NATIONAL INSTITUTE FOR OCCUPATIONAL
SAFETY AND HEALTH

84-191

ORIGINAL

IN RE: NOTICE OF PROPOSED)
RULEMAKING 42 CFR PART 84 --)
REVISION OF TESTS AND REQUIREMENTS)
FOR CERTIFICATION OF RESPIRATORY)
PROTECTIVE DEVICES)

STATEMENT FOR THE RECORD

January 20, 1988

Reported by:
NAN S. ROSE

I N D E X

INFORMAL HEARINGS

WEDNESDAY, JANUARY 20, 1988

A P P E A R A N C E S:

CENTERS FOR DISEASE CONTROL, 1600 Clifton Road, N.E., Atlanta, Georgia 30333, represented by GENE W. MATTHEWS, Legal Advisor.

NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH, 944 Chestnut Ridge Road, S-118, Morgantown, West Virginia, 26505-2888, represented by JOHN B. MORAN, Director.

NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH, 1600 Clifton Road NE, Atlanta, Georgia 30333, represented by NELSON A. LEIDEL, Sc.D., Senior Science Advisor.

(Begin proceedings at 9:00 a.m.)

MR. MATTHEWS: Good morning. Let's go ahead and get started.

This is the first of two informal public meetings concerning the federal regulations proposal on respirators. The formal title of this regulatory proposal is "The Revision of Tests and Requirements for Certification of Permissibility of Respiratory Protective Devices Used in Mines and Mining."

This notice of proposed rulemaking is being published by the National Institute for Occupational Safety and Health of the Centers for Disease Control, which is part of the U.S. Public Health Service. These organizations are all within the Federal Department of Health and Human Services.

My name is Gene Matthews. I will serve today as the presiding officer. I am with the Office of General Counsel for the Department of Health and Human Services, and I serve as the legal adviser to the C.D.C.

This informal public meeting is being held in accordance with a Federal Register Notice of October 8, 1987, which indicates that the

administrative record of this rulemaking will consist of the August 28th, 1987 notice of proposed rulemaking. All the other relevant federal registry notices, agency records on this subject, all the written submissions made in response to the notices, and the record of the informal public meetings.

The record of the informal public meetings will consist of the meeting schedules, the transcripts made by NIOSH of the oral comments at the meetings, any written comments submitted by presenters at the meetings, and statements or comments regarding the oral presentations that are made at either public meeting, which are submitted by interested persons within 30 days following the close of the Washington public meeting.

I will note for you that the closing date for the written comments concerning these meetings will be February 28th, 1988. No written submission or any portion thereof made in response to this notice will be received or held in confidence.

As you will note, 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 participant may present relevant written information, data or views for inclusion in the record of the meeting.

In accordance with that October 8th notice, participants were requested to notify NIOSH by January 5th of their intent to appear in this San Francisco meeting. They were also requested to notify NIOSH by January 12th if they were interested in participating in the Washington, D.C. meeting.

This meeting is scheduled for one today. I am informed that three participants have requested to appear today and make statements. We have received no advance written statements from any of the participants today.

The way we will proceed is if a participant is not present when his or her 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 this meeting who did not request an opportunity to make an oral presentation may be given an

opportunity to do so at the conclusion of each meeting at the discretion of the presiding officer.

The purpose today is to provide interested parties an opportunity to do three things: Number one, to make oral presentations on the record today; number two, to hear the oral comments that are being made by others; and number three, an opportunity to submit to NIOSH within 30 days of the Washington meeting any statements regarding oral presentations made at either public meeting.

I would like at this time to introduce the official representatives from the agency. There are three representatives from the NIOSH office of the director, Mr. Larry Sparks, if you'd hold up your hand and stand up? Mr. Larry Sparks, Mr. John Moran. John? And Nelson Leidel. And Nelson serves as the docket officer with respect to this rulemaking. Then we have two representatives from the NIOSH Division of Safety Research in Morgantown, Miss Nancy Bollinger and Mr. Gary Mills. We also have an attorney from the Office of General Counsel in Atlanta, Georgia, Miss Gwen Strickland, and we have a representative

from the office of the director of C.D.C., Mr. Bob Kingon.

At this time NIOSH has a brief statement, which they would like to read into the record, and I believe Mr. Moran will do that now.

MR. JOHN MORAN: Good morning.

For the record my name is John Moran, and I am reading for the record the NIOSH opening statement of these informal hearings regarding the notice of proposed rulemaking 42 CFR Part 84, revision of tests and requirements for certification on respiratory protective devices.

