force test panel grid as a basis for selecting test subjects for workplace protection factor studies. The adoption of this system was based on the recognition that no singular face piece could fit everyone and that the grid system was an adequate means to classify the test subjects. Implicit in this recommendation was the assumption that if a wearer whose face and lip lengths matched the same face and lip lengths which defined a particular stratum, and who achieved a 'satisfactory' face fit during a workplace protection factor study, then everyone whose facial measurements fit into the same category would automatical-

ly achieve the same level of face fit.

FILCON disagrees with this assumption. The anthropometric panel grid is not basically wrong, it's just incomplete. Analysis of various data sets of protection factors shows that the range of protection factors within a particular stratum was considerably larger than the range of mean protection factors between adjacent stratums. Clearly something was missing and this is the third dimension.

Defining the third dimension proved to be really challenging. It became clear that no single value could adequately serve as a universal measure. This forced us to look at the third dimension as a set or protrusion points extending from and perpendicular to the ridge of an enclosed endless loop. Further analysis showed that a set of troughs that existed between each of the protrusion points had to be added to the set of protrusion points it a complete set of potential leakage sites were to be defined.

This concept led to a model of the human face. If we look at protrusion points, say for a half-face mask, we're looking at six (6) major points. The ridge of the nose and cheekbones, the jaw area, and possibly the chin. If you add the number of troughs in between you're looking at a potential leakage site of twelve (12) possible points. In the case of a full-face mask we're looking at the forehead, the temple crest, again the cheekbones, the jawbones and the chin. The total number of leakage sites here would be a sixteen (16).

Face fit could then be explained if we consider a facepiece as a similar rim with the same number of potential leakage sites. Mathematically perfect face fit could be expressed as a one to one (1:1) correspondence between all points on both rims when the rims are in contact with each other. Face mask leakage consequently is directly proportional to the number of contact points disengaged. Since leakage could occur at a singular site or at a combination of leakage sites, the number of possible combinations is extremely large. This fact makes it impossible to adequately categorize an individual in a particular stratum of the anthropometric grid because the stratum itself is not sufficiently categorized. There is simply no basis currently--there is no current basis available--to adequately define this third dimension. Because of this fact any assignment of a general protection factor to a particular face mask style would be risky. Under these circumstances workplace protection factors would also have to be diminished. Workplace protection factor studies could only yield valid test results for the subjects participating in the test. This information consequently supports a case against generalization and for individual testing whether results are generated by laboratory or workplace protection factor testing.

A third issue is the effective dead space that occurs from extended use of respirators throughout the work day. Dead space deals with carbon dioxide buildup inside the mask. Dead space causes hyperventilation and hypoxypulmonary vaso constriction. That is, cardiac stress. The effects of dead space accumulate as

the day progresses and demands some sort of relief. We have heard comments, I believe Ching-tsen Bien mentioned yesterday about the doctors putting a limitation--correct me if I'm wrong Ching--on the amount of time that workers could be tested. Is that correct in the . . . ?

CHING-TSEN BIEN: Temperature and humidity.

TRENTON NIEMEYER: Temperature and humidity. Okay, maybe I'm mistaken. It is proposed that this response must be controlled if workplace protection factor studies are to yield accurate exposure estimates. To do this workers must be monitored continuously during the test to make sure that the face mask is not removed. When it is possible to do this we submit this action will force the subject to reduce his or her work rate in order to conserve available oxygen. Air intake will be reduced and this will create a distortion of the test results. Like it or not, extended test durations will not provide accurate results until such time as some sort of dead space compensation is introduced. Until then shorter test durations are recommended and this suggestion pushes workplace testing closer to laboratory face fit testing.

Now time and terms--what ... involved with--I wanted to get into such issues as the mathematical inconsistencies of using log normal distributions for quality assurance and the elimination of all qualitative face fitting for respirator selection. I'm going to have to roll it up into another day. When I . . .

TRENTON NIEMEYER: . . . invitation to come to this conference I was real pleased, and my enthusiasm got the best of me. The last forty (40) days with the exception of Christmas has been fourteen (14) to sixteen (16) hours a day. Anyway, we do what we can.

We also believe that individual testing should be looked at from the macro level. The use of statistics to make generalizations based on sample test results leaves open the possibility that at least part of the time wrong decisions will be made. You have for example a ninety five percent (95%) probability assumed with a ninety five percent (95%) confidence level, does this mean that five percent (5%) of the time a mistake will occur? If so, what does this mean for the individual industrial worker?

If we consider the population of respirator wearers to be conservatively estimated at one million, potentially fifty thousand (50,000) workers could be effected adversely by the use of statistical decision making. That's a lot. Philosophically the use of statistics should have some limits. In the absence of alternative basis for making decisions, statistics seem the best way to handle uncertainty. However, in the case of face fitting individual testing could yield a higher rate of certainty. We believe the individual testing should be given a preference on this basis. Okay, that's it. Thank you very much for the opportunity to express our opinions. Questions?

