

Critical Issues Conference On In-Facepiece Sampling

PART 1

International Society For Respiratory Protection and National Institute For Occupational Safety and Health

- PROCEEDINGS -

Tuesday, January 8, 1985

Mr. Wilmes: Welcome to the ISRP/NIOSH sponsored critical issues conference on in-facepiece sampling. My name is Don Wilmes. I am the president of the International Society for Respiratory Protection. In a few minutes you will be hearing from John Moran, director of safety research at the National Institute of Occupational Safety and Health, who are cosponsoring this conference.

Without going into detail that will be covered in later presentations, I would like to briefly discuss the purpose of this conference and why I feel this subject is a critical issue. I first became aware of the issue late last summer during one of my visits to NIOSH in Morgantown.

Warren Myers, from NIOSH, discussed with me some of his preliminary findings and demonstrated his experimental procedures. Some of this information has been reported at the American Industrial Hygiene Conference earlier last year. This preliminary work was very impressive and I continued to follow Warren's experiments.

In late October of this past year, at the Lawrence Livermore National Laboratories, I was told of corroborating work done by the Health and Safety Executive in the United Kingdom. Although the work was done completely independent of the NIOSH research, the same inferences and preliminary conclusions were drawn. This research was done by Bob Bentley's group and will be also presented later today.

At this point it became obvious to me that a conference should be held to discuss this matter. The primary researchers agreed to participate and

NIOSH volunteered to cosponsor this conference.

In addition, several other interested parties have done some relevant work in this area and you will be hearing from them also later in the day.

Our Society's charter provides that we perform a professional educational function, a free and open exchange of information. My preliminary input concerning this issue is that it is a highly controversial one. The ISRP is not a consensus organization, nor does it have a position on this issue, other than deeming it important enough to hold this critical issue conference.

Before any issue can be properly resolved, it must be clearly understood. The purpose of this conference and our Society is to provide a forum from which an exchange of information can lead to the necessary understanding of the issue.

Now, before I introduce John Moran, from NIOSH, I would like to discuss a few of the administrative aspects of this conference. First, you will notice a great deal of microphones around this area. The conference in its entirety will be recorded and transcribed and proceedings will be published as proceedings of this conference. The lady sitting at the table is responsible for providing us with a transcript. In order that a good transcript be produced, it is necessary that all discussion and comments coming from the audience be made using the floor microphone. While we are a small enough group that we came probably discuss it and hear each other, unfortunately, it cannot be recorded unless you use the microphone. I would like to ask each of you during the discussion period that you come to the microphone, identify yourself and proceed with your questions or discussions, whatever.

Also to promote free and open

discussion, it is understood that all comments from any individual represent that of the individual and not necessarily the organization which they represent.

During lunch break you will be on your own. There is a fairly good restaurant -- a good restaurant next door and there are also some within several blocks of this area.

We will attempt to stick fairly close to our schedule, however, if discussions after the presentations should become lengthy, we do have a scheduled 45-minute period which we can extend into. There will also be a coffee break later this morning and one this afternoon, with refreshments provided.

At this time I would like to ask John Moran to come forward.

Mr. Moran: Thank you, Don. We, at NIOSH, are indeed pleased to cosponsor this activity. We believe it's important on matters such as this, and the type of work that is being generated by the basic research that is going on in our laboratories and others on matters of this potential importance, that information be provided to audiences and individuals such as yourselves and in early time, rather than waiting the year or two required to get this type of information documented and published in peer review journals.

NIOSH and DSR have been doing - started a little over two years ago a fairly large amount of research in the respirator area. Most of this is fairly basic. The work that Warren will be talking to you about this morning that we are doing is only one program of several that we have under way. I anticipate we may have future conferences such as this to talk about these issues.

It is interesting that we began in this country using quantitative fit some 25 years ago and we only are now beginning to deal with the issue of probe bias and probe location. We are hopeful that this type of work and this type of an

interchange will begin to focus our attention on the important and critical issues involved in these overall aspects of respirator programs and, in keeping with revisions to Part 11 which we hope to get moving this fiscal year, will, indeed, put us in the future in the position that NIOSH has taken in that regard, which is to more fully assure that respirators which are certified by NIOSH and MSA, indeed, provide to the user that which they expect.

So we are, again, pleased to be here and hope that we will have a vigorous discussion of this issue and that we can identify those areas of research that need to be pursued further on this matter to really permit us to get a handle on the magnitude and the potential implications of this problem. Thank you and welcome.

Mr. Wilmes: I guess we are ready to begin--

Mr. Billings: I have some overheads.

Mr. Wilmes: You have some overheads? All right. Initially we are going to begin with a small history as to how we arrived where we are today. Charles Billings, of Johns Hopkins, will present some of the unpublished work done at Harvard under the Atomic Energy Commission contract.

Mr. Billings: Thank you very much, Don. I appreciated it. When I got the notice from Don of this conference I sent back my \$20.00, as most of you did, and I wrote down on the bottom of the page -- it asked if we had anything to present, and I said if Bill Burgess wasn't going to be in the room that I would be pleased to present some of the early work that was done at Harvard.

On the in-facepiece sampling. How many people in the room know Bill Burgess? Okay, a few. How many people belong to the American Industrial Hygiene Association? Again a larger number.

Okay, so for some of you who have a little snow on the roof like I do, this will be a repetition of some work that you are familiar with. For something like 50 percent of you, who are relatively new to the field, it will represent, I hope, a brief review of what happened, as John pointed out, about 25 years ago which bears on this problem.

Now, the Hopkins interest, as you may know, is that we have contracts or have had contracts looking at specific aspects of respirator testing. For example, we are concerned with quantitative fit testing. We have just had a review of quantitative fit testing parameters, and so on, and some work in that area, and also characteristics of leaks of various kinds.

So what I am going to be telling you about is not the Hopkins program specifically but earlier work that was done in my laboratory and other laboratories at the Harvard School of Public Health back in 1959 and 1960, about 25 years ago. And it bears on this specific problem of in-facepiece of mask cavity sampling. As Don pointed out, it is a sort of a basic review of the thinking of some 25 years ago.

Now, those of you who are familiar with the business know that in 1960, if you cast your mind back to about 25 years ago, in 1960 the respirators were tested by the Bureau of Mines schedules and I don't remember the numbers. But they were essentially tested with regard to things like silica and lead fume on head forms. They were essentially head form tests and the clouds were generated in chambers, and the device performance was tested with regard to, for example, the characteristic performance of the filter element, say -- something like that.

At least in my understanding, there wasn't any way of testing quantitatively the performance of a respirator on an individual's face. And those same Bureau of Mines schedules which later, of course, were brought into MSHA and brought into NIOSH -- the certification was for substances not significantly more toxic than lead. And I think those schedules, 21B or whatever it is, 16, they say that today, that the concern of the development was materials which were not significantly more toxic than lead.

All right, then in 1940, '45, '50 the Atomic Energy Commission was formed to develop the technology associated with atomic energy and one of the first important characteristics of that, after we figured out what some of the problems were going to be, was that a lot of the materials that were going to come into laboratory use and other uses were going to be a lot more toxic than lead. For example, beryllium is of the order of 100 times more toxic than lead; and plutonium is 10^9 or 10^6 and polonium is 10^9 more toxic than lead.

And so there was put together a respirator advisory committee and Ed Hyatt and Les Silverman and maybe some of you in the room were on that committee to come up with a guideline for the kinds of respirators that the Atomic Energy Commission needed for these materials which would be significantly more toxic than lead. And this led to the development of a

proposal by the Harvard group under Les Silverman -- again, many of you or some of you probably knew Les. He died, unfortunately, in 1966 at the age of 51, right at the peak of his career in a sense.

At any rate, he put together a program for support by the Atomic Energy Commission and it was a continuation of some of the work that was going on in air cleaning. The objectives of the study were to develop performance factors with regard to fit and leakage for respirators that currently existed. We needed some information on performance of devices that were presently available.

Early work had indicated that there might be some substantial leakage but there wasn't a great body of data on that, that is, developed respirators on people's faces. In order to do that it was necessary to develop evaluation procedures that could be used on workers for the determination of performance under work conditions. Does that all sound very familiar? Reminiscent? That is exactly what this meeting is about, isn't it? -- 25 years ago -- and then to go on and evaluate existing equipment, the sort of thing that NIOSH has been doing and some of you also have been doing in various groups; and finally develop and evaluate a new respiratory protective device which would be effective and comfortable.

So those missions, if you will, or the objectives of that program, which was set in place in late 1959 at Harvard, are pretty much the objectives, and so on, of the respirator developments in the United States today. We still have the same kinds of questions.

Now, in order to do that, Bill Burgess and Les Silverman and Felix Stein and to some extent Mort Corn worked on developing a set of procedures for doing the respirator evaluation. This led to the development of a number of respiratory protective devices. The outcome of that, as many of you probably know, was the device that was marketed finally by MSA, that is, the powered purifying air respirator in the United States.

So that led to a ten-year -- roughly a ten year period which ultimately ended up in a product, although it didn't start up exactly product-oriented. It ended up with that concept of powered air purifying respirator.

The first transparency shows a little bit about the concept, if you will, of the device. And these are taken directly, as was mentioned, from some unpublished and published work. For example, much of what I am going to tell you is in the

American Industrial Hygiene Association Journal, Vol. 22 in 1961, by Burgess, Silverman and Stein, called, A New Technique for Evaluating Respiratory Protective Devices. So all I am doing really is reviewing what was being done at Harvard.

The concept then is we want to sample the performance of a respirator. It had never been done before. And we would like to know the actual performance protection provided. So let's sample from inside the cavity -- a new concept. It had never been done before -- very, very limited, with the exception of biological warfare information, that is, the people at Frederick, at Ft. Detrick, had in fact developed an inmask sample by 1960 but for B. Globii, for a specific biological agent. Apart from that one technique, there had been no attempt to develop any formal way of doing inmask or doing respiratory performance when people were wearing them, in a quantitative sense.

The principle of the method is shown here. Let me follow this through, the respirator is put on the subject. The subject is put in an exposure chamber, and we will talk a little bit about that for a moment. There is a sampler in the exposure chamber. The exposure chamber actually was a head dome or hood helmet arrangement over the top of the head of the subject. The sample samples from inside the exposure chamber. So there is an open face filter holder sampler sampling from inside the chamber. This samples 100 percent of the time, passes through a critical flow orifice to a vacuum pump. So you are sampling on the order of a liter a minute constantly from the chamber. There is nothing new about that at all. That is essentially an accepted procedure. No one would argue about that.

