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DEPARTMENT OF HEALTH & HUMAN SERVICES

National Institute for Occupational Safety and Health
Centers for Disease Control

Informal Hearings

Notice of Proposed Rulemaking
42 CFR Part 84

Revision of Tests and Requirements for Certification of Respiratory Protective Devices

Washington, D.C.

Wednesday and Thursday,

January 27 and 28, 1988

Informal hearing conducted by Gene W. Matthews, Esquire, Legal Advisor, Centers for Disease Control, beginning at approximately 9:00 a.m., in the Auditorium, Hubert Humphrey Building, 200 Independence Avenue, Southwest, Washington, D.C. 20205.

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CHAIRMAN MATTHEWS: Good morning. I'd like to welcome you all here on behalf the of Department of Health and Human Services. In case you're not sure where you are, this is the Respirator Public Meeting, otherwise known as the Public Meeting Concerning the Proposed Regulation for 42 CFR Part 84 entitled Revision of Tests and Requirements for Certification of Permissibility of Respiratory Protective Devices used in Mines and Mining.

This is the second of two informal public meetings on this subject promulgated by a rule of the Department of Health and Human Services, U.S. Public Health Service, and the presenting agency for this rule is the National Institute for Occupational Safety and Health of Centers for Disease Control.

My name is Gene Matthews, I'm the presiding officer for this hearing. I am with the Office of General Counsel of HHS and I serve as the legal advisor to CDC in Atlanta.

This meeting is being held in accordance with the Federal Register notice of October 8, 1987. As indicated in that notice, the administrative record of this rulemaking proceeding will consist of the August 28, 1987, notice of

proposed rulemaking, all other relevant Federal Register notices, agency records on the subject, all written submissions made in response to the notices, and the record of informal public meetings.

The record of the informal public meetings will consist of meeting schedules, transcripts made by NIOSH of the oral comments at the meetings, any written comments supplied by presenters at the meetings and statements or comments regarding the oral presentations made at either meeting which are submitted by interested persons within 30 days following the close of this Washington public meeting. That means then that the closing date for such written statements or comments will be February 28, 1988.

The written submission should be sent to the NIOSH Docket Office in Atlanta as indicated in the address in the Federal Register notice. No written submissions or any portion thereof made in response to this notice will be received or held in confidence.

The proceedings of this meeting will be transcribed. Any interested person may, consistent with the orderly conduct of each meeting, record or otherwise make a transcript of each meeting. Each participate may present

relevant written information data or views for inclusion in the record of the meeting.

In accordance with that notice, participates were requested to notify NIOSH by January 12th of their interest to appear in this meeting here in Washington. The meeting here is scheduled for two days, today and tomorrow. I'm informed that as of January 12th, 23 participants requested to appear. The schedule containing those participants is available at the door and you should have gotten a copy when you signed in. There were some, I believe, at least one, advance statement filed by one of the submittors. I have one from the door, the Safety Equipment Institute. More may appear so you may want to check at break if they do show up.

We will proceed in the order listed on the schedule, beginning with number 1, going through 23, and I understand with the exception of two federal agencies, Department of Labor and Department of Interior, beginning with number 3 through 23, that represents the order in which the request to present were received by the NIOSH Docket Office.

Now, if a participant is not present when their presentation is scheduled to begin, the remaining participants will be heard in order. At the conclusion of the meeting an

attempt will be made to hear any scheduled participants who missed their assigned time. Interested persons attending the meeting who did not request an opportunity to make an oral presentation may be given an opportunity to do so at the conclusion of the meeting at the discretion of the presiding officer.

I suppose I should ask at this time, is there anyone here that now knows that they would want to be making an oral presentation whose name does not appear on the list? Your name is?

MR. O'LEARY: Chris O'Leary.

CHAIRMAN MATTHEWS: And you are representing?

MR. O'LEARY: Arthur D. Little.

CHAIRMAN MATTHEWS: You're number 24, then.

MR. O'LEARY: Thank you.

CHAIRMAN MATTHEWS: The purpose of the meeting today is to provide the interested parties an opportunity, number one, to make oral presentations on the record to date. number two, to hear the oral comments that are being made by others; and number three, to submit to NIOSH within 30 days of this meeting any statements regarding the oral presentations that were made at either public meeting. As I indicated, such

written statements should be sent to the NIOSH Docket Office.

NIOSH has representatives here today that are prepared to listen and consider what is presented. They are not prepared to engage in dialogue or debate. I suppose now we need to introduce the representatives of NIOSH who are present. I will introduce Larry Sparks, he's the senior person present, and has a statement to put on the record, and Nelson Leidel, the Docket Officer and, Nelson, if you would take charge of introducing the rest of your folks here.

DR. LIEDEL: Why don't NIOSH people just introduce themselves going through the audience since we're scattered.

MR. MILLS: Gary Mills, Chief in Injury Research Prevention.

MS. BOLLINGER: Nancy Bollinger, Chief Certification.

MR. PALLAY: Larry Pallay, Research Injury Branch.

MR. WILLARD: Craig Willard.

MR. BORE: John Bore, Industrial Hygienist, Certification Branch.

MS. MORGAN: Nancy Morgan, Certification Branch.

MR. COFFEY: Chris Coffey, Respirator Certification.

MR. REED: Larry Reed from the Division of Standards Department in Cincinnati.

MR. MOYER: Ernest Moyer, Injury Prevention Branch.

MR. PAVELCO: Ron Pavelco, Certification Branch.

MR. KNOWLES: Don Knowles.

MR. TERRY: Sam Terry.

DR. LIEDEL: Mike Comdon, Certification Branch.

CHAIRMAN MATTHEWS: Just slipping in the back of the room is Diane Porter of the NIOSH Director's office in Atlanta. At this time NIOSH has a statement to enter into the record and Larry Sparks will do that.

MR. SPARKS: Good morning. My name is Larry Sparks. I'm with the Office of Director of the NIOSH. I am here this morning to read into the record a statement. This statement was given also in the San Francisco hearing and except for the change, some changes in the relevant dates, is precisely that same statement and I believe copies of this were available to you at the door. If we're short we'll be making some more. The statement reads as follows.

We are here today to solicit comments on the proposal by the National Institute for Occupational Safety and

Health to revise tests and requirements used in certifying respiratory protective devices. The current regulation under which NIOSH certifies respirators, 30 CFR Part 11, was originally promulgated in 1972. During the last decade there has been a growing consensus among respirator maufacturers and user communities that these requirements should be revised. NIOSH has, therefore, developed the current proposal to reflect technical advances in the field and the more complex environments of today's work places. Most importantly, the proposal will provide respirators that are safer and more reliable. It will also permit innovation in respirator design since it is a a performance-based rather than a specification-based standard.

In order to facilitate useful input at these hearings, NIOSH has conducted a preliminary review of the written comments received on the Notice of Proposed Rulemaking. NIOSH would like to highlight several areas of apparent misinterpretation of the proposal which have been reflected in the comments received to date. This overview is intended to be helpful for those providing comments for the record. While these issues are not an inclusive listing of all the comments raised, it would appear that some clarification by NIOSH would

be helpful with respect to the following six issues:

One, the focus on mines and mining. The fundamental NIOSH regulatory authority for certifying respirators is derived from legislative mandates in the Mine Safety and Health Act of 1977. Both the current certification regulation, a joint regulation, between NIOSH and the Mine Safety and Health Administration, and the prior certification procedure used before 1972, used by the Bureau of Mines, have as their basis the testing and approval, which began in 1919, of respirators used in mining.

Over the years, respirators approved by the BOM and the current NIOSH/MSHA procedure have gained wide acceptance and use outside the mining environment. They have been required by such regulatory agencies as the Occupational Safety and Health Administration, the Environmental Protective Agency and Nuclear Regulatory Commission.

Although more than 95 percent of all respirators sold, certified by the present system, are not used in mines or mining, all the models currently certified are used in mines and mining, with the sole exception of devices sold for protection against vinyl chloride.

The terms "mines" and "mining" are not limited to underground mines. Mining activities vary as widely in nature and scope as do other industrial activities. Routine exposures to gases, vapors, dusts, fumes and mists, and emergency exposure to fires, explosions, and oxygen deficiency are as possible in general industry as in mining. Industrial work sites could, therefore, be equally appropriate test sites for the required workplace testing. The alternative simulated workplace testing described in Section 84.32 could be based on these equivalent activities.

Thus, the argument that a "mines and mining" focus in the proposed regulation would result in respirators that are not suitable for other uses is no more true now than it has been since 1919. Indeed, a respirator intended for mining use is not particularly unique unless it is a respirator such as a powered air purifier that contains electrical components. In the current regulation, these latter devices require additional approval from MSHA before use in underground mines is permitted because electrical components may ignite methane and cause explosions.

Two, Economic Impact of the Regulation. In accordance with established regulatory procedures, NIOSH

contracted for a study of costs associated with the proposed Part 84 regulations. A report, "Economic Overview of the Respirator Industry," developed in Phase I of a two-phase project, was delivered to NIOSH in March of 1982 and was circulated to all respirator manufacturers for review and comment. No comments were received.

Phase II involved the development of questionnaires designed to assess the cost impact, as estimated by the respirator manufacturers, of each major provision in the proposed rule. Questionnaires were sent to all manufacturers for their response. Although all did not responsd, NIOSH received enough information to make an informed estimate of the costs associated with the proposed rule. The estimated cost was substantially less than $100 million.

To ensure all relevant economic impact information is considered, last month the Office of Management and Budget designated that as a "Major Rule" and has directed NIOSH to submit a Regulatory Impact Analysis with the final rule.

As reflected in the docket, some comments estimate that it will cost $700 to $900 million to comply with the regulation. Based on information submitted to the docket, it appears that these estimate are based on two critical, but

incorrect, assumptions. First, all workplace testing must be performed in mines; and, second, each exposure agent for which the respirator would provide protection, for example, hundreds of organic vapor compounds, must be tested individually.

Section 84.31 in the proposed rule, "Guidelines for Workplace o Simulated Workplace Testing," makes no mention of mines or mining. The section requires that tests be done under conditions reasonably representative of those in which the applicant anticipates the respirator will be used. That's 84.31(B), and subsequent sections are consistent with this statement.

The term "reasonably representative" also has bearing on the incorrect assumption that each agent of potential exposure must be tested. It is not the intent of the proposed rule to require manufacturers to conduct workplace or simulated workplace testing for every contaminant for which this device may be used. Rather it is proposed that the respirator manufacturer, who is in the best position to know the product and its marketplace application, conduct appropriate workplace or simulated workplace testing to properly reflect the intended use of the product.

This is consistent with present requirements of 30

CFR Part 11, where a few representative challenge gases, vapors and aerosols, are used as laboratory test agents. For example, if an applicant wishes to obtain dust approval under the current 30 CFR Part 11, NIOSH tests using only a silica dust as a challenge aerosol.

Three, Self-certifications Concerns. Concern has been also been expressed the proposed regulation will, in essence, permit self-certification. It is alleged that respirator manufacturers will conduct the required tests and certify their own products as complying with the regulation. An example would be the present self-certification by manufacturers of most other personal protective equipment, such as safety glasses.

To the contrary, the proposed regulation clearly states in Section 84.30 and in the preamble under a discussion of 84.30 that NIOSH will require manufacturers to conduct and report the results of tests, as currently required under 30 CFR Part 11.11(d). NIOSH will have the option to repeat any or all such tests of the applicant's device in its own laboratories. Under the current regulation NIOSH must repeat all tests, even test procedures for which no failure has occurred for many years.

The proposed Part 84 thus permits NIOSH to focus its resources for verification testing on the most critical performance issues. This will improve respirator reliability and reduce both the costs and the time required to process applications. It is evident throughout the proposed rule that NIOSH will be the sole certifier of respirators that meet the requirements of 42 CFR Part 84.

Four, The Workplace Testing Protocol. Another concern refected in comments to the Docket is that NIOSH has not issued a workplace testing protocol, thus preventing the manufacturers from effectively responding to the proposed rule. NIOSH is currently preparing a document to provide performance-based guidance for field testing. Comments will be solicited on this draft guidance and will be made a part of the record prior to final rulemaking.

NIOSH intend to afford the manufacturers maximum flexibility in developing and utilizing workplace or simulated workplace testing methodology. We intent to permit any scientifically valid methodology that will appropriately reflect the work conditions that are reasonably representative of places and conditions in which it is anticipated the respirator will be used, Section 84.32(b).

This flexibility in a workplace testing protocol is important, and even critical, for permitting and encouraging innovation in the respirator industry. Currently this flexibility is severely restricted by the detailed test procedures described in the NIOSH Laboratory Test Procedures for Respirators.

The proposed rule also contains provisions that will permit a manufacturer to obtain certification for a higher level of performance. Thus for the first time, a manufacturer has an incentive to develop a truly superior product and has the potential to obtain a marketing advantage with the superior device. This provids a marketplace incentive totally absent in today's respirator market. NIOSH is concerned that a NIOSH-specified protocol could limit flexibility and chill innovation in the development of improved products.

Field testing of respirators is not a new or untried idea. Over the past 15 or more years substantial field testing of respirators has occurred in the respirator community, both in the United States and internationally.

Concerns about NIOSH acceptance or possible rejection of a manufacturer's workplace or simulated workplace study are addressed in Section 84.32(c)(2). As detailed in

Section 84.80, a manufacturer is permitted to appeal if NIOSH deems any test to be inadequate.

Five, Organic Vapor Cartridges. There are comments in the Docket which indicate that the required humidity conditioning requirements proposed for organic-vapor cartridges would necessitate a cartridge four times larger than the cartridges presently certified under 32 CFR Part 11. NIOSH is unaware of any published technical data to substantiate this claim, nor has it been received. In addition, the same humidity conditioning and testing are required if the proposed rule for other sorbent cartridges, such as for acid gases, yet no similar comments have been made for any cartridge other than organic vapors.

NIOSH recognizes that respirators fitted with organic vapor cartridges are often stored and used by workers in high humidity environments. However, current regulations fail to adequately address the performance of these devices in high humidity environments. More and more frequently these cartridges and cannisters are being used for protection agains organic vapors that have poor warning properties, such as smell, irritation and so forth.

These public health considerations place a burden

on the certification process to assure the proper and adequate function for respirator users. By necessity, the revised high-humidity test requirement is more stringent than under the current regulation. No advancement in sorbent technology has occurred in this application in decades.

We believe the five-year grandfather period proposed in the new rule in Section 84.2(b)(1) allows ample time to address this requirement, particularly in light of ongoing research by manufacturers and others on this problem.

Six, Filter Technology. Comments have also been made that certain filter devices presently in use will not meet the revised test requirements. Over the past four to five years research has shown that filters that pass the present certification criteria, in which penetration of specified aerosols is averaged over the full duration of the test, may mislead respirator users, for example, filter penetration is dependent on particle and aerosol size, filter loading, and the condition of the filter as affected by humidity during storage. In addition, initial penetration of a new filter may be very high compared with total penetration averaged over a long test period.

Although advances have occurred in filter

technology for other other applications, this has not been true for respirator filters, except for reductions in the breathing resistance of some high efficiency filters.

The adverse effects on filter efficiency due to humidity and other contaminants, such as oil mists, in the workplace are very real and have been amply demonstrated. Thus, for public health reasons, NIOSH has incorporated a liquid, as well as a solid, aerosol test into the requirements for all filter types.

NIOSH considers this proceeding as an important part of its efforts to develop the final rule. It should be noted that the comment period will remain open for 30 days following today's hearing, therefore closing on February 28th, 1988. Your participation and contributions to the public record are greatly appreciate and will provide additional important information on which the final rule will be based. Thank you.

CHAIRMAN MATTHEWS: Thank you. Again I will call to your attention that at the door there should be a list of participants and also a copy of the statement which has just been read into the record by the agency. I would also encourage any late arrivals to be sure and sign in at the door.

Let's proceed then to participant number 1 on the list here, two federal agencies that want to make brief statements. Do we have Charles at Atkins here from Department of Labor?

MR. ATKINS: Good morning. I'm Charles Atkins. I'm Director of Health Standards Program for Occupational Safety and Health Administration. I would like to read into the record our statement, but I would also say that there are copies not available on the table at this time, but they will be before the day is out. We will have them over here.

We would like to congratulate NIOSH for its hard work and dedication to the revision of the certification program for respirators. Revision of the program as it now stands in 30 CFR 11 is badly needed and a sound certification program is one of the most important foundation blocks for maximizing the effectiveness of the use of respirators, especially in the presence of truly hazardous air contaminants.

For these reasons, OSHA believes that the NIOSH proposal and the program it recommends are of extreme significance to the field of respirator protection. Contrary to some positions that have been stated, we believe that this project should continue to completion under the present process.

However, as much as we support the activity and encourage its completion, we believe very strongly that the proposal as published in the Federal Register has some serious problem areas that need to be addressed, provisions that need to be changed in order to make the certification program an effective tool for OSHA to use in its own standards and enforcement activities. We have submitted our comments regarding those problems to the NIOSH Docket and I will not comment on them any further except with regard to how some of the issues were address in the NIOSH opening statement.

First, if indeed the intention of NIOSH is to allow workplace testing and simulated workplace testing to be performed elsewhere other than in mines, that intention should be stated explicitly within the standard.

However, even then, OSHA's position remains, as stated in our written comments, that in view of the variability and lack of controllability of workplace testing, such testing is entirely inappropriate for certification purposes.

The NIOSH statement pointed out that field testing is not new or untried and that it had been occurring for 15 years. What was not said is that the results of those fields tests illustrate exactly why they are unsuitable.

One need only look at NIOSH's own primary lead smelter study to see a variation in protection factors from 10 to 2200 for negative pressure air purifying half masks and from 23 to 1600 for powered air purifying half mask respirators.

Compare these results to the DuPont study for negative pressure air purifying half masks, the results of which range from 94 to 27,000, three orders of magnitude variation, one order of magnitude higher than the NIOSH results.

Then there's the University of Utah measurement at a copper smelter which produced protection factors from about 3 to 83 for negative pressure air purifying half masks, compared to NIOSH's 10 to 2200 for the same type of respirator, and DuPont's 99 to 27,000.

Clearly, if workplace testing has been going on for 15 years it seems to boil down to 15 years of confusion. A history like that is certainly no testimonial for the reliability of this type of testing.

Finally I would like to address the need for a well defined specific test protocol. Although NIOSH points out that a protocol will be published later for comment in the Federal Register, it is further stated that NIOSH intends to

permit any scientifically valid methodology that will appropriately reflect work conditions representative of places and conditions in which the respirator will be used.

In the first place, NIOSH should define what it means by "scientifically valid methodology." That means a set of specific criteria needs to be established. Moreover, with all due respect, the function of a protocol is to standardize a procedure so that it can be repeated and one set of results can be compared to another set. Thus, if two different respirators have been certified for the same performance, it needs to be clear to the user that they have been subjected to the same criteria.

The protocol must also be independent of specific workplace conditions unless the certification will only be good for use in the kind of workplace where it was tested. It seems to OSHA that these points are self-evident. For any certification program to be meaningful, it is absolutely essential that all testing be done according to same protocol and that the protocol be well defined and also be mandatory.

The issues I have addressed in these remarks do not cover the entire range of problems we covered in our written comments. There are others, for example, our objection

to the sliding scale of achievable protection factors, which we consider of equal concern. We urge NIOSH to give serious consideration to all comments we have submitted to the record and hopefully to modify the proposal accordingly.