We are here today to solicit public comment on the proposal by NIOSH to revise tests and requirements used in certifying respiratory protective devices. The current regulation under which NIOSH tests and certifies respirators (30 CFR Part 11) was originally promulgated in 1972. During the last decade, there has been a growing consensus among respirator manufacturers and the 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 workplaces. More importantly, the

proposal will provide respirators that are safer and more reliable. It would also permit innovation in respirator design, since it is 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 concerns 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 formal 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 MSHA under 30 CFR 11) and the prior certification procedure (used before

1972 under the Bureau of Mines (BOM)) have as their basis the testing and approval, which began in 1919, of respirators used in mining. Over the years, respirators approved by the Bureau of Mines 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 OSHA, the EPA, and the Nuclear Regulatory Commission. Although more than 95 percent of all respirators sold, those which are certified under the present system are not used in mines or mining, all of the respirator models currently certified are used in mines and mining (with the sole exception of devices sold for the protection against vinyl chloride).

The terms "mines" and "mining" are not limited to underground mines. Mining activities vary widely in nature and scope as do other industrial activities. Routine exposures to gases, vapors, dusts, fumes and mists, and emergency exposures to fires, explosion, 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 regulations, 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 Respiratory Industry" (developed in Phase I of this 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 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 $100,000,000.00.

To ensure that all relevant economic impact information is considered, last month the Office of Management and Budget designated this rule as a major rule under Executive Order 12291 and has directed NIOSH to submit a Regulatory Impact Analysis with the final rule.

As reflected in the docket, some comments estimate that it would cost seven to nine hundred million to comply with this regulation. Based on information submitted to the docket, it appears that these estimates 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 or Simulated Workplace Testing, makes no mention of mines or mining. The section requires that testing be done under conditions "reasonably representative of those in which the applicant anticipates the respirator will be used." And that's 84.31(b). Subsequent sections, 84.32 and 84.33, 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 the device may be used. Rather, it is proposed that the respirator manufacturer, who is in the best position to know the product and its workplace application, conduct appropriate workplace or simulated workplace testing to properly reflect the intended use of the product. This is consistent with the 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 11, NIOSH uses only a silica dust as a challenge aerosol.

Issue three, self-certification concerns: Concern has been expressed that 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 Section 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 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.

Issue four, workplace testing protocol: Another concern reflected in comments to the Docket was 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 intends to afford the manufacturers maximum flexibility in developing and utilizing workplace or simulated workplace testing methodology. We intend to permit any scientifically valid methodology that will appropriately reflect the "work conditions that are reasonably representative of the places and conditions in which it is anticipated the respirator will be used," as quoted in 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 Tests Procedure 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 provides a marketplace incentive totally absent in today's respirator market and not possible under the current regulation. 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.

Issue five, organic vapor cartridges: There are comments in the Docket which indicate that the required humidity conditioning and testing requirements proposed for organic-vapor cartridges would necessitate a cartridge four times larger than the cartridges presently certified under 30 CFR 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 in 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 canisters are being used for protection against organic vapors that have poor warning properties. 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 that 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 these problems.

Issue 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 or 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 filtration technology for other applications, this has not been true for respirator filters (except for reduction 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 the last day of hearings in Washington; therefore closing on February 28th, 1988. Your participation and

contribution to the public record are greatly appreciated and will provide additional important information on which the final rule will be based.

This concludes the Institute's opening statement. Copies of this statement are available here in the hearing room and will be made available in the record. Thank you.

MR. MATTHEWS: Thank you. There were some late arrivals. I believe copies of this are available at the back door. Did all of the late arrivals sign in? It is critical that we have at least a phone number to contact you if we need to, okay? There is a sign-up sheet. Miss Duhan in the back -- hold up your hand, Jenny. She will take care of that.

I would also like to express thanks to the San Francisco City and County Health Department for making the room available to us and offering their hospitality so that we could conduct the proceeding here today.

Let me now check and see. There were three participants who had indicated they wanted to make presentations today. There are more than that here. Let me just briefly call the roll

here. I see Mr. Cowan is present from The Jefferson Group. Is there a representative here from Moldex Metric, Inc. from Culver City?

MR. BIRKNER: Yes.

MR. MATTHEWS: And you are?

MR. BIRKNER: Jeff Birkner.

MR. MATTHEWS: And is there a representative of E. D. Bullard Company of Sausalito?

MR. KING: Yes, John King.

MR. MATTHEWS: John King? Now is there anyone else that is interested today in making a presentation or an oral statement on the record, or wants to submit a written statement for the record at this time?

(No response.)

MR. MATTHEWS: No. Okay. We will go ahead and proceed then in the order of Moldex Metric, Inc., E. D. Bullard Company, then The Jefferson Group. Mr. Birkner, if you are ready to proceed. You indicated that you wanted 15 minutes, and you are J. S. Birkner?

MR. BIRKNER: Yes. I'll only need approximately ten minutes.