In order to find out the leakage a filter was placed inside the respirator cavity, a small diameter, about a one inch diameter filter was placed in a special filter holder down inside the cavity. And the next slide should have a little more detail. But in any case, this was sampled by a valve arrangement which allowed a sample to be taken in the same sense through a critical orifice to that vacuum source. But that sampling was configured in such a way that it only sampled on inhalation. We were concerned with leakage and the consequences of that leakage to that worker so sampling was provided only on inhalation, and how that was done is shown in some later slides.

So, if you will, you have - If you can imagine this and there are some pictures

later on -- you have a worker with a respirator on, a subject with a respirator on, and there is a hood over the individual's shoulders of transparent plastic. Aerosol is provided to that and a sample is taken from that outside the subject in the chamber and another sample is taken here during inhalation only.

Okay, the next transparency shows some details of the in-mask cavity filter holder. This is one inch in diameter. This is an inch in diameter. This is 3/16 of an inch thick. And it is connected to a small diameter hypodermic needle so instead of using what is now common, a bulkhead fitting through the cavity, what was done was, this filter holder was assembled, a filter was placed here, was screwed together. It was shoved in from inside the cavity so that the needle stuck out through the front of the facepiece. And it was located in general in this area here, that is, between the nose and the mouth.

I don't know that there was anything done of the type of looking at specific locations. Again, Bill Burgess would know in more detail what he actually did with regard to location. But in general it was placed - it couldn't be placed near the nose, it has to be placed in this area here, where there is a little bit of space, big enough to get that in.

So we are looking at sampling directly from the concentration that exists in the cavity only on inhalation. So you are seeing only the inward leakage. You are not sampling on exhalation.

Okay, the next transparency I think shows a schematic of the exposure chamber. As I mentioned, this is simply cylinders of plastic. An aerosol was brought to a plenum chamber at the top, distributed by a polyurethane foam uniformly over the whole chamber. It was about this big, that is, on order of a little over a foot in diameter and about this high. Again, as I said, there are some slides later on.

The aerosol was brought to the chamber. The head would be in here with respirator on it. The sampler is inside. The aerosol flows down and is extracted by means of an outer cylinder, the outer concentric cylinder, and passes out through the top. So the subject is exposed, if you will, in the head area to a uniform concentration of material at all times.

The next slide I think shows the electrical schematic, if my memory serves me correctly -- no, the next one

shows this in an early configuration. The first annual progress report shows the head dome, in this case the head form with the respirator on it, and some of the associated piping and ducting. This, of course, was held overhead and was essentially portable: it could be moved around.

The apparatus is shown in the next schematic but in general what we had was a nebulizer, a compressed air source, a flow meter for the compressed air and, obviously, a pressure gauge. A small pharmaceutical nebulizer operated at about two or three liters a minute, something like that. This impinges in series to essentially cut out the larger particles, to try to make this aerosol as monodispersed as possible but not completely uniform, and followed by a drying chamber and some flow meters associated with that. So you had a dried uranine aerosol. I assume everyone is familiar with uranine aerosol so we don't need to go into that in any detail.

This is a later configuration. This is the one that actually appeared in the paper; the first one was in the report. But this is essentially the same thing - compressed air source, rotometer, nebulizer, and impinger or two, a drying tube - a mixing tube and a drying tube and aerosol delivery to the head form. This is essentially what it looked like in the second iteration.

This is a later shot of the head dome used with a subject instead of a head form. You can see the general size of the aerosol exposure chamber, for those of you who didn't have the opportunity to see this when it was in place at Harvard. It is roughly the size of the subject's head and has pads for riding on the shoulder, at the top of the head and the top of the chamber, essentially touching. And this is a little bit more detail on the inner and outer cylinders and the aerosol supply and aerosol extraction section.

Now we are coming to how it works in practice. This is what is called the respirator sampling director. How do we sample only on inhalation? And how do we interpret that information?

In addition to putting the filter holder in the cavity and having the hypodermic needle come through to extract your sample, another needle, another hypodermic needle was placed in the cavity to sense the internal pressure, that is, when the pressure in the cavity goes negative on inhalation that sends a signal to essentially a diaphragm with a microswitch on it. It is called a Fischer Porter pressure comparator. But what it

really is, it is a diaphragm with a microswitch on it.

As you go negative, of course, on the respirator, that pressure is sensed by means of a hypodermic needle and some tubing. This, of course, is open to the room so as the cavity goes negative with respect to the room, this diaphragm moves a little bit, closes the microswitch. And this essentially activates three major components that we are concerned with. One is the sampling valve -- once the cavity goes negative we want to start sampling. So it opens the sampling valve on the sample line inside the cavity. At the same time we are concerned with the actual volume that the worker is inhaling. We need to know the inhalation volume. And that is done by what is called aliquoter, which is described in a couple of other shots later on. And finally, we want to know what volume we sampled in order to make a concentration. And that is done by means of an elapsed time indicator.

So what happens then in operation is that you install a respirator on the worker. You set up the concentration of uranine and put your filter in place, put your pressure tap in place, and then as the individual breathes in and out this sample is taken from inside the cavity on inhalation by means of the sampling valve.

At the same time the pressure signal from here is monitored so you will know approximately how much air the individual is breathing. I think that is shown, if I am not mistaken, on the next one.

Yes, this is the air flow volume indicator or aliquoter. Here is the same test respirator we saw in the first shot, in the first transparency, but with an additional hypodermic needle to sense the internal pressure. Then that pressure is led by means of a tube to the Fischer Porter precision calibrator, that is, a diaphragm with a microswitch in it. When this diaphragm closes the microswitch, when the pressure goes negative, it opens an auxiliary valve, such that air flows - this whole line is negative; the diaphragm is closed -- air flows outside through a resistance into the cavity. It is a very, very small amount of air. In other words, it is going back through this line through a very high resistance. And the amount of air that flows back into the cavity is measured by means of this soap film flow meter. That is a typical soap bubble calibrator, the kind of thing that we use now for calibrating our rotometers -- in other words, when you inhaled this went negative, pulled air from outside and the soap film moved a little bit. When the cavity went positive this line stopped, the

valve stopped -- the line went positive so the valve stopped so the film would stop.

So by measuring the length of movement of the soap film you could get an indication of the amount of flow that had gone onto the cavity, that is, the actual amount of air inspired, because this was in parallel with the resistance of the canisters or the cartridges.

That is shown here. This is the calibration of the relationship between the flow rate, the tube flow, versus pressure drop through the respirator. For example, if this is a filter cartridge, and let's assume for the moment that it is because we are using an aerosol challenge, at a flow rate in liters per minute of about 85 you have about 2.5 inches or a little over 2.0 inches of water resistance. My recollection is that, that would be approximately correct for a filter respirator plus the valve.

At the same time, at that same pressure drop, we would be pulling instead of about 35 cc a minute - at a flow rate of about 80 or 85 liters a minute through the cartridge, the normal flow rate, minute volume, we would be pulling less than 1000th of that flow through the auxiliary line in order to measure the total minute volume. In other words, we are using this aliquoter line as an index of the mean volume. The reason for that is because the intent of this was to get performance at various work rates as measured by the minute volume.

Instead of having, as we have now, for example, for quantitative fit testing a standard protocol of head motions, and so on, this was intended for use on bicycle odometers or treadmill kind of work, that is, actual physical work. What one was concerned with was the respiratory kinetics or respiratory dynamics, and that was gotten from a measure of the minute volume, which was inferred from an aliquoter volume, a minute volume of the aliquoter.

Some of the early data, shown on the slide -- and like everybody that has slides and transparencies, I apologize for the quality of the slide. Those of you beyond the first row won't be able to see the data but I brought it anyhow. And I have heard it just as many times as you have, sitting out where you are sitting. This is some of the early work that was done of three major manufacturers half mask respirators. The manufacturers included MSA, American Optical and Willson. And I suspect there are representatives of at least two of those companies in the room, if not all three.

This is some of the very, very early work that was done on the penetration. Now, what is not called protection factor, of course, was really penetration. What we were concerned with was penetration, the actual quantity or fraction of material penetrating as a function of the breathing rate. As I mentioned, the work rate, the minute volume, was one of the parameters of concern. The leakage is a function of effort, if you will, which is not, of course, addressed directly in many of the protocols that are now used. This is obviously, at least initially, a research tool.

So what we find is that -- observations of the group, Bill and Les and Mort and Felix -- is that if you get poor fit you get, in general, about one-tenth to two-tenths of a percent, that is, your efficiency is about 99.6 or 99.7 or 99.8 on this particular respirator, whoever manufacturer X happened to be. But if you got what we call poor fits this went up by an order of magnitude. There is nothing surprising in that you say. Everybody in the room knows that, sure, but you are looking at 25 years of experience and knowledge and discussion, and so on. But that was a fairly important observation at that time - if the fit is poor, then you get a lot more leakage. How much more leakage? Ten times as much. Okay, fine.

Another respirator, manufacturer Z, had a somewhat different experience in terms of the penetrations, that is, the penetration factor, if you will, or the fit factor. That is, it ranged all the way from 0.2 or 99.8 approximately or 99.7 all the way up to about 60 percent - that is, all the way down to about 60 percent, again as a function of, quote, fit. It was impossible to fit this particular respirator on this particular subject.

So again we see the early effects of attempting to quantitate what does fit really mean. Now, the conditions of test are sedentary, that is, sitting down, presumably, not doing any external work. And the minute volume in liters is on the order of ten to 20, about a quarter to a half a cubic foot a minute, which I think you would agree is probably consistent for a sedentary minute volume.

This is simply an extraction of the results of the tests with subjects wearing respirators. Sedentary breathing - effects of fit are noted during two tests. Bad fit increased the normal penetration by an estimated factor of ten. Z respirators were a factor of ten less effective in the collection of test aerosols than were the X respirators. And Z and X,

of course, are two of those manufacturers and I don't know which ones they were.

What the purposes of these test were, were not only to characterize the leakage - development of a method for testing for leakage, but also to look at the ways of getting around the leakage problems. As I said in my introductory remarks, this led to ultimately the development of a power air purifying respirator. In the case of the MSA configuration it is, as you, a half mask. And it is supplied by a battery pack and a motor blower mounted on the belt. The respirator is normally always positive with a volume on the order of 100 liters a minute or thereabouts.

These are some of the early concepts of that ultimate design. This shows the early thought about having positive powdered purified air respirators. It is one of the first sketches, if you will, of what ultimately became a configuration that was reduced to practice and ultimately marketed by MSA.