In summary, OSHA applauds the NIOSH effort to revise the certification program and we hope that this rarely occurring opportunity to have really constructive impact on the effectiveness of respirator protection not be lost or diluted. Thank you very much.

CHAIRMAN MATTHEWS: Thank you very much. Presenter number two, David S. Brown, Department of Interior.

MR. KARAZY: I am not David S. Brown. My name is Nick Karazy. David S. Brown is the Director of the Bureau. He couldn't be here. I'm with the Bureau of Mines at the Pittsburg Research Center and I want my comments to apply strictly to closed circuit breathing apparatus.

The Bureau of Mines at the Pittsburg Research Center has been conducting for 15 years a research program for respiratory protective equipment used in mine escape and rescue. This type of equipment is exclusively closed circuit, used infrequently outside of the mining field. This being the case, it has been the Bureau largely alone that has

investigated the improvement of closed circuit apparatus for escape and rescue.

Also investigated have been physiological limits to stressors imposed by these apparatus and the best ways to test the apparatus. For these reasons we believe the Bureau should participate along with MSHA and NIOSH in the approval process of apparatus for mine escape and rescue.

NIOSH is proposing major procedural changes in the federal approval regulations. We recommend that major changes be made the technical aspects of the regulations also. The present human subject tests used for closed circuit apparatus are nonspecific and redundant. We recommend they be replaced with three more specific tests, namely a normal use test, a high performance test, and a human factors test.

The normal use test would be used to determine the quantity of deliverable breathing gas to the wearer at a realistic workload. Since the duration of an apparatus depends on the breathing gas use rate which varies with the user's weight, physiology and workload, all of which are not quantified under the present and proposed test schedules, the manufacturer must guess at how much oxygen to provide his apparatus for approval. We propose a test that would consist

of a constant specific oxygen consumption rate. A manufacturer will then know precisely how much oxygen to provide for a desired duration.

We also recommend a closed circuit apparatus be classified not by duration but by quantity of deliverable breathing gas, thus not leading wearers into believing that apparatus will always last a certain amount of time. A high performance test is recommended to observe how well an apparatus performs under a higher work load. This test would alternate between the work load of the normal use test and another higher work load. Both of these oxygen consummption rates would be specified, making this test quantitative also.

A qualitative human factors test performing various activities appropriate to the expected uses in an unstructured manner is recommended to evaluate the apparatus/user interface. Stooped walking, crawling, climbing steps or a ladder, bending over, turning head sideways or up and down, handling anticipated equipment, or any other appropriate activity may be performed in this test as thought necessary with no specific time period required for each activity. Either a breathing and metabolic simulator or a human test subject on a treadmill can be used in both the

normal use and high performance test.

The Bureau of Mines has been developing breathing and metabolic simulators since the 1970s. They will be commercially available this year. We prefer the use of such simulators over human subjects because of the ability to quantify input metabolic levels. For those manufacturers without access to a simulator, however, a human subject on a treadmill can be used by varying the speed or grade until the desired oxygen consumption rate is achieved.

Continuous monitoring of average inhaled CO2 and O2 concentrations, breathing pressures and wet and dry bulb temperatures is recommended for both normal use and high perform tests. Since the human subject is on a a stationary treadmill this is easily accomplished and necessary for thorough evaluation of a breathing apparatus rather than intermittent sampling as is done now.

Average inhaled gas concentrations, which include the effects of apparatus dead space, are recommended to be measured when possible. With the development of a fast response wet bulb thermocouple by the Bureau, wet bulb temperature measurement,taking into account the moisture content of the inhaled air, is now possible. The Bureau of

Research has found that the wet bulb temperature of inhaled air is what is sensed by the wearer, and not dry bulb temperature. Therefore, it is recommended that wet bulb temperature be the measure of note.

Our final recommendation is developing new stressor limits based on recent physiological research. Some of the present stressor limits are believed to be unnecessarily conservative in view of physiological research sponsored by the Bureau performed at the Pennsylvania State University. Our specific recommendation are included in our written comments.

With regard to closed circuit apparatus, what is wrong with 30 CFR 11 is not who does the testing, but the tests themselves. Merely passing off the testing to manufacturers will not solve that problem. The technical deficiencies of the approval regulations must be addressed to do that. What are we do to with with the written comments?

CHAIRMAN MATTHEWS: Provide them to Mr. Liedel, Docket Officer. Thank you very much. We now move to Presenter Number 3, Neoterik Health Technologies, Inc., Kenneth Vaughn.

MR. VAUGH: Mr. Matthews, ladies and gentlemen, good morning. I'm Ken Vaughn. I am representing Neoterik Health Technologies. We are offering these comments is a

further contribution to the proposed rulemaking. We are a small business located in Maryland. We design, manufacture and sell products, including respirators, which need NIOSH certification. In December we sent comments in writing to the NIOSH Docket Office in Atlanta and the comments we will be making today are in addition to those.

First, we are pleased that NIOSH is posing to keep its role in the certification program for respirators. We strongly believe that a more effective NIOSH certification program will provide increased protection for the users of respirators. Contribution to workers' safety made by NIOSH, made by NIOSH personnel like Nancy Bollinger, Chis Coffee and Sam Terry is substantial, needs to be recognized and must be allowed to continue.

The proposal includes a requirement for so-called workplace or simulated workplace tests. Because I'm the first manufacturer on this morning I'm sure that everybody is expecting me to talk about this and I'm not going to disappoint anybody. These tests are described as a crucial new requirement and are tests and a requirement which we oppose absolutely and I'd like to explain why.

Our first point, the requirement is unfair,

devastatingly unfair, to small business. One of our respirators can be as good as, or better than, one produced by a large manufacturer and yet not be certified because we might be unable to organize a field test. Clearly there are giants in our industry, like 3M or MSA, companies that could wield enormous commercial influence and are far more likely to receive willing cooperation from user companies than we are. There is built in bias against small business.

Secondly, certain large companies will be able to perform field tests within their own company or within their own conglomerates. Third, certain large companies will be able to perform field tests within the locations of their current major customers. There will be an opportunity to offer commercial benefits to these customers and so the results, including subjective comments, may be influenced to be favorable and to gain certification. This is a built-in bias against small companies.

Certain large companies will perform their own sample analysis or use laboratories within their own organizations. This is a built-in bias against small companies. The field test protocols are not included for comment. How can we consider a new test if the test procedure

itself is not available until the time of final rulemaking.

We must oppose a requirement which is, in the words of rulemakers, the most significant of the new requirements when we don't understand it. These procedures will directly affect our ability to stay in business. As a small company we do oppose this open-ended approach to certification and when the procedures are available we would welcome the opportunity to comment on them.

The cost impacts at this time cannot be determined. However, whatever these impacts are, they will be biased against the small businesses in the industry. The incremental expenses involved are going to be more burdensome for us than the large companies. The greater the expense the more disproportionate the effect and the greater the bias against small companies.

Field tests will introduce large elements of variability, subjectivity and lack of control into the certification business. In other words, the lucky ones will get approved. We must emphasize the very broad significance of this workplace test proposal. As a small manufacturer we believe that we may not be able to meet this. The costs, the organization, the time and the complexity will be too great.

If you ever wanted a regulation, if you ever wanted a regulation that was biased overwhelmingly against small business, then this is it. If you ever wanted a regulation likely to drive small business out of an industry, then this is that regulation. And if you ever wanted a regulation to stiffle innovation, this is it. And for what?

Why does NIOSH propose and I quote, "this most significant of new requirements." Where's the list of failures attributed to the lack of this requirement in the present NIOSH program? What were the causes of these failures, if they exist, and is it really difficulty to devise controlled laboratory tests to search for these causes?

Why burden the industry and single out and punish the small manufactures in order to introduce a technique which has no documented success, no documented procedures, no obvious role to play and no track record proving that it can distinguish good respirators from bad ones. This requirement will result in much more expensive respirators, less competition among manufacturers, less innovation in design and less protection for wearers.

I'd like to introduce at this point a set of documents, like to introduce it, not read it. I have marked it

Neoterik Exhibit A. As I'm sure you know, the major European nations have now completed the multinational project to produce a single European standard for respirators. This same standard has been prepared by the same TC79SG3 working group.

We are entering these documents into the record for your review. I would like to list some of the countries involved in this program: Austria Belgium and Denmark, Finland, Greece and Holland, Ireland, Italy, Norway, Portugal, Spain, Sweden, United Kingdom and West Germany. Particularly. please, consider how this same program deals with the question of practical performance tests. I'd like to refer you as an example only to one document in here, N-168, which is the respirator protection devices standard for full face pieces.

In this document Section 4 is the requirements section and section 4.5 in this standard says "The complete apparatus shall undergo performance tests under realistic conditions." That's what it says. It says, "These general tests serve the purpose of checking the equipment for imperfections that cannot be determined by the tests described in other parts of this standard."

Now, this requirement we submit, is essentially

the same requirement as the one NIOSH is attempting to meet by introducing the field testing protocols as part of the approval program. The European standard then continues, "Where full face mask is to be used for filtering devices, testing has to be done in accordance with Paragraph 5.2."

Section 5 contains all the test procedures. Section 5.2 is one of the procedures within Section 5 and it's headed "Practical Performance Tests." I quote, "All tests shall be carried out by two subjects at ambient temperature and the test temperature and humidity and shall be recorded." And the section listed and defines the following, "items to be assessed by the wearer, a walking test, and then a defined work simulation test."

Finally, the standard says, "Where in the opinion of the test station, approval is not granted because practical performance tests show the apparatus has imperfections related to wearer's acceptance, the test station shall provide full details of those parts of the practical performance tests which revealed these imperfections."

Summarizing this, the same standard has been able to include laboratory test procedures for practical performance testing and a system for updating these procedures based on

results. These procedures, together with the other tests, achieve everything that NIOSH claims for its own field test requirement. At the same time the same standard does not introduce the bias and the costs of variabilities and the other undesireable consequences of the NIOSH proposal.

It goes without saying that the professionals who drafted 42 CFR Part 84 must be fully aware of what their counterparts in Western Europe are saying. At least we hope it goes without saying. It would be strange if in revising standards of such importance that there was no seeking of input from the people in Europe who are doing the same thing.

Therefore, we assume that NIOSH must have reason for not adopting the same approach and we would like to know what those reasons are. We are submitting the same practical performance tests as a replacement for the NIOSH workplace testing requirement. The same tests do exist for all types of respirators, but, of course, the test procedures could be changed.

However, practical performance tests are the best way to satisfy this particular need and field testing complications and protocols must be ruled inapplicable to the product certification program.

We would like to oppose, too, the procedure 84.229, the sequential analysis of performance test results using one-sided tolerance limits. The consequence of this paragraph is to tighten in an unspecified way, to tighten every single specification limit in every test contained in the document. The consequence of this paragraph is to change every single specification because the pass-fail requirement in the specification will no longer apply.

This procedure in this context is a flawed technique, will result in higher costs because of a misapplication of statistical theory to quality assurance. This procedure is a statistical quality control technique and has an application in estimating the extremities of an uncontrolled production process. It attempts to predict future events, based upon certain mathematical assumptions, and to attach probabilities to these events.

The basic assumptions of .229 are the test results obtained can be fitted into a predetermined pattern, predetermined mathematical pattern, and that all future results from future tests on future products will fit the same predetermined pattern. But the testing and evaluation done under 42 CFR 84 does not not satisfy these assumptions.

Under CFR 84 the manufacturer submits pretested and verified products for repeat testing. These products have been produced, inspected and tested before being submitted. This inspection and testing program is explicitly required by NIOSH and so by definition the products do not fit a predetermined mathematical pattern. They don't follow a normal normal curve, binormal curve, or any other mathematical pattern. The products are simply products which have passed a final test specification and any attempt to manipulate these test results according to statistical theories of distribution is spurious.

The 42 CFR 84 contains a procedure for obtaining type approval. Document contains a specification and it contains test procedures. A submitted product is subjected fundamentally to two basic questions. The first is, does it meet the specification, and this question is answered by performing tests against the specification.

If the answer is yes, then the second basic question is, can this performance be maintained in production. And this question is answered by the review of quality control and quality assurance program, including the final test requirements. It can not be answered by manipulating the type

approval test results.

Mathematically the situation is that a small sample of products are submitted to a retesting program. There's no information concerning the population submitted to the original testing program at the manufacturer's. In other words, the survival rate is not known and further the module, assembly, component and piece part survival rates are not known.

What is known is that there have been inspection and test activities and it is certain that as a result any distributions, any mathematical distributions, that may have been present have been truncated and distorted as a result of the inspections and the tests. And so the products submitted to NIOSH are a small sample of an indeterminant, truncated mathematical distribution, the yield of an unknow survival rate, built from an unknown number of small parts, each of which is also a small sample of an indeterminant, truncated mathematical distribution, the yield of an unknown survival rate. The situation certainly does not satisfy the assumptions for the application of procedure 84.229. You simply can not do it that way.

Consider, for example, the noise level

requirement. Specification in 84.228, says maximum 80 DBs. Suppose three respirators are tested by NIOSH and the results are 72, 73, and 74 DBs. How do we interpret these results? 84.229 says that NIOSH can use this data to guess what percentage of future product shipped to users by the manufacturer will fail in the field.

Now, we say that any such guess is erroneous and spurious. We say that what these results show are that the product did, in fact, survive its repeat testing; that the testing programs, therefore, have some correlation; and that the product is capable of meeting the specification. How many defectives may or may not be shipped to users is a function of the manufacturer's quality control program and is not a function of the retest program contained in 42 CFR 84.

It could be argued that in our example above the test results were too close to the limit. But what does that mean exactly? If it means the limit as proposed in the standard is too high, if you think the limit is too low, then come back, propose what you believe is the correct limit, and let's discuss it. We would urge you to delete 84.229. It's invalid, it's not going to improve protection and will significantly increase costs. Please note again that this kind

of requirement is nowhere found in European procedures. We urge you, please, to consider these comments carefully because they are items which are very important to us. Thank you very much.

CHAIRMAN MATTHEWS: Thank you very much. We will move on now to Presenter Number 4, Racal Airstream, Incorporated, P. J. Richardson. Let me just comment, we had indicated in the notice that we would like the comments to be no longer than 15 minutes, if possible. If you think yours are going to go longer than that, please let the Docket Officer or myself known in advance.

MR. BYRD: My name is Donald Byrd and I'm the technical director of Racal Airstream, a manufacturer of respiratory protective equipment located in Frederick, Maryland. P. J. Richardson, our president, was scheduled to speak this morning, but a schedule conflict arose which precluded his appearance this morning. I'm very pleased to speak to you this morning on the matters arising from the NIOSH Notice of Proposed Rulemaking, 42 CFR 84.

Racal Airstream has presented formal documentation and comment to the record in written form. Our comments were extensive and I hope complete. I will not waste your time this

morning on a step by step, line by line repetition of that commentary. I do however, propose to summarize the feelings and recommendations of Racal Airstream in regard to the concept and implementation of 42 CFR 84.

When NIOSH first proposed the rulemaking in August 1987, we tried to get clarification on various matters within the document. We were told repeatedly we must comment on the document as presented. We have done so.

Last week in San Francisco, and I guess parenthetically today, this morning, a clarification was read into the record. To date and to my knowledge, Racal Airstream has not received a formal copy of this clarification notice. Only through the diligence of a member of the ISEA was a copy procured. I have therefore, not had the appropriate amount of time to comment on the supplement to the Notice of Proposed Rulemaking.

NIOSH, when it published the Notice of Proposed Rulemaking, 42 CFR 84, did itself, manufacturers and users a tremendous disservice by not at the same time releasing the anticipated test protocol series. It left all commentors at the mercy of their imaginations and any scraps of knowledge which have emanated from NIOSH as to what the protocol might be

like. The comments to NIOSH, as received by late December 1987, must reflect this confusion and concern.

To state that the protocol would be released prior to final rulemaking was unfair and extremely counterproductive to the needs of a good rule. NIOSH in its proposal suggests that all testing shall take place in mines or simulated mines.

More than 90 percent of the respirators manufactured in the United States today are not used in mines. Agreed, there may be the possibility that certain respirators which are normally used in nonmining situations may be used in the mines. However, the overriding majority of respirators approved to date are not used in mines.

Other agencies, including NRC, OSHA and EPA, have required NIOSH-approved respirators. NIOSH has tested these respirators in general laboratory situations. Manufacturers have also done the same. Although a limited amount of testing has been done in the field, the overriding experience is in the laboratory testing.

NIOSH had it's own problems correlating it's laboratory data with its field testing data. Organizations such as Los Alamos National Laboratory, under contract to OSHA, have also had difficulty correlating their data under simulated

work conditions to laboratory-generated data.

All this shows is that field testing is in its infancy as far as development of techniques and technology and should not now be used as the means of certifying and approving industrial respirators. To convert over to untested protocols with noncorrelatable data may provide a tremendous disservice to the respirator-using public.

NIOSH suggests that, as necessary, it will verify certain field tests done by the manufacturer. I seriously question whether NIOSH or the manufacturers have the current capability of measuring contaminant infiltration into respirators and have any sort of correlation with laboratory data which provides sufficient grounds of confidence necessary for approval.

I shudder to think of situations where NIOSH's field data did not agree with the manufacturer's. Would the certification be denied? Who would be right in view of the infancy of the techniques and the technology since neither the manufacturers nor NIOSH can honestly say that they're right in their analysis. Who will arbitrate the difference and who is willing to take the chance on certification under these conditions?

If we are going to go to the field testing protocols for certifying respirators, then an extremely long time period must be allocated to assure that protocol and technologies have been developed which will indeed accurately show the performance of a respirator in the field. This will be an extremely expensive undertaking. To move to field testing as the means of certification at this time is very, very risky and premature.

NIOSH suggests that all current respirator certifications will expire five years from the date of promulgation of this rule. I doubt that the personnel with experience in the unknown protocol are available or could be found in sufficient quantities to enable NIOSH to recertify all required respirators in this very short time period.

A new NIOSH black hole would form and respirators would not be approved on time or in sufficient quantities to service the respirator-using public. NIOSH would again be exposing itself to the inefficiencies and ridicule evident in the late 70s and early 80s. I would hope that NIOSH, with its advances in processing and approval procedures of the last five years, would not permit itself to again slide into that type of performance.

I should, therefore, like to suggest that the time period for grandfathering be extended to ten years or more to permit an orderly gearing up for field testing, both through protocol and equipment development, as well as personnel training and development.

The economic cost to the respirator user community will be horrendous. The increased cost of respirator testing and the expected retesting as a result of inexperience in this discipline by both manufacturers and NIOSH personnel will be passed on to the end user as price increases.

The employer who provides respiratory protection to his employees as a matter of good will may very well choose not to provide it because of its increased costs. Those employers who provided better respiratory protection to their workers may choose to provide more marginal, perhaps cheaper, respiratory protection because of the increased cost. This could lead to poorer protection to the respirator user population as a whole.

I could go on and on, but I'm afraid my time may run out in the middle of a sentence. I should, therefore, like to summarize our feelings in a few more sentences and provide more positive input to NIOSH.

One, withdraw the notice of proposed rulemaking as it currently exists.

Two, unify the notice of rulemaking with a protocol and put it out for comment again.

Three, solicit constructive suggestions from knowledgeable people in industry, research, manufacturing, et cetera.

Four, provide a six-month period for commentary on the unified document.

Five, extend the grandfathering to a minimum of ten years to allow an orderly transition.

Six, go to negotiated rulemaking.