MR. MATTHEWS: All right. If you could

pull the microphone over a little closer so that the court reporter can hear you.

MR. BIRKNER: I'm Jeffrey Birkner, and I'm the technical service manager for Moldex Metric, Inc.

Moldex is a safety product manufacturer of hearing and respiratory protection. We are a manufacturer committed to serving the public by manufacturing products which provide protection for end-users according to recognized standards.

Moldex is also an active member of the Industrial Safety Equipment Association, and provides input on proposed standards, guidelines, and various other aspects of the best ways to protect the end-users.

Moldex believes that the current NIOSH testing and certification schedules (30 CFR 11) need to be updated. Upgrading of these standards is necessary to better protect the public. We believe that it is long overdue.

Unfortunately, the proposed 42 CFR 84 presents many problems for the manufacturer and the public. We do not believe that it is a realistic alternative as submitted and must be withdrawn. One of its most serious flaws is that

it only applies to respirators used in mines and mining related work. Approximately 90 percent of American workers who use and depend on respiratory devices are not in mining or mining related industries. It is imperative that a respirator certification standard be applicable to all respirators, and not only regulate respirators used in mining applications. If NIOSH wishes to take such a narrow role for certifications, then they are doing a great disservice to the American workers, and they are defeating their own mandate of protecting these workers.

NIOSH has proposed that manufacturers conduct their own certification testing. To date, NIOSH has done all such certification testing. The system has worked well and provides certifications in an expeditious manner. It also provides the necessary consistency between comparable products and manufacturers. We do not believe that manufacturer certification testing would be a benefit to the public for such a critical health concern. Such self-certification testing would remove the checks and balances of a system which, in fact, need the opposing forces of government and manufacturers to best serve the

public's interests.

As part of this self-certification system, NIOSH has proposed that every manufacturer do field tests to determine a workplace protection factor or simulated workplace protection factor. Although this type of testing might be useful, the state-of-the-art is not at a point where such testing has been shown to be accurate or consistent. NIOSH has not yet provided their proposed protocol. Assuming such protocols do exist, we do not believe that this protocol has withstood the test of time necessary for any legitimate scientific procedure. NIOSH would require that such workplace protection factors be conducted in mines. There are not enough mines in operation to certify all the respirators in the market today without creating a tremendous backlog in the certification process. If other work environments are used, there would have to be a good correlation between the mines and the work environment used. This would increase certification lag times even further, possibly leaving the public without certified respirators for their specific needs for a long period of time. Again, if such testing is to be conducted,

we firmly believe that it must be done by NIOSH.

Based on industry estimates, implementing the proposed NIOSH standard would probably cost in excess of seven hundred million dollars to the industry. This would be prohibitively expensive. This cost would have to be passed on to the consumer and may seriously limit the resources most companies would have for new innovations. It is these innovations which in the past have helped the American workers by providing them with more efficient, comfortable, and affordable protection.

In particular, such a tremendous implementation cost could put small companies such as Moldex out of business. Putting companies such as ours out of business does the public a great disservice. We provide a good, safe, and affordable product, and are committed to the effort of protecting the public. We wish to continue in this role.

Some of the other proposed rules in this document would only serve to confuse the end-users which may result in gross misuse of our products. For example, NIOSH would allow manufacturers to advertise their product as having a protection

factor higher than the minimum required by the proposed regulation. This would be contingent on NIOSH's approval of the data submitted by the manufacturer. This may create a type of competitive situation which must be avoided. This may also create terrible confusion to the end-users, and could instill a false sense of confidence in the employer, who may rely solely on this information. A standardized minimum protection factor should be provided with each respirator. The employer must then perform their own fit testing and field fit checks to ensure that the respirator is providing the necessary protection for their particular use situation. Some of the test standard procedures are unclear, difficulty to comply with, and have been made excessively stringent for no apparent reason. The list goes on. These are only but a few of the problem areas in the proposed ruling.

What are the alternatives?

The Europeans have spent a tremendous amount of time in developing a standard which is being well received as a method for most European nations. This standard is the CEN Standard, C-E-N.

We propose that NIOSH consider using this as a base from which to develop a workable testing and certification regulation. What are the advantages of using the European standard? Some countries have begun to implement standards very similar to CEN, and they seem to be working quite well. It may save a tremendous amount of cost and time for NIOSH. It has all the basic elements that NIOSH has proposed, such as sodium chloride filter testing, fit testing for inward leakage, and a simulated workplace test which addresses user acceptance. It requires the regulatory agencies in their respective nations to test and certify respirators. In addition, it provides the simplicity yet strength for manufacturers to fall within stricter boundaries, ultimately providing better protection for respirator users. Finally, consider the impact of having an internationally accepted standard for respiratory protection. Standardized respiratory protection would help developed nations, and even more importantly, guide nations not yet fully developed in such areas.