A lot of work went into doing a positive face seal. Instead of doing the whole cavity positive, a lot of work, thought and effort and design and development was provided in making just the seal, a dual channel seal, and making the seal positive. The idea being here, of course, that you wouldn't have to provide as much air volume. All you would have to do is to provide the seal volume. So this configuration could be a lot smaller. I am not sure that ever flew from a product point of view. Many of you have more practical experience that I do and might have some added details on this.

But the concept I think is still a good one. In other words, a double seal. The inner seal is impermeable; the outer seal is porous, open cell foam. So the leakage is outward at all times. If there is a leak between the impermeable inner seal and the face, clean air leaks in from the seal configuration, not from the external environment.

A lot of work was done in developing these and a certain amount of testing was done. That information is contained in a variety of progress reports.

The substance of all of these tests and that experimental period, from about 1960 to about 1970, at the Harvard School of Public Health, was about ten or twenty papers ten or fifteen papers and maybe another ten or fifteen presentations, primarily by Bill Burgess and some of the other people who worked on this. If you are familiar with the historical development of the project and the things that Bill was doing, there are articles in the Journal - Journal of American Industrial Hygiene Association -- During that period, from '60

to about 70, in which he describes all of the elements of the program that they were looking at.

But the ultimate experimental technique was this figure that I have just described to you where the primary thrust was using a uranine aerosol which could be collected inside the respirator and assessed externally by means of a photo fluorometer.

I think that is the last slide, Warren. Thank you very much. I would be pleased to elaborate or answer any questions anybody has.

I might say that I have had the opportunity to review some protocols from time to time that involved the problem of respirator leak and quantitation of respirator leak and I normally say that I think this approach probably will come out as the one that we would have to consider very carefully. If we really want to know what the people are breathing, we are probably going to have to sample - collect the sample in the cavity. In the cavity sampling is important -- collection of the sample in the cavity is important or may be important for certain aerosols. Certainly for particulate aerosols or fibrous aerosols I think that is fairly safe statement.

The other one is that I hope that you would agree that sampling only on inhalation would also be an important experimental adjunct. And I don't see why most of these tools and techniques couldn't be miniaturized now with modern electronics and made a lot smaller and a lot more portable and field implementable.

Mr. Wilmes: There are no questions or comments? I think we will take a short break. We are running a little bit ahead of time. Let's reconvene in 15 minutes, at ten o'clock.

Mr. Wilmes: I believe we are ready to begin again, if you will be seated. The next speaker will be Warren Meyers. I believe our remarks have suitably introduced Warren.

One thing I would like to ask the participants is that during the question and answer period that will follow we try to hold our questions to questions regarding the experimental procedures that he has gone through and hold our "what does this all mean?" discussions until tomorrow, after you have heard the entire presentation. Warren?

Mr. Myers: The primary goal of any sampling system designed to measure concentration of airborne contaminants is to provide a quantitative estimate of

the airborne concentration in the environment from which it is obtained.

In regard to this investigation the environment is the cavity between the body of a respirator and a wearer's face, simply identified as the facepiece cavity. With negative pressure respirators, that environment is best characterized as being very dynamic, subject to dramatic changes in instantaneous air flowrates, minute volumes and inboard contaminant leakages.

In-facepiece sampling refers to a measurement system which is composed of two general aspects. The first aspect is sampling or sample collection, which involves collecting a sample of contaminant from within the facepiece cavity. The second aspect is sample analysis which deals with quantifying the amount of contaminant collected.

The validity of contaminant measurements made by in-facepiece sampling or any other sampling system is greatly influenced by the accuracy, precision, sensitivity, etc., of the analytical methods and upon the actual representativeness of the collected samples to the environment from which they were obtained.

The analytical methods used are generally well defined and are presented in the published literature. However, the same cannot be said about the technique used to obtain the sample from the facepiece cavity. The current technique for sample collection on half mask respirators in the United States is to locate a sampling probe on the midline of the respirator body at a position that falls somewhere between the nose and mouth of the wearer. Generally the probe is attached directly to the wall of the respirator. The internal diameter of the sampling probe and the sampling flowrate used for in-facepiece sampling are not standardized and do vary widely. Furthermore, samples are collected during both the inhalation and exhalation phases of the respiratory cycle.

The efficacy of in-face piece sampling has never been demonstrated in the published literature, even though in-facepiece sampling has been done since the early 1960's. One possible reason for this is the often used assumption that leakage through the facesal perimeter mixes uniformly and completely within the facepiece cavity.

The purpose of this research is to investigate whether or not that assumption is true and determine how certain parameters of the man/respirator system may affect the

representativeness of samples collected by current in-facepiece sampling techniques.

In order to accomplish the experiment a model was developed to predict the actual concentration that would be present within the facepiece cavity.

We define the quantity C_I as the average concentration present during inhalation. The respiratory minute volume is designated as Q_R . The concentration of substance in the leak and the minute volume of the leak are denoted as C_O and Q_L respectively.

The theoretical concentration of vapor present in the facepiece cavity during inhalation can be expressed by the following relationship -- I might add that this relationship was developed for gases and vapors and I would add that it is not suitable for particulates -- C_I is equal to C_O times the quantity, Q_L divided by Q_R .

In actual practice, however, C_I cannot be calculated directly from this equation because the quantity Q_L is not known. As a result, an estimate of C_I is made by collecting a sample from inside the respirator cavity. The usual sampling strategy is to collect a sample over both the inhalation and exhalation phases of the respiratory cycle.

The calculation of the true inhalation exposure can be made from such a sampling scheme using the equation given in this slide. The quantity C is the concentration measured by in-facepiece sampling over the inhalation and exhalation phases of the respiratory cycle.

K_1 and K_2 are the constants for the duration of inhalation and exhalation respectively and x_{i1} and x_{i2} are the sampling biases occurring during inhalation and exhalation respectively. And n_L is the lung retention characteristics of the contaminant.

However, the given quantities required in this equation also, in general, are not known. For example, different aerosol size distributions or different gas/vapor contaminants have markedly different lung retention characteristics and, therefore, different values of n_L . Likewise, it is hard to determine K_1 and K_2 since these coefficients will vary with different respiration rates and also between individuals. Furthermore, the corrections for sampling bias have not been determined.

An alternative approach that would greatly simplify the estimation of the inhalation concentration would be to collect samples only during the inhalation phase of the respiratory cycle. The

feasibility of using such an approach has been demonstrated by Furst and Riediger who have described a system, for use in laboratory setting, which collects samples from the respiratory cavity only during inhalation. My reference there to Riediger and Furst was made because at the time that we started this and I wrote this I was not aware of the Harvard work until just very recently.

For this sampling scheme the true inhalation concentration would be calculated as follows, where C is equal to the concentration measurement made by in-facepiece sampling and x_{i1} the inhalation sampling bias.

This investigation was to provide an assessment of whether certain parameters of the man/respirator system may introduce bias into the sampling estimates of the concentration collected from within the cavity of a negative pressure respirator. If good mixing does occur inside the facepiece cavity, samples collected by in-facepiece sampling should closely approximate the theoretical levels predicted.

If, however, good mixing does not occur, then samples collected by in-facepiece sampling would be different from theoretical levels. This difference can be expressed as sampling bias. As system parameters are varied between different levels, determination of any sampling bias caused by such variation would provide an indication of whether good mixing is occurring within the facepiece cavity.

The process of identifying and selecting factors for inclusion into the study was based upon a fault-tree analysis of the current technique for in-facepiece sampling. That process identified many potential factors of the man/respirator system that could possibly introduce bias into the sample collection process. Based primarily upon professional judgment and experience, five factors were selected from that fault-tree analysis for study. These factors were -

- sampling probe location.
- Sampling probe depth.
- Leak site.
- Breathing distribution pattern and
- measurement sample rate.

The sampling probe location factor deals with the position of the probe on the midline of the respirator in the area between the nose and mouth. In practice, the midline probe location on any given mask is fixed. However, its

positional relationship to the nose and mouth will naturally vary between different wearers and also for an individual wearer during multiple donnings. The three levels of probe location selected for study were: one, at the nose; two, at a position between the nose and mouth; and three, at the mouth. They were selected based upon the physical limits created by nose or mouth entry to the respiratory tract and a reasonable midpoint represented by midway between the nose and mouth.

The probe depth factor deals with how deeply the probe mouth is extended into the cavity of the respirator. The three levels chosen for study were; one, flush; a quarter inch insertion; and three, the half inch insertion. These depths were chosen because experience indicated that a half inch probe depth on a half mask respirator could be practical on most people, while flush represents the physical limit of the mask and a quarter inch represents a midpoint.

The leak site factor deals with the location of the leak on the faceseal perimeter. The three leak sites selected for study were: one, at the nose; two, at the cheek; and three, at the chin. These sites were selected based upon experience and professional judgment which indicates that nose, cheek and chin represent likely areas of faceseal leakage.

Each leak site was created by inserting a piece of tubing through the respirator body at the faceseal lip. In addition, all three sites were located on the same side of the respirator. This was done based upon consideration of the symmetry of the respirator about its midline. In regard to the study, it should make no difference whether the leak occurred on the left or right hand side of the respirator.

The breathing distribution pattern deals with the ratio of the inhalation flow volume that occurs through the nose and mouth. It was noted from questioning a number of respirator wearers that most would breathe through their nose during quantitative facepiece fit testing but breathe through their mouth while working. As a result, three levels of effect chosen for study were: inhalation flow all through the mouth; and inhalation flow all through the nose. These levels were selected because they represent the physiological limits, that is, all nose or all mouth breathing, and a reasonable midpoint.

The last factor studied, measurement sample rate, deals with volumetric rate of

sample through the sampling probe. The three levels of measurements sample rate chosen were: one liter per minute; two liters per minute; and three liters per minute.

The purpose of studying sample rate was to consider the sampling probe as an open duct with a capture zone that could be defined by velocity contours. Thus, by varying the measurement sample rate and holding probe diameter constant, the effect of different sizes of capture zones on sampling efficiency can be evaluated. The rates on one, two and three liters per minute were selected because currently employed in-facepiece sampling techniques most often use sample rates in this range.

The complete test apparatus consisted of three major subdivisions: acetone generation; respirator test setup; and sample collection and analysis.

The acetone generation and storage subsystem consisted of a syringe pump, a dilution air source which was controller, and a vapor reservoir. The syringe pump and air flow controller were calibrated. Based upon the mean acetone delivery rate and the mean dilution air flow and standard temperature and pressure corrections, the average vapor concentration of acetone, designated as C_Q , could be calculated.