Seven, allow 60 days for the posthearing comment period. Thank you very much for providing Racal Airstream with the opportunity to comment on this most important matter.

CHAIRMAN MATTHEWS: Thank you, sir. Let's move on to Presenter Number 5, American Optical Corporation, Joseph Zdrok.

MR. ZDROK: Good morning. My name is Joseph Zdrok. I am the regulatory affairs manager at American Optical Corporation, Southbridge, Massachusets. American Optical is a manufacturer of respiratory products and we object to the NIOSH

requirement of workplace and simulated workplace testing for respirator certification.

The proposed regulation has been revised to allow testing and certifing respirators in mines and mining only. While the Mine Safety and Health Act of 1977 requires NIOSH to approve and certify respirators for mines and mining, the act does not prevent NIOSH from approving and certifing respirators for nonmining use. In fact, NIOSH has in the past addressed the needs of nonmining general industry for certified respirators.

More than 90 percent of NIOSH-approved respirators in use today are used in nonmining applications. Other regulatory agencies such as EPA, OSHA and NRC, require NIOSH-certified respirators for nonmining use.

In many instances the respirator needs of the general industry user conflict with the respirator needs of the miner. For example, an SCBA with a harness designed to meet the needs of a fire fighter in mines may not meet the needs of the nuclear industry where decontamination is a major factor since the fire proof design would most likely entail using a somewhat porous material that would trap radioactive material. The scope of the proposed respirator certification program

should be expanded to include the vast majority of respirator users in general industry.

The proposed regulation will also require all workplace testing to be done in mines or mining operations. There are not enough operational mines that exist in the U.S. to accommodate all the manufacturers of respirators for the number of tests required. If all the respirator manufacturers attempted to test several respirators per year, and considering a typical test will take at least 30 days to complete, the existing mines would have a test in progress 100 percent of the time. It is obvious that such disruptive practices would not be tolerated by the mines and they will more than likely refuse to cooperate.

Also, most types of respirators may at sometime be used in mines. However, subjects wearing organic vapor or paint spray respirators, for example, would be hard to locate. Work place test results are unreliable in predicting respiratory performance. The inherent variability of the data makes it unusable for certification and does not assure reliability of the respirator to the user.

Furthermore, analytical methods with very high sensitivity must be used in order to make meaningful

measurements. For the few methods that do exist, necessary handling of the samples in the workplace greatly increase the possibility of contamination of the samples.

Technology does not exist today to perform workplace testing of respirators against most hazardous substances found in the workplace. Analytical methods do not have sensitivity sufficient to make meaningful measurement of performance, especially with those respirators having high assigned protection factors.

Additionally, no test methods exist for field testing gas and vapor respirators. Respirators such as pressure demand, SCBA or air lines with anticipated protection factors in the 1,000 to 10,000 range, it is necessary to have contaminant concentrations that are much higher than the practical limit of analytical detection.

Analytical chemists have a rule of thumb that says at least 10,000 to 100,000 times higher. Finding workplaces with such consistently high contaminant concentrations and sufficient numbers of workers in these high concentrations whose exposures are of a duration sufficient to collect valid samples over a reasonable period of time would be impossible. It is highly unlikely that such workplaces exist anywhere, let

alone in the mines.

Finally, workplace studies are extremely costly. NIOSH released a draft of workplace field test protocol for peer review in August of 1987. The purpose of the research protocol was to verify the assigned protection factors for half and full face piece negative pressure respirators.

In order to make any meaningful cost estimates, however, a test positive protocol is needed. Because no proven reliability protocol exists, the respirator manufacturers were forced to use the draft research protocol developed by NIOSH as a basis for the cost estimate. The protocol states that 126 data points will be required for each substance tested in each of the industries studied. NIOSH states that three to six substances for each type of respirator will be required. For the cost estimate the industry selected a conservative number of three substances.

For example, for a dust respirator, three different type dusts will be tested; for an organic vapor respirator three different organic vapors; air line respirator three different substance, and so forth. The protocol also stated that different facilities in numerous industries would be studied for this cost estimate the industry conservatively

chose to not factor in the need to evaluate different facilities or industries.

Experience in the industry has shown that to obtain 126 data points it has been necessary to collect samples from 200 tests in the workplace. Approximately 75 of the data points will be discarded after or during analysis because the workplace concentrations of the contaminant were too high or too low for valid analysis. In addition, some testings will be invalidated in the field due to pump failure, sample or sample line disconnections.

The overall cost estimate to do an in-field evaluation of respirator performance against one substance is $53,000 and nine-tenths of a person years of effort. The tremendous expense of field testing will place a severe burden on the user community since the costs will ultimately be borne by the user. Even with these very conservative assumptions, it is estimated that a manufacturer with a comprehensive product line would encounter a need to conduct over 1,000 such field evaluations, a tremendously large testing burden. This adds up to direct costs of over $53 million and over 1,000 person years of effort for that particular manufacturer.

This cost will, of course, ultimately be passed

along to the consumer and will result in fewer models of respirators available to the user. Because of these concerns and the impact that this proposed regulation could have on respirator users and manufacturers, we suggest that the best interests of everyone affected that this proposal should be withdrawn.

This document should also be revised, taking into account the comments offered at this meeting, and republished with a test protocol. NIOSH should also consider entering into negotiated rulemaking prior to republishing in order to take advantage of the best available respirator technology.

CHAIRMAN MATTHEWS: Thank you, sir. We are intending to take a break in the vicinity of 10:30. Why don't we go ahead. Is SEI prepared to go? Are you pretty much going to follow your written statement? Why don't you go ahead and handle that now and we'll take a break after this is done. You're Mr. Smith?

MR. SMITH: That's correct. Mr. Matthews, ladies and gentlemen, good morning, I'm George Smith, Chairman of the Board of Directors of Safety Equipment Institute, better known as SEI. I appreciate the opportunity to participate in this hearing on NIOSH's proposed rulemaking 42 CFR Part 84.

The Safety Equipment Institute was founded as a nonprofit organization in 1981 and provides a third-party certification program. Its purpose is to assist government agencies and the safety equipment industry in their mutual goal to provide the American worker protective equipment in keeping with recognized standards and to recognize, for the convenience of users, those products which are certified to meet the applicable standards.

SEI's certification programs rely on the scrutiny of two independent third-parties for product testing at independent laboratory and quality assurance audits of the manufacturing facilities. Six SEI certification programs are currently operating: Eye and Face Protection; Emergency Eyewash and Shower Equipment; Disposable Coveralls, as to labels and sizing; Gas Detector Tube Units, which was a program we picked up after NIOSH had discontinued it; Head Protection for Industrial Workers; and Head Protection for Structural Fire Fighters.

These certification programs include testing to the requirements of NIOSH, and ANSI AND NFPA standards. All product models are certified to the most comprehensive standard available. SEI's third-party certification program provides

repeated quality assurance to users of the safety equipment that products bearing the SEI certification label have been manufactured to meet the same level of quality and performance as do the product models that were actually tested. This third-party review provides a confidence to users that manufacturers' self-certification could not.

With this background, I would like to address several areas of your proposed new standard for respirator certification that are confusing and could pose a serious threat to the American worker.

While recognizing NIOSH's position as to its regulatory authority, as a clarifying point for the entire regulation, I would suggest the elimination in Section 84.3 of any reference to mines or mining work sites in the definitions of simulated workplace and workplacs.

My first real concern is with the lack of a protocol at this time. While the proposed standard for certification has been issued, a tested and proven protocol outlining the requirements, rules, details and procedures for the required workplace testing has not yet been released. Since there are no specifics outlined in the proposal, everyone has been left guessing and at this time it is impossible to

provide any meaningful comment. Review and validation would require a significant of time, and this is essential.

Additionally, in the preamble you state that model workplace testing protocols are too voluminous for publishing in the Federal Register and once they are developed, they will be given to respirator manufacturers as nonmandatory guidelines.

I see this as a serious threat for the safety of American workers which I represent in my capacity as Director of Safety for the International Brotherhood of Electrical Workers. A protocol which is not mandatory is impossible to enforce.

The second area we are concerned about is the allowance of respirator manufacturers to do their own product testing. As a representative of workers I am greatly concerned about having protective equipment that protects. Manufacturers conducting and reporting the results of their tests to NIOSH is not enough. Under the current regulations NIOSH must repeat all tests. This third-party testing, as well as quality assurance audits, give me some confidence that the product that is manufactured next month will give the same or better protection as that product that is tested today.

This, of course, is where third-party certification helps all of us. It could be governmental or it could be private, but it must be third-party certification, not self-certification. Experience has shown that it is extremely difficult for an individual manufacturer or an individual industry to police itself through self-certification.

As I see it, NIOSH would play a weak role in auditing the tests and virtually no role in approving test details or in any on-site scrutiny of such testing. It would be a devastating step backwards for the safety of American workers to permit this type of self-testing.

If NIOSH is unable to continue the testing of all respirator respirator, it is vital this function be turned over to independent third-party certification organization such as our Safety Equipment Institute.

Requirements have be included in the proposal in Subpart B, Sections 84.11, 20, 21, 30, 31, 32 and Subpart H in 84.70 which could all be met by SEI. SEI's program already parallels or in some cases exceeds these requirements. SEI could, as an independent third-party, handle all of these functions as a partner with NIOSH.

We suggest the use of a consensus process through

various groups representing labor, government, respirator manufacturers, general industry, construction, mining, industrial hygiene and safety, to develop an appropriate and carefully prepared standard. The standard would provide an assurance to users that the manufacturers operate in such a way as to consistently produce quality products that have gone through objective and repeatable laboratory testing and quality assurance audits.

The Safety Equipment Institute has a proven track record, with six years experience and is administering the six certification programs I've already mentioned. These programs are working for the benefit of American workers, as proven by the fact our certification programs have resulted in the remember design of some equipment because of the failure to meet minimum performance requirements of the standard when initially tested.

In subsequent testing of equipment and quality assurance audits, voluntary recalls have been conducted by several manufacturers of industrial protective helmets and safety eyewear due to serious failures. Such redesign and recalls would not have occurred had it not been for third-party certification. In these situation the manufacturers believed

that their products were meeting the appropriate standard.

In the scenario NIOSH has created for self-certification of respirators, it would allow manufacturers to make claims about their products that may or may not be substantiated by actual testing. Having this stamp of approval from a federal government agency on a product that has been self-tested may provide inappropriate confidence in a product.

SEI is committed to the goal of protecting American workers with safety equipment in keeping with recognized standard and the current state of the art. As we have stated before, we are highly interested in working with NIOSH to develop a meaningful certification program for respiratory protection equipment.

SEI is managed by a wide cross section of interests, which include corporate users, organized labor, the insurance industry and one safety equipment manufacturer. SEI has achieved recognition and support for its certification programs by choosing the best qualified independent laboratories and quality assurance auditors. These independent organizations test to the most comprehensive standard, be they ANSI, OSHA, NIOSH, NFPA, ASTM, or whatever. Both compliance testing and quality assurance audits are repeated at regular

intervals to maintain certification and the costs are brone by the participating manufacturers.

The support and need for the programs SEI provides is shown by the thousands of requests the SEI office receives for copies of the SEI certified product list and through industry recognition in the form of a $25,000 grant just given us from the National Safety Council Foundation For Safety and Health for educating the public about the SEI services.

In closing, we believe that self-testing can only lead to abuse which would permit unsafe equipment to be in the workplace. In order to assure that employees are protected from the hazards of the workplace, it is necessary that rigid controls be established to assure adequate testing and quality assurance by manufacturers of protective equipment. The Safety Equipment Institute stands ready to assist in this task.

CHAIRMAN MATTHEWS: Thank you, Mr. Smith. Thank you also for preparing other participants here at the meeting with a copy of your remarks in advance. I have 10:26. Why don't we take a 15-minute break and begin with participant number seven, Siebe North, say 10:45 we'll start back.

(Thereupon, a recess was taken and then the proceedings continued as follows:)

CHAIRMAN MATTHEWS: Could we proceed, please. While you are getting seated, someone inquired of the schedule for lunch and proceeding through the rest of the day. I would assume we should try to take a break for lunch around 12:30, or wherever we fall in the sequencing of presentations and we would try to reconvene at 2:00 and probably with another afternoon break, go into the vicinity of five or 5:30. We will go ahead then and pick up with Presenter Number 7, Siebe North, Inc., and Mr. James Spool.

MR. SPOOL: Good morning. Thank you, Mr. Matthews. My name is James Spool and I am General Counsel of Siebe North, Inc., a major manufacturer of respirators certified by NIOSH under 30 CFR Part 11 for use in all applicable industries in accordance with OSHA, MSHA, EPA and NRC regulations. Accordingly Siebe North will be subject to the regulation of proposed rule 42 CFR Part 84 if it is ever promulgated. We have already filed a detailed written commentary on the proposed rule and I wish to thank NIOSH for the opportunity to present this oral testimony at this hearing as well.

The first point I want to make this morning is an amplification of our written comments on Section 84.40, the

certification label. Specifically Siebe North recommends that NIOSH mandate the use of specific certification label language by manufacturers with respect to at least four generic restriction on respirator use when such use restrictions are applicable.

The four generic use restrictions are the prohibition against use for protection against contaminants which do not have adequate warning properties; the prohibition against use for protection against IDLH atmospheres; a requirement for all respirators that they be used only in accordance with a complete respirator program such as required under 29 CFR 1910.134, or which encompasses all the aspects of respirator use identified in Assumption I of Appendix A of Part 84. The fourth is a requirement for all negative pressure respirators which notifies the user that no negative pressure respirator excludes 100 percent of contaminant in the breathing zone and that positive pressure respirators permit less breathing zone contaminant than do negative pressure respirators.

These generic limitations are some of the less understood aspects of respirator use and they apply to the products of all manufacturers. We recognize that these

limitations must be taught as part of a user's training, but as a practical matter they frequently are not.

The current practice by some manufacturers who voluntarily include in their instructional materials warnings covering some of these topics is ineffective and counterproductive overall because the variations in text result in confusing variations in meaning and because not all manufacturers promulgate these warnings.

The Department of Labor recommends to NIOSH that such use restrictions be left to OSHA and MSHA regulation only is unworkable because OSHA and MSHS regulations do not deal with respirator labeling. While OSHA, MSHA, EPA and NRC could designate by their regulations when these use restrictions are applicable, placing the warnings on the NIOSH certification labels, when they apply, will give the greatest assurance that the warnings will most likely reach and be read by the workers who wear the respirators. We strongly recommend that NIOSH include this mandatory labeling proposal in any rule which replaces 30 CRF Part 11.

Next I would like to focus on some of the points raised by NIOSH in its statement fro the record which was read here this morning and last Wednesday in San Francisco. The

decision to designate Part 84 as a Major Rule under Executive Order 12291 is welcome news. I trust that the requirement to make a thorough regulatory impact analysis will provide the basis for greater participation by the respirator industry in the further development of Part 84.

A more cooperative interface between NIOSH and the respirator industry is badly needed. Indeed, I strongly urge NIOSH to take the bold step and convert this proceedings into a negotiated rulemaking. The industry has much to contribute to the creation of an effective certification regulation and a negotiated rulemaking is the fastest way for NIOSH to take advantage of the industry's expertise. This is not a new recommendation, but NIOSH's continued refusal to consider it in the development of 42 CFR Part 84 is inexplicable.

The decision to reopen the record of this rulemaking to permit comments on the so-called performance based guidance document for field testing, whatever that is, is also good news of sorts. However, it would have been much better news had NIOSH announced this morning that it had taken the advice of the Department of Labor, the respirator industry and virtually everyone else who has contributed to the Docket in this proceeding, and that they were deleting workplace

testing altogether.

Workplace testing is an idea whose time has not yet come and NIOSH's literally blind insistance to the contrary will succeed only in delaying promulgation of a needed replacement for Part 11 for another ten years.

The section of this morning's NIOSH statement entitled "The Focus on Mines and Mining," deserves further comment. The references in Part 84 to mining and mines appear in the statement of purpose in Section 84.2 and in the definitions of respirator, workplace and simulated workplace in Section 84.3.

By contrast, neither "mines" nor "mining" appear anywhere in 30 CFR Part 11. The question must be asked, and has been asked, why does NIOSH feel that Part 84 must be explicitly limited to the certification of respirators for mines and mining only, when it omitted that explicit limitation from Part 11 back in 1972? This morning's statement fails to answer this question.

That statement and the preamble to Part 84 refer repeatedly to the Mine Safety and Health Act of 1977, implying that this legislation somehow mandates this change. We all know, however, this is not the case. The sentences in Sections

8.42 H 844 and 957 of Title 30 of U.S. Code, originally enacted in 1969, were unchanged by the 1977 Act.

Therefore, I put the question again to NIOSH, why have you changed the coverage of the respirator certification regulation? If, as this morning's statement appears to suggest, NIOSH does not consider the limitation to mines and mining to be a significant factor in the certification process, then why was the limitation put into Part 84 in the first place? It certainly wasn't in the earlier drafts of the proposed rule which appeared before May 1986.

Given it's acknowledgment in this morning's statement that more than 95 percent of all respirators sold are not used in mines and mining, NIOSH, owes the vast community of respirator users, respirator regulaging agencies and respirator manufacturers, some forthright answers to this question.

Moving now to the question of economic impact, it is obvious that the economic study on which NIOSH relied had at least one failing. It was based on too few responses and it probably had other failings as well. However, NIOSH's criticism of the ISEA study is wholly wrong. Since ISEA's testimony later in this hearing will explain this NIOSH error in great detail I am constrained by time to only point out that

NIOSH's suggestion that the workplace testing Sections 84.31, .32 and .33 not limit workplace testing to mines and mining sites only, turns the English language on its head.

The Section 84.3 definitions of workplace, simulated workplace and respirator, all limit these terms to mines, mining work sites and mining. Thus, the use of these specially defined words in the workplace testing Sections, 84.32, .32 and .33, incorporates the definitional references to mines, mining work site and mining into these sections. To say otherwise is pure unadulterated double speak.

Time does not permit a detailed critique of the NIOSH statements included under the heading "The workplace testing protocol." However, Siebe North would like to point out, even if NIOSH were to take the Department of Labor's advice and limit performance testing to simulated work environments in laboratory test chambers, the flexibility in testing protocols which NIOSH plans to allow is highly likely to be counterproductive.

Rather than permitting and encouraging innovation in product design, this regulatory flexibility is more likely to encourage innovation in the design of test protocols intended to permit lower quality or poorer product to compete

against products of higher quality and better design. It literally makes no sense for NIOSH to allow 22 respirator manufacturers to certify 22 different dust respirators using 22 different test protocols.

Quite frankly, the respirator user will be much better served if NIOSH uses the same measuring stick to measure all manufacturers who seek certification of the same class of respirator. NIOSH should leave the marketing incentives where they belong, in the market, and not in the hand of a government bureaucracy.

This morning's NIOSH statement also makes reference to the appeal procedure contained in Section 84.80. As we said in our written comments, while a procedure including a hearing before an administrative law judge is better than nothing, it is worth little more than nothing if, as in this case, the recommendations of the ALJ are not binding on the Director of NIOSH, and the right to appeal to the courts from the Director's decision is not available. Section 84.80 provides neither and is, therefore, of little benefit to manufacturers.

