

RESPIRATOR RESEARCH, WHERE IT NEEDS TO GO

John R. Froines, PhD
Deputy Director, NIOSH
5600 Fishers Lane
Rockville, Maryland 20857

I want to add my welcome to Jim Oppold's. We greatly appreciate your participation in this effort. This morning I intend to explore the directions in which Occupational Safety and Health will move in the 1980's, and how respirators will be an important part of future developments. I'll also make some remarks about the direction that NIOSH is going, or thinking of going, in respirator research. Whatever happens in the 1980's, we will need the help of the people in this room in setting research priorities and carrying out specific activities.

First, let me tell you briefly how this workshop got under way. During a program planning session with NIOSH division directors, we spent considerable time discussing the problems of our Testing and Certification Branch. I felt at that time that if NIOSH were to focus its activities only on a reworking of the Testing and Certification Branch, we would be looking at only half of the pie. We really needed to look at the issue of research as well. It was also clear to us that we knew very little, if anything, about respirator research in other countries. We were familiar with the research issues in the United States, but we had very limited knowledge of international activity. This international workshop then evolved to address these two concerns.

As many of you know, NIOSH recently convened a panel of consultants on testing and certification of personal protective equipment. The panel consisted of Morton Corn, Mary-Win O'Brien, Richard Brief, Robert Firenze, and David Scott. The efforts of this group have been immensely important to us. We expect that this workshop will produce equally valuable results. The people who are here today are precisely those we hoped would attend, and we will follow up with you in the future. Finally, it is the goal of this meeting to help determine our priorities for respirator research.

Now, I'd like to talk for a few minutes about where I think our research is going. Within the last 10 years the world's industrialized nations have enacted major environmental and pollution control, consumer safety, and occupational health legislation. It should be emphasized that the United States is by no means the only industrialized nation to commit itself to controlling the environment in general and the workplace in particular. That's why I think it's particularly important that we begin to pay closer attention to what is going on in other industrialized nations, particularly European countries and Japan. We at NIOSH have at times been too parochial in our views.

The Occupational Safety and Health Act is 10 years old, and in my view we've come a long way. We exist in a rather interesting climate that sometimes causes nervousness, sometimes optimism. I doubt that the framers of the Act in 1970 really understood the impact the Act would have. I don't think that they understood at that time how it would affect productivity, capital formation, technological innovation, reindustrialization, and the other themes now being discussed in the United States.

There is no question that there has been a significant growth of interest in occupational safety and health in this country in the past 10 years, and I would argue that this meeting is an example of that. OSHA has enhanced the awareness of labor, management, and the general public. Public awareness has increased through the efforts of people in this room, through media attention to certain hazards, and through numerous other activities.

There has been a clear change in union involvement in safety and health in this country. A few years ago there were only half a dozen full-time safety and health professionals in labor. Now the number is more like 100. Efforts to educate and train workers have increased dramatically. Three years ago OSHA spent approximately \$700,000 a year on training and education. Now OSHA spends about \$14 million dollars a year on education and training in its New Directions Grant Program.

There has also been a heightened Congressional interest in occupational safety and health in the past few years. Usually the occasions on which we have been asked to testify to Congress in the past few years on occupational safety and health problems reflect not a negative Congressional interest generated by the current anti-regulatory climate, but rather a significant positive interest in occupational safety and health problems.

NIOSH criteria documents and our field research have clearly led to an expanded knowledge of workplace problems. The formation of the Inter-Agency Regulatory Liaison Group, involving the interaction of the Environmental Protection Agency, Consumer Product Safety Commission, Food and Drug Administration, and Occupational Safety and Health Administration, is a very significant positive step. The formation of the National Toxicology Program also represents a step forward in toxicologic testing. Thus, increased interest, commitment, and activity make up one side of the equation, if you will. The other side is the clear concern about the Nation's economic vitality and the impact of regulation on that vitality.

One can quote from a number of publications on the latter concern. Newsweek, in its recent special report on productivity, tells us, "Lately the rainbow seems to have blurred or even broken. For the past decade Americans have watched helplessly as the purchasing power of paychecks has been mercilessly eroded. They have raided their savings and sacrificed their future security to present needs. Many of their jobs are in jeopardy and some have disappeared forever. Meanwhile they have seen once proud industrial plants age and close. For the first time public opinion polls show that the average U.S. citizen is not at all sure that his children's lot will be better than or even as good as his own." In explaining his economic revival plan, the President Carter has said, "Our task is nothing less than to revitalize America's economy. Increasing productivity is the foremost economic challenge of the 80's. We will meet the challenge with a more productive America as if our economic life depends upon it because it does." There is a very lengthy and very good article in this month's Atlantic called "American Industry, What Ails It and How to Save It." I recommend it to you.