In conclusion, we do not believe that the proposed NIOSH 42 CFR 84 is the answer. We

respectfully request that NIOSH withdraw the present document and assemble a committee of experts, including manufacturers, researchers, end-users, and health professionals to consider all options, including CEN, and develop a standard that will truly benefit the American worker.

Thank you.

MR. MATTHEWS: Next we have representing the E. D. Bullard Company, Mr. John King. Proceed.

MR. KING: I think it is clear NIOSH want to make changes, and we in the industry support that goal.

However, the manufacturing community would like to work with NIOSH to make transitions as smooth as possible.

I'm vice president in charge of engineering and quality assurance for the E. D. Bullard Company. Prior to this I was in charge of engineering and quality assurance at North Safety, formerly the Safety Products Division of Norton Company. I've been in the safety industry more than 15 years, and more specifically have directed R & D efforts with most kinds of industrial respirators, including breathing apparatus.

I serve on the ISEA Respiratory Standards Committee, and I helped draft ISEA's technical comments to 42 Part 84.

However, since E. D. Bullard is only in the business of supplying respirators, I will direct my comments exclusively to this area. For brevity, I will only address three illustrative items.

Point one is that since NIOSH does not use breathing machines to assess the performance of supplied air hoods and helmets, and historically quantitative fit testing has been primarily associated with facepieces, NIOSH has not been in a position to perform detailed lab studies. Rather than set higher performance standards for such devices, NIOSH has chosen to assume that relatively poor performance is intrinsic to their design; thus, assigning a minimum protection factor of only 25. Certification of a specific device to a higher level of protection does not remove the stigma associated with hoods and helmets, certainly in the user community, of 25 for a protection factor.

The second point I wanted to make was

that since contaminant leakage through a filter media is not involved with air line respirators, it is inappropriate to downgrade the performance of these types of respirators to that of powered air purifying respirators, which also have a protective factor of 25.

All supplied air respirators as well as PAPR's should be evaluated on breathing machines, at not only standard work rates of say 40 liters per minute volume, but also at 70 liters per minute. However, since there are internal air volume differences between hoods and masks, the required internal pressures should probably be different. In any case, breathing machines should be used.

The third and last point I'd like to make is that referring to Section 84.233. My question, as a design engineer, is why do positive pressure atmosphere supplying respirator facepieces have to be subjected to a negative pressure face seal leakage test if the device is not intended for such use, and what constitutes a negative pressure mode? I can envision a loose fitting mask that is designed to maintain a positive pressure inside at all times, and has a

face seal that continually bleeds air when coupled to an airline source. Why does such a device need to be tested in a negative mode is my question. NIOSH's requirement here seems design restrictive, and is yet another example of inhibiting innovation, which I'm sure NIOSH is trying to avoid.

These are but a few examples illustrating technical problems that we believe are not properly addressed by 42 Part 84. There are dozens of other similar issues, many of which have already been addressed in the ISEA comments.

We believe that NIOSH needs to recall this document and work with the industry to bring forth a proposal that we can all live with.

Thank you.

MR. MATTHEWS: Thank you very much.

Now representing The Jefferson Group from Washington, D.C., Mr. Mark Cowan. Mr. Cowan has requested 30 minutes, and in view of the apparent absence of any other presenters, his request for 30 minutes is granted.

MR. COWAN: This nine-page addition to the proposal certainly throws into question much of what everyone is saying this morning, but I

think everyone has proceeded with their comments as originally drafted, because it takes more than 20 or 30 minutes before a hearing on major rulemaking to decipher nine pages of changes and clarifications.

I think what the nine pages of changes and clarifications does, though, if nothing else, is underline the fact that there has been widespread, broad, deep confusion over just what NIOSH did intend, and I commend NIOSH for taking the time do this. It might have been more helpful had presenters received this prior to the morning of the hearing so they could have reflected these changes and suggestions in their comments, but that I understand is sometimes impossible.

I'd like to deviate from my prepared remarks and make a suggestion based on what is in here and what I've heard, and that is that it might make sense for NIOSH to consider pulling together both the proposal and the protocol into a uniform document at some point, republishing that, and asking for comments on an entire comprehensive document, rather than giving commentors 30 days after a hearing next week to comment on what is admittedly an incomplete document, and then at yet

unidentified points in the future proposing the protocol and supposedly asking for comments on that as well. It would seem to me the two are intimately linked, one to another. In that same regard, inasmuch as OMB has now declared this to be a major rule, I'd like to formally request that NIOSH consider providing 180 days of comment time, not 30, because to pull together economic data from industrial sources of variabilities and capabilities and means takes quite a bit of time, and I'm sure that everyone wants to have a valid and sound economical analysis the second time around. 30 days makes that, I would suggest, impossible. Now I can start.