In its statements under Heading 5, "Organic Vapor Cartridges," NIOSH has completely failed to tell us why the new

OV cartridge criteria are required. These new criteria have only one benefit, they increase service life, but neither the workers who use these cartridges, nor their employers who buy them, are complaining to us or anyone else that current service life is too short. If the market is providing no incentive to increase OV cartridge service life, then why is NIOSH tampering with the market by mandating an increase.

The NIOSH response to this question is "public health considerations." Of course, that's an answer NIOSH frequently gives to tough questions. It signals the fact NIOSH doesn't have a sound technical basis to support an arbitrary decision. Our advice to NIOSH is to look for a better answer other than if it ain't broke don't fix it.

We do have another question about NIOSH's remarks on the organic vapor cartridge issue. NIOSH statement says, and I quote, "More and more frequently these cartridges and cannisters are being used against organic vapors having poor warning properties." Even if this were true, what has this got to do with organic vapor cartridge performance criteria, particularly service life? Since such uses violate OSHA and MSCH regulations, is NIOSH intending to use its regulatory powers to force manufacturers to design their OV cartridges to

facilitate their misuse? Certainly NIOSH owes us a better explanation on this point.

Considering next NIOSH's statements under Heading 6, "Filter Technology," NIOSH again fails to provide any rational explanation for its arbitrary decision that a particulate filter must meet both liquid and solid aerosol tests. If anything will inhibit innovation, it is this new NIOSH requirement for a universal particulate filter. Most particulate filter applications are not in atmospheress containing both solid and liquid contaminants.

Since there is a market demand for dust filters for atmospheres having no oil mist, why require an oil mist capability? It makes as much sense as requiring chlorine cartridges to have an amonia capability. Here again NOISH is tampering with the market without providing any scientific basis other than public health considerations.

Mr. Chairman, in closing I want to make it clear that Siebe North recognizes full well that 30 CFR Part 11 requires wholesale revision. However, our conclusion is 42 CFR Part 84, as it currently stands, is not an adequate substitute for the existing regulation. Accordingly, we recommend that NIOSH withdraw 42 CFR Part 84 as it currently stands and

convert the proceeding into a negotiated rulemaking.

Next, NIOSH should eliminate the express limitation to respirators used in mines and mining, as well as the requirement for workplace testing. If any performance testing is to be prescribedd, it should be limited to tests which can be performed in an environmental chamber.

Third, NIOSH should assure that the revised regulation prescribes all tests and test criteria so that the same measuring stick is used for all manufacturers seeking certification of respirators of the same class. And finally, NIOSH should specify that its certification labels include prescribed expressions of generic use limitation.

I have one final request, Mr. Chairman, and that is that NIOSH extend the post-hearing comment period to 60 days to allow a full critique of NIOSH's statement of this morning. Thank you very much.

CHAIRMAN MATTHEWS: Thank you. Agenda Item Number 8, Freudenberg Nonwoven Company. I understand that John L. Manns is not going to be here and he is being represented by Mr. Petkiewicz.

MR. PETKIEWICZ: Good morning. My name is Chet Petkiewicz. I'm the Director of Research and Development for

the Freudenberg Nonwoven U.S. We have made an official comment to NIOSH prior to this, but we do have some additional statements we would like to make for the record.

The newly proposed NIOSH standard published in the Federal Register on August 27th, 1987, contains some points which preclude a clear, objective and practical judgment of respirator filters. Our objections to this new proposed standard are listed in Figure 1 and we have three objections that we would like to make specific comments on. I'll read these anyway so that you'll understand what we are talking about. These are our objections to the newly proposed NIOSH standard dated August 27, 1987.

Our first objection deals with Subpart 5, Section 84.273, and the comments that we are going to object to, quoting from that subsection, "Filters of particulate respirators shall be tested for instantaneous penetration filter efficiency against both solid and oil liquid particles in the following manner." We will raise some objections to this point.

The second objection also deals with Subpart 5, Section 84.273(d). "Filter shall be tested each at a continues airflow rate of 32 and 85 liters per minute." We will raises

objections to that.

Third objection, Subpart 5, Section 84.273(h), "If filter penetration is increasing when the 100 plus or minus five milligram challenge point is reached, the test shall be continued until there is no further increase in penetration."

The following text elucidates our specific objections to the proposed standard and serves to substantiate our cause for concern. Number one, objection to the use of solid and liquid aerosol for testing.

Testing of respirators against both liquid and solid parcels is not necessary. It is our opinion that it is sufficient for a respirator to meet the required specifications against solid or liquid particles, but not both solid and liquid particles. The specific end use requirements would determine whether the respirator would have to provide protection against solid or liquid aerosols.

The well-known class of electret filters are made with electrically charged synthetic fibers. This class of filters offers the dual advantates of high filtration efficency at relatively low breathing resistance. Depending upon the electret filter structure, the electret filter would cause the respirator to filter solid and liquid parcels in a different

way. The requirements to filter solid and liquid aerosols is not necessary and serves only to increase the breathing resistance of the filter without serving any other useful function. An example is the requirement for high efficiency against liquid aerosols when the respirator is to be used against solid particles. In addition, the added discomfort to easy breathing is done to the end user at a higher cost.

We feel that the respirator should provide the protection which is required, but at the same time not increase breathing resistance and cost without any added benefit to the user. We recommend that two different classes be established according to the end use requirements, one for protection against solid aerosols, one for protection against liquid aerosols.

The chemical nature of the aerosols which shall be used is not specified in the proposed standard. It is known that solid particle with equivalent particle size but different chemical composition will pentrate identical filters at different levels due to the differences in adhesive forces.

If you look at this figure, Figure Number 2, you'll find that we have here efficiency for quartz particles as well as latex particles, and I think it's clear to see that

you will find different filtration efficiency depending on the type of solid aerosol you have. This is basically the point we would like to make. You need to specify the type of solid aerosol you have, otherwise the testing really doesn't mean anything.

Figure 2 is one example of the difference in particle penetration for solid particles of different composition, but tested under identical conditions. The efficiency against quartz dust particles is higher for all particle sizes than the efficiency against smooth latex particles. For test purposes, the chemical nature of aerosols should be specified even when the difference in efficiency against different solid aerosols is relatively low.

In addition, only those aerosols should be chosen for testing purposes which do not attack the filter media. The aerosol should not attack the filter chemically or physically, nor should the aerosol neutralize the beneficial electric charges of electrets.

We are informed NIOSH is considering using as test aerosols sodium chloride as a solid particle and DOP as liquid oil particles. Sodium chloride has proven to be a suitable solid test aerosol for all filter media available in the

market. It is in use today in many standard test procedures, for example, British, German and European standards. We consider sodium chloride, therefore, to be an acceptable test aerosol for determining the filter efficiency against solid particles.

We strongly recommend, however, that DOP not be used as a liquid oil test aerosol because of its different effects on the filter materials available in the market. DOP does not have any negative effect when used for testing pure mechanical filters, for example, glass fiber filters. It is known, however, that DOP neutralizes the electrostatic charges of electret fibers in a very short period of time. This neutralization of electric charges causes a reduction in filter efficiency, negating a major benefit of electret filters.

If we take a look at Figures 3, 4 and 5, if you look at Figure Number 3, the two top curves represent filtration efficiency against DOP particles, in one case an uncharged aerosol, in another case a neutralized aerosol. It becomes clear that the efficiency decreases very rapidly with the challenge of DOP aerosol particles.

If you now take a look at this line, this represents the challenge of an electret filter with sodium

chloride particles. In this case the efficiency increases presumably becuase of two factors. One you don't have neutralization of electret fibers and, secondly, you have a dust cake which is building up in the filter. This data that we are presenting comes from the international scientific community in the U.S., Japan and Germany.

Again I have two other figures that I would like to present. Figure Number 4 also shows the effect of DOP challenge on electret filter. We will take a look just at one curve. If you look at this curve coming down, extending down, again it just simply illustrates that the challenge by DOP aerosol particles rapidly diminishes the filtration efficiency of electret filters.

Figure Number 5, again taken from the international community, this represents data for four different types of electret filters. In this case Curves A and B for resin wool made of two different compositions. Curve Number D is an electret filter made from polypropylene and filter Number E is a filter made from polycarbonate. You'll find in all cases of electret type of filters you get a very rapid decrease in the efficiency of the filter when challenged by DOP aerosol particles.

It can also readily be shown the neutralization effect is not caused by all liquid oil aerosols. Some results are shown in Figure Number 6 for some of our electret filters. If you look at Figure Number 6, you'll see that we have challenged some of our electret filters with two different aerosols, in one case DOP, and in another case paraffin oil aersol. You'll find there is a drastic difference in the filtration efficient depending upon the type of liquid oil aerosol that you use. Again DOP clearly shows that you get a screening or neutralization effect of electret filters, whereas in the case of paraffin oil aerosol you don't see that effect. It doesn't have the same effect.

Two samples of same material were challenged separately with DOP and paraffin aerosols. Both aerosols had a comparable mass concentration. Air flow and all other test conditions were identical. The particle diameter of the monodispersed DOP aerosol was 0.3 microns, while the diameter of the dispersed paraffin oil was 0.4 microns. We do not believe that this difference is significant.

Figure 6 shows that the initial penetration values were nearly the same for the two test aerosols. The data also shows that there are large differences between the two aerosols

as a function of time dependent loading. The penetration of the paraffin oil aerosol increases only slightly with time, due to the slight wetting of the fibers. When challenged with DOP, however, there is a strong increase in penetration from the start of testing. This penetration increases rapidly up to approximately 100 times the initial value. These data clearly show that the electrostatic charges of an electret filter are destroyed by DOP aerosols.

All of the above examples clearly demonstrate that DOP is not suitable as a test aerosol. As an alternative to DOP we suggest paraffin oil. Paraffin oil is already used as a test aerosol in the German and CEN standards, and is considered to be suitable for all filter material on the market.

Number two, our objection to the use of two air flow rates for testing. Both penetration and pressure drop are dependent upon the corresponding air flow rate. Therefore, it is possible that a respirator will pass the requirements of the standard at one flow rate and fail at a second flow rate. In order to avoid such situations we recommend that the standards specify only one flow rate for determining penetration and air flow resistance values. Specification of one flow rate would allow for a clear classification of the filter media.

Number three, objection to the proposed test limit penetration values. As we have previously stated, electret filter media are approved and used in the market for respirators. We have also previously stated that electret filters offer the dual advantage of high efficiency and low air flow rate. When such electret filters are continuously loaded with liquid oil aerosols a slight but constant increase in penetration results with an increase of aerosol loading. This behavior assumes that no significant dust cake will be formed on the filter material during the challenge with liquid oil particles.

An example of this effect can again be seen in Figure 6 when we compare the DOP loading to the paraffin oil loading. In this case an electret filter is loaded with paraffin oil mist. It is unrealistic, therefore, to expect that the penetration of an electret filter remains constant when the challenge point is reached.

By the appropriate construction of a filter media it is possible, however, to obtain penetration values of a respirator which will be below the required tolerance limits during the total recommended usage time. This would occur regardless of the slight but constant increase of penetration

with increased aerosol loading. We recommend, therefore, that the proposed standard require that the penetration at a given loading value, for example, 100 milligrams, plus or minus five milligrams, be used. Thank you very much, Mr. Chairman.

CHAIRMAN MATTHEWS: Thank you. We will now proceed to Presenter Number 9, Edison Electric Institute, Eric Hans Bauman. No one from Edison Electric?

A PARTICIPANT: He wanted to make his presentation later this afternoon.

DR. LIEDEL: Right, he had requested that.

CHAIRMAN MATTHEWS: So we will past over Number 9, Edison Electric, and proceed now to number ten, ISEA, Frank Wilcher.

MR. WILCHER: Good morning, Mr. Chairman. My name is Frank Wilcher and I am President of the Industrial Safety Equipment Association.

The Industrial Safety Equipment Association, known as ISEA, is a nonprofit organization composed of approximately 80 manufacturers of personal protective equipment for industrial environments. This includes hard hats, safety eyewear and, of course, respirators, which we are discussing today.

Since its inception in 1934 ISEA has been dedicated to the safety of workers who rely on protective equipment and to the welfare of the safety equipment industry.

As a results-oriented association, ISEA is primarily dedicated to fostering public interest in safety and encouraging the use of proper equipment to deal with industrial hazards. Toward this end we work very closely with our member manufacturers and others to help them develop consensus standards for product performance and use.

In fact, during my 14 years with ISEA one of my major activities has been working with regulators, ISEA members and end users of their products to ensure that we were working to develop the best possible products to ensure maximum safety for workers. While there have obviously been disagreements between the interested parties, we have always been able to have open discussions and a fair exchange of information, experiences and expertise. It is my view that this kind of give and take is one of the key ingredients of a productive regulatory process.

The process through which 42 CFR Part 84 has been developed has been disappointing. I don't think there's been the necessary give and take between the interested parties.

And to the extent that there has been dialogue, specifically between the respirator manufacturers and end users, it has been at our initiative and outside of what has seemed to be the interest of the regulator.

To demonstrate that point I will recall a conversation I had with a high-ranking labor official whose responsibilities include workplace safety.

I called my contact to share our views on the proposed 42 CFR Part 84, to hear his views and to inquire as to when his organization would be submitting their comments for this Docket. I must say I was shocked when this individual indicated his organization wasn't going to respond because the workers he represents weren't affected. He was obviously surprised when I advised him of our view that his constituency would be significantly affected by the outcome of the proposed rulemaking.

All of this is to say, Mr. Chairman, that the process of this rulemaking has been one of the most confusing and disorganized regulatory processes in which we have participated.

Let me say that I'm not here to complain, rather to offer constructive suggestions as to how we can get the

process of revising and updating 30 CFR Part 11 back on track. That, I am sure, is your interest and I know it is ISEA's.

I had originally planned to speak from an industry-wide perspective on several overriding problems with the NIOSH proposal as published and amended in the Federal Register. These issues included, one, the procedural defects with the proposal; two, the economic impact of the proposal; three, application outside mining operations; and, four, the absence of testing protocols.

Last week, and again this morning, NIOSH issued a lengthy statement which addressed each of these issues and other more technical points. The NIOSH statement was presented as a clarification of their original intent and expressed surprise that any misunderstanding occurred at all. I find this somewhat disingenuous for two reasons.

First, each of the misunderstandings NIOSH spoke to were presented to them by ISEA and others several months ago. If they were indeed simply misunderstandings, why did NIOSH wait until last Wednesday morning in San Franciso to say so?

Secondly, the clarifications are, in some cases, even more alarming. I would like to address each of the six

points raised in the NIOSH statement and point out why ISEA continues to have significant problems with each. By doing so, I will, coincidentally, address the issues mentioned above.

Number one, the focus on mines and mining. According to NIOSH, it is a misunderstanding to suggest that the proposed rule applies only to mines and mining situations. If this is the case, we are pleased in that we strongly argue against such a limited focus.

However, if one reviews the definitions provided in the notice of proposed rulemaking, they allow for no other interpretation. For example, a respirator is defined as "any device worn by an individual engaged in mining." Simulated workplace must be reasonably representative of mines or mining" and workplace is defined to mean "any mine or mining work site."

Clearly if a "mines and mining" limited focus is not what NIOSH had intended these definitions should be significantly expanded.

Number two, the economic impact of the regulation. Regarding the economic impact of the proposed rule we are gratified that the Office of Management and Budget responded favorably to our request that this rule be redesignated as a

Major Rule under Executive Order 12291 and that a full regulatory impact analysis will be prepared. ISEA is eager to work with NIOSH in the collection and analysis of data, as well as the final operations of the regulatory impact analysis.

As to our existing impact estimate of over $700 million, we admit to using assumptions since so little information was available from NIOSH. However, the two assumptions the NIOSH report dismissed as incorrect are themselves incorrect.

First, the location of workplace testing is irrelevant to the cost formula. Introducing nonmining locations would favorably impact feasibility, but would have no impact on our cost estimates.

Second, we did not cost out separate tests for each exposure agent. Rather than pricing tests for "hundreds of organic vapor compounds, " we allowed only three. Similar limitations were applied to dusts, fumes and other agents. In short, we would argue that our impact estimates were extremely conservative.

Number three, self-certification concerns. To address the issue of self-certification, I think it useful to examine the current process and how the proposed rule differs.

At present NIOSH requires manufacturers to test their products and submit the test results to NIOSH. The proposed rule would do the same thing. However, NIOSH currently conducts confirmatory tests on all requests as standard policy. The proposal states only that NIOSH may conduct confirmatory tests. Moving from an across-the-board, uniform procedure to one which could be applied arbitrarily or at random is in the best interests of neither the manufacturers nor the end users of respirators.

Number four, the workplace testing protocol. The concerns raised earlier regarding the absence of a workplace testing protocol have not been alleviated by NIOSH's statement for the record. While we obviously need to examine the protocol in order to comment intelligently on its feasibility, we can not comment on it in isolation, and hope that NIOSH will allow and encourage our significant involvement in drafting the protocol.

Number five, organic vapor cartridges and filter technology. The NIOSH statement concluded with discussions of two technical issues, organic vapor cartridges and filter technology. Once again NIOSH's comments do not clarify the situation and, to some degree, actually add to the confusion.

ISEA recognizes that public health considerations have a valid role in these deliberations, but they must be based on a nonsubjective assessment of real needs. NIOSH argues that few advances have been made in these technologies and public health has suffered for it. That is clearly not accurate. For example, significant advances have occurred in the nonhigh efficiency filters while high efficiency technology has not changed appreciably for 40 years.

Furthermore, whether vapor cartridges under the proposed rule would be two, three or four times longer, depends, to a large extent, on whether NIOSH wants manufacturers to continue their standard practice of exceeding, rather than simply meeting, NOISH requirements. We assume and hope the former is the case.

Mr. Chairman, in addition to my oral comments today I would like to refer you to the 78 pages of detailed written comments ISEA has submitted to the Docket. A great deal of thought and effort was put into their development and I hope that NIOSH will match that level of effort in their examination and review process.

Mr. Chairman, I would like to make the following recommendations. One, given the confusion and the absence of

give and take of information early on in the rulemaking, I would like to recommend that the record for comments on this hearing be extended from 30 to 60 days. This will give those, such as my friend in organized labor who until recently thought the workers he represents wouldn't be affected by the proposal, the necessary time to study and process all of the materials in the Docket and the information which has been made available through the two public hearings so that he can make meaningful comments for the record.

Number two, NIOSH should bring together experts from industry, labor, other end users, concerned regulatory agencies, and respirator manufacturers to review the issue in its totality.

Number three, with this body of knowledge and collective of perspective, NIOSH will then be better positioned to complete development of the protocol and revised 42 CFR Part 84.

Number four, at this point I would strongly recommend that NIOSH publish the entire proposal, including the protocol, in the Federal Register still as a notice for proposed rulemaking.

Number five, once the notice for proposed

rulemaking is published, NIOSH should provide a six-month comment period so all the affected parties will be able to respond in a productive, constructive and meaningful way to the complete package. It appears to me that this process will help create an environment in which all of the affected parties will feel they have participated in a logical, fair and open rulemaking process, thereby ensuring the best possible results for worker safety.

I would like to conclude my comments on an hopeful note. While the process of this proposed rulemaking has been both confusing and disorganized, I am very hopefully that the positive give and take which is finally emerging will continue, thereby giving all affected parties the opportunity to participate in a meaningful way.

I am sure the results of this effort will appropriately update the outdated 30 CFR Part 11 and create a process which will provide the best possible protection for workers. I an sure that is NIOSH's goal and that is the ISEA goal. Thank you very much.