The acetone-air mixture was plumbed into a 22 liter reservoir which helped dampen fluctuations in the concentration. The reservoir was allowed to exhaust to a hood and was maintained at less than one-half inch positive water pressure. Vapor was transported from the reservoir to the respirator test setup via tubing. This tubing was then connected, as appropriate, to each leak site on the face seal perimeter.

The respirator test setup consisted of the half mask respirator mounted on a headform by an air tight seal. The respirator was equipped with organic vapor cartridges.

The pressure within the facepiece ranged between zero and approximately one inch negative water pressure during inhalation. The sampling probe used for the study has been previously described in the literature by Liu, et al. The headform was plumbed to accommodate air flow breathing patterns occurring either simultaneously or separately through the nose and mouth. It was attached to a breathing machine, which was operated with a 622 workrate cam. The tidal volume produced by the cam was 1.6 liters. During testing the frequency of the breathing machine was adjusted so that the total

minute volume, Q_p , corresponding with each measurement sample rate was approximately 32 liters per minute.

To allow measurement only during inhalation, the exhalation phase of the breathing cycle was routed directly to the atmosphere and not through the respirator.

Leakage in to the respirator resulted from the negative pressure that occurred inside the facepiece cavity during the inhalation phase of each breathing cycle. The leakage rates were determined with a bubble flow meter.

The sample collection and analysis portion of the system consisted of a Tylan flow controller which controlled the sample flowrate and a Miran 1A infrared analyzer calibrated for acetone.

Use of a flow controller allowed easy control and adjustment of the measurement sample rate to one, two or three liters per minute. The collected sample was diluted with acetone clean air to produce a final minute volume of approximately ten liters per minute. The volume of dilution air was also controlled by a flow controller. The absorbency response of the I.R. was recorded on a strip chart recorder for future data reduction and analysis.

While it was possible to predict the acetone concentration present in the facepiece cavity, it was desired to confirm this predicted value through experimental measurement. Such measurement would require that an unbiased sample be collected from the system. Through experimental trial and error, a sampling location was selected immediately outside and behind the test headform in the plumbing leading to the breathing machine. For each test the measured true concentrations were compared with the theoretical concentration values.

The bias in the measurement of the true concentration was determined by the following equation: where C'_j is equal to the experimentally determined true concentration; and C_j the theoretically predicted true concentration.

On the MSA respirator the theoretical true concentration, C_j , was 145 plus/minus 1.5 ppm, while the experimentally determined true concentration, C'_j , was 147 plus/minus 8.1 ppm. The bias in the experimental measurement was 0.1 plus/minus 5.6 percent. On the Scott respirator C_j was 141 plus/minus 1.2 ppm and C'_j was 139 plus/minus 3.1 ppm. The bias in experimental measurements was 1.8

plus/minus 4.2 percent. On the U.S. Divers respirator C_j was 149 plus/minus 1.0 ppm and C'_j was 149 plus/minus 5.8 ppm. The bias in C_j was minus 0.2 plus/minus 4.0 percent.

This close agreement in the measured and theoretical concentration values indicate that the predicted theoretical concentrations could be verified through experimental sampling. Since the estimate of the true concentration could be readily obtained during each test, it was used as the concentration of acetone against which the results of in-facepiece sampling were compared. In addition, it served as an internal indicator of system integrity and operation.

The concentration of acetone measured via the current technique for in-facepiece sample collection is identified as the measured in-facepiece concentration.

From the measurements of the true concentration and the in-facepiece concentration, the sampling bias associated with in-facepiece sample collection could be determined. the sampling bias was calculated as follows: where $C_{cap\ j}$ is equal to the concentration estimate made by in-facepiece sampling and C'_j equals the experimentally determined true concentration.

Before proceeding into a discussion of the data, I would like to present a video presentation of our laboratory setup and show you some actual observations demonstrating in-facepiece sampling bias.

As of this date, we have completed testing on the MSA, Scott and U.S. Divers half mask respirators. The following discussion will cover results obtained on those three respirators. These data will be summary in nature. More detailed data presentation of the test results on the MSA half mask is provided or can be provided in an article manuscript which is available.

A data summary of vapor concentrations measured within the facepiece cavity by in-facepiece sampling on the MSA, Scott and U.S. Divers half mask respirators are presented in the next slide.

These data were obtained from sampling only during the inhalation phase of the respiratory cycle. The experimentally determined true concentration is identified as C'_j and the concentration measured by in-facepiece sampling is identified as $C_{cap\ j}$. Mean values are based on 81 tests on each respirator.

On the MSA respirator the mean concentration determined by in-facepiece sampling was 122 plus/minus 54.4 ppm, compared to the true concentration of 147 ppm. The range in the concentration measurements obtained by in-facepiece sampling was from less than one ppm to greater than 294 ppm.

On the Scott respirator the mean concentration determined by in-facepiece sampling was 75 plus/minus 44.4 ppm, compared to the true concentration of 141 ppm. The range in the in-facepiece measurements was from 8 ppm to 201 ppm.

On the U.S. Divers respirator the mean in-facepiece measurement was 118 plus/minus 57.2 ppm, while the true concentration was 149 ppm. The range in the in-facepiece measurements went from 10 ppm to 274 ppm.

A comparison of the sampling bias associated with in-facepiece sampling on these respirators is presented in the next slide.

The mean of the sampling bias plus/minus one standard deviation observed on the MSA respirator was minus 17 plus/minus 381 percent. The mean value is rounded to the nearest whole integer. The range in the bias measurements went from minus 98 percent.

On the Scott respirator the mean sampling bias was minus 47 percent to 42 percent. The mean sampling bias associated with in-facepiece sampling on the Scott respirator was significantly different from the sampling biases associated with the MSA and U.S. Divers respirators.

The mean sampling bias on the U.S. Divers respirator was minus 91 (sic) plus/minus 38.3 percent, ranging from minus 92 percent to 84 percent.

The finding that sampling bias was significantly different on one of the respirators may indicate that certain design features of the mask may be able to aggravate or mitigate sampling bias associated with in-facepiece sampling.

Statistical analysis of the data indicates that the following factors had significant contributions to the sampling bias observed with in-facepiece sampling on one or more of the respirators tested.

Varying the leak site at the face seal interface.

Varying the breathing pattern.

Varying the sampling probe location on the facepiece midline.

Varying probe depth within the facepiece cavity.

And an interaction between breathing

distribution pattern and the site of the face seal leak.

A comparison of significant factors on each respirator is presented in the next slides.

With the MSA respirator leak site, probing location and the breathing pattern-leak site interaction were all causes of significant sampling bias.

On the Scott respirator leak site and the breathing pattern-leak site interaction were found to be causes of significant sampling bias.

With the U.S. Divers respirator leak site, breathing pattern, probe depth and the breathing pattern-leak site interaction were found to be causes of significant sampling bias.

On all three respirators leak site and the breathing pattern-leak site interaction were causes of significant sampling bias. The coefficients of correlation, the R^2 value, were good for each respirator indicating that a large portion of the observed sampling bias could be explained with the main effect in a two-way interaction model that we used in our statistical analysis.

The variability in the estimate of concentration obtained by in-facepiece sampling demonstrates the wide range of uncontrolled sampling errors that may be occurring during quantitative facepiece fit testing and workplace protection factor testing on negative pressure half mask respirators.

The variability of quantitative facepiece fit testing results has been demonstrated time and again and discussed at great length. The general conclusion most often put forward is that respirator fit is a function of several factors, for example, subject variability, fit variability, etc., which sufficiently explains the observed measurement error.

However, the results of this study suggest that a major portion of the variability associated with quantitative facepiece fit testing may actually be due, in part, to the large sampling bias associated with current in-facepiece sampling technologies. The effect of in-facepiece sampling bias on the variability of quantitative fit test results is perhaps more easily visualized by comparison of fit factors instead of sampling bias.

In this table the estimated fit factor corresponds to the fit factor calculated from each of the 81 in-facepiece concentrations measurements made on the three respirators.

True fit factor is calculated using the

mean of the experimentally determined true concentration.

The true fit factor calculated on the MSA respirator with the leak conditions created in these experiments was 87. The arithmetic mean of the fit factors calculated by using the concentration measurements obtained by in-facepiece sampling was 213, ranging from a low of 44 to a high of 4727. On the average the arithmetic mean fit factor overestimated the true fit factor by 250 percent.

On the Scott respirator the true fit factor was 119, while the arithmetic mean of the calculated fit factors was 367, ranging from a low of 86 to a high of 2082. On the average the arithmetic mean overestimated the true fit factor by 310 percent.

On the U.S. Divers respirator the true fit factor was 104. The arithmetic mean of the calculated fit factors was 177, ranging from 56 to 1384. On the average the arithmetic mean overestimated the true fit factor by 170 percent.

Based upon consideration of these preceding results, it is hypothesized that material coming through a leak on the face seal perimeter is streamlining within the cavity of the respirator. Further evidence for this hypothesis was provided by visual observation made within the cavity of a full facepiece respirator.

A single leak was introduced into the facepiece cavity between the interface of the respirator face seal and head form. Ventilation smoke in the leak made the streamlines clearly visible. These are the streamlines, coming from the side, across the face, into the mouth area. A demonstration of these streamlines will be given for those interested, immediately after we break for lunch. I will have a test demonstration over here, on the side, if you would like to see that.

One noteworthy aspect of the methodology used in this research was that the sampling bias estimates have been made only when an inhalation volume was passed through the respirator. The accompanying exhalation volume was not routed back through the respirator.

As a result, two important questions can be raised in regard to the data. First, does the cycling of both an inhalation and exhalation volume through a respirator increase the turbulence of air flow on inhalation and, therefore, decrease the sampling bias? Second, would sampling during exhalation, after presumably complete mixing has occurred in the lung, reduce the net effect of sampling bias

during inhalation?

Visual observations made of the leak streamlines in the fullfacepiece respirator test setup demonstrated that routing an exhalation flow through the respirator did not appear to affect the leak streamlining produced during inhalation.

In regard to the second question, sampling over inhalation and exhalation versus over inhalation only, can in some instances moderate to a varying extent of the moderating effect would be dependent on the normalized exhalation time; the sampling bias experienced during exhalation; and most critically, the amount of loss in concentration due to lung retention.

Now, the predicted concentration measurement from inhalation and exhalation sampling, C_p , and we saw this once before, could be calculated as follows -- now, in our test system C_j is known from experimental measurement and K_j is equal to 0.47; K_2 is equal to 0.53 and n_L is equal to 0.05. If we assume x_{i2} is equal to one, that is, no sampling bias on exhalation, then the concentration could be predicted and verified by actual sampling on specific test setups where x_{i1} had been determined.