Good morning.

MR. MATTHEWS: Good morning.

MR. COWAN: I am, as you know, Mark Cowan. I'm president of The Jefferson Group, which is a Washington based public affairs firm. I appreciate your including me on your agenda this morning to give you my comments on the impact of your proposed 42 CFR 84.

My firm represents the Industrial Safety Equipment Association, and they will, of course, provide detailed comments on technical aspects of

this proposal as a number of their members have this morning.

As a former safety and health government official and regulator, I'd like to address today what I view as some of the public policy implications of the proposed regulation.

As background, from 1981 to 1982, I was President Reagan's Deputy Assistant Secretary of Labor for Occupational Safety and Health. As such, my responsibilities included oversight of all OSHA rulemaking and regulatory as well as deregulatory undertakings. Later, I served as Chief of Staff of the Department and to the Secretary of Labor, as well as serving as a member of the Vice President's Task Force on regulatory reform. Through this variety of positions I oversaw not only OSHA regulatory affairs, but also a vast variety of regulatory matters from a panoply of origins.

Contrary to that which is perceived by many, this administration has not only deregulated through its endeavor to remove uesless, costly and ineffective regulation, but it has also regulated where the evidence warranted action. During my tenure as the Deputy Administrator at OSHA, for

example, we issued a number of major and far reaching regulations; regulations of a very significant nature to both workers and management.

As one example, we drafted, proposed and enacted the Hazard Communication, or labeling standard, as it is more commonly known. It wasn't easy. Everyone didn't like it, but it made sense, and only become a reality through a reasonable, reasoned process, through a process wherein the views of those regulated, industry, those affected, labor, and those interested were solicited, analyzed, discussed in a give and take, open environment, and thereafter, as is appropriate in the case of OSHA or NIOSH, accepted or rejected based on the totality of the situation.

We promulgated the Hearing Conservation amendment to the occupational noise standard. This regulation wasn't insignificant nor easy to fashion either. But again, we undertook to regulate what we thought was a fair and equitable process through which all parties participated, creating and participating during the process, not just in the eleventh hour, an end result which

provided a net benefit to workers, and was by and large widely accepted.

Later, as Chief of Staff to the Secretary, where I had partial responsibility for directing a 24 billion dollar budget and a staff of approximately 18,000, we effectuated other regulatory initiatives.

All of this is to say, Mr. Chairman, that as a matter of public policy, I am not opposed to regulations which ensure a safer workplace environment. Indeed, I am very much in favor of such activity by the government on behalf of workers. However, when the government undertakes major change, with significant impact to industry, it must recognize the need for creating an atmosphere which is open, fair, and deliberative. By trying to create this kind of atmosphere, with give and take from both sides, the government is better able to bring about change, which is ultimately acceptable to all sides.

I've traveled here today because I think that the history, as I know it, the developmental process, and the substance of 42 CFR 84 exemplifies the type of government activity, and I

believe in this case totally unintentional, which gives regulators the unflattering image of being out of touch, ivory tower speculators. It is just such a perception which, in fact, in my opinion contributed, not insignificantly, to the election of Ronald Reagan as the President of the United States. The proposed 42 CFR 84 as it now stands could well serve as an example of that which makes government look like the enemy, rather than the friend, of both workers and industry, not to mention the public at large, who ultimately have to pay the bill, whether it is under a hundred million dollars or over seven hundred million dollars.

I hasten to add and mean sincerely that none of my comments are directed at individuals, and particularly not at the outstanding staff of NIOSH, whether at the lab or elsewhere. Rather, they are directed at a proposal, an abstract proposal, which in my opinion is not well thought out and is in need of much work as it has not tremendous resemblance to that which is called for in the workplace today.

Before I offer specific objections, a final general observation of the problem may be

warranted. It is my understanding that this proposal was assembled by a variety of individuals over a period of many years at several different locations. It is my further understanding that all parties outside government and many within the government, including many within the Occupational Safety and Health Administration and the Mine Safety and Health Administration, were kept in the dark relative to many of the final provisions, including certainly the missing provisions of this proposal. This, Mr. Chairman, is what might be referred to as regulating in the blind, and it is dangerous not only for those regulated, but for those in the marketplace who must accept the impact of the regulation.

The needs and uses for industrial respirators are not what they were when the initial regulations were created. No one argues with that. Moreover, the technology for developing and producing respirators has changed dramatically, and perhaps most importantly, the technology for testing respirator effectiveness has changed.