CHAIRMAN MATTHEWS: Thank you. Presenter Number 11, Thomas H. Seymour.

MR. SEYMOUR: Mr. Matthews, ladies and gentlemen,

my name is Thomas H. Seymour. I am a registered professional engineer, a graduate fire protection engineer from the University of Maryland, I have a master's degree in engineering administration from George Washington University. I have been fire training instructor for the University of Maryland's Fire Training Extension Program since 1960 and have taught courses for a number of other state fire training programs around the nation.

I'm here today to speak on my own behalf and I am not speaking for my present employer or for the University of Maryland. I wish to commend NIOSH for moving this important effort of updating and improving the respirator certification program citeria and requirements to this stage. I am opposed to withdrawing this proposal and starting all over again. NIOSH needs to continue the rulemaking process by publishing additional changes and taking public comments on the same.

I support the proposed criteria for recognizing closed circuit positive self-contained respirators, also the proposed requirements for full face pieces to pass the impact testing requirements of Section 84.22(e), as a good step in the right direction. Such full face pieces, when worn, will satisfy the requirements of safety eyewear and, therefore,

remove any need to wear safety eyewear inside such full face pieces.

The test for flammability of full face pieces is an important step in improving the quality of self-contained respirators that will be approved in the future. The proposed test is almost identical to that used in West Germany for many years. For example, these requirements will prevent in the future the use of plastic clips that have been used in the past to hold face piece lenses in place. This was done for several years by one of the major respirator manufacturers.

Fire fighters wearing such face pieces with SCBA in actual actual fire fighting environments experienced catastrophic failure of these face pieces by the plastic clips failing and the lense piece moving such that an opening occurred around the seating or seal area of the lense itself. This quality of equipment should not be permitted to be approved by NIOSH in the future.

I do wish to object to the respirator, "workplace and simulated workplace" definitions being restricted to mines or mining work sites, which I assume NIOSH means to include such workplaces as open pit mines, sand and gravel pits, and quarries. This is far too narrow.

NIOSH must recognize the use of their criteria by many other federal and state regulatory agencies, including her sister agency, OSHA, which NIOSH is required by law, the OSHA Act, to be the safety and research arm of OSHA. I have some additional comments which are in writing which I wish to submit to the public record. Thank you.

CHAIRMAN MATTHEWS: Thank you very much. We move on to Number 12, Pro-Tech Respirators, Inc., William F. Moon.

MR. MOON: Good morning, Mr. Matthews, ladies and gentlemen. My name is William Moon and I am President of Pro-Tech Respirators, Incorporated, in Buchanan, Michigan. Pro-Tech is a small manufacturer, primarily of air purifying respirators, and we have the following comments on the proposed rulemaking 42 CFR Part 84.

Although Pro-Tech is a small firm, it is our objective to manufacture respirators which can be certified by NIOSH. We have been manufacturing such respirators since 1974. We feel that the proposed regulation is, in many ways, an admirable effort. Certainly we have needed to have improvements in the old 30 CFR Part 11 for many years and ISEA, of which I am a member, and a member of the Standards Committee also, has been working very hard on this for many years.

The proposed regulation, in our opinion, falls short of its objectives in several ways. The most important of these is the much discussed lack of definition of the field testing protocol. This is a major part of the regulation and we simply have no information about the field testing protocol.

Not knowing what the field testing protocol is going to involve means that we can not really intelligently comment on the document as a whole. Many before me have gone into greater detail on this, but I certainly support the comments which they have made concerning the lack of information, the lack of a field testing protocol, which is a key part of the proposed Part 84.

I would also like to support the comments which have been made concerning the ISEA Standards Committee's estimate of $780 million as the cost of field testing only those respirators which are presently approved. This cost estimate did not include products which are yet to be developed. It is possible that it may have been inflated slightly by the fact that we assumed that we would test, field test, three substances of each type, for instance, three dusts or three organic vapors, instead of the one which NIOSH has implied would be adequate.

However, let me point out that estimates of this sort are noted for their lack of accuracy. Our friends in the nuclear power plant industry have had a great deal of difficulty coming anywhere close in their estimates of the costs of building nuclear power plants and what happens to them is perhaps similar to something that might happen to us because a regulatory agency enters in the picture after the effort has begun and informs them that the effort is not adequate in the manner in which it's being undertaken, therefore, the costs are escalated over and over again. I think that this same kind of thing could happen to us with a field testing program if we don't have far more information than we have at this point.

Also I would like to say it shouldn't be inferred from the fact that ISEA has come up with a cost estimate for doing field testing that this means that ISEA or that the respirator manufacturers feel that they know how to conduct field testing. Most respirator manufacturers have told me they simply feel they do not have the necessary instrumentation, they don't have the methods, the technology does not exist to allow field testing of respirators to be conducted at the level of accuracy which is being required.

In fact, some kinds of respirators really cannot

be field testing very effectively at all and there are some types of substances in the workplace for which suitable test equipment is simply not available.

Also speaking as a businessman, the huge cost of field testing of respirators is going to have a stiffling, choking effect on our efforts to develop new products. The delays, the huge increase in expense, plus the great delays in time, mean it would be extremely difficult to get a suitable return on investment on a new respiratory product. The time delays required are even more important than the increased amount of money needed to fund the field testing efforts.

Therefore, we think that the proposed Part 84 will have the opposite effect to that suggested by NIOSH. NIOSH has stated that they felt that this would encourage development of new products, perhaps more creativity and imagination in the development of products, and we feel it will have the opposite effect and that the people will begin to spend much more time on developing test protocols than they will on developing new products.

I have two other objections to the NIOSH proposal. The first, as previous speakers have mentioned, that all filters must be tested against oil mist. It is my experience

that oil mists are found in a very small percentage, perhaps less than two percent, of industrial respirator applications. It does not seem reasonable to require that all respirator filters be tested against oil mists and I would recommend that NIOSH consider a special class of filters which would be used against oil mists and this would allow much more economical and efficient filters to be used in a great majority of applications.

The second criticism I have concerns the organic vapor cartridge problem. All of those people who do testing of organic vapor cartridges know that cartridges which are preconditioned at high humidity and then are tested at high humidity also, this results in much shorter cartridge life and if this is left in the protocol or the Part 84, we will have to design much larger, much heavier cartridges, which the workers will probably not enjoy using and I would like to point out that there is no increased level of protection due to these larger cartridges. They would simply last longer, but I do not see this as any great value. Furthermore, there has been no demand felt by any of us in the marketplace for such larger cartridges.

In summary I would like to say that we hope that

NIOSH will withdraw the proposed standard and begin again to develop a new standard, perhaps using a consensus performance standard approach or perhaps negotiated rulemaking.

CHAIRMAN MATTHEWS: Thank you. We move now to Presenter on Number 13, Scott Aviation.

MR. GANZENMULLER: Good morning. My name is Earle Ganzenmuller. I am Product Line Manager for Air-purifying Products for Scott Aviation. We are very concerned that if the rulemaking in 42 CFR Part 84 goes forward as proposed there will undoubtedly be fewer manufacturers of respirators. The smaller manufacturers will go out of the respirator business out of necessity. Respirator prices of those remaining manufacturers who elect to stay in the business will increase dramatically to cover the increased cost of obtaining approvals by following the draft workplace field test protocol released by NIOSH in Peer Review August 1987. We understand that NIOSH plans to publish the field test protocol at the time of final ruling, but at this time we can only respond to the limited information they have already made available.

Industrial and fire service users recognize Scott as a major manufacturer of respirators. We have approximately 90 certification numbers covering approximately 800 different

respirators. Scott was an originator of self-contained breathing apparatus that's a major portion of our health safety product business. The estimated costs to Scott to test all Scott/NIOSH-approved air purifying respirators presently being marketed is $65 million, again based on the limited NIOSH published guidelines we have to work with.

As Product Line Manager for Scott Air Purifying Respirators I would be remiss in my responsibilities to Scott and our parent organization, Figgie International, if I was to make any recommendation other than to consider getting out of the air purifying segment of the industry if the proposed rulemaking was enacted. An alternative may be to restrict the manufacturing and marketing of air-purifying respirators to a select few models and applications where substantial volume exists to spread the cost over many units. If the other manufacturers elected to follow this same rationale, workers' safety would be compromised immediately. After all, who's going to go through all the development, tooling, manufacturing and testing expense to manufacturer products when the chances of recovering your costs within a reasonable period are small or none?

I personally can not understand why more of the

user community is not challenging this proposed new regulation. Probably many users do not comprehend the technical aspects of certification. They probably don't understand that their general industry and construction requirements for respirators are completely ignored by limiting the certification only to respirators for use in underground mines and mining. NIOSH has purposely ignored the need of all these other workers. The proposed new regulation must not be become the standard. It must be withdrawn.

If NIOSH feels that its resources should not be wasted by performing respirator testing, it is suggested that NIOSH work with industry to develop a suitable consensus standard, including establishing a qualified third-party organization to test and certify the manufactured products under methods consistent for all manufacturers.

This will continue to assure users of base line respirator performance from which to make their selection. In addition, NIOSH could and should use their technical expertise to make available more performance information of various air-purifying sorbents against the many toxic contaminants in the workplace, also develop and make available to the air purifying manufacturers designs of proper end-of-service

indicators to warn workers when an air-purifying cartridge or cannister is no longer working or face piece fit has been compromised.

I would briefly like to address the NIOSH statement with regard to the organic vapor cartridges and the comment that only organic vapor cartridges were addressed, not acid gas cartridges. The most difficult bench test requirement of organic vapor cartridges or cannisters is after equilibration with 85 percent humidity in air. The moisture blocks the available sorption sites on the activated carbon, which reduces its sorption capacity.

No comment was made with regard to acid gas cartridges or cannister after 85 percent relative humidity equilibartion and break-through performance at 64 liters per minute, twice the present flow requirement in 30 CFR Part 11, because the typical sorbents used for acid gas applications are enhanced by the presence of moisture. The most difficult test would be with complete absence of moisture.

I thank you very much for allowing me to make this presentation.

CHAIRMAN MATTHEWS: Thank you, sir. Presenter Number 14, 3M.

MR. COLANDER: Good morning. I am David Kolander, the Marketing Director for the Occupation Health and Safety Products Division of 3M.

I am compelled to express 3M's deep concern regarding the lack of sufficient information and supporting documentation contained in the August 1987 Federal Register notice, which set forth the many significant changes NIOSH is proposing to make to respirator certification. Because NIOSH did not provide extensive information on what is being proposed, and why the changes are being proposed, it is difficult for 3M and the other respirator manufacturers to prepare meaningful comments.

We still feel strongly the best course of action is for NIOSH to recall the proposal and reissue it with supporting documentation, accurate cost estimates of compliance, presented in sufficient detail to allow a meaningful dialogue atmosphere with the industry.

I will move to specific concerns 3M has about the proposal. First, workplace testing. 3M believes that workplace testing, as proposed by NIOSH, is a requirement that is impossible to comply with. Whether or not the tests are conducted in mines is immaterial. It is still impossible.

This morning NIOSH stated "NIOSH is currently preparing a document to provide performance-based guidance for field testing. Comments will be solicited on this draft." You may ask, as we have, why not include this document in the original proposal? Because NIOSH has not, however, 3M requests that the comment period on 42 CFR Part 84 be left open for 180 days after the publication of the NIOSH performance-based guidance document for field testing.

Let me clarify one thing. Workplace testing and evaluation of respirators is something that 3M supports and is currently conducting for research purposes with our own products today. Nevertheless, given today's state of the art workplace testing techniques and knowledge, it is a task that is extremely difficult to do.

The testing limitations are wide. The challenge is to measure small concentrations of microscopic particles inside respirators while being used in the workplace on the worker's face. Today the analytical instruments available for workplace testing, with the sensitivity needed to give accurate measurements, are all but nonexistent. There are a few common workplace contaminants, lead, zinc and asbestos, which can be readily measured. The vast majority, however, can not.

Also our efforts at 3M in workplace testing have made it very clear that contaimants are not isolated in the workplace. In a foundry, where you're measuring silica particles, you will find particles of carbon, lead and iron oxide in the test samples. In a chemical processing plant, where you are attempting to measure benzene levels, you will commonly find traces of toluene, xylene and hexane.

The actual workplaces are extremely complex and challenging environments to be used for certification requirements. Workplace testing can be extremely valuable to a respirator manufacturer in determining how the respirator performs on the job, but with the inherently high variability associated with workplace testing, such results are poorly suited for a certification requirement. Few here this morning would disagree that any test requirement which is a tenet for certification must provide reliable, reproducible results.

Practical limitations to workplace testing. NIOSH has totally ignored the practical limitations of workplace certification. 3M has approximately 200 current respirators requiring testing. Imagine the problem, if you will, of finding 200 work sites where the employers will let you tie up their workers, maybe 100, 150 workers, for several days to test

your respirator.

Envision these same employers when 20 respirator manufacturers descend on them with the same request. Practically speaking, in the workplace testing that we have done at 3M, it is extremely difficult to find one or two suitable work sites and one or two cooperative employers to evaluate one or two of our respirators, much less 200.

NIOSH has recently been director by OMB to submit a regulatory impact analysis. 3M requests that as part of this analysis NIOSH survey the users of respirators to obtain a measure of the practical problems of conducting thousands of workplace certification tests.

The cost limitations have been well documented this morning. I'll omit those in my comments at this time, but I do want to comment about the NIOSH cost study questionnaire. In their statement this morning NIOSH said, "In accordance with established regulatory procedures, NIOSH contracted for a study of costs associated with the proposed Part 84 regulations. Questionnaires were sent to all manufacturers for their response. Although all did not respond," I believe about half did not respond, "NIOSH received enough information to make an informed estimate of the costs associated with the proposed

rule. The estimated cost was substantially less than $100 million."

I have conducted market research studies for 3M in my career. I've personally designed and administered dozens of questionnaires. I've reviewed hundreds of questionnaires and I've studied hundreds of completed industrial market research reports. I am well qualified to comment on the market research conducted for NIOSH. I can say without qualification, the design and administration of the procedure, the questionnaire, the treatment of data, the final report all lacked even the remotest resemblance to an acceptable market research study. As a professional researcher, I would elect not to be even associated with it.

The conclusions NIOSH has drawn from this attempted market research study are irreparably flawed and of no value. For an issue as complex as this one, with a universe of only 20 respondents, even the rank amateur market researcher, fresh out of school, would quickly conclude that type of investigation must be done with direct personal interviews, not with a huge mail questionnaire.

There were many major flaws in the questionnaire and the process, which I won't cover except for the topper.

They asked the respondents to estimate the cost of workplace testing, but guess what? They did not provide any protocols to allow the respondents to make even a reasonable estimate of test procedures and costs. Does that sound familiar this morning?

I've gone on at length about a topic, the highly suspect research procedure used to misrepresent the cost of workplace testing, that you may consider an over-reaction. However, I submit that it is indicative of the NIOSH administration in Atlanta and are typical response to our industry, don't bother us with the facts, our mind is already made up. It's time for the people in Atlanta to adhere to fundamental policy for all government agencies, be responsive to your constituents and engage in meaningful dialogue with them.

The $700 million in new costs would have a drastic impact on the market. Small employers would no longer be able to provide their workers with respiratory protection. Major employers undoubtedly woud cut back on discretionary use of respirators.

It's doubtful a cost increase of this size would ever be fully borne by the marketplace. Consequently, 3M

estimates we would be forced to undergo a drastic reduction in the categories and types of equipment that we manufacturer, if we were to remain in the respirator business at all.

Frankly speaking, if 42 CFR Part 84 were enacted in its present form the mostly likely scenario for 3M will be to remain in the industry with existing products until the five-year grandfather clause expires, and then simply exit the market.

The proposed changes for respirator certification also include major revisions in laboratory testing. As with workplace testing, 3M finds many of these proposals equally unacceptable.

First, NIOSH is proposing that all particulate filters meet both a solid and a liquid oil mist test. If adopted, filter material from most respirator manufacturers, including 3M, that is currently designed for solid aerosol test challenges will need to be redesigned to also meet the liquid oil mist test. These changes will result in filter materials that have higher breathing resistance and poorer loading capacities. Workers wearing these respirators would find them harder to breathe through, making the respirators less acceptable to wear.

In their statement this morning NIOSH said, "Thus, for public health reasons NIOSH has adopted a liquid, as well as a solid aerosol test." We had comment before about public health reasons. It is a wonderful phrase. In our experience with Atlanta I think it ranks right up there with "trust me" and "the check is in the mail."

If public health is NIOSH's true motivation, 3M submits that NIOSH must create two categories of particulate filter respirators, solid particulates and liquid oil mist containing particulates. In this way the workers that are exposed to solid particulates will still be able to obtain respirators with low breathing resistance, the type that is preferred by most workers today.

The second change proposed by NOISH would increase the size of current organic vapor cartridges by a factor of four with corresponding -- again we have heard a great deal this morning about that already, but specifically NIOSH proposed to increase the relative humidity and double the air flow rates in testing of cartridges. In their statement this morning NIOSH said "We are unaware of any published technical data to substantiate this claim." I suggest that they consult with their technical people in Morgantown for a basic updating

on carbon technology today.

In the next paragraph this morning NIOSH stated, "We believe that the five-year grandfather period allows ample time to address this requirement. The way I interpret that, in other words, there is no published data to show larger cartridges will be needed but you have five years to figure out how to comply because we know it's going to require larger cartridges. It's hard to have it both ways.

Does NIOSH really believe that the certification procedure can or should be used to force invention and to force innovation beyond today's known limits of carbon technology? As stated previously, compliance with the proposal provides longer respirator service life, it does not increase the protection of the worker while he's wearing the respirator.

The true effect of this proposal, as NIOSH well knows, would be that none of existing approved organic vapor cartridge systems with half mask or full face masks would be NIOSH-certified for use. Every worker now wearing a typical cartridge respirator would be forced to wear the much larger, heavier, chin or front or back-mounted style of cannisters; in effect moving back to the technology of the 30's. This is in direct contrast to the preference of end users for these

products, where cartridge style respirators are far and away the most widely used of the air purifying gas and vapor respirators.

In both of these areas NIOSH has totally ignored the inputs and documents provided by the Industry Safety Equipment Association and by ANSI. Both groups have previously described to NIOSH in detail the effects of these proposed test changes. We truly need immediate and responsibile dialogue in this matter, not stone-walling.

In conclusion, NIOSH has made a genuine effort to address several of the known deficiencies in the current system. We can clearly see, however, that some of the changes recommended by NIOSH will make respirators extremely costly and less acceptable to workers. We submit the certification requirements and test procedures should be, one, a meaningful indicator of the device's performance in use; two, readily interpretable by both the manufacturers and the certifying agency; and, three; tests that will provide reliable, reporducible results.

Meeting these three criteria is a monumental task. It becomes an even greater task if the regulatory agency does not develop and maintain a meaningful dialogue with those

subject to its regulations. We strongly recommend that NIOSH take advantage of the expertise available in Morgantown, in other government agencies, in industry, labor and the respirator manufacturers to develop meaningful, feasible and reliable tests for evaluating and certifying product perform. We believe a consensus approach is the correct approach.

One final point, in my job I try to spend 40 percent of my time in the field, out of my office. That works out to approximately 100 days a year of contact with end users of our products, with industrial hygienists, with safety directors, safety distributors, and government agencies.