The sampling bias in the inhalation and exhalation sampling measurement, measured on selected tests, are given in the next slide.

It can be seen from these data that sampling over exhalation may moderate, to varying extents, the effect of sampling bias during inhalation. For example, on test one of the sampling bias measured during sampling over inhalation was minus 15 percent, while when sampling over inhalation and exhalation it was minus 14 percent.

Likewise, in test five, sampling bias from inhalation sampling was 32 percent, while from inhalation and exhalation sampling it was 11 percent.

The somewhat large sampling biases associated with inhalation and exhalation sampling may indicate that the initial assumption made of no sampling bias during exhalation flow may have been incorrect. This would indicate that some sampling bias is also occurring during exhalation.

It should also be noted that the moderating effect of sampling from exhalation flow will vary as lung retention characteristics vary. That is a very important point.

In conclusion, this research suggests that face seal leakage is not mixing instantaneously and uniformly within the facepiece cavity and, as a result, strong

concentration gradients develop within the mask during each period of inhalation. This is in contradiction to the assumption, often applied when doing in-facepiece sampling, that good mixing is occurring in the facepiece cavity during inhalation because of turbulent air flow in the mask.

Large sampling biases have been found on three half mask respirators. These sampling biases on the average cause an underestimation of the leakage concentration within the facepiece and, consequently, the fit factor of the respirator is overestimated.

Factors included in our research which were found to contribute significantly to sampling bias are: varying the leak site at the face seal interface; varying the breathing pattern; varying the sampling probe location on the facepiece midline; varying probe depth within the facepiece cavity; and an interaction between breathing distribution pattern and the site of the face seal leak.

It is hypothesized that face seal leakage is streamlining within the respirator cavity during inhalation. The position of these streamlines relative to the sampling probe location and depth appear to be the major cause of the observed sampling bias.

Research efforts are now being extended in our laboratory to consider full facepiece respirators. Factors being considered for future study are differential leak rate, multiple leak sites, differential breathing rates and leak site geometries. Thank you.

Mr. Wilmes: Are there any questions regarding this presentation? If you would just step forward and use the microphone?

Mr. Billings: Thanks very much, Don.

Mr. Wilmes: Please announce your name also.

Mr. Billings: Yes, the name is Billings, Charlie Billings, from Johns Hopkins. I guess I didn't take out of your presentation what the actual Q_L leak rate was. Did you say what that was? The actual amount of material that you are putting into the cavity?

Mr. Myers: That was different for each one of the respirators tested. It was a function of the pressure drop created by the individual cartridges. It ranged probably between about 300 ml/minute up to maybe 380, 390 ml/minute.

Mr. Billings: That is actually a

variable then in the experiment that is unquantitated? Is that what you are saying?

Mr. Myers: No, no. It is quantitated and it is accounted for in the treatment of the data.

Mr. Billings: Okay. Would care to speculate what the effect of larger and smaller leaks is? Supposing Q_L is a variable, as it would be in practice - do you want to say what you think is going to happen?

Myers: I don't know. That is why we want to look at differential leak rates. At this point in time I really don't know, Charlie.

Mr. Brennan: Bob Brennan, Scott Aviation. Warren, when you publish the data, there are a couple of background items which you didn't cover today which I would like to make sure we get information on. For instance, the half facepieces, I assume they were all twin cartridge type?

Mr. Myers: Yes.

Mr. Brennan: Right. Did you make measurements of the cavity volume in each of the facepieces? And if you didn't I would like you to go back and estimate the cavity volume you were dealing with and publish that with the data because I will bet, from looking at your data, the Scott had the smallest volume; the MSA had the largest volume; and the U.S. Divers was in the middle. One of the things that we would really like to get is as much data as possible on varying internal geometries in these phenomena.

Mr. Wilmes: Thank you. Jim?

Mr. Johnson: Jim Johnson, Lawrence Livermore Lab. Would you describe the size of the leak that you mounted in? Is it an eighth inch piece of tubing sticking in there?

Mr. Myers: No. That is a 16 gauge needle.

Mr. Johnson: So there is imbedded into that little holder that is set on the respirator a 16 gauge needle?

Mr. Myers: Yes.

Mr. Johnson: Okay.

Mr. Myers: And, Jim, at the demonstration I can actually show you that.

Mr. Billings: Charlie Billings again. I wonder if the previous speaker but one, the fellow from U.S. Divers, would tell us how he would like us to measure this mask cavity dead space? What is your experience in that? Mask cavity dead space is a fairly interesting factor.

Mr. Brennan: I take exception to U.S. Divers.

Mr. Billings: What did I say? Scott -- I

am Sorry, Scott.

Mr. Brennan: All right, I wasn't referring to a measurement of dead space traditionally, as we would measure it in CO₂ retention. I am referring back to the total cavity volume measurement which, basically, can be done by tipping the respirator back and pouring water through the exhalation valve if you plug up the dummy head. You can pour it out again and make a direct volumetric measurement. It has also been done at the University of Pennsylvania with tiny plastic balls doing a living subject with cotton in his nose. There are many ways to do it. What I am looking at here is the gross volume for starts. When you get around, Warren, to the full facepiece I think you are going to find -- I have always been an advocate of offsetting the sampling probe in a full facepiece because almost every manufacturer designs for close to laminar flow in inhalation over the lens to keep it clear.

Mr. Myers: Yes.

Mr. Brennan: So it has always bothered me to put a facepiece right in the middle of that --

Mr. Myers: You mean a probe?

Mr. Brennan: Yes.

Mr. Myers: Okay, you said a facepiece.

Mr. Brennan: I am sorry. It has always bothered me to put a probe through the facepiece right in the middle of what we very, very carefully try to get a clean flow of dry air --

Mr. Myers: Yes.

Mr. Brennan: -- and then put the probe right in the middle of it.

Mr. Myers: Yes.

Mr. Brennan: And I have always offset the probes in full facepieces. I would be very interested to see your data.

Mr. Myers: Following up on what Bob mentioned there with full facepieces, one of the things that we thought may be occurring with the half masks, as I have mentioned these were both twin cartridge half masks, you can see, particularly on the Scott respirator, I believe that the angle of the cartridges are somewhat different than the other facepieces and it is possible we thought that maybe our sampling probe was actually in the stream coming from or coming through those cartridges so that we were actually sampling very near that clean volume coming into the respirator. But, Bob, your point on volume is well taken and I believe that Robert Bentley, in his presentation, will talk some more about the effect of the dead space volume, both mask cavity

and anatomical dead space, on the measurement of that bias. Any other questions? Yes, Dave?

Mr. Swift: David Swift, from Hopkins. The dummy was at room temperature?

Mr. Myers: Yes.

Mr. Swift: And the exhalation temperature was room temperature?

Mr. Myers: Yes.

Mr. Swift: Okay. Have you thought about the mixing that might occur as a result --

Mr. Myers: Of higher temperatures?

Mr. Swift: -- exhaling at body temperature and natural convective phenomena?

Mr. Myers: No, not at this point in time. Just to follow that up, the reason we did this is that I was willing to make an initial assumption that there was no sampling bias on exhalation, that, in fact complete mixing of the leak concentration had occurred within the volume, the tidal volume, so that the only way you would have sampling bias is from some maybe dead area within the mask. But from our results at this point of time that is something that we probably will try to look at because the data indicate that there is some sampling bias there even on exhalation. And that may be corrected with use of heated air.

Mr. Schneider: Scott Schneider, of the Carpenters Union. Warren, you said that you had zero to one inch water pressure on inhalation. That is the negative pressure -- right? -- inside the mask?

Mr. Myers: That was the change in the pressure over the breathing cycle.

Mr. Schneider: Right. How did you arrive at that figure? Do you know anything about what the actual water pressure should be?

Mr. Myers: That was with the actual cartridges on the respirator.

Mr. Schneider: So you are saying that is the negative pressure that is created within the mask? That one inch water pressure?

Mr. Myers: Yes, with a 32 liter a minute volume --

Mr. Schneider: I see.

Mr. Myers: -- and the pressure dropped on the particular MSA, Scott or Divers --

Mr. Schneider: Can we know how that relates to real life situations?

Mr. Myers: I would assume there should be a very strong relationship because those are the actual cartridges that are used. And if the 32 liter a minute is predictive of, you know, workplace

use situations, that pressure should be pretty realistic.

Mr. Schneider: Oh no, it is going to vary through, depending on the comparison between the fit in the real life situation versus the fit in the laboratory situation on a headpiece.

Mr. Myers: The pressure going down as the leak increased?

Mr. Schneider: Depending on the comparison of the seal on the headpiece --

Mr. Myers: Yes?

Mr. Schneider: -- versus the seal on the person, wouldn't it?

Mr. Myers: I am not really sure that I understand your question, Scott. Would anyone else like to address that?

Mr. Wilmes: This is Don Wilmes. I think what Scott is referring to is -- I think there might be a little confusion in that the leaks you generated were induced leaks, and I think what he is trying to do is correlate a negative pressure to a leakage rate in the respirator under normal use conditions. However, this was an induced leak --

Mr. Myers: Yes.

Mr. Wilmes: -- it was set at a particular value only to determine a sample bias. The results, the fit factors, or whatever you reported, are not relevant to use except that they could occur at that level in actual use, but what they actually are in use is not predicted by any work you did.

Mr. Myers: Yes. Bob?

Mr. Brennan: Along that line, Warren, your use of the fit factor -- I think it should be emphasized, am I not correct that the table you gave of fit factors, this is a created fit factor and perhaps the use of fit factor may be extremely misleading when you publish the data without some sort of explanation? It took me a minute when I saw the slide -- when you setup fit factor, if someone is looking at this data, they may look at it and say, oh, well, of course that means that this respirator fits better than that, and it is not really emphasized, I think, that you didn't create the same leak in each facepiece --

Mr. Myers: Right.

Mr. Brennan: You merely gave the same area and the total leakage was a function of the particular pressure drop over the cartridges, which has absolutely nothing to do with what goes on in real use.

Mr. Myers: Yes, that is true. That is true. Any other questions?

Mr. Wilmes: This is Don Wilmes again. I notice you mentioned -- at your flow

rates of 32 liters a minute which came on your breathing machine did you use?

Mr. Myers: The 622.

Mr. Wilmes: Okay. Then you probably meant 40 liters a minute, didn't you?

Mr. Myers: No.

Mr. Wilmes: You measured the pressure drop at 32 to correspond to it?

Mr. Myers: Yes.

