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TESTIMONY

by

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at

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Remarks re: Hearing and Conference

The purpose of my presentation is to 1) convey to this audience the background of concern which led to the appointment of Consultants by NIOSH Director Dr. Anthony Robbins to review current Testing and Certification procedures of NIOSH for Personal Protective Equipment (PPE) and Hazard Measuring Instrumentation (HMI), and 2) to convey the spectrum of concerns shared by the Consultants which are embodied in the report submitted to Dr. Robbins on November 21, 1979. It was not possible to accurately convey the nuances of concern or the emphases on issues in the report; I hope to do so here. The members of the Consultant Group which approached the task of individually reviewing the mass of materials and documents listed as Appendix C to the report were, in addition to myself, Richard Brief, Robert Firenze, Mary-Win O'Brien, and David Scott. The materials transmitted to the Consultants were not the only resources available to us: we interviewed NIOSH personnel, as listed in Appendix C of the report, and also visited the NIOSH Morgantown, West Virginia facilities where the testing and certification facilities and staff are housed. Although each consultant approached aspects of the program individually with evaluation in mind, the general conclusions of the report were unanimous. In fact, the unanimity reached by the process of each of us examining different facets of the program, was a source of surprise. It is to the credit of Dr. Robbins that he interpreted the field failures of devices in the field as a possible indicator of a broader, more endemic need of the user, and a possible reflection on the inadequacy of the then existing government procedures. He appointed the Consultants and gave us the directive to examine the entire testing and certification procedure.

The conclusions and recommendations in the Consultant Report range from the topic of adequacy of the existing NIOSH legislative mandate to the detailed testing procedures and research conducted by the Testing and Certification Branch. As our efforts started and continued during the summer of 1979, it became increasingly clear that it would be a band-aid approach to a larger problem if we accepted the current framework of government activity in PPE and HMI testing and certification, and only addressed deficiencies in that system. Rather, we chose to approach our tasks by visualizing the needs from the user standpoint and focusing on a government program that would fully meet user expectations and needs. We did not restrict ourselves to a critique of current NIOSH activities. In fact, because the Testing and Certification Program had its beginning roots in the U.S. Bureau of Mines and was until recently performed and administered in conjunction with the Mine Safety and Health Administration and the U.S. Fire Administration, in essentially the same manner as it was administered decades ago, it is timely and appropriate to examine major changes in the program to meet needs stimulated by recent health and safety legislation, including the OSH Act of 1970 and the MSH Act of 1977. Professional colleagues who have been associated with PPE testing and certification for many years - indeed, some have grown up with the industry, have told me that the initial government effort was to assist manufacturers in order to stimulate the development of a very much needed national industry. Today, we were told, PPE sales alone exceed $\$160 \times 10^6$ per year and this figure will double by 1982. This is hardly an infant industry, one requiring stimulation for growth. The same firms in this business originally have thrived over the years; also, large organizations have entered the field during the intervening years. In general, manufac-

turerers have sophisticated technical personnel and facilities to back up their products. In other words, the review commissioned by Dr. Robbins was appropriate not as a short-term response to some spectacular equipment failures in the field, but because the needs of those in the workplace have been better defined and articulated, usage has expanded, and the government machinery to address these needs was straining under a system, including goals, defined and implemented decades ago.

It is appropriate at this time prior to addressing the issues for discussion at this Hearing, to quote from page 19 of the Report Under Conclusion 5, which relates to the then current NIOSH testing and certification program. We stated that: "It is our unanimous opinion that the technical qualifications and task performance of the Testing and Certification Branch staff is satisfactory. The Branch requires definitions of goals, objectives and functions and the associated restructuring and evaluation of performance to meet these goals and objectives. In this way, the considerable technical talents now onboard will be mobilized and more efficiently utilized." We believe that NIOSH has a capable and committed staff; the system in which they do their work must be revised to meet the needs of the 1980's.

I will now move on to the issues which we focused upon and for which NIOSH has requested your input at these Hearings.