There is no doubt, therefore, and for that matter none of the involved parties with

which I'm familiar disagree, that regulations affecting respirator certification need revision. NIOSH is doing the right thing by attempting to revise 30 CFR, and I want to make it absolutely clear that neither I nor those who I represent are arguing that 30 CFR as it stands is the answer. From conversations with end-users represented by labor unions, with respirator manufacturers, and finally, from discussions with former colleagues still in the governmental regulatory process, there is almost universal recognition again that with more than 15 years under the belt, it is time to modify how respirators are certified in the United States. Why then is this proposal not the answer?

Mr. Chairman, I need not tell you that there is widespread concern within this proposal. It is my understanding from associates that many manufacturers and end-users have registered protest against this proposal, and have called for its withdrawal. I'm also told that many Senators and members of the United States Congress have asked for the proposal to be recalled. Finally, it is my understanding that not one of the more than 60 institutions representing the views of

workers, end-users, manufacturers, public interest groups, and even other government regulators who submitted comments on the proposal 42 CFR 84 to Atlanta, supports the proposal as it now stands.

The question then is where did the process go wrong?

While NIOSH may not, and I am not willing to stipulate they are not, but while NIOSH may not be required by law to consult with representatives of the potentially affected parties, to have done so on a greater degree than was done, if it was done at all prior to the proposal, would I believe have ensured that what some are calling due process, what others call fairness, and what I call smart regulatory practice would have prevailed.

To my knowledge NIOSH conferred with, in the true sense of that word, with none of the affected parties in the development of their proposal. Worker representatives were not called in to provide their unique insights; manufacturers were certainly not consulted on the practicality of the proposed changes during the prescribed time frame; indeed, some of the proposed changes have yet to be proposed, nor were others more

experienced, and not more experienced in the area of safety and health, but more experienced in the practice of issuing regulations, other federal regulators brought into the process and consulted as to how to begin the process of building consensus for a major regulatory change before it was popped on the public.

For any agency to even initiate a new proposal, affecting the safety of literally millions of workers, without telling the affected parties exactly what they'll be required to do, how they will be expected to do it, and when they will be required to do so, is neither fair nor in my opinion smart regulation.

Had NIOSH consulted and worked with other more experienced government regulators, and the reason I'm going through this parenthetically is not to say, "Boy, aren't you dumb. You should have done all these things, and if you had done them everything would have been better," but to say that the regulatory process is an evolving process, and the fact that NIOSH did not do these things is history, and history is prologue to the future. And there is still time and opportunity to consider adopting this approach as both of the

earlier speakers suggested might make sense.

Let me talk about some of the specific problems, many of which are addressed in the nine-page memo, and if in fact are accurate, will make moot some of the points I'm going to make. Let me run through them as quickly as I can.

42 CFR 84 limits its focus to the certification of respirators used in mines or under mining conditions.

One of the most confusing aspects of the proposed rulemaking is the extent to which NIOSH will continue to certify respirators other than those used in mines or under mining conditions.

As it stands, other agencies such as the EPA, the NRC, and OSHA require the certification of all respirators, regardless of what they are designed for or where they are used. While NIOSH is not legally bound to test all respirators, under an agreement between NIOSH and these other agencies, NIOSH currently certifies all respirators. And while certain things may or may not have happened since 1919, it would seem to me that something as important as this ought to be made crystal clear in the proposed regulation on what the intent of the agency is, if it is not

made clear in the document itself. Past practice is only useful if we are undertaking minor amendments to existing rule. Here is my understanding: NIOSH is moving in a new direction with an entirely new proposal, even with a new number, and it would seem to me that the better part of valor for the sake of those who are getting the bullet fired at them would be to explicitly state what the intent of the agency is. If it is to continue a practice that has been going on since 1919, then it is not very difficult to state in the subsequent proposal, if there is one, that this is the way NIOSH intends to go.

Because literally 42 CFR 84 addresses only respirators used in mining environments. The definition of a workplace is a mine. It is very simple. It is clear. Very few lawyers would argue with it. Therefore, it ignores 90 percent, or according to NIOSH's number, 95 percent of the respirators in use today. This creates a mystery as to what will be the process for cerifying, and testing the majority of respirators used by American workers and bicollateral, the majority of respirators manufactured by American manufactured respirators.

Even though not mandated by law to do so, will NIOSH continue to certify all respirators or will NIOSH and OSHA continue their agreement under which NIOSH certifies all respirators. And if this is the case, will 42 CFR 84 then cover all respirators, even though it technically addresses only those respirators used in mines. If this is not the case, then what will be the process for certifying non-mining respirators. Will OSHA continue to require respiratory certification. Will OSHA take responsibility for certifying non-mining respirators, or farm the responsibility out to another agency. We don't know, and that is really the problem.

Without these questions answered, it is difficult to comment intelligently.

Given we must assume that OSHA, the EPA and NRC will continue to require NIOSH certification of all respirators, I'll proceed on that basis.