GWEN STRICKLAND-CID: We've completed all of the presenta-

tions scheduled and we are ahead of schedule. I'd like at this time to get a show of hands of those who plan to come back for the discussion. You may want to opt to do your open discussion now as opposed to coming back after lunch. Does anyone plan to come back after lunch for the open discussion? If so, please identify yourself.

We'll open for floor now. Dr. Campbell, would you come forward and he fill facilitate the open discussion until such time as you feel ready to leave.

DONALD CAMPBELL: The contention of the open discussion period was simply to give you participants an opportunity to provide additional comments that you may have in response to presentations that you've heard today or over the last couple of days. So if there are any interests in expressing additional comments that you may not have originally planned to provide, or comments or questions in response to things you've heard. There has been a good bit of opportunity during the presentations for individuals to ask questions from the floor, so maybe all of that discussion has already occurred. So I ask if there is any interest or any particular additional comments any of you would choose to make at this time?

JERRY SHERWOOD: I wonder if I might be permitted to make one (1) point. I know I'm here as an assessor and therefore very neutral, but I've played with respirator fitting since 1950. We published in the 1950s the first description of a penetration through a facepiece, and controls to prevent that happening.

Later we were involved at the same time as Les Silverman and Bill Burgess were working in the United States we were working in the UK with problems in the atomic energy industry where we had severe respirator problems in handling of plutonium. The cause of this became quite clear in that the particular procedure at the manufacturing plant was that the workers were allowed a discomfort allowance when wearing a respirator.

Accordingly, whenever they entered the area a clock entered the time they went in and recorded the time they went out. Nobody paid the slightest attention to the state of the respirators, which in fact were a type--an old war service mask type--where there was not individual fitting on each occasion, but the mask had standard elastic straps, was just put on, and these having been laundered many times generally hung on the chest rather than on the face.

Similarly, having been laundered many time, there was nearly as much plutonium on the inside of the mask as the outside. And so we got right at the start the vital need to have a proper program of control on respirator usage. We borrowed one of the earliest AEC Harvard blown respirators and what we found there was that if you inhaled deliberately fast you could always beat the pump. That is the message that still remains today somewhere thirty (30) years later.

Because of this problem we felt that the only solution was to provide a blouse with headpiece and the chest being covered in a single bag rather than just a head covering. The significant

thing about this is when you breath in your chest comes out. So the volume of air needed to meet peak demand is not increased. We found you could get a much better protection with a blouse, tight fitting around the waist and fitting at the wrists, than you could with any head covering. And I would commend to you again the value of using a blouse rather than just a headpiece for a PAPR type device. That's all I want to say on this one. Going negative is critical in any positive pressure system.

DONALD CAMPBELL: And, in fact, some of the earlier work-place studies on PAPRs where the measured workplace protection was less than was expected some have suggested that was the result of over breathing the blower on the apparatus.

Any other comments? Everyone is worried about the weather reports.

TRENTON NIEMEYER: All through the last three (3) days I've had an uneasy feeling that we're looking for specific directions. There has been a lot of interesting presentations made, a lot of good contributions. But eventually all this has to sift into one (1) or more specific directions. What's going to happen down the road and how is information going to be utilized to maybe formu-late some tentative proposals? Is it going to show up in 42 CFR, or is it going to be some separate avenue?

DONALD CAMPBELL: I think the focus of this meeting is regulations and so they would show up in that form. As we mentioned earlier there probably are a couple versions of those regulations, and NIOSH is planning now to go forth with a version

of the regulation that does not include workplace testing. And the purpose of this meeting is to address the next version which will hopefully include some resolution of the topics that we are discussing today. And the basic driving force behind that is simply a concern of the institute to have a high degree of confidence in the performance that's provided by respirators that NIOSH certifies. So I--I mean, that is the bottom line question of all of this, and that's the focus, and that should be the direction in which we're heading. How do we assess the performance of respirators? Now there are a couple aspects of that. One is are they used properly and maintained and is there an appropriate respirator program? The other aspect of it is, if they are used properly, are we confident that those respirators that are used properly are going to provide the expected level of protection. And that is the focus of the certification program and the focus of our concerns here.

TRENTON NIEMEYER: Has the latest draft of 42 CFR been published?

DONALD CAMPBELL: No, no it has not. There was a first proposal made, and there is a second version of that proposal which is about to be published. And don't ask me what about to be published means. It will be soon.

TRENTON NIEMEYER: Then it's reasonable to assume there will be more issues coming up and the need for maybe another conference down the road.

DONALD CAMPBELL: Well, sure. The next thing that is likely

to happen--there are two (2) parallel paths here--one regulation would involve the version of the regulation that does not include respiratory protection, and that is the version that is soon to be published. This public meeting is a pre-rule making activity that would be followed by--somewhere down the road--a proposal for another version of regulation. So that would be the next step in response to this meeting.

GWEN STRICKLAND-CID: I don't think we should say soon. I don't know that we have any kind of time table. So we don't get anybody's expectations up.

DONALD CAMPBELL: I understand, and I suspect everyone else understands that, too, yes. Okay, thank you very much.

(Whereupon the conference was adjourned.)