Agency Approach to Testing and Certification

NIOSH does not explicitly in the announcement solicit comments on Section II, Investigation of Legal Authority section of the Consultants Report. The examination of NIOSH's statutory authority in that section of the report is related to the solicitation of public views on the four viable alternatives for the existing respiratory testing and

certification program. NIOSH indicates that at this early stage, the development of a new testing and certification program under Department of Health and Human Services (HHS) regulations where NIOSH alone would test and certify respirators is the alternative which would "provide more effective control of the respirator approval program and result in a more efficient testing and approval system." The consideration of ingredients of a respirator T & C program can be considered independently of the question, which of the four viable approaches is used for the program? It is not clear to me that the certification of private laboratories to assist NIOSH with the T & C workload, is not a more realistic approach to the T & C workload burden which can be projected as a result of regulatory stimulation of respirator requirements by users. The greater liability considerations applicable to private laboratories, as discussed in Section II of the report, does not appear to be a major obstacle, particularly if NIOSH retains the final authority for certification and approval based upon contractor laboratory test results. The latter is Alternative 3 in the Federal Register announcement of this Hearing. Alternative 4, a self-certification program whereby industry would test and certify respirators based on performance standards specified by NIOSH, strikes me as a very weak alternative. Alternative 1 for doing some fine tuning of current procedures, is clearly inadequate, as the Report strongly indicates. The views of those at this Hearing on these alternatives is clearly of critical importance.

Whichever alternative is finally focused upon by NIOSH in seeking to fulfill its responsibilities to those at work who require PPE and HMI, the division of responsibilities between the government (NIOSH) and manufacturerers must be made absolutely clear. Therefore, I will now

discuss the Consultants views of this division of responsibilities.

1. Division of Responsibilities

The consultants were unanimous in assigning to NIOSH the responsibility to set performance standards and design criteria for PPE and HMI. The nature of tests to assure that standards are met is also a NIOSH responsibility. The responsibility to assure users that all PPE and HMI units in the field adhere to performance standards is the manufacturers' responsibility. NIOSH must establish a scheme for sampling and testing units in the field to assure users that manufacturers' units are, indeed, meeting standards and criteria for design and performance. The approval and certification of an individual PPE or HMI is the analogue to a construction permit: it is not an operating permit. The latter is the net result of a series of manufacturing steps that leads to the distribution and sale of reliable units in the field. The operating permit is contingent on demonstration of reliability of field units.

In the past, an approval by NIOSH was interpreted by users as assurance that units purchased on the market were uniformly reliable. In reality, although issuing approvals, NIOSH could not give any such assurance. As consultants we think it is the responsibility of the manufacturer to give this assurance and it is the responsibility of NIOSH to confirm that the manufacturers' assurances are well taken by users. It is not, in our opinion, for NIOSH to approve a quality assurance program of a manufacturer; it is for NIOSH to determine that PPE or HMI manufactured in a plant with quality assurance procedures meets standards for performance set by NIOSH. Failure of units in the field to do so is answerable by the manufacturer.

There is an analogy in our perception of the division of government-private sector responsibilities in the automobile industry. Vehicle safety standards and emissions standards are established by Federal agencies assigned these responsibilities. The automobile manufacturers are compelled to meet these standards. The EPA, for example, randomly selects production vehicles to assure that standards are met.

The necessity is great for stringent performance standards for PPE and HMI. In the case of these units, lives literally depend on the integrity of the device and its predicted performance in the field.

Statutory Authority of NIOSH

NIOSH was recently active in certifying six different types of HMI and PPE, including three types of respirators and coal mine dust samplers, sound level meters and gas detection indicator tubes. The authority for these certifications stems mainly from the Mine Safety and Health Act. It was projected by NIOSH that a 10% per year growth in requests for certifications would not be unrealistic. The Consultants addressed the question of agency authority to enter new areas of testing and certification in Section II of the report. One can very briefly summarize the conclusions of our investigation into this subject by saying that only the Mine Safety and Health Act contains explicit language related to PPE and HMI testing and certification, but the OSH Act in its directive to NIOSH to "develop and publish....such criteria as will effectuate the purposes of this Act" permits NIOSH to move ahead with a certification program. Certainly, by cooperating with OSHA in that the latter, in its standards enforcement activities, will recognize only NIOSH certified PPE and HMI results, OSHA can be a powerful stimulus to a NIOSH program of voluntary, if not required,

certification of devices. The Consumer Product Safety Act also seemed to us to offer a model for product certification by manufacturers that their product meets NIOSH standards and criteria for performance.

Thus, our investigation of the legal options available to NIOSH to effectuate the presence of PPE and HMI of predictable performance in the field resulted in our concluding that NIOSH has several alternative ways to achieve the result with the existing statutes on the books. We look forward to testimony on this question at this Hearing.

Within the context of a Testing and Certification Program, as described above, what specifically should NIOSH focus its technical in-house talents on? The Consultants were specific in their views in this regard, and I will now formulate some of their opinions.