It must be understood, as I noted, that what I have to say is built around the assumption that OSHA will continue to require NIOSH certification of all respirators, and that NIOSH will continue to certify all respirators.

42 CFR 84 provides no protocol for mandated workplace testing.

While the proposal places a number of new requirements within the certification process, it fails to spell out the specific requirements. There is no protocol specifying exactly what the affected parties will have to do, nor how they are to do it.

To propose a new regulation without any of the details and then to ask for reasoned commentary is like putting a donut on the table and asking the baker to describe what ingredients he or she has used to make the hole in the center.

Since there is no specificity to this proposal, it has made it virtually impossible for users, labor, or industry or others to provide meaningful comment. The fact of the matter is that they don't know what NIOSH is asking them to do.

42 CFR 84 is a major rulemaking and not a minor rulemaking. I'll skip that portion of my testimony for the record. If you want to go ahead and put it in, you have it there, but based on what we've heard this morning, OMB has asked that a full regulatory analysis be undertaken to

clarify this question, and I have asked that a longer time period be given commentors so they can provide not only their comments, but also financial information may be of use to NIOSH and to whoever would be involved in preparing the IRA.

(The Administrative Procedures Act and Executive Order 12291 provide guidelines for proposing new regulation. Certain criteria must be examined and met before a major rulemaking moves forward.

Economic impact analysis is supposed to be one of the guiding principals within the regulatory process established by our government. Any proposal having an estimated economic impact of greater than one hundred million dollars is determined a major rulemaking and must undergo significant analysis before it is proposed.

Given that by all industry estimates the minimum impact of 42 CFR 84 will be at least seven hundred million dollars, there exists a clear requirement for such an analysis. But there is more. This economic impact analysis requirement was either waived, circumvented or mistakenly ignored.

Why did this happen?

It is my view that this mistake was primarily due to the fact that the proposal was incomplete making it impossible for anyone to develop realistic economic impact figures. This allowed NIOSH to come up with what appeared to be reasonable estimates concluding that the economic impact would be less than one hundred million dollars. The Office of Management and Budget, apparently, bought this flawed assessment.

Had NIOSH developed a protocol, outlined the specifics, and consulted with the experts and affected parties, there would have been a greater likelihood that the real costs could have been determined. Then the proper economic studies could have been undertaken, thereby demonstrating the real costs of the proposal and placing it in the proper category as a major rather than a minor rulemaking as required under Executive Order 12291. If this proposal is to survive public scrutiny, these tasks must ultimately be undertaken.)

Workplace testing is another area which causes serious concern to people in the workplace. Mr. Chairman, as you know, there is no broad precedent for workplace testing for

respirators. While the concept superficially makes sense, difficult to argue that testing a product in the environment, the exact environment in which it will be used, it is my understanding further that neither labor nor industry is philosophically opposed to the concept of workplace testing. But it is also my understanding, from discussions with industry experts primarily, that the technology for workplace testing is far from fully developed, and is in no way proven in the scientific sense of having undergone full scale testing with proper peer review to ensure that the testing can be replicated time after time, case after case.

Given that there is no proof of technology for workplace testing, it is currently not feasible, nor I would submit to you fair, to impose such a requirement at this time.

At the risk of belaboring the point, Mr. Chairman, had NIOSH provided a protocol and then created a regulatory environment of positive give and take, open discussion and constructive fact finding where impacted parties had a voice, we might not be faced with having to comment on an incomplete proposal today.

What specifically will be the requirements and standards for workplace testing? To this day, the day of the hearing on the proposal, no one knows.

42 CFR 84 requires testing in and for the wrong environment. Comments in the nine-page document notwithstanding, the definition of workplace in the proposal is mines.

Should we all agree that workplace testing is possible, and that new technologies can be developed to satisfy the requirements once they are spelled out by NIOSH, 42 CFR 84 again defines the workplace as a mining environment. This requirement, in my view, is not in the best interests of workers or manufacturers.

Using mines or their equivalent as the required workplace test site, is based on what must be a very limited view on the vast needs of respirator users. It appears to either misunderstand the existence of many different types of respirators currently on the market or in developmental stages and the variety of uses for which they are intended, many of which are not applicable to mines. Such a testing procedure does not guarantee, in my view, the best possible

protection for all workers.

The first problem with the proposed workplace testing, as generically called for in 42 CFR 84, is there are not enough mines in the United States to test all of the respirators currently on the market.

And speaking as one who represents mine owners, I would be very surprised if most mines would be willing to interrupt their operations and lend their workers to respirator manufacturers coming in to certify their respirators.

Secondly, the notion of testing all respirators under mining conditions is not in the best interests of the majority of the workers currently using respirators. In fact, were it possible to test all respirators in mining environments, and that became the practice, it could pose a real threat, or at least a set back, to worker safety.