Mr. Wilmes: Oh, okay.

Mr. Myers: We actually measured the pressure drop during each breathing cycle.

Mr. Wilmes: All right. The 622 came delivers a minute volume of about 40, I believe.

Mr. Myers: Well, if you turn it up fast enough, if you cycle it fast enough.

Mr. Wilmes: Okay. I guess what I am getting at is that --

Mr. Myers: The cycling rate was about 18 a minute.

Mr. Wilmes: Oh, okay.

Mr. Myers: It was not 24.

Mr. Wilmes: All right, I understand.

Mr. Myers: I mentioned in the presentation that the cycling frequencies were adjusted to give us approximately 32 liters per minute on each of the rest setups, regardless of the in-facepiece sample flow being one, two or three liters a minute. Other questions? Thank you.

Mr. Wilmes: Let's see, we are a little bit ahead of schedule again. Would you like to demonstrate your test setup at this point or would you prefer to wait?

Mr. Myers: Let's wait. There is obviously not enough room there for everyone to get around.

Mr. Wilmes: Right. Okay, why don't we break now and reconvene here at 1:30?

AFTERNOON SESSION

Mr. Wilmes: I believe we are about ready to begin. If I could ask Earl to make the announcement outside that we are about ready to begin, I would appreciate it. I think there are still some people standing outside. I guess we would like to start this afternoon's presentation with Bob Bentley, from the Health and Safety Executive in the U.K. Bob's group is one of the groups that independently have addressed this issue and come to their own conclusions also. I would like to turn it over to Bob.

Mr. Bentley: Okay, Mr. Chairman, ladies and gentlemen, first of all, may I thank you for the invitation to attend this conference and at least pass on to you some of the findings of our recent work?

Now, I would like to describe a piece of work that has been done as an aid to another project. Very briefly then, the

criterion for accepting a piece of respiratory protective equipment is the level of overall protection it affords to the wearer.

For a respirator this demands that, in addition to an effective faceseal and a suitable leak tight exhale valve system, a filter of adequate efficiency is required, according to the desired level of protection.

Assessment of the integrity of a respirator may be carried out in several ways. The British standard specification, 2091, for respirators for protection against harmful dusts and gases details separate tests for filter efficiency, valve leakage and faceseal leakage. Note, this is not total inward leakage.

In this case the respirator is worn by seated, non-exercising subjects who are exposed to a test cloud of a contaminant of known concentration, which is arrested by the filter of the respirator and easily detected by a suitable laboratory instrument.

One such test agent is an aerosol of sodium chloride. In this case the sample for analysis is collected by a suitable tube system after it leaves the exhaled valve of the respirator.

Now, this technique raises problems because the efficiency or, in U.K. terminology, the penetration of the filter and the faceseal leakage may be determined at different volume flowrates because, in the first case, the efficiency is a laboratory bench test and, secondly, the faceseal leakage is a wearer test on a man. Additionally, due to the problem of the variation of the efficiency of certain filter materials with flowrate, then the simple addition of penetration and faceseal leakage, although it is called for in BS 2091, can produce misleading results.

A further complication is the necessity of applying the correction factor to the result to take account of the solubility of sodium chloride in lung fluids.

Additionally, the British standard specifications for breathing apparatus call for tests again on the faceseal leakage of the appropriate face mask by collecting samples for analysis after they leave the exhale valve. In this case argon gas is the recommended test agent.

So in order to arrive at an estimate of the performance level, using either of the above techniques, then the total inward leakage in the device must be calculated by the addition of faceseal

leakage and valve leakage, and in the case of respirators, the filter penetration.

The limitations of such techniques are obvious. The introduction of the filtering facepiece respirator made the previously described technique impossible to operate due to the construction of the respirator.

A way forward which was then used by various workers to improve the method of measuring total inward leakage was by collecting a sample for analysis from within the breathing zone of the mask while it was being worn by an exercising subject. The essential requirement for such a technique is the insertion of a suitable leak tight sampling probe into the wearer's breathing zone such that samples may be withdrawn by a pump system for analysis.

Variations of this technique have been used to collect samples either continuously or only during the wearer's inhalation breathing phase. This is the so-called pulsed sampling technique, when suitable switching equipment is required. The British standard specifications, 6016, for filtering facepiece respirators details such a technique.

The sampling systems are well-defined and the probe is normally situated on the outer skin of the respirator, at about the midway point in the vertical and the horizontal plane.

Now, until recently it was assumed that external contaminants which leak into a face mask mix completely with the relatively clean air inside the mask. Consequently, sampling of this air by a probe on the outer skin of the mask would give a reliable estimate of the concentration of the contaminant and, hence, a protection level could be assigned to the particular respirator.

Some work which has recently been carried out in the laboratories of the Health Safety Executive has raised a number of questions about such assumptions and the viability of this technique to give a meaningful estimate of the protection level to any particular device. The work was started during a program which was to aid the development of unified European standard specifications by the Committee CEN-TC79, and it was directed essentially towards a conventional half mask respirator which, in England, to classify as a type B device, according to BS 2091, requires less than or not greater than a ten percent total inward penetration. And this is made up of five percent for the faceseal leakage and two percent for filter materials if they are of

the degradable type and five percent if they are of the mechanical type.

During this work to aid the CEN Committee a series of tests was conducted to determine the effect of total inward leakage, of inhalation resistance and filter weight. Because we had the facility available in my laboratory, we opted to use a dual tracer system, whereby we employed SF-6 gas at a low concentration in air, to which was added an aerosol of sodium chloride at a concentration of six milligrams per cubic meter, and a mass median diameter of 0.6 micrometers. This is, in fact, the specification recommended in the BS specification 4400.

Samples were withdrawn for analysis and, hence, determination of total inward leakage by a probe system. Five different subjects each wore four respirators on separate occasions in an experimental rate while walking on a treadmill. The respirators in this case were minus air filters but clean air was admitted by a wide bore tube and during the exercises the inhalation resistance was varied in discrete steps by means of an external butterfly valve fitted into the air inlet tube.

The total inward leakage into the respirator was then assessed simultaneously by SF-6 and sodium chloride. And during the exercises samples of air were withdrawn from the respirator by a pump attached to a single tube system. So the sample was then divided externally from the respirator and a portion was passed to a flame photometer for sodium chloride content and an electron capture detector for estimation of SF-6.

In separate experiments both pulsed sampling during the wearer's inhalation phase and continuous sampling techniques were used.

We were surprised at this stage when the results obtained using both methods and both tracer agents were consistently in disagreement. We made repeated checks of the integrity and the calibration of the measuring equipment and this still did not produce a satisfactory solution.

Now, we have done previous experiments of this type, using dual tracers, but in this case they were both gases and they had produced results which were essentially in agreement. In this case we had used argon and SF-6.

So our attention was then focused on the technique of measurement of total inward leakage by withdrawal of a sample from within the respirator, and the possible effects upon the measured result of, (a) the dead volume of the mask and, (b) the

sample probe position.

A simple theory has shown that the measured inward leakage could vary considerably due to the dead volume of the respirator. Now, this is something within British specifications that has been totally ignored, although the proposed European standards do contain a limit for dead volume of respirators.

But typical half mask respirators have shown that the wearer will re-inhale approximately 20 percent of his exhaled breath. These are tests made using a breathing simulator technique with carbon dioxide.

In addition, we must remember that there is the problem of the solubility of sodium chloride in lung fluids so the correction factor must be applied to results.

So we deduced at this stage that the differences in the TIL measurements between SF-6 and sodium chloride were probably in disagreement because of the insoluble nature of SF-6 and the extreme solubility of sodium chloride and, of course, the dead space.

A correction factor was then devised on the respirator dead volume and it was applied to the previous two sets of results, and almost immediately we started to get a fair degree of correlation. At this stage we were, I think, more than a little confused and decided to try and look at the problem from first principles. And here may I offer an apology to a number of the people in the audience who, I know, are well-versed in all these techniques, and we are taking an extremely simple case and trying to consider just what is happening. So if we consider, first of all, the respirator as a box, with a clean air inlet at one end and an exit for the wearer's mouth at the other -- could somebody switch the projector on, please?

- a simple box, where clean air is coming in at one end from the filter system and it is going out to the wearer's mouth here - we have probes in position at PL or P3. And if we make some simple assumptions, first of all, let us take a leakage of ten percent of the challenge atmosphere at a concentration at point L, we assume the effective dead volume of the respirator is 20 percent, based on measurements of typical respirator, and that we use either a completely soluble aerosol tracer or an insoluble gaseous tracer. The sampling probes are situated either at positions P1 or P3, and within each respiratory cycle the times of inhalation

and exhalation are equal.

Then if we now look at the figure one and slide two, we can show that because of dead volume the inhaled concentration, due to a leak at L seen by probe at P3, will predict a leakage of 12 percent for continuous sampling, ten percent for pulsed sampling technique, however, the man will receive eight percent. Because if we visualize the box respirator, starting to sample at the end of an exhalation phase, by definition the respirator contains clean air. So, therefore, on respiration the man receives, first of all, the concentration due to the dead volume of the respirator, which is 0.2, plus the remainder of the inhaled air with the contaminant. In this case, the volume works to the wearer's advantage and indicates that a ten percent will be shown but the man will receive only eight percent.

If we now move the leak to L, at this point nearest to the wearer, then using the same set of test conditions as those previously postulated, then the following values are predicted for sampling probe which is now situated at P1, relatively close to the wearer's mouth. When an absorbed tracer is used so that, as before, at the end of exhalation the respirator contains clean air but the probe records contaminant for the whole time during inhalation. So the inhaled air contaminant concentration is equal to 0.1 times the external concentration C. The exhaled air contaminant concentration is equal to zero. By definition it has all been absorbed. A mean value of those two gives us 0.05 and a correction factor is applied for the sampling of using sodium chloride.

The correction factor applied for continuous sampling and for pulsed sampling only, and then the leakage equals to ten percent. The man receives ten percent and the continuous sampling device also registers ten percent.

If we now move on to a non-absorbed tracer, and again if we start at the end of an exhalation phase, the respirator this time contains contaminant at a concentration of $0.1C$ because, by definition, it has not been absorbed, therefore, the inhaled contaminant concentration becomes a dual purpose component. First of all, the man will inhale the volume in the respirator, which is at a concentration of $0.1C$ by definition, but the whole time the leakage is going in and out at that point. So we have the dual purpose situation here so that indicated at P1 we have, for continuous sampling, 12 percent; for pulsed sampling 12 percent; and in this case the man will

actually receive 12 percent.