NIOSH has a dedicated, hard-working staff located in their Morgantown facilities. However, it's been my observation and that of others in our industry, that the Atlanta staff has little knowledge of the real world of respirator users. I would like to use this forum today to extend both an invitation and a challenge to NIOSH to leave their sheltered environment in Atlanta, spend some time in the field with safety directors, with hygienists, and with respirators users.

Talk to the people that have to select the respirators, the people that have to train the employees in the

correct use of the respirators and are charged with implementing sound respirator programs. This type of contact by NIOSH will only strengthen and improve their ability to determine sound respirator policies and certification requirements. Thank you.

CHAIRMAN MATTHEWS: Thank you. I now have 12:12. Let's go ahead with Ocenco, Incorporated, and then see where we are about lunch. Number 15, Ocenco. Nobody here? Let the record show that Ocenco was -- We will drop them down on the list. How about Number 16, Safety Equipment Distributors Association.

MR. BENNETT: Mr. Matthews, Mr. Chairman, thank you for the opportunity to participate in this rulemaking process. My name is Alan Bennett and I am the President of the Safety Equipment Distributors Association, known as SEDA. SEDA is a trade association representing 167 safety equipment distributors throughout the United States. Respirators are a major portion of the equipment sold by our members.

The current respirator certification standard, 30 CFR 11, is more than 15 years old and it is in need of revision in order to keep up with technology in respirator evaluation. During this period manufacturers have made considerable

advances in respirator design and there are many more models available today to meet the users' needs than were available in 1972, when the first NIOSH regulation was listed.

Indeed, listings in the latest NIOSH Certified Equipment Publications indicates that more than 15 new respirator manufacturers are in existence today than existed in 1972. The existence of a large number of producers of respirator insures higher degree of competition. Competition in turn keeps the price for the consumer down and spurs product innovation.

SEDA believes the proposed regulation will reverse this trend in the manufacturing of respirators in the United States. In fact, we believe 90 percent of the manufacturers will no longer produce and supply respirators if the currently proposed regulations become effective. The industry estimates the cost of work place testing of respirators alone will cost the industry more than $700 million. This cost approximates annual sales of respirators.

The cost of workplace testing and the cost of redesigning the many respirators in existence today will force most suppliers of respirators out of the business. Most of the respirator manufacturers are relatively small businesses and do

not have the capital or resources to comply with such requirements, even if the requirements were technically feasible.

In addition, many of the respirators produced today by these manufacturers that do remain in the business will not be sold if the proposed standard becomes final because of the cost to manufacture and sell them under the new requirements will be prohibitively high.

The ultimate impact is respirator users will have much fewer choices for new and innovative products and the distributor will have fewer suppliers to choose from.

The proposed regulation clearly limitis its scope to respirators used in mines and mining. We do not under this limitation since more than 95 percent of the respirators used today are from outside of the mine and mining operations area. To leave the needs of the vast majority of respirators users unaddressed is a great disservice to the public. The scope of this standard should be expanded beyond that of mining and mines.

Many of the proposed technical requirements in the regulations are not feasible with today's technology and will result in respirators with poor user acceptable. The ISEA

technical comments point this out very, very well. SEDA supports the comments submitted by the Industrial Safety Equipment Association, ISEA, and would like, in addition to what we will present here today, request they be incorporated as SEDA comments on the proposed rule.

It appears to us that the new proposed regulation will wipe out the many advantages and advances in respiratory protection that has been made over the last 15 years. The Safety Equipment Distributors Association, SEDA, strongly recommends that NIOSH switch gears and begin a consensus process in order to develop a state of the art, realistic standard for respirator certification.

We hereby request that the proposed rule be recalled until such time as complete testing protocols and rationale for the proposed changes are provided to the public so we can develop meaningful comments on all of the proposed changes. SEDA believes this is the best method of assuring the continued advancement of respiratory protection. Thank you, Mr. Chairman.

CHAIRMAN MATTHEWS: Thank you. We probably have time for one more. Why don't we go ahead with presenter number 17, Mine Safety Appliances Company.

MR. GRUNBERG: Thank you. I am Rich Grunberg, the product line manager for air-purifying respirators with Mine Safety Appliances Company in Pittsburg, Pennsylvania.

MSA is very concerned about the new respirator certification regulation NIOSH is proposing. It's incomplete and lacks the rationale necessary for such sweepings changes. Our main concern centers around the requirement for workplace testing as the primary element for certification. We see several major problems connected with this approach.

Now, we support the use of field testing, but see its value in the research and development of respirators, not in providing a true evaluation of a respirator's performance in any application in the workplace. NIOSH has in its proposal allowed for simulated workplace testing if substantial correlation can be shown to workplace tests.

To this point, however, there has been little, if any, correlation shown between any two field tests, let alone actual workplace versus simulated workplace tests. Analytical and sampling methods have yet to be proven which will give accurate, repeatable results in the actual workplace where the number of variables are infinite and in many cases uncontrollable. We think NIOSH should rethink the role such

testing should play.

Bench tests will determine if the method of contaminant elimination the respirator employs is effective. What then is required is to determine if the respirator, as a unit, will function properly under use conditions and what level of protection is possible with that particular device.

Doing use testing in an actual workplace may tell you how that respirator performed that day, on that particular individual, under those given conditions, but due to the uncontrollable variables found in any single workplace on a day to day basis, let alone between different works sites, won't indicate the level of protection a respirator will give from workplace to workplace, user to user, day to day.

A better approach would be to characterize workplaces and determine what the most critical conditions are, such as humidity, contaminant, work rate, type of activity, et cetera, in which a particular type of respirator is to be used and simulate those in a controlled environment. This would give a more realistic bench mark of how a respirator performs if used correctly.

It is impossible to test a respirator as it may be used and worn in real life. You can not legislate against

misuse. No amount of testing will determine the protection afforded if a respirator is not used and maintained correctly 100 percent of the time.

The results of workplace testing will not guarantee an individual's actual protection. This type of testing should be treated in the same manner that EPA mileage estimates are for automobile. When you look at a sticker on a new car, they give you highway and city mileage estimates. They have simulated these driving conditions. They also state though that your mileage may vary depending on your personal driving habits. These figures state what the mileage potential for that particular automobile are. They are dependent on the way you drive. These figures are used by the potential buyer for comparison.

It's the same for use testing of respirators. They should tell the user the protection the device is capable of providing if it's worn and maintained in the prescribed manner, not what protection you will definitely get when wearing it in the workplace. If a user is well trained and conscientious he should get comparable protection to that found in testing. If not, who knows what the results will be, but he does know the potential. Meaningful, repeatable results can

only be obtained under more controlled conditions. Therefore, we feel NIOSH should stipulate laboratory simulated workplace versus actual workplace testing.

Also, if it is NIOSH's intention to require workplace testing for each contaminant the respirator is to be approved for, the costs will be astronomical. This will benefit no one. First, the respirator will become much more expensive. Second, the cost associated with such testing could and probably would drive many manufacturers out of the market. This reduces competition and selection, thus, making the user a two time loser. He has less to choose from, pays more for it and the level of protection is not necessarily any greater.

Again, it makes more sense to characterize the workplace in which the respirator is to be used and and to allow laboratory simulated workplace testing. No matter which approach is taken, there are, to my knowledge, no specific protocols in existence for testing of respirators against various contaminants under actual work conditions.

It has been suggested that NIOSH will publish a generic protocol, thus requiring each manufacturer to develop their own specific protocol. We can not agree with this approach either. All like respirators must be tested in the

same manner under the same conditions. In this way the user is comparing apples to apples. It is NIOSH's intention to make these protocols available prior to final rule promulgation.

How can a rule be promulgated requiring testing for which no validated protocol exists?

Although there has been workplace testing done in the past by such companies as DuPont, 3M and even NIOSH, workplace or simulated workplace testing is still have much in its infancy. There is much left to be learned and there needs to be more work done in determining such things as why workplace studies vary so widely from laboratory simulated workplace tests. It is our opinion that after such work is completed we will see a major cause has been the methods of workplace sampling and analytical analysis.

NIOSH has a workplace protection factor study underway at this time, which will hopefully produce good field test data. That data will then be used in an attempt to show correlation to laboratory simulated workplace testing.

NIOSH should recall the proposal in order to wait for the results of their own study before mandating a requirement for which they themselves have no assurance can be accomplished giving accurate and timely results. The rule

should be then reissued complete with specific protocols for testing in order to give everyone an opportunity to comment on the complete document. If the NIOSH proposals are correct, they will stand the test of public comment.

One other requirement I'd like to comment on is the new organic vapor cartridge bench test. We fail to see the rationale behind the increased relative humidity requirement. The current test requires equilibration at 85 percent relative humidity and testing at 50 percent relative humidity. Raising the relative humidity to 85 percent for testing, while it will provide a cartridge with a longer service life, is not warranted. Unless NIOSH is aware of field complaints which we are not, there have been no requests from users for longer service life on our organic vapor cartridges.

This new requirement would necessitate a change in all present organic vapor cartridges. Our tests indicate that it would take two and one-half times more charcoal per cartridge to meet the new minimum service life requirements. Since no manufacturers would likely produce cartridges designed to meet the bare minimums, we estimate that a minimum volume used would be three times those of the present. To have cartridges which give the same service test time as the present

would take a cartridge of about four times the size.

Now, weight suspended on a half mask respirator is a major concern as it affects face piece to face seal. A cartridge three times the size and, therefore, triple the weight, would have a very detrimental effect on face piece to face seal, thus less overall protection. A user certainly won't need to change his cartridges as often. If this is the true reason for the requirement, it's not in keeping with the implied goal of the proposed rule, which is greater worker protection.

There many more areas of concern and we have addressed these in our written comments, but time doesn't really permit comment. The bottom line is we feel many areas of the proposed rule, especially work place testing, need rethinking. We hope that common sense will prevail and NIOSH will pull this document back until the many questions can be satisfactorily answered and then reissue a complete certification rule for comment.

As a manufacturer, we are most willing to assist in developing a certification document. In fact, we feel as a manufacturer we should be a part of this rulemaking, possibly in the form of negotiated rulemaking, before the proposed rule

is released for public comment. Remember, we, like NIOSH, also have a responsibility to protect the health of the American worker.

In closing, we again request that NIOSH recall the proposed rule as it presently stands and reissue it when it can be done as a complete document with specific protocols. During this interim we would like the opportunity to take part in the process, like I said, possibly through negotiated rulemaking, to develop a certification rule in everyone's best interests. Thank you.

CHAIRMAN MATTHEWS: Thank you very much. I think we will stop here. Just a couple of comments, first of all, thank you to Nelson Liedel that the heat is on. We appreciate it very much. We will break now for lunch. We will pick up at two p.m. with presenter number 18, Interspiro. It obviously looks like we at least have a chance of finishing the previous requesters' presentations by COB today. That's not certain because we have skipped at least two and we have Mr. O'Leary from Arthur Little who has asked to present as well.

Nevertheless, just so you can plan your own agendas, NIOSH has announced this to be a two-day hearing. Given the traveling conditions in some parts of the country

with the storms, we will set up shop here again tomorrow morning, even if we finish the agenda today, at nine a.m. to see if anyone else walks in the door that had not had an opportunity to get here today. So you can plan your schedules accordingly. Any other questions on that? We'll see you back here at two p.m. with Interspiro.

(Thereupon, a luncheon recess was taken and then the proceedings continued as follows:)

CHAIRMAN MATTHEWS: Let the record show it's two p.m. and we are proceeding now to participant number 18, Interspiro USA, Inc.

MR. ALMQVIST: Mr. Chairman, my name is Hans Almqvist. I'm the president of Interspiro USA in Branford, Connecticut. We have made recent comments to the standard and I would like to present a few things to underline these comments. Our comments relate only to open circuit breathing apparatus and our activities are mainly in the fire and hazardous materials handling.

The first comment I would like to make is face seal leakage, and I refer to Subpart R, Section 84, 230 through 84 238. Our comment is the proposed standard doesn't take into consideration the existence of positive pressure only

respirators. The specified test in negative mode is impossible to perform, especially if the activating of positive pressure is an automatic function triggered by the first inhalation. NIOSH approved respirators with this function are commonly sold today. Our recommendation is we would suggest the deletion of a negative pressure test for such respirators. The test according to Section 84 233C will be sufficient to assure a good face seal. However, a number of subjects needed in the test should be specified.

My next subject is gas flow tests and I refer to Subpart S, Section 84 248-6(a). Our comment is static flow tests do not represent a respirator's ability to deliver a specific flow of air at specific breathing pressures during real life dynamic conditions. For instance, long airways and flow restrictions can cause an increased response time which renders the static flow test inadequate.

I brought some graphs to substantiate that comment. This is the test equipment used. We have a breathing machine, we can run dynamic tests and static tests, and we get the result on XY recorder measuring flow rate and breathing pressures.

We have tested this unit with two different units,

Unit A, and I show now the result of static pressure tests. You can see that the test shows that this unit easily meets with the required standard, 300 liters per minute, and still maintain positive pressure. You make the same dynamic testing. We show more or less the same thing. We have breathing pressure here and flow here and it's more or less the same graph as the first one, static pressure.

For Unit B, on the other hand, this shows the static testing and also in this case we easily meet 300 liters per minute requirement for positive pressure. Then we are measuring dynamic pressure. We can see that is negative already at a flow of about 160 liters per minute.

Our recommendation is static flow tests should be amended to dynamic flow tests. You see here the flow in Section A-2 and A-3 should be replaced by peak flow rates.

My next subject is carbon dioxide tests and I refer to Subpart S, Section 84 248-10. And I have three different comments. The first is testing of the minimum volume of 10.5 liters, representing a person's ventilation at rest, is inadequate to fully represent the dead air space condition for a repirator.

Our test shows that at low ventilation at an

external dead space of approximately .5 liters, only half of the dead space is ventilated and takes part in the air exchange. The result would be that the measured reinhaled carbon dioxide concentrations are too low to reflect carbon dioxide concentration at higher elevations.

To illustrate this I brought some graphs. This is the test setup breathing machine and in the action of carbon dioxide in relation to the ventilation. Again I have Unit A and Unit B. The first, Unit A, was tested at standardized 10.5 liters per minute and we can go directly to external dead air space measured. It is .19 liters.

We tested Unit A with a different ventilation, in this case 40 liters per minute and we can see the external dead space stayed approximately the same value. This unit A is a respirator with a very low, small dead space and in this case it's no problem to test 10.5 liters per minute.

On the other hand, Unit B, this is a at test 10.5 liters per minute and we can see also in this case we have a low dead air space, .23 liters. If we test the same unit at 40 liters per minute we can see the external dead space has increased to .5 liters. The different external dead space measured in the two tests for Unit B clearly shows the test at

10.5 liters cannot be the only test to determine the impact of a dead space. Our recommendation is to change this test to test at 40 liters per minute.

Next comment regarding carbon dioxide testing is the following. Increased reinhaled carbon dioxide will lead to increased ventilation. In the suggested range of two to two and a half percent carbon dioxide, the increased ventilation is substantial, 30 percent or more. For open circuit respirators increased ventilation will reduce the real service time. This effect is individual. Some persons can take higher carbon dioxide.

However, if you look at some reports in the literature we have come to the following graph. This shows that if you have a work load representing 40 liters per minute ventilation and you increase the reinhaled carbon dioxide, you have a substantial increase in the ventilation. Again. For an open circuit respirator that would mean reduced service time.

My next comment regarding carbon dioxide is the term "continuously recorded" in paragraph 84.248-109(c) is not clear. If carbon dioxide is recorded as a functional time the average concentration will be incorrect and our recommendation is that the wording that should be used is to "continuously

recorded as a function of inhaled volume." And I would like to make a correction there in our written comments. We by mistake had said "exhaled" volume. It should be inhaled volume, of course.

Last, but not least, respirator testing, referring to Subpart D, Section 84.30 through 84.34. Our comment is regarding workplace and simulated workplace testing, we conclude this there test is expensive, which will add considerably to the cost of a respirator. It is unclear if a respirator intended for fire service or hazardous material handling should be tested in the mine or in the environment more related to fire department and industrial use. The guidelines open many alternative interpretations regarding test conditions and test performance.

Our recommendation is the standard should include more specific rules regarding workplace conditions and refer to manufacturing independent laboratory with appropriate testing facilities, preferably nonprofit organizations operating in the public interest. Thank you very much.

CHAIRMAN MATTHEWS: Presenter 19, the law firm of Wickins, Coaches and Cale, Washington, D.C., Greg Paley.

MR. PALEY: Good afternoon. I'm Greg Paley, with

Wickens, Koches and Cale, legal counsel for the Industrial Safety Equipment Association.

While we agree in principle with the creation of new certification standards, there are numerous fundamental shortcomings both in the content and procedures used to promulgate the standddard which mandate its revocation. Consequently, we seek to have the proposed regulations withdrawn until the legal and technical errors are corrected.

The legal transgressions emanating from the promulgation of the new regulation are threefold: The failure to provide adequate notice and opportunity to comment on the details of the proposed rule; the failure to engage in a regulatory flexibility analysis; and the failure to comply with the Federal Paperwork Reduction Act of 1980.

The most fundamental legal error arising from the promulgation of the proposed regulations is the failure to provide interested parties with adequate notice. Guaranteed by both the Administrative Procedure Act and the Due Process Clause, this failure cannot withstand judicial scrutiny.

The goals sought to be achieved through imposition of notice and comment procedures are twofold: Providing the

agency with an opportunity to benefit from the experience and input of parties who file comments; and ensuring that the agency maintains a flexible and open-minded attitude toward its own rules.

There are no fixed guidelines to measure the adequacy of notice and comment opportunities. Under the Due Process Clause, however, these procedures must meet minimum standards of fundamental fairness. This consists of an opportunity to be heard in a meaningful time and in a meaningful manner. Thus, while the specific process may vary from case to case, interested parties must be given an opportunity to effectively participate in the promulgation of agency rules and regulations.

The importance of public participation becomes even more critical when the proposed rules consist of technical data available only to NIOSH. In addressing this scenario courts have strictly adhered to the view that when a proposed rule is based on scientific data the agency should identify the data and methodology used to obtain it.

In the instant matter interested parties have been denied the opportunity to review the scientific data relied on by NIOSH. While providing general notice of the new

certification requirements, basic details on how the regulations will be implemented, NIOSH fails to provide the degree of detail necessary to effectively comment on many of the proposals. In several instances critical details either are entirely absent or so ambiguous as to render their value meaningless.

Perhaps the most promiment area impacted by the defective notice involves the imposition of workplace testing without a corresponding protocol. In a substantial departure from existing respirator certifications,the NIOSH proposal requires that all respirators be tested under workplace or simulated workplace conditions. While this idea may sound good on paper, its feasibility is unclear at best.

Specifically, the absence of clear guidelines detailing the requirements for workplace testing makes commentary impossible. For example, the NIOSH proposal does not specify how many workplaces need to be included in the test, nor how many subjects in each workplace need to be studied.

Further, the NIOSH proposals require a manufacturer to utilize the testing methodology which will gauge respirator effectiveness against hazards substances found

in the workplace. However, this technology does not exist. If it does, the industry is unaware of it. Despite this, NIOSH has failed to disclose the methodology it assumes will work.

In addition to the complete absence of many details, the NIOSH proposals also contain specific requirements which are too vague to implent or comment on. This is as egregious an error as providing no details and yields the same result, defective notice nullifying the opportunity to comment.

For example, the proposed regulations mandate that all major respirator modification requires resubmission and recertification by NIOSH. However, the definition of "major modification" is so broad that all changes would require recertification. Additionally, the proposal does not state what NIOSH will do if the modification meets the requirements and is proved. Will a new approval be issued; will the old approval be modified? It is simply impossible to comment without knowing NIOSH's intention.