The June 30, 1980, Business Week issue is devoted entirely to the subject of reindustrialization. Let me read a quote which I think is particularly important: "The first step is to recognize that the U.S. indeed faces a crisis and that there is no option available but to redo the manufacturing sector of the economy. Regulatory laws, including the anti-trust laws, should be changed if it can be shown that they interfere with the ability of U.S. companies to compete effectively with other countries, especially Germany and Japan, in the world market."

There has certainly been a clear anti-regulatory mood in Congress recently. There is concern in the Administration and the courts over the inflationary impact of standards, over the matters of cost effectiveness and cost benefit. The recent Supreme Court decision on benzene* clearly will impact standards setting at OSHA, and the benzene decision will impact NIOSH direction as well.

We have a mixed climate today, 10 years after passage of the Occupational Safety and Health Act. There is critical negative public concern over the direction of the country with respect to its economic vitality, and simultaneously there is interest, awareness, and activity with respect to occupational safety and health. The tension between these two themes is going to be with us throughout the 80's and well beyond. How the matter is resolved is going to be very important to NIOSH research.

*Industrial Union vs. Petroleum 100 S. CT. 2844 (1980)

It is clear that whatever economic revitalization we effect must occur without sacrificing workers' lives. We must not fall back into the conflict of job health and safety versus the nation's economy. That equation is bankrupt.

Historically, NIOSH research has been driven by the choice of a chemical, the development of a criteria document, the transmittal of that criteria document to OSHA and the hope that a standard would be set and followed by some measure of enforcement. That view of how one establishes research priorities is indeed too narrow and is not really responsive to current occupational health needs. This isn't the place for a lengthy discussion of those issues. It is important to say, however, that economic, social, and engineering considerations are becoming more and more important.

We agree with Nick Ashford that expansive environmental regulations may tend to encourage technological innovation. We believe that environmental regulations can force firms to implement product or process changes, often incidentally shocking them out of inflexible production systems. The regulations may provide the catalyst necessary for innovation not only to meet regulatory demands but also throughout their operations. Another effect of regulation is the development of products and processes that actually control environmental pollution. Regulation has virtually created a whole new demand for increased production of existing abatement technologies as well as development of new and improved techniques.

The bottom line of all this is that while we are talking about revitalizing, recapitalizing, and rebuilding our Nation's economy, we should not be considering withdrawing social legislation on the environment or on occupational safety and health. That is not the direction in which we need to be moving.

Rather we need to accept the challenge of incorporating occupational health and safety issues, programs, and designs into the rebuilding of the economy. We have been meeting with members of the Department of Commerce, the Office of Management and Budget, and other members of the Administration, to raise these issues and to begin to redirect NIOSH research toward these issues.

In the intermediate future, we will direct research efforts into new energy technology, the electronics industry, the new biological industries, and the service sector. We will also look carefully at the rebuilding of the iron and steel industry. These examples of areas we've explored, not through the traditional NIOSH mechanism, but rather because they are expanding, growing, rebuilding industries. These are the emerging industries which require early investigation of safety and health issues. This approach suggests, as I think you must well know, that we are going to place great emphasis on engineering controls and control technology research.

This workshop is about respirator research needs, but I would be remiss if I didn't reassert our commitment to studying the issue of control technology very seriously. The current climate doesn't give us an indication of whether any new standards will be promulgated by OSHA. Certainly the process is slow. There are immense difficulties in the standard setting process. That makes it even more important for NIOSH to do more research in control technology. We intend to build into our field studies a component to look at control technology, to begin to link those epidemiologic activities and problem-solving efforts and develop information about controls.

We're concerned also about how we develop additional routes of dissemination of information on controls. One of our problems is that we have been an Institute which too often has talked to itself and has had too little dissemination of information to a wider audience. We've been talking about how we can make the research that we do, particularly in our field activities and control technology, available to a wider audience.

We certainly need to find out more about what's going on in foreign countries. We know very little. It was impressive that a noise control book that OSHA just published is really a reprint of a Swedish document. It's embarrassing that we weren't able to publish a noise document from OSHA that was a true product of United States effort.