If we now move the probe to P3, with the leak still at L, and again still -- this is with the absorbed tracer this time -- then again starting at the end of exhalation, the respirator is full of clean air because of the solubility, and on inhalation, with the respirator full of relatively clean air, the contaminant concentration becomes zero. We are postulating now the leak is effectively coming up here and going straight into the mouth.

However, in real terms, some mixing almost certainly will occur and we made the assumption that as the concentration, say, at this point will be 100 percent, and, say, at that point it will be zero, is reason from our simple treatise to take the midway point in the respirator as being half the actual inhaled contaminant concentration. So this will be then 0.05 percent.

So on exhalation then, the contaminant concentration becomes this rather ponderous thing here and we finish up with the mean value of one percent and the correction factor is applied to it.

For continuous sampling we predict a one percent measurement. In pulsed sampling we predict zero. But the man will actually receive, still by definition, ten percent going this way.

If we now just move to the next one, which is the non-absorbed tracer, again with probe at P3, then at the end of exhalation, remember, the respirator is full of contaminant at a concentration of 0.1 times C, so the man will actually receive during inhalation the summation of the air in the respirator at that concentration which he has just exhaled, plus the leakage the whole time.

And doing the arithmetic again, we have come up with values indicated at P3 so that for a continuous sampling exercise we would collect 5.3 percent; on a pulsed sampling exercising we would record zero and the man would actually receive 12 percent.

Now, I must admit that is an extremely simple case and we were then concerned as to whether we could follow this up in real life and make some measurements on respirators.

So if we were to now take a respirator, a real half mask respirator, and fit it to a dummy test head which has, through the mouth cavity, concentric tubes, one 40 millimeters in diameter, one 29 millimeters diameter -- there is also a separate sampling tube through the center which, in this case, is blanked off.

And the typical half mask respirator is sealed on by means of cement all around the edges, as far as we are able. Here is

the wide bore tube which is supplying clean air to the respirator. And from here we can take samples.

And a series of tests made with the breathing simulator operating at 40 liters a minute, which in this case is the tidal volume of two liters and 20 respirations a minute, and the experimental setup is such that --

-- there is our schematic dummy head with the respirator bonded onto it, the concentric tubes passing through the mouth, then passed via convoluted breathing hoses back to the breathing simulator at this end. The return line passes through a high efficiency filter which will absorb sodium chloride and simulate absorption by the lung, and finally back out through the respirator. The valves in the system make sure that the gas flow goes the correct way around.

The whole thing is placed inside the test chamber, to which can be added the suitable test contaminant; clean air admitted via the external tube, a butterfly valve to control the breathing resistance.

At this point we had a leak which we have induced upstream from the respirator.

This represents homogeneous mixing, as far as is possible. The projected leakages which I mentioned previously from a simple theoretical concept are shown in the upper portion. So if you could concentrate above the arrow, please, for the time being, then those are the values which we have just predicted, P1, P3, on men, using either absorbed, non-absorbed, continuous or pulsed sampling techniques.

Now, the values in the lower table are the measurements that were actually taken with that leak introduced at the point L_H of the respirator. So this time can I ask you to look, please, at the lower table, or the lower portion of the table, this time the left-hand columns. And the actual value of the leakage that we are measuring at the breathing simulator in this case was 6.2 percent, 7.1, 7.3, 7.1, and comparing with 6.7, 8.0, 7.3, 7.3, and so on.

But we have postulated that in the previous theoretical concept the inward leakage was ten percent. So we made a simple correction to bring that up to ten percent and, in turn, all the other values were corrected so we now transfer our attention to the numbers in the brackets, if you will. And these can then be compared, that row of numbers with that one; that row of numbers with that

one; and so on.

So we started to get a reasonable agreement at this stage, not surprisingly because the leakage was out by the respirator.

Now, the predicted results from figure one did assume complete mixing but in practice, in exaggerated form, as was shown in my original figure two, then a degree of streamlining within the mask may probably occur. Here, in the top section again above the arrow, are the predictions that I made previously, using either a probe at P1, P3 or what the man would actually receive in either an absorbed tracer or non-absorbed, in a continuous or a pulsed sampling mode.

A number of tests were then made with a leak, a deliberate leak, introduced into the respirator at the nose point -- I beg your pardon, at the chin. The deliberate leak at the chin and the breathing results were repeated and the values obtained again are the left-hand columns. And the sample (BS) is the sample taken at the breathing simulator where we assumed mixing is optimum in our particular setup, and we can see we are recording values of 5.4, 0.9, 5.5, 5.1, 0.4, 5.6, 6.0, 4.0, 6.8, and so on.

Again because of the philosophy of a ten percent leak in the predicted leakages, we corrected all these to make them into ten at that point. So correspondingly, all the numbers moved up and we are now dealing again with the values in brackets. So what I would like you to do now, please, is to look at the two columns of figures, that one compared to the column in brackets; that one compared to the column in brackets; and that one, clearly by definition, we have made that so.

So we are starting to get experimental results which do at least give some support to our theoretical concept.

The next stage was then to actually make a full series of tests with the respirator sealed onto the dummy test head, in a chamber which was sufficiently large to accommodate all the system, including an operator who was able to move the sampling probe from the position P3 in towards the dummy's mouth at P1, during tests.

During separate tests again we used sodium chloride or SF-6, either in pulsed sampling or continuous sampling. But this time we made a deliberate leak via a piece of capillary tubing at the point L_H , the nose. And a series of tests were made using the breathing simulator by taking samples at either P1 or P3, using the two tracer techniques.

The lead tube was withdrawn from that point. The hole was resealed and the same piece of capillary tubing was inserted at this point, under the wearer's chin, and the whole process was repeated.

The piece of red plastic tubing is actually not the tubing that is inserted; it is merely there for indication purposes.

So these are, in fact, the results that were obtained using this technique. If we could concentrate first of all on the results above this line, and look, for example, with the probe at position P3 — bear in mind, this is on the outer skin of the respirator — The leak we have introduced by measuring at the breathing simulator is recording 5.4, 5.8, and with SF-6 7.5, 7.4. However, the probe at P3 is seeing 15.9, 12.0, 14.1, 16.4.

The probe at P1, which is close to the wearer's mouth, is showing a result which is not totally dissimilar to the measured leak at the breathing simulator.

If we now transfer our attention to the lower table, and remember the physical leak that produced these values is the same one being used here, the man records either 5.6, 5.4 with sodium chloride; 7.3, 7.2 with SF-6. And the probe at P3 is now measuring 3.9, 5.8, 3.9, 4.9.

On the other hand, if we were to push the probe into the respirator so that it was approximately flush with the wearer or the dummy head's mouth, then we see an increased concentration here of 9.6, 8.9, 7.0, 9.3.

So it would appear then from our results that a leak at the nose appears to streamline down the respirator skin and the probe situated on the outside edge of the respirator, here, is actually looking at almost a neat jet of contaminant being directed towards the sampling probe. Conversely, a leak at the chin — the contaminant gases appear to streamline around the wearer's face and disappear into the mouth and they may or may not be picked up by the sampling probe. And, of course, it is likely that the measured leakage will be affected by many other factors. In this case we are postulating the presence and the type of inhalation valve — all these respirators are fitted with inhalation valves — whether it opens at a butterfly, which almost certainly it will, what the orientation is that this butterfly valve will take when it opens, whether the man breathes through his nose or through his mouth or a combination of both, and also the sample withdrawal rate will have an effect upon this wearer.

We are also predicting, of course, that the same problems that prevail with respect to the half mask respirator which

we investigated are also likely to prevail for full facepieces.

Now, the situation with filtering facepiece respirators is of particular importance because such devices must use a sampling probe in order to withdraw a sample from the respirator. We have carried out some limited experiments on one type of filtering facepiece, using the same experimental procedure as before.

Now, the actual spread of leakage values was appreciably reduced but the general trend was the same as for the conventional half mask respirator.

So what we are saying then is that the results of this limited study have shown that it is vitally important that the testing protocol includes precise dimensions of the sampling probe and sampling system and the actual position of the sampling probe within the respirator. I must make it clear that we concentrated only on extremes. You recall from the previous slides that we had a leak at the nose and the chin, which were top and bottom, and we also had the sampling probe either flush with the mouth or flush with the skin of the respirator. Clearly, there are all stages in between, which will have to be considered.

We have postulated from our results that the use of an insoluble tracer appears to offer a working solution to the estimation of inward leakage. Now, unfortunately of course, the efficiency of filter materials cannot be assessed using a gaseous technique. And one idea that is now under consideration in the laboratory in England is that of a dual tracer test hood.

A man wearing the respirator is then in an atmosphere containing an insoluble tracer. The filter of the respirator outside of this area of an aerosol, which is a soluble tracer, therefore the two parameters could be obtained independently but, more importantly, at the same flowrate. The sample, of course, would have to be taken after the exhale valve, according to British standards specification. And immediately we could then dispense with problems of probe location and depth, and so on, mixing problems within the system — whether they would be mixing in an optimum manner is open to speculation but, clearly, they would be mixed very much more effectively after the exhale valve than they would in any other position.

The other problem, of course, is that separate tests would be required to assess the back leakage of the exhale

valve and some suitable computation, taking into account all of these measurements, to arrive at a protection factor. I stress that this is purely speculation at this stage, just one of the ideas that we are actually considering.

So summarizing then, there is a need for more work to be conducted on techniques evaluating total inward leakage of respirators so that more meaningful assessments may be made both during inter and intra-laboratory tests.

I would like to stop at that point, Mr. Chairman, and apologize because I don't have a solution, only reiterating the problems. Thank you.

Mr. Wilmes: Do we have any questions of Mr. Bentley? I guess your presentation was very clear.

Mr. Bentley: Or very unclear.

Mr. Brennan: Mr. Bentley, my name is Brennan, Scott Aviation, besides SF-6, I am wondering if the British Safety Executive has experience with any other gaseous challenges, such as helium — you mentioned argon, which I think I saw published a few years ago. Did you use any other gaseous challenges? Or why did you settle of SF-6?

Mr. Bentley: Well, I think SF-6 was largely — it has been used in Germany by Reidiger and Furst. It is relatively easily detectable. It is very easy to generate the test cloud of a sufficiently low concentration that, in fact, an operator may enter it without any form of respiratory protection at all.

You are quite right, we have looked at other tracer gases. We did consider helium at one time. And I have an unpublished paper with me that I would be pleased to show you afterwards, where did some direct comparisons between helium, argon and sulfur hexachloride, and we obtained good correlation between argon and sulfur hexachloride but helium was way out on its own. There are quite substantial differences between either of the other two gases. Incidentally, that work was for full facepieces, not for half masks.