Given the technical nature of the proposed rule and the severe impact on the regulated industry, the failure to provide adequate notice and opportunity for meaningful comments is dispositive as to the reasonableness of the rule.

Consequently, the rule should be withdrawn until

interested parties can be fully informed about the specific details of the proposal. Then and only then can the Administrative Procedure Act and due process guarantees be met.

In addition to the defective notice just discussed, there are other significant legal errors which point to the need for the withdrawal of the proposed rule. The Regulatory Flexibility Act of 1980 requires that a flexibility analysis be prepared in conjunction with any rulemaking that would significantly impact small businesses.

Despite this mandate, NOISH concluded that a flexibility analysis in the instant matter was unnecessary because of the minimal impact on small businesses. Contrary to NIOSH's conclusions, small entities will be uniquely affected by the proposed regulations. Not only will small respirator manufacturers be affected, but small companies purchasing respirators will also be severely impacted.

Under the proposed regulations respirators manufacturers are facing substantially increased production costs. The imposition of workplace testing increases the cost of recertifying existing respirators, as well as the cost of producing new respirators to meet the proposed standard.

Further, the cost of plant audits and additional

paperwork requirements have also raised the economic stakes for manufacturers. Increased production costs will force small manufacturers to choose between charging higher prices for their product, rendering them less marketable, or ceasing production altogether.

While large manufacturers may be able to absorb the increased costs without substantially raising prices or ceasing production, smaller manufacturers will not be as fortunate. Consequently, economic realities may force these manufacturers to stop production altogether.

In addition to the impact on small respirator manufacturers, small companies purchasing respirators for employee use will also be adversely affected. Because of the higher cost of respirators, many such companies will be forced to cut back on respirators purchases and provide them to only those employees who absolutely require them. Employees in marginal need areas, those who would benefit from respirator use, but who are not required to wear them, will be left in the cold.

Hence these companies will be forced to reduce respirator purchases, thereby impinging on worker safety and efficiency, as well as reducing the market for respirators.

Given the potentially devastating impact on small entities, NIOSH's decision not to conduct a regulatory flexibility analysis is clearly flawed.

While the Regulatory Flexibility Act provides no independent cause of action itself, failure to consider the impact on small entities will be subject to judicial review. Consequently, NIOSH can not ignore with impunity the effect of its rules on small entities as it has done to this point.

In addition to the legal areas addressed thus far, the NIOSH proposals also conflict with the Federal Paperwork Reduction Act of 1980. By the terms of this act, government agencies are directed to minimize the federal paperwork burden for individuals and companies and minimize the cost to the government of collecting information.

Despite this mandate, NIOSH's proposals increase both the burden on individual companies and the cost to the government. For example, extensive paperwork and informational material must accompany all certification or recertification applications, burdening both the manufacturer preparing this information and the agency which must wade through this material.

Likewise, the paperwork burdens are unnecessarily

increased by the requirement that manufacturers notify NIOSH whenever a rejected lot of respirators is produced, regardless of whether they are shipped out. The value of this requirement is unclear. If a defective lot of respirators is produced but not sold, NIOSH should have no interest in the respirators. Instead, the manufacturer must prepare paperwork for NIOSH and NIOSH must analyze the data.

While certainly not a serious legal problem, as the defective notice and lack of regulatory flexibility analysis, the failure to comply with the Paperwork Reduction Act further compounds the problem with the new rule and provides additional support for the withdrawal of the proposed certification regulations.

In conclusion, I'd like to reiterate our request to have the proposed certification regulations withdrawn. NIOSH's failure to employ adequate notice and opportunity to comment, to engage in a regulatory flexibility anaylsis or comply with the Paperwork Reduction Act mandates this conclusion.

In addition to revocation of the proposed rule, NIOSH can provide additional due process protections by publishing the workplace testing protocols in conjunction with

the revised certification regulations. Thank you.

CHAIRMAN MATTHEWS: Thank you. Presentation Number 20, Clifton Precision, Patrick McLaughlin.

MR. McLAUGHLIN: Thank you, good afternoon. I have entered into the Docket several pages of written testimony as to our problems with the 42 CFR-84, but I would like to limit my comments this afternoon to those which really are about the protocol and the inconsistencies between open and closed circuit SCBAs regarding service time. I would like to simply read them.

First the open circuit one. Service time shall be measured with a breathing machine operated as described in 84.284-3(b) The open circuit apparatus should be classified according to the length of time it supplies zero oxygen to the breathing machine." That's pretty straightforward. If you read 84.284-3, it explains the ventilation rate that you should expect and the duration that would determine the length of the device, which is all relatively straightforward.

Now, as far as the closed circuit apparatus is concerned, in service time, closed circuit apparatus under 84 384-9, it indicates the closed circuit apparatus shall be classified according to the length of time it supplies adequate

breathing gas to the wearer during use test number four described in Table 4 of 84.248-14. Again says "The service time obtained on use of Test 4 shall be used to classify the closed circuit apparatus in accordance with provisions of Subpart B." Now, that's all well and good.

The only probleim is that they have left out a very important criteria as far as the closed circuit device. We have a wearer in there which is not defined in any way, shape or form. We don't know whether he's five foot two, weighs 140 pounds, or he's nine feet tall and swings from trees.

So if you are a manufacturer trying to develop an apparatus which is to have a service life on a closed circuit apparatus, you are at a loss to know exactly when to say enough is enough as far as the amount of gas that you put into the apparatus. And it seems that even though both of these paragraphs are meant to determine the service life of a particular piece of equipment, the latter, as far as the closed circuit apparatus is concerned, doesn't do that in any way, shape or form.

Now, open circuit devices, we may all agree or disagree about the ventilation rate that is called out in the

current specifications as being adequate or inadquate, but at least it's a consistent measuring point and if you are a manufacturer of the device you know exactly what you must do to spend your development money to go out and put a piece of equipment and put it up for sale in the community.

But in a closed circuit device that's not true. You really have no means of knowing prior to starting your development work what is really adequate. I believe NIOSH is missing an opportunity to correct a long-standing error. It was in 30 CFR and there's been no effort that I can see, at least in this current requirement to correct that mistake. And with such loosely defined criteria, it's nearly impossible to design and develop new equipment which the using community, on one hand, would say that they want, lighter weight, longer duration, easier breathing, cooler breathing, closed circuit devices, but with this type of criteria as a manufacturer it is virtually impossible to know how to attack the problem. Thank you.

CHAIRMAN MATTHEWS: Thank you. Number 21, Parmelee Industries Inc., Alan Sankpill.

MR. SANKPILL: Good afternoon, My name is Alan Sankpill, I'm president of Parmelee Industries, Inc., with

headquarters in Kansas City, Missouri. We're a 50-year-old manufacturer of industrial personal protective equipment, primarily eye and face and respiratory protection equipment. We employ approximately 460 people, so we're a small business. We appreciate the opportunity to appear here today and to comment on the proposed standard.

Others speaking today have addressed many of the concerns that we have regarding the standard so I will not repeat all those comments. However, Parmelee Industries has several concerns regarding the proposed rule for certification of respiratory protection devices.

First, we believe that the filter technology required in the proposed rule does not exist today. We believe there is a distinct possibility that the technology may not be developed at all in the five-year period allowed. To assume that simply because new filter technology is mandated by a standard will suddenly cause the technology to appear is a rash and unwarranted assumption. What will NIOSH do and what will end users do if no such technology emerges in the five-year window?

Second, we believe certifying all respirators to the same level of performance allows manufacturers to build in

an important safety factor in the performance of those products. Allowing manufacturers to request certification to higher levels of the program will encourage manufacturers to reduce that safety factor to gain a competitive advantage. The temptation to over sell the capabilities of equipment will be very great. We believe this is a dangerous and unwise proposal.

We also believe that our constitutional due process rights have been violated because the new respirator standard was promulgated without a corresponding protocol to explain how the standard will be impleted.

Mr. Chairman, I'm not a lawyer, I'm an engineer, so I will not try to make a scholarly legal argument. However, I understand that both the Fifth and Fourteenth Amendments of the United States Constitution prohibit governmentmental actions which would deprive any person of life, liberty or process without due process of law. While scholars have long argued over the legal nuances of due process, our view is simply that fundamental fairness should accompany any official action which adversely affects private interests.

The concept of fundamental fairness is embodied in two related requirements which at minimum must be present to

satisfy the due process guarantees, the right to adequate notice and the right to meaningful opportunity to be heard on a proposal before it is finalized.

The guarantee of proper prior notice is the most essential ingredient of due process and serves as the linchpin for all other procedural rights. Without such notice additional procedural protections are nullified. For example, how can we meaningfully comment without full knowledge of what is being commented on>

This is exactly the problem facing our company in the matter at hand. In August we were given a notice of a substantially revised respirator standard and asked to comment on the feasibility and economic impact of implementing the standard. However, how can we comment without knowing how the standard will be implemented? How can the cost and feasibility of workplace testing be measured when we do not even know if the technology exists to do such testing repeatedly and reliably? Without the protocol guidelines our hand are tied.

For a small respirator manufacturer such as Parmelee Industries, a significant change in manufacturing, testing or certifying respirators can have a devestating impact on production. While a large respirator manufacturer, with

more resources and product lines, may be able to absorb the changes without shutting down, a small company such as ours may not be able to continue production while attempting to implement the numerous changes suggested in the proposed standard.

We have a very large investment in testing equipment to meet the requirements of the current standard. Consequently, we need as much time and information as is possible to gear up for the changes.

To facilitate this, Parmelee Industries requests that NIOSH publish the protocol and schedule a set of hearings to provide truly proper notice of the proposed changes, as well as adequate time to assess implications of the standard and a meaningful opportunity to comment on the protocol and the standard together.

Without these fundamental, minimal procedural protections, Parmelee Industries will be effectively censored from participation in the promulgation of a standard that will have a substantial, long-lasting and potentially devastating impact on us. Thank you very much.

CHAIRMAN MATTHEWS: Number 22, Filcon Corporation.

MR. NEIMEYER: Mr. Chairman, my name is Trent

Niemeyer. I'm the Chief Executive Officer for Filcon Corporation. We are located in St. Paul, Minnesota. Filcon Corporation is a development stage company engaged in developing innovative respirator designs. Part of our manufacturing charter specifies that only innovative designs will be promoted because the market is so saturated that further addition of similar designs would be financially unsuccessful.

As a result of this condition, the implementation of 42 CFR in its current form would have a major, and most likely a negative, impact on our operation. We, therefore, request that the following comments be considered.

First, we endorse the comments and position taken by the Industrial Safety Equipment Association, with the exception stated later in this presentation. We simply ask their comments be incorporated into ours for the record.

Item Two, this refers to Section 84.2, Subsection B. The grandfather clause should be withdrawn because it puts Filcon and other development stage manufacturers in an adverse competitive position relative to manufacturers who already have approved respirators in the marketplace.

We would be forced, for example, to sell our

respirator with more stringent performance characteristics and at a proportionately higher cost to the same customer who can purchase a less stringent, less costly respirator approved under the grandfather clause. The grandfather clause could consequently becomes a barrier to market entry and that violates the antitrust laws in general and Executive Order 12291 in particular.

Our recommendation is that a transition date and an earlier test submission deadline with sufficient time period between the two to allow all manufacturers who apply to be tested and certified. Any other alternative system system which supports the same goals would also be a recommended alternative.

Item Number 3, Sections 84.31 to 84.33, inclusive, the cost of conducting workplace or simulated workplace testing should be analyzed in greater detail and any future proposals submitted by NIOSH should include dry run cost studies. While it's difficult to determine exactly what costs would be incurred due to the absence of specifics on the test protocols, it is very likely that the $250,000 to $500,000 estimate made by the Industrial Safety Equipment Association in its comments could be true.

If this were the case, total start-up costs for Filcon and or start-up companies would well exceed the "1.1 million to 1.25 million range. This would make obtaining financing almost impossible because respirator products would not offer the investors a rate of return comparable to other investments. New ideas by innovative companies such as Filcon, therefore, would be prevented from entering the marketplace. In this respect 42 CFR violates Executive Order 12291.

Item 4, this relates to Subpart Q, the general construction and performance requirements. We recommend the inclusion of a loophole provision in this section similar to the language and intent of Section 84.311. While there is value in standardizing the performance of respirators and let's keep an open mind policy should be maintained regarding design criteria, if the respirator industry to be successful in eliminating many of problems currently confronting respirator users, innovative designs must be freely considered.

Item Number 5, this relates to Subpart E and Subpart D. We recommend filter leakage rates for particulate filters appear on the approval label or at least in the instructions. This would provide easier interpretation of performance levels for nonrespirator-oriented users.

Item Number 6, this relates to Subpart Q, Section 84.220, Subpart G. We recommend the addition of the phrase "or other devices which prevent ambient air from entering the nose" after the word "nose clips."

Item Number 7, this refers to Subpart R. We recommend that a provision be included which gives the respirator wearer the option of using respirators at higher protection factors if specific measurements for each user justify the increase. We believe users should be encouraged to obtain quantitative data and not be hindered by a regulation which suggests that such effort would be legally unacceptable. The benefits would be lower risk of harm to the user and lower equipment costs for the employer.

Item Number 8, we disagree with the Industrial Safety Equipment's comments and recommendations to eliminate the frowning exercise from the face fit testing protocol. Our experience is that the concavity formed by the cheekbone, teeth and jawbone area is a definite source of leakage and is due in part to a design limitation in all the currently available face pieces. I'm not at liberty to reveal what this limitation is presently, but at a future date Filcon will release this information.

We also disagree with the Association's comments about monthet respirators. If properly designed, they respirators can be used for production use. Secondly, we believe these respirators can programmed to accurate measure inhalation leakage and that consequently comparative testing should be allowed.

Item Number 9 refers to the additional comments on Section 84.3 14 Subpart C. We recommend separating this provision into two classes. The first would be for respirators used in non IDLH atmospheres and would allow the respirator to be temporarily removed to inspect an end-of-service-life indicator. The second class would be for respirators used in IDLH atmospheres and would require the wearer be able to inspect an end-of-service-life indicator while still wearing the respirator. Specific reference is made to the use of monthet respirator for production use in the chlorine manufacturing industry.

Last, Item Number 10, when 42 CRF is examined in its entirety, there is a very strong uneasy feeling that less than satisfactory care was exercised in writing the proposal. Given all the limitations and problems that have been expressed so far, or will be expressed in these hearings, any effort to

implement the proposal in its current form will be so damaging an act as to constitute malpractice. We believe the proposal should be completely withdrawn and rethought.

We recommend that the task be broken into stages and that the manufacturers be contacted individually and informally for recommendations before another proposal is formally submitted. For our part, we are very much willing to work with NIOSH toward this end. Mr. Chairman, thank you very much for your time. We appreciate it.

CHAIRMAN MATTHEWS: Thank you. Number 23, Organization Resources Counselors, Inc., Richard F. Boggs. The Docket clerk says that they will appear tomorrow. That brings us to the end of the first pass-through. As indicated in the opening statement that I made, we will go back now and call for Presenter Number 9, then Presenter Number 15 and then Chris O'Leary of Arthur D. Little had indicated that he wanted to speak today. Is there anyone here now representing Edison Electric Institute?

MR. YOHAY: Yes, sir.

CHAIRMAN MATTHEWS: Please proceed.

MR. YOHAY: Mr. Chairman, it's really not necessary for me to take the stand. I simply want to have

Edison's comments submitted into the record and don't desire to testfy any further beyond than that, if I may. Do you want me to enter an appearance formally? I'll do that.

CHAIRMAN MATTHEWS: That's fine. You just did it as far as I'm concerned.

THE WITNESS: My name is Stephen Yohay on behalf of Edison Electric Institute and these are the comments.

CHAIRMAN MATTHEWS: Thank you.

CHAIRMAN MATTHEWS: Your name again was Stephen?

THE WITNESS: Yohay, Y-o-h-a-y.

CHAIRMAN MATTHEWS: Thank you, sir. We now go back and check for Presenter Number 15, Ocenco, Incorporated. All right. No one responded. Let's go now to Chris O'Leary of Arthur D. Little, who had indicated at nine o'clock this morning you wanted to make a presentation. Please proceed.

MR. O'LEARY: Good afternoon. My name is Chris O'Leary. By way of introduction, I am a consultant in Occupational Health and Safety with Arthur D. Little and I am immediate past Chairman of the Respiratory Protection Committee of the American Industrial Hygiene Association. I am here today representing Arthur D. Little's Center for Respiratory Protection, a group of 40 to 50 senior ADL staff members,

including certified industrial hygienists, certified safety professionals, physicians physiologists, scientists and engineers, who provide applications, testing and engineering services and assistance to respirator manufacturers and users.

Our comments address what we perceive to be the central issue raised by the proposed rule, the requirement that manufacturers collect workplace protection factor data and submit those data to NIOSH in the use of the certification process.

Within the context of respirator certification, we discussed the technical feasibility and desirability of obtaining workplace factor data, as well as some of the interpretative issues that would be raised. We conclude that using workplace protection factor data to bridge the gap between laboratory generated performance data and workplace performance data will serve neither the regulatory nor the user community well.

We suggest an alternative approach based on the modification of existing evaluation techniques that would not require the development of an entirely new analytical methodology. Two observations about the use of respirators in American industry will help provide a context for our comments.

To the extent that users of respiratory protection do not receive the intended level of protection, we have observed that it is attributable to either, one, a flaw in the design and construction of the device; or, two, a flaw in the administration of the respirator program in the user's workplace.

Design flaws include issues of construction and technology that are characteristics of the respirator itself. Administrative flaws include problems with the selection, fitting and maintenance of respiratory protective equipment, as well as the training and supervision of respirator users. Once the nature of the problem is understood, remedial measures appropriate to the situation can be designed and implemented.

Our second observation is that by an overwhelming proportion, the administrative problem is more prevalent of the two types of problems just mentioned. Staff members of the Center for Respiratory Protection visit hundreds of work places every year and in virtually every case where respirators are misused the reason is not the absence of effective, well-designed, well-constructed equipment. Instead, the reason is that respirator users are not trained, fit tested or medically qualified or the respirator selected is inappropriate

to the application.

This observation is adequately supported by the technical literature. A survey of 159 companies in the spray painting Industry by Tony and Barnhart revealed that only nine had formal training programs. Of the 55 types of respirators used in these companies, only ten were specifically approved for spray painting operations.

In another report, Review and OSHA Compliance Activity for the period from 1977 through 1982, the following statement was included, "During this period approximately 27 percent of inspections in which respirator programs were reviewed resulted in a citation for a specific program deficiency. Of inspected work sites in which respirators were in use to provide protection from concentrations of air contaminants in excess of the PLD, 56 percent had deficiencies at least in one program area. Since the violations were of the type that have been shown to lower the level of protection provided by respirators, many workers may have been exposed to inhalation hazards as the result of ineffective respirator programs."

The presence in the marketplace right now of effective respirator equipment obviously does not mitigate the

need to update 30 CFR 11. The fact that 30 CFR 11 has resulted in a whole generation of excellent respirators does not mean that recent technical and scientific advances should not be incorporated into a better certification procedure. We enthusiastically support NIOSH's goal of updating 30 CFR Part 11. We hope that the result will be enhanced protection for American workers, stimulation of technological innovation and simplification of the certification process.