How relevant is all this to a discussion of respirators? The implication of this is that we will require, during the foreseeable future, more rather than less dependence on respirators. The number of respirators in use throughout the United States is great. It is growing. The industry is certainly large, and there is no question that the need continues and the need for respirators is going to continue to grow.

In 1958, Harry Jordan published a paper in which he said that the use of respirators is not an engineering solution for any problem and its effectiveness cannot be readily determined or predicted over a period of time as a corrective measure. Therefore, respiratory protective equipment is at best a second choice. This probably accounts, at least in part, for the traditional lack of interest in the respiratory protective equipment field on the part of most industrial hygienists.

At the American Industrial Hygiene Conference this year, however, it appeared as though industrial hygienists are now giving greater attention to the respirator, almost to the exclusion of engineering controls. As we walked around the exhibit area, we saw only one company advertising engineering controls. The focus of attention was indeed on respirators.

Controls have historically been implemented slowly. In some major American corporations, implementation of controls may occur relatively quickly. But I would argue that for thousands of industries in the United States implementation of controls has been slow. OSHA's ability to determine whether those controls have been implemented has also been limited. It is very difficult for OSHA to do the kinds of follow-up to determine if controls have been implemented, even though it is their policy that those follow-ups occur.

The slow pace with which engineering controls have been implemented has two effects: continued reliance on respirators and therefore concern for the adequacy of respiratory protection. In numerous industrial establishments around the country which have been cited for toxic overexposure years ago, controls are still very slowly being implemented. This will continue. I might say that we could speed up the process if we knew more about the nature of those controls, if we knew more about what they should be. That is an issue on which NIOSH and OSHA need, as I have said, to do significant work.

The lead standard has been particularly significant for respirator discussions. The standard OSHA promulgated allowed for a better look at respirator questions such as the use of respirators over extended periods of time. Primary lead smelters are given 10 years to comply with the standard and secondary smelters and battery plants are allowed five years to comply. The textile industry, another industry in which long-term respirator use can be expected, was given four years to comply with the engineering control provisions.

I believe that the standards promulgated in the last couple of years are models of the way OSHA will approach the use of respirators. When a standard is promulgated, industry will be provided a reasonable period of time to install engineering controls. There might be a debate about what "reasonable" is in this context, but in the lead standard, for example, we assume that 5 to 10 years is reasonable. Therefore there will be a continuing need for respiratory protection over extended periods of time. I want to talk about OSHA's experience and problems with respect to respirator use. OSHA has found continuing problems in respirator programs. Let me just go through quickly with you one year of their experience.

Over the last year OSHA carried out 1,463 health complaint inspections. In 22 percent of those inspections the permissible exposure limit for at least one of 66 different substances was exceeded. Of 818 general schedule inspections, again 22 percent revealed overexposure to toxic materials. Of 288 follow-up inspections, 16 percent of the exposures were still above the permissible exposure limit. In 97 monitoring inspections of State plans, 25 percent of the workplaces exceeded the permissible exposure limit for at least one substance. Out of 1,424 referral inspections, 14 percent of the workplaces were above the exposure limit. That's a significant number of inspections in which the permissible exposure limit was exceeded.

How have we fared in general with compliance experience in respirators between July 1, 1972, and August 30, 1980? In eight years, OSHA carried out 526,000 safety and health inspections. These included complaint, general schedule, follow-up, and fatality. Out of those 526,000, inspections citations were issued for 313,665, of which there were 12,626 violations of 29 CFR 1910.134, standards for respiratory protection. That means that for that eight-year period, four percent of all citations issued showed respirator infractions, or rather, violations of 29 CFR 1910.134. More than one-third of all health citations involved violations of 29 CFR 1910.134.

The record of the Occupational Safety and Health Review Commission documents the types of violations we are talking about. I won't take time to give you more than a few examples. In one case an employer trained workers in respirator use, but failed to instruct them in the limitations of respirators. In another case, workers who used respirators were allegedly not medically evaluated by a physician, and the company erred in not testing workers in respirator fit. The use of facelets which interrupt the seal between respirator and face is a modification that violates the approval of the respirator. Failure to regularly clean and inspect respirators is another common problem.

Based on the OSHA and the Review Commission experience we are lead to conclude that there is a continuing need for a good respiratory protection program but there are serious inadequacies with existing programs. We believe that workers are not being provided adequate respiratory protection.