Given that approximately 90 percent of the respirators that are used today are used under non-mining conditions, the requirement of 42 CFR 84 would mandate that all respirators meet mining standards rather than specific workplace needs. For example, using respirators to prevent the

inhalation of paint vapors out in the open at a construction site would be using respirators tested for inside mining exposures rather than respirators tested for outside use.

Mr. Chairman, NIOSH knows that there are hundreds of different respirators on the market today, and that most of them have been developed to meet specific needs to ensure the best possible worker protection under very specific conditions. To require that all respirators be tested under mining conditions would be a step backwards from the progress which has been made by NIOSH to ensure maximum worker safety by testing products in simulated environments most closely akin to those in which they will actually be utilized by workers.

The economic impact, as I stated earlier, and more needs to be talked about this later outside the context of this hearing, when you are considering the true regulatory impact, the economic impact of 42 CFR 84 is very difficult to ascertain based again on the incomplete information included in the proposal.

Based on a certain supposition the industry has made, the figure of seven hundred

million dollars has been bantered about. I don't know whether the actual figure is seven hundred million dollars or four hundred million dollars or a billion three. The point I'd like to leave you with today, and I mean this in a helpful manner, is that if indeed NIOSH wants to know what this costs, and I'm sure you do, it is important that those who are going to have to bear the costs have before them, in order to assess the costs, a complete document which lays out for them all of elements of the proposed certification process and clarifies all the questions, some of which I have raised here, some of which industry has raised, so everyone understands what is intended. That doesn't necessarily guarantee support and it doesn't guarantee opposition, but what I think it does guarantee is you can then have a non-hostile dialogue between all the parties about whether the regulation makes sense, how it can be improved or modified, and what is necessary to make it something that the majority of the world can buy into and support.

From a public policy point of view, which is where I started, I think 42 CFR 84 could have been factioned better. Having made numerous

mistakes when I was in the same position that NIOSH now finds itself, I don't fault NIOSH for that, other than to say maybe you made a mistake, maybe it could have been done differently. My purpose here today is not to try and show you how smart I am, because I'm not very smart, but to say that the experience of this regulation so far I think calls for a step back and a reconsideration of what has been said, so that NIOSH and the people that they serve, whether manufacturers or laborers, can move forward at least in a semblance of togetherness.

During your hearings here in Washington I'd like you to consider the following things in terms of a course of action: First, I believe 42 CFR 84 as it now stands must be seriously altered or withdrawn.

NIOSH should bring together experts from industry, from labor unions, and concerned regulatory agencies outside NIOSH to review the process in its totality. From my own experience as a regulator, the information this process will bring out will make possible a new proposal which will serve your goal of updating 30 CFR 11, have broad acceptance, and most importantly, will

enhance current levels of worker protection.

NIOSH should expand the scope of its respirator certification program to include the vast majority of respirator users in general industry and construction. Failure to do this specifically leaves the users and manufacturers of these respirators in a form of regulatory limbo, with one agency requiring certification, and the certifying agency ostensibly refusing to consider it.

If NIOSH no longer wishes to perform this function, then I believe NIOSH has the rare opportunity to act as a catalyst for developing a consensus standard and taking the lead in identifying a government agency and respected non-government agency third party as a vehicle to formulating an outside body as a certifying entity. I won't be so presumptuous today to suggest what body might fill that role, but there are a number, or it could be a newly created organization.

But whether through a negotiated rulemaking or calling together all interested parties at a consensus conference, such as those used by NIH, NIOSH cannot and should not continue

to ignore the wealth of information and knowledge and the anxiety that exists amongst those who are impacted by this regulation. I call on you today therefore to talk, to discuss, and to move forward in a reasonable manner with this regulation changed to 30 CFR which everyone supports.

Thank you very much again for the opportunity. Thank you.

MR. MATTHEWS: Thank you very much. It is now 10:10. We have reserved the premises for all day. But there is no reason we have to stay if no one else has any further comments. Is there anyone here today who would like to take this opportunity to make an oral statement on the record?

(No response.)

Seeing no one else, and if there are no other comments concerning this, then I declare this first informal meeting adjourned. I want to thank everyone for their time and their consideration on this, and there will be an opportunity if anyone wants to prepare written comments concerning what was discussed here today, please provide those comments to the Docket Officer of C.D.C. NIOSH before the 28th of

February, 1988.

This meeting stands adjourned. Thank you.

(Whereupon, proceedings were concluded at 10:15 a.m.)

CERTIFICATE

I, Nan S. Rose, a Notary Public, do hereby certify that the foregoing transcript is a true, accurate and complete transcription of my stenographic notes to the best of my skill, knowledge and ability.

Signed this 9th day of February, 1988.

Nan S Rose

NOTARY PUBLIC