I want to draw the attention of the Docket to one recent technical development in particular that has illustrated the need to update 30 CFR Part 11. In 1984 Myers, et al., then with NIOSH, published data that showed that, "Quantitative fit factors, as presently determined, are not indicative of the workplace protection provided by powered air purifying respirators equipped with high efficiency filters."

This information called into question the long-standing practice of using data generated in the laboratory as a predictor of actual workplace performance. It also has contributed obviously to the urgency of the current rulemaking.

In the proposed 42 CRF 84 this gap between laboratory performance data and that measured in the workplace

is bridged by requiring the collection of workplace protection factor data. Whether that approach is the best alternative is discussed now.

Briefly, we at the Center believe that requiring the collection of workplace protection factor data will provide information of little value to the certification process and would not directly address the real cause of substandard respirator performance in the field. The use of workplace protection factor data, as outlined in the proposed rule, would involve at least two steps. First, an appropriate workplace in which measurements could be obtained needs to be identified. Second, the data obtained in that workplace then needs to be extrapolated and generalized to other necessarily different working environments.

First of all, issues pertinent to site selection. The spectrum of variables that characterize a working environment is not only difficult to define, but the effect of each of the variables on the performance of a particular respirator is poorly understood. For the sake of this discussion we have outlined four groups of variables that will affect the level of protection afforded by a given respirator in the field.

First, variability in contaminant characteristics, including issues like the physical form of the contaminant, concentrations, particle size, other contaminants that exist at the same time in the same place.

Second, variability in work activity, including issues like the level of effort, range of motion, the number, length, duration, frequency of work breaks, the performance of fine motor control tasks versus gross motor control tasks, and so forth. Obviously, variability in meteorologic conditions and environmental conditions inside the workplace as well.

Finally, variabilities in work demographics, like gender, race, age, level of education and so forth. Even if a typical, or, as stated in the proposed rule, a strenuous state could be defined for each of the four groups of variabilities, their interdependence increases the difficulty of finding a workplace in which typical or strenuous conditions exist for each one. For example, it may be difficult to find a workplace in which strenuous work activity is performed, if at the same time you were looking to identify a workplace in which extreme environmental conditions exist.

In addition, the relationship between geographic location, environmental conditions and work force demography,

may make the task of finding of a test site in which those three groups of variabilities are appropriately defined difficult.

These hypothetical problems could also have practical ramifications. Since workplaces in which strenuous work activity is required often employ predominantly men, selection of a test site based on that criteria may preclude the identification of a performance problem specific to women.

In general, identification of a test site based on any single, or any two of the four areas of variability that I just discussed, by virtue of the definition, by virtue of the way in which that site is identified, may preclude identification of an important design flaw.

Second, I want to discuss the extrapolation of data from one workplace to another. It's axiomatic, I believe, that data collected in one workplace may be or may not be able to be extrapolated to another workplace. Data demonstrating the respirator works in workplace X may not apply to workplace Y or even to workplace X on another day with different people.

There are several reasons for this. The most obvious is the tremendous variability that exists between and within workplaces, the effect of which on respirator

performance is unclear. It is also likely though since the administrative deficiencies that result in reduced respiratory protection will be suppressed in a closely monitored field test, the workplace protection factor may not reflect actual working conditions even in the workplace in which the data is collected.

It is the very workplace specific nature of the most prevalent problems, the most prevalent administrative flaws in industrial respiratory protection that will make not only extrapolation, but duplication and replication of workplace factor data difficult.

The most dangerous problem associated with extrapolation of field data will occur, however, if the nature of the site at which the original measurements were made prevents the identification of a design flaw, as we just discussed with gender specific flaws.

For these reasons we believe that it is neither possible nor desirable to devise and execute a workplace protection factor test within the context of certification. Certainly workplace protection factor data are invaluable to users' appropriate selection of equipment and to manufacturers looking to improve their product.

In fact, Drs. Rosenthal and Paul of the Johns Hopkins University School of Hygiene and Public Health suggest workplace performance testing as a respirator program evaluation tool when they state that, "In mask sampling over entire work shifts can provide an objective means of evaluating respirator program effectiveness."

For the purposes of certification, however, we believe that the alternative approach outlined in just a minute is preferable. Many of the deficiencies we have described that would accompany workplace protect factor testing for certification purposes would be easily and successfully addressed if the tests were to be conducted in a laboratory setting. A test panel balanced for facial size and gender would asure the identification of design flaws specific to those characteristics.

A rigorous test protocol would eliminate the problems, or at least control the problems associated with extrapolation of workplace specific data to other environments and would preclude having to generalize about the performance of a respirator in all workplaces based on its performance in one or even a few work places.

Elimination of as many sources of variability as

possibly will enable NIOSH to focus on what is really the central issue, will the respirator, when used within the context of a respiratory protection program that complies with OSHA requirements, protect workers.

We recognize that existing laboratory tests do not provide a strenuous challenge nor do they approximate the activities that occur in American industries. However, it must be recognized that much of the research that first identified the gap between laboratory performance tests and workplace performance tests did not even attempt to approximate typical workplace activities.

Myers, et al., in their discussion of the methodology by which they original PAPR research was conducted state, "The use of some whole body exercise in the quantitative fit test regimen was prohibited by the size and structures of the portable test booth."

This landmark research which identified in a dramatic way the gulf and the gap that exists between quantitative fit test data and the workplace performance factor data was conducted without any exercises whatsoever, apart from facial movements and repeating of the alphabet.

We respectfully suggest that the logical

alternative to the quantitative fit test used by Myers, which does not predict workplace performance well, is a test that incorporates body movements typical of industrial work activities. Such a bench mark workplace performance test could be performed in a laboratory environment in the same manner for all respirators and would provide a logical, defined, rigorous and equivalent challenge to the candidate device.

The bench mark workplace performance test should be viewed as analogous to the rainbow passage. While we know of no instance in which workers actually repeat the words of the rainbow passage while on the job, nonetheless it is widely used as an exercise for speaking and mouth movement. It is valid because it is rigorous, reproducible and representative of the real mouth movement of real speaking people. Two different respirators evaluated in the same manner using the rainbow passage will yield results that can be compared as apples to apples.

Based on our experience with the development of similar tests for other government agencies, it is clearly possible to define and develop an analogous test protocol for whole body movement. Though such an exercise regimen would not exactly replicate any specific workplace, it would be rigorous,

reproducible and representative and would thus provide a challenging, consistent and meaningful test. In addition to its obvious utility to certification, the data could also be used by respirator program administrators to carry out their assigned tasks.

In conclusion, the real problem identified by Myers, et al., was not that laboratory data in general could never be used to predict workplace performance of respirators. Instead the important point made in their research is that the laboratory test that they used, which lacked whole body exercise, did not generate data that correlated with workplace protection factors. That conclusion does not necessarily preclude the use of all laboratory tests in the certification process, but it certainly suggests that any test which is used provide a rigorous challenge to the candidate respirator.

In fact, the use of a laboratory based bench mark workplace performance test in the respirator certification process addresses a number of difficult problems associated with workplace performance factor testing, such as the selection of a typical or strenuous workplace, extrapolation and generalization of results and the possibility of failing to identify important design flaws.

In addition, a bench mark workplace performance test will provide useful comparative information to health and safety officials charged with respirator program administration and will thus stimulate technological innovation and development.

The most important task with which NIOSH is charged in the area of respirator certification is the provision of effective, well-designed and well-constructed pieces of equipment. Respirator program administrators can then make their selection based on the knowledge that the certification process was rigorous, reproducible and representative. A favorable performance on the bench mark workplace performance test will provide them, respirator program administrators, with a presumption of performance that is not now available to them and which could not be provided via workplace performance factor testing in a workplace dissimilar to theirs.

These safety and health professionals can then turn their attention to the existing and pending OSHA requirements, satisfaction with which is the most direct way to address the ubiquitous administrative flaws in the field.

We appreciate the opportunity to present our

comments on this important issue. It's clearly the goal of these hearings and the rulemaking process in general, as well as the spirit in which we submit our comments, that a more excellent certification process results. We hope that our comments and perspectives will contribute to the attainment of the goal. Thank you.

CHAIRMAN MATTHEWS: Thank you. It's now approximately 3:00. Is there anyone else here today that wants to make an oral presentation? Let the record show that no one else has indicated. I think that probably will wrap it up then for today. We will start at nine o'clock tomorrow morning, beginning with, calling for the oral presentation of Number 15, Ocenco, then Number 23, ORC, and after that we will again provide the opportunity, if anyone else has oral presentation to make, they may do so at that time. Thank you very much for your patience and your attention. We're adjourned until nine o'clock tomorrow morning.

(Thereupon, at approximately 3:00 o'clock, p.m., the above proceedings were adjourned until 9:00 o'clock a.m., Thursday, January 29, 1988, at the proceedings were as follows:)

CHAIRMAN MATTHEWS: Good morning. This is the

second day of public meetings on proposed 42 CFR Part 84. We will first pick up from yesterday. There were two participants that did not speak at their appointed times. We will also find out if anyone else is interested in making a presentation.

One other point, the OSHA representative later on in the day yesterday had a prepared statement with copies available and they're at the table at the rear. If you want a copy of the OSHA statement, it's now available.

We will proceed first with Participant Number 15, Ocenco, then Participant Number 23, ORC, and then inquire -- I guess I should inquire at this time, is there anyone else who is interested in making an oral presentation? No one, okay. Let's proceed then with Ocenco. Is the representative here?

MR. HAZELTON: My name is Dave Hazelton. I'm an attorney with the law firm of Latham and Watkins. I've been asked to make a brief statement on behalf of Ocenco. I'd like to read into the record and then submit somewhat more elaborate comments as well.

Ocenco, Incorporated, is the largest provider of self-contained self-rescuers to the underground mines of American. Our collective years of experience in underground mining, coupled with our understanding of respirator

manufacture and design, provide us with a unique and practical perspective on the proposed rulemaking for 42 CFR Part 84. With concern for the safety of underground miners and understanding of the needs of the coal industry, we submit our comments on the subject rulemaking.

Ocenco, Incorporated, fully supports the formal transfer of responsibility for respirator testing from the Department of Labor, MSHA, to the Department of Health and Human Services, NIOSH. For years NIOSH has performed the service of respirator testing without clear mandate. Transferring these responsibilities from 30 CFR, Mineral Resources, to 42 CFR, Public Health, is appropriate. Our objections are to the content of the proposed CFR Part 84.

The proposed changes to the test and certification requirements will have a severe detrimental economic impact on our already depressed coal industry and offer no increase in safety to underground miners.

Given the number and severity of objections which have been voiced against these proposed changes, it is obvious that finalization of CFR Part 84, as it is written, is premature and ill-advised. We, therefore, propose the following actions be taken.

First, the content of 30 CFR Part 11, exactly as written, be transferred to the Department of Health and Human Resources under 42 CFR. This will officially mandate NIOSH testing without disrputing industry and possibly endangering human life.

Second, NIOSH and MSHA should complete the Memorandum of Understanding which will define the consultive role of MSHA in the process of certifying respirators targeted for uses in mines and mining. The unique conditions of underground mining dictate that MSHA continue its role in approving devices for this severe environment.

Third, changes to the existing requirements for certification of respirators should be made with cognizance of the environment in which those respirators will be used. For example, NFPA standards should be considered when drafting requirements for respirators used in fire fighting.

Our specific objections to the contents of the proposed changes are addressed in the attached written commentary, which I'll be submitting. We ask these concerns be addressed prior to any rewrite of the existing certification standards. Very truly yours, Ocenco, J. P. Droppleman, President. Thank you.

CHAIRMAN MATTHEWS: Thank you very much Presenter Number 23, Organization Resources Counselors, Inc., Richard F. Boggs.

MR. BOGGS: Good morning. I am Richard Boggs, Vice-president, Organization Resources Counselors, Incorporated. This testimony supplements the written comments submitted to the NIOSH Director, Division of Safety Research, on December 15th, 1987. ORC is pleased to present this testimony to NIOSH regarding the notice of proposed rulemaking published in the Federal Register.

ORC sponsors an occupation safety and health group, which is comprised of more than 75 companies from a wide range of industries and with employment sizes ranging from medium to large. All of these companies have a strong commitment to employee safety and health. Members of this group work with ORC on rulemaking activities and other aspects of employee safety and health. This statement is, however, solely the responsibility of ORC and may differ from company comments submitted.

ORC supports a strong and active role for the federal government in the testing and certification of respirator protective devices used by all sectors of the

American working population.

Respirators are an important source of protection for those individuals who may be exposed in the course of their employment to potentially toxic air-borne substances. It is vital that the respiratory protective devices used by all workers be as safe and effective as modern science can make them.

An effective testing and certification program for respirators, run by an agency of the federal government, can give assurance to employers and workers alike that the respirators have passed at least minimum standards for quality and performance. ORC believes that respirators should not be the first or only means of worker protection considered, but rather should be one part of an integrated and comprehensive safety and health program.

In any evaluation of ways to deal with potential workplace hazards, engineering controls should always be the first consideration. Every workplace is unique, however, and often engineering controls are not feasible or practical. When this is the case, work practice controls, the use of respirators and administrative controls, all have an important role to reduce employee exposure to health and safety hazards

in the workplace.

Most employers are neither large, nor sophisticated, and their understanding of potential health and safety problem in the workplace is as limited as the resources available to deal with them. For this less sophisticated employer, respirators are often the most important protection for employees potentially exposed to air-borne toxic substances. For these employers the availability of reliable, effective, properly tested and certified respirators is especially important.

Large corporations usually have the resources to properly evaluate the available respirators and to chose those appropriate for their needs. For employers with fewer resources the selection of an appropriate respirator can be a very difficult task.

Therefore, ORC believes it is imperative that those in the federal government who have responsibility for managing the nation's safety and health resources take seriously the task of assuring that safe and effective respirators are available to all employers and employees.

ORC and its member companies have worked for many years to encourage and assist the development of effective

testing and certification programs by agencies of the federal government.

For NIOSH to abandon the testing and certifying of respirators for general industry is unacceptable. NIOSH has a responsibility to this nation's working men and women and what it is proposing to do is abdication of its responsibility.

The following comments address some of the specific issues raised by NIOSH's notice of proposed rulemaking on the testing and certification of respirators. ORC believes that limiting the testing and certification of respirators to only those used in mines and mining, as stated in the proposed revision, is irresponsible and a basic abdication of NIOSH's duty to protect the safety and health of workers.

The great majority of respirator users in this country are found outside of the mining industry. These individuals deserve respirators that are adequately tested and certified under conditions related to those they will experience in their own workplace.

Given the importance of an effective respirator testing and certification program for this nation's working population, ORC requests that NIOSH repropose it's notice of proposed rulemaking and in cooperation with OSHA and MSHA

reconsider its approach.

ORC is pleased to note that NIOSH, as evidenced by its statement for the record issued on January 20th and 27th, 1988, has decided that it is inappropriate to limit 42 CFR Part 84 only to those respirators used in mines and mining.

However, when NIOSH refers to comments expressing concern with its narrow focuses on mines and mining as being an "apparent misinterpretation of the proposal," ORC must disagree with NIOSH. ORC believes that NIOSH in its Federal Register notice has been very clear and consistent in its narrow focus on mines and mining.

To understand some of the reasons why ORC believes 42 CRF Part 84 was and is directed towards mines and mines, it is useful to examine the exact language. For instance, on page 32402, summary, the middle of column one, NIOSH states and I quote, "Requirements and tests are included for new types of respirators used in mines and mining. New and revised requirements and tests are incorporated which more completely address mine and mining conditions and their effects on respirators. Administrative changes are included which would generally improve the respirator testing and certification program."

On page 32402, and I quote again, "In accordance with the Mine Safety and Health Amendements Act of 1977, 30 U.S.C. 842H and 957, which has been enacted for the purpose in part of developing and promulgating improved mandatory health or safety standards to protect the health and safety of the nation's coal or other miners, the issuance of certificates of approval for respirators is limited to only those respirators used in coal or other mines."

And at page 32405, I quote again, "The purpose of this part is to prescribe procedures and requirements for the certification of respirators for use in mines and mining." There are several more in our testimony, which is also in the Federal Register notice, which I will not quote.

ORC believes that the evidence of NIOSH's own words as published in the Federal Register is clear. NIOSH intended 42 CFR Part 84 to apply only to respirators used in mines and mining.

ORC has always understood that the purpose of a notice of proposed rulemaking was to make clear the intent of the proposing agency. To assert, however, that a proposed regulation could mean, or could be interpreted to mean, something other than what it says is to purposely obscure the

intent. ORC believes that NIOSH's respirator testing and certification program should address the needs of general industry as well as the mining industry.

Toward that end, ORC urges NIOSH to repropose 42 CFR Part 84, in cooperation with OSHA and MSHA, to specifically address the needs of general industry for adequate respirator testing and respirator certification programs.

One other comment, this proposal requires that any testing carried out under these proposed regulations must meet the requirements of the Department of Health and Human Services for protection of human research subjects, as discussed in 45 CFR Part 46, Subpart A.

This is an extremely involved and complex regulation and to comply with its many requirements would result in a large paperwork burden. This in turn would delay the certification process, increase costs to the manufacturer, and ultimately the user.

This regulation was developed for the testing of new drugs, vaccines and medical procedures, that entail unknown and potentially large risks. The kind of testing that NIOSH proposes to require industry to perform entails little, if any, additional risk to the field test subject beyond that

associated with the individual's normal employment.

Respirator fit testing involves virtually zero incremental risk for the individual. It could be argued the potential for improved respirator performance associated with fit testing actually results in an incremental decrease in the risk associated with an individual's normal employment.

In closing, ORC would like to recommend that NIOSH repropose 42 CFR Part 84. In its reproposal NIOSH should modify its narrow focus on mines and mining to specifically include the needs of general industry for an effective respirator testing and certification program and respond positively to the many excellent recommendations it has received.

In its modifications to 42 CFR Part 84 NIOSH should also make provisions for a three-month comment period prior to the closing of the record. It has taken more than ten years to reach this point on the revision of 30 CFR Part 11. It would be a great waste if through a lack of cooperation and communication this opportunity to craft a superior respirator testing and certification program were to be lost. Thank you very much.

CHAIRMAN MATTHEWS: Thank you. That completes the

presentations by all the participants who asked to be listed. I will ask one more time, this is the last call, is there anyone else here who would like the opportunity to make an oral presentation at this meeting?

Seeing that there are none, I will call your attention again to the Federal Register notice of October 8, 1987, which says that, "The record of the informal public meetings will remain open for 30 days following the close of the Washington meeting to allow interested persons to submit written statements or comments regarding oral presentations made at either public meeting."

Seeing that there are no other comments, I would personally like to thank Nelson Liedel for all his work in coordinating these meetings and we stand adjourned.

(Thereupon, at approximately 9:30 o'clock, a.m., the above proceedings were concluded.)

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CERTIFICATE OF COURT REPORTER

I, KATHRYN A. STRICKLAND, a court reporter, do hereby certify that the proceedings in the foregoing pages, 1 through 175, are a true record of the proceedings taken by me in Shorthand at the time and place mentioned mentioned in the caption hereof and thereafter reduced to typewriting under my supervision; that I am neither counsel for, related to, nor employed by any of the parties to these proceedings; and, further, that I am not a relative or employee of any counsel or attorney employed by the parties hereto, nor financially or otherwise interested in the outcome of this action.

Kathryn A. Strickland

KATHRYN A. STRICKLAND
Court Reporter