In addition, we are faced with the problem that workers are unwilling to wear respirators for extended periods of time, even though they are being asked to do that throughout industry in the United States. We have done a great deal of research. We've made significant accomplishments in understanding the problems of respirator design, especially face fit. We have begun to understand respirator fit for different face sizes and shapes. However, the fact remains that workers are not wearing respirators. We need to be thinking very carefully about how we're going to determine the basis of the problem and subsequent resolutions.

At OSHA standards hearings we listen to testimony from workers who tell us they will not wear respirators, that respirators are an inadequate means of protection, they are uncomfortable, unsafe, hot, and on and on.

I think that the problem is that we professionals do not take that testimony and those really anguished cries seriously. Yet worker criticism is far too widespread for us not to take it seriously. It is not really a question, as far as I'm concerned, of worker negligence. It's rather a problem in the basic design of respirators. I'm not referring to respirators used on an acute basis, like emergency self-contained breathing apparatus. I'm talking about the vast majority of respirators. I know I could find people who would argue that there are effective respirator programs in the United States. I would agree that there are some. But I would think that they are the exception that proves the assertion.

We have spent a great deal of time in the past few months talking to people about the issue of worker acceptance of respirators. We've talked to industrial hygienists. We've talked to compliance officers. We've talked to NIOSH personnel and others. What we find can be summarized by a quote from John Moran, who is here and who testified at the NIOSH public hearing, "As a consultant having reviewed the respirator programs of hundreds of private companies I can state that I have not, with the exception of the nation's very largest corporations, ever observed a proper and adequate use of respirators in the occupational setting."

We look at a letter to Eula Bingham from the Carolina Brown Lung Association, clearly an advocacy group, clearly a group whose primary concern is the health of the worker. They tell Dr. Bingham quite emphatically, "Workers should not be forced to wear masks 8 hours a day." A recent AIHA Journal article by Tom Smith and Mike Varner tells us that cadmium workers are not wearing respirators. Other data we have seen seem to confirm this.

NIOSH sponsored a study about 10 years ago entitled "Coal Mine Dust Respiratory Protective Devices." It was done by Harris at Eastern Associated Coal. His conclusion: "While most miners felt presently available respirators are acceptable for intermittent use, over a third of the miners indicated these respirators are unacceptable or marginally acceptable." The list goes on and on. In general, we find respirator use only when we're dealing with substances like SO₂, where there is a noxious environment.

Whether the problem is heat, sweating, strap headaches, irritation behind the ears and over the mastoid process, ingrown hairs, dehydration, inflamed sebaceous glands of the cheeks and skin, edema of the scalp due to impeded lymph damage, respiratory stress, poor fit, difficulty in speech transmission, visibility limitation, and fatigue--whether it be any one or all of those--workers are not wearing respirators for extended periods of time.

It seems to me then that we do have a basic design problem. It is not, I would assert, a problem which will be solved by hiring some psychologist and trying to deal with it as though it were a behavioral issue. It is not a behavioral issue.

One thing we may need to do is provide workers with more information about the nature of the hazard. With lead exposures, for example, we find that the information has not been available. It would be interesting to see what the relationship is between worker acceptance of respirators and knowledge of the particular hazard.

I would argue, by the way, that very often employers are not aware of the hazard. We shouldn't limit ourselves strictly to the employee in the design of a good respirator program. Knowledge of the hazard, of course, needs to be widespread, both to the employer and the employee.

OSHA currently has three respirator policies. If a worker is overexposed to one of the substances in 29 CFR 1910 with respect to the time-weighted average, respirators are required for eight hours a day essentially. However, in coke ovens, where there was significant worker reaction to the requirement for respirators, OSHA has a different respirator policy. Workers in the regulated area need not wear a respirator in clearly delineated areas that have been shown by air sampling to be consistently below the permissible exposure limit. Such locations may include large areas such as the push side bench, or small areas such as the bench level between batteries. This policy was an attempt by OSHA to address the concerns of coke oven workers, who did not want to wear respirators.

In the lead standard there is yet a third respirator policy. The time a worker is required to wear a respirator is determined by the protection factor of the respirator and by the levels of lead. Hence a worker need not wear a respirator for any longer time than would be required to achieve the permissible exposure limit. There is a significant series of assumptions associated with that policy. That policy presumes the protection factor is accurate. It presumes that both the workers and the employer are going to know what levels of lead they're working with and are going to act accordingly. I would suggest that the effectiveness of that policy can be questioned. However, the policy grew out of concern for the fact that workers would refuse to wear respirators for long periods of time.