Ms. Iverson: Sandy Iverson, 3M. I noticed you had two sets of results, one for a leak introduced in the clean air, which I assume was to simulate a leak in the valve; and then one for a leak at the chin area. In each case you normalized the results using the predicted values for what the man inhales. In the first case it gave you good results for leaks — the predicted penetration measured at your location P1 and P3. In the second case your actual measured values were really closer that the ones that you received

after normalizing. Do you have any comments on that?

Mr. Bentley: The short answer is, no, I don't -

-- I stress that these are experimental studies that have been ongoing and it is very difficult to get repeatability from one experiment to the next when fitting a respirator onto a dummy head by a sealing technique of this type. Incidentally, we found extreme difficulty in sealing a respirator onto a dummy without extensive use of filler materials. So I can't offer any solution to that particular question you posed.

Mr. Brennan: A follow-up question to that, I had assumed that you were making a correction merely because you didn't hit ten percent concentration. Are you making the correction for that reason or did you measure a ten percent consumption of contaminant -- I am sorry, did you demonstrate ten percent leakage and not to be able to measure it? I just assumed you weren't able to make a ten percent concentration exactly.

Mr. Bentley: That is right. We aimed for ten percent and we finished up with something like 6.5 -

Mr. Brennan: So you are not normalizing because you didn't detect ten percent that you knew was there. You are normalizing because you did not generate ten percent.

Mr. Bentley: Because we didn't generate ten percent, that is right.

Mr. Wilmes: Thank you very much, Bob. I want to say that all the presenters will be available up here or around here after the completion of today's presentations, should additional questions arise. I am sure Warren and Bob and the rest of them will be happy to answer more of them once you have had time to think about the problems.

The next presentation will be by Haskell Mullins, of 3M, who has replicated some of the work performed by NIOSH. This work is very recent, done in the last couple of weeks. Haskell?

Mr. Mullins: Thank you, Don. The title of this presentation is in-facepiece sampling and accuracy as measured using particulates.

A purpose of the work was to investigate the nature of particulate leakage by the face seal parameter. Most of our work during this investigation was done with negative pressure respirators. Dust/mist type are sometimes called disposable respirators.

It has been assumed that sampling from a single probe located somewhat in the center of a respirator has always given a representative sample. And this sample

would correspond to the amount of leakage inside the respirator cavity. That is, of course, if we meet certain sampling criteria. Normally, two liters per minute is the sampling rate. I was glad to hear this morning that, that was kind of verified.

Another consideration is sampling time. Of course, the sampling time can vary from test to test, depending on the analytical demands and the sensitivity of the techniques being applied. Examples of these are like field testing where it can take from 30 minutes to as long as 120 or 150 minutes. Another example of sampling is real time sampling. All that requires is just enough time for the instrumentation to stabilize, which can be a fraction of a minute, two, four, five or six minutes.

A good example of real time sampling is the application of the quantitative fit testing, where the testing agent or the contaminant outside is compared to the inside concentration of the respirator. This ratio of the inside to outside concentrations is the fit factor. So sometimes it is also called the protection factor, depending on what kind of testing it is being applied to.

Obviously, the quantitative fit testing is done to determine how well a particular respirator fits an individual or a group of people. During this testing a single respirator could be repeatedly put on a person and we could easily obtain factors that would be plus or minus 100 percent. I have done this a number of times and perhaps some of the rest of you have noticed this in your testing.

Until recently, actually very recently, it was thought that most of the variability in this quantitative fit testing was due to a couple of factors, the actual fit itself -- is the fit really real? There could be slight structural changes during the application of taking on and off a respirator. Another consideration would be the breathing rates and the ratio of mouth to nose breathing. Another consideration could be just how precise is the inside and the outside measurement?

But a new concept has been followed up and it could be as large as all the other factors put together. What we really want to know is what is happening inside the respirator cavity when these leaks around the perimeter are occurring. Does the incoming contaminant have enough time to completely mix in the respirator cavity and could there be areas where dynamic concentration bands exist? That is

really what this investigation is getting down to.

During our study we tried to eliminate some of these factors. The way we did it was using a waxed respirator on a manikin. What this did was to eliminate the fit, the actual fit, and the structural stress on the respirator. The breathing rate was controlled at 25 cycles per minute with a breathing machine equipped with a 622 work rate cam. And the volume displacement was about 40 liters per minute.

For simplicity of design our manikin was made with a breathing port half way between the nose and the mouth regions. Precision of our instruments were found to be good, and by good I mean that the relative standard deviation never exceeded eight percent of some mean value.

Getting started into the research, we had to make some basic decisions with respect to our approach. The first thing we did was pick the hardest possible thing to work with, particles. The reason we did that was that no one else was doing it and it is an area that we thought the work should be done in, and I think it is needed.

The other choice we made was to use both inhalation and exhalation in our test apparatus. Both these decisions were because of the complexity of the requirements -- it did take longer to prepare the apparatus and longer to check it out.

We limited the first preliminary study to just three factors. Those factors were sampling probe placement, location of a leak site, and we also thought it would be pretty interesting to look at multiple leaks.

The system we used is very similar to what was reported this morning. We are using three probes in vertical placement. Each probe is about one inch apart. The top probe in the nose area, the second probe in the nose and the mouth, and the third at the mouth region. Our manikin only had one sampling port or breathing port and that was done because of the complexity of the design. So that should be considered when you are viewing these results -- just remember that it is not a system that breathes out of the mouth and nose or either one. The leak locations were at the nose, number one; the second location was at the cheek; and the third location is at the chin. We had the nose and cheek on opposite sides of the respirator. We felt that this would give the leak sites less interference or dependency on each other and perhaps allow them to independently set up the flow patterns.

The test apparatus is broken up into

three sections. This is a particle generator. There is a lot of information there.

Actually, part of the system reduces to this, where a solution containing DOP and isopropyl alcohol is forced through a syringe drive mechanism through a critical orifice -- ten microns, very tiny -- and as it is forced through this orifice, it is also being vibrated. And the tipper vibration rate of this one is 164 kHz. And what this does, it causes the jet stream of the fluid to be dispersed into particles. And the parameters that we have here generate particles in the neighborhood of 2.5 microns.

The next part of the system is where the respirator and the breathing machine are attached. And what happens, the dilution air from the generator which is flowing at about 90 liters per minute is routed through a box with an outlet that has a filter on it. There are four sampling lines, three lines to each probe, one for the inside concentration of the box, and what we did initially is that we compared each line to the challenge concentration to make sure each line was individually sampling the same amount. So during an inhalation stroke the challenge concentration would be routed through one, two or three, or any combination of the leak sites, down into the plumbing into a reservoir, actually a flask, and then poured onto the pistons of the breathing machine apparatus.

What this is is to try to show the particle distribution throughout the breathing machine. You can see the route of the flow on inhalation, homogeneous mixing and then out the system.

The exhalation cycle would like this, where this valve is attached to a switch, which is opened and closed with a cam on the breathing machine -- the valve is open half the time; closed half the time - so when the valve is closed the flowrate of the air is back up, sweeping up the respirator. In this particular model the air in the exhalation cycle would represent 100 percent lung retention because it was clean air with very little particulate in it.

Well, once we generate the particles and get them throughout the test system, then we have to detect them. This is a forward light scattering counter that uses wide angle and the particle size range is well within the limits that we were using. It goes from 0.3 to about 20 micron. We were working with a 2.5 micron particle. The

sampling rate for this particular instrument was at seven liters per minute so that when we were picking up our sample from the respirator ports we had to dilute it with five liters per minute flow of clean air. The electrical signals from the detector were transmitted over to an integrator, a Camberra unit. And we had it set up so that it would look at the signals for six-tenths of a minute and we would look at 100 of those signals or 100 channels, and for each determination it is actually sliced up into 100 areas so there is pretty good integration.

Once the sample was sliced up into 100 prospective areas, that information was fed to a Texas Instrument printer where it printed out the results. And there are several different options of printing out. Basically, what we wanted to do was just look at the regions of interest and we always had these marked off into 100 channel units.

Well, working with this system, one of the observations that I made was that we were always having some particle loss. What I found was that when I had a high concentration, challenge concentration, and removed the respirator and pulled that particular concentration through the system, as long as the concentration was high I got a fairly high reading here also, usually about 95 percent. As this concentration became less, the particle loss became greater. So I made a series of measurements.

And the areas that I was concerned with were just the relatively low readings so that this was kind of typical of the response that I would get in the flask reservoir. As you notice, the ratio of flask concentration to challenge concentration continued to drop as the challenge concentration decreased. It is very nice that this turned out to be a linear relationship. As a matter of fact, it is so straight that it is 0.999-plus.

What this did was allow us to be able to take a reading in the flask reservoir and correct it for the loss.

This is just a plot of the data -- a pretty straight line, as you can see.

The next thing we wanted to do was to see how much precision we were getting out of this system. And precision, by definition, is the reproducibility of the same measurement. Well, this

system has a flowrate going through it of about 90 liters per minute and it is kind of hard to measure seven times in zero amount of time. So "same" is not really the same. The point I want to make is that it is a dynamic system and these results also depend on the stability of that particular system. The bottom line is that there is very little standard deviation, relative standard deviation differences, with the worst cases being, as might be expected, with the low concentration at about eight percent.

One of the first things I wanted to do was just to see how rubber facepieces compared with disposable respirators. These are fit factors at the probe locations one, two and three, and the leak sequence is single leaks at positions one, two and three, dual leaks and triple leaks.

The point of this particular overhead is that there is a lot of variability. Each respirator was made to match up as close as possible with the same size leaks and both show a lot of variability. Both probe location and leak location has an effect - - seems to have an effect here. And this is the only thing that we did with the rubber facepiece. All the following information is with disposable type respirators.

The next thing we wanted to look at is was there really any difference between inhalation and inhalation plus exhalation cycles? The same leak sequence as before. And these measurements were taken from the mixing flask and show that there is really not too much difference in the concentration in the flask. The factors are fairly close and the inhalation plus exhalation values are always higher. It is an interesting trend.

Looking at the same test, now we are working with the probes in the same three locations, and here again a lot of the factors are relatively close but some of them are very far apart. For example, this one here, and in this case the inhalation value is less than the inhalation plus exhalation. But over here there is another difference where the inhalation is higher than the inhalation plus exhalation. That just shows a lot of variability, higher than what might be expected -- higher than what I expected before I started the test.

More excerpts from the Critical Issues Conference will be published in the next ISRP Journal.