OSHA is currently working with a draft of its cotton dust program directive, which, in fact, does the same thing. It determines the concentration of cotton dust in the air, determines the protection factor of the respirator, and adjusts the time required for wear of that respirator accordingly. Therefore, OSHA has attempted to be responsive to workers' complaints about respirators but in doing so they have created inconsistent respirator policies and in my view have created a situation where worker protection is questionable. NIOSH testing and certification efforts have also reinforced the problem of worker acceptance.

I think that what we have done in NIOSH through our testing and certification program, and what OSHA has also done, is stifle innovation in respirator research and new respirator development that would have increased worker acceptance. In the last 10 years we have placed a great deal of our funds and energy into a testing and certification program that stifled the kinds of innovation we need in the future. And I think that when OSHA adopted 29 CFR 1910.134, the requirement that employees use NIOSH certified respirators, the problem was reinforced by the regulatory posture. At the same time, of course, we've tried to use that regulatory posture to protect workers.

Let me give you my conception of what the research agenda should be. I am not by any means being exhaustive. Others will add to it and I hope that by the end of this workshop we'll have a priority list which will enable us to move ahead.

In general, we're going to have to evaluate the effectiveness and limitations of current programs of respiratory protection. We need to be concerned about worker acceptance as controls are implemented. We need to design research to look at that issue. I think it's important that we take a look at the impact of some of the OSHA standards, to evaluate, for example, precisely what the impact of the lead standard has been for respirator use. We need to look at the worker education and training provisions in the standards, and the medical protection provisions.

It's extremely important that we study the effectiveness of respirators under actual use conditions. The data that have been developed in that area up to now have been very depressing. We need to look at issues of respirator reliability in the field. Our information on protection factors is generally based on laboratory tests in which wearers undertake limited body movement. The actual protection provided by respirators in the work environment may be less.

We need far more research on positive pressure respirators, that is, powered air-purifying respirators. New technology, new design such as the PAPR will receive highest priority for funding from NIOSH. In our view, the powered air-purifying respirators are very promising. They represent an innovative advance, one of the most innovative advances in the last few years. However, there are limitations. For example they're not useful for gases and vapors. There has been criticism of the shield because of vision impairment. In paint spray operations, the shield is certainly a problem. Weight is also a problem. We clearly need to look at the protection factor, and as more powered air-purifying respirators are used, we'll expect to identify additional problems.

There is a policy issue here about whether courts will interpret a powered air-purifying respirator as a respirator or an engineering control. That is going to be litigated in the future. It's an issue that has policy and legal implications. We would argue that a PAPR is not an engineering control. We need to study the durability, expected life, maintenance, and cleaning of these types of respirators.

We really do need to begin to support innovation in respirator research. That's the message here. Because of the reliance on disposable respirators, single-use respirators, we clearly need to do further research on the reliability of this device, especially their protection factors in the field.

We are concerned about end-of-life indicators and mask sensing devices for sorbent breakthrough. We're concerned about awareness of supervisors, workers, and management about respirator service life. We're going to have to be looking at filter and sorbent efficiencies. We agree very strongly with Dr. Raven who in his very fine review piece in the AIHA Journal last year when he spoke about the need for "The development of a physiologically sound medical screening examination for the industrial physician to use in determining the capability of a worker to use a respirator." Other points Dr. Raven makes are equally important. For example, he says, "In addition, the psychological correlates of an individual with respect to his ability to wear a respirator under stresses received no attention. That seems to me to be quite tragic in many respects." We agree and I would urge you to read Dr. Raven's conclusions.

We are thinking about whether or not we can establish a kind of rating system for respirators. How do we take into consideration the data we have about worker acceptance, about ease of use and so on? I won't try to define the parameters, but we'd hope to put together a kind of rating system, a kind of National Transportation Board testing of respirators, a kind of Consumer Reports rating system. I'm not suggesting we're definitely going to do that, but I am suggesting it's something we need to think about. As we do all this, we will be meeting with OSHA to discuss how, over some time period, we'll review 29 CFR 1910.134 in the context we've discussed here today. We will begin to talk about what kinds of modification in the respirator standard are going to be required.

These are all important issues. Out of this meeting, and these papers, we should try to come up with some sort of priority list about how best to proceed. I've touched on some of the things that I think are important, but I have been by no means exhaustive. I welcome the participation of every one of you. Thank you very much for your time and your patience.