Performance Specifications and Guidelines

With reference to PPE, NIOSH could set leakage performance standards for classes of devices under conditions of use. Thus, respirator X must permit no more than Y% by weight penetration of aerosol Z when challenged at specific concentration and particle size of aerosol and the device is worn during workload performance A, for example. We visualize NIOSH personnel or their research agents engaging in these same tests to determine they are feasible. We also visualize NIOSH describing in great detail the conduct of tests to permit manufacturers to set up their own test facilities to test their product and, if a voluntary certification program is used, to certify them. Of course, in the event of either a voluntary or non-voluntary certification program, with testing by NIOSH or by the manufacturer, we visualize NIOSH gathering production units and units delivered for usage in the field, in order to test them and verify that off-the-shelf items perform as expected.

Many tests and specifications used by NIOSH until the program was placed in abeyance by Dr. Robbins were old and lagged the state-of-the-art. Examples of such tests were the silica dust and lead fume tests and the Uranine dye test. NIOSH must update tests and demand technical progress from manufacturers so that users are assured of devices which are based on the advanced technology available in the U.S. and elsewhere. In the opinion of the Consultants, the former system of testing and certification encouraged the perpetuance of outdated technology. There was no incentive for improving a device once it was certified. By placing time limits on valid dates of certification and by continuous upgrading of certification specifications and standards, NIOSH can stimulate improved PPE and HMI.

The consultants believe the responsibility for researching new devices is that of the manufacturer. The device proper must meet specs and standards researched by NIOSH and must do this by performance in tests developed and tested by NIOSH.

There is an area of PPE concern that illustrates the possible functioning of a new system for NIOSH testing and certification of PPE. There is a desperate need for PPE that better meet the needs of women at work. The face fit problem for women is a major one. NIOSH could perform, or contract the performance of research related to proper face fit characteristics of women and could specify dimensions of PPE classes of devices which would meet the user needs ascertained by NIOSH. Manufacturers would then be required to incorporate into their products the features that would meet NIOSH specifications for face fit.

The research role of NIOSH vis-a-vis specifications of devices is a large and formidable one. As consultants we are aware of major questions that must be addressed. For example, with the broad array of organic vapors that workers may potentially be exposed to, what is the preditability of usage for one vapor from tests on another, or on a series of compounds? What is a minimum data set of test data to assure users of PPE respirator devices in the field? In the area of fitting of respirators to respiratory impaired individuals, what are guidelines for such usage of devices by diagnosed bronchitics or asthmatics, for example. The Consultants believe these are bona-fide questions for NIOSH research to address, and, once answers are available, to distribute the knowledge to users and to establish performance requirements for manufacturers. With the areas of agency activity envisioned by the Consultants, the development of in-place respirator testing methods for rapid leakage determination in the field, is clearly a NIOSH responsibility. The requirement that these tests be met on whatever statistical basis is finally evolved, is the product manufacturer's burden. As I will later discuss, the rapid dissemination of failure information and stop-sale issuances are NIOSH responsibilities, in our opinion.

The PPE field, in general, and including respirators, does not appear to us to have benefitted from the virtual revolution in new materials. We believe this failure to integrate advances in materials science into PPE products stems in large part from inadequacies in the recent NIOSH approach to Testing and Certification. It is conceivable that NIOSH would develop prototype products in its research program for the purpose of demonstrating the validity of associated performance standards. As consultants we are not condemning all recently used NIOSH

tests and certification process ingredients. The total system was not effective; parts of the system may be salvageable and integrable into a new system. It is hoped that those appearing at this Hearing will pass judgment on the strengths and weaknesses of recently used tests for NIOSH certification of PPE and HMI.

Before leaving the subject of performance specifications, standards and guidelines, the practice of NIOSH maintaining detailed engineering drawings of all manufacturers' products which were certified must be addressed. The Consultants do not understand the rationale for that practice. It was tacitly assumed by us in approaching our evaluative tasks that NIOSH personnel literally reviewed these drawings and their updates; they did not. Then why require their submission and submission of all updating changes? The only test of concern to a user and to NIOSH, in our opinion, is the test of performance. In the cases of failed respiratory protective devices which firemen utilized in 1979, we were informed that all engineering drawings for the failed valves were in order - and had been in order - since 1938, when they were first submitted for approval testing! The matter of government agency involvement in manufacturer design drawings for PPE and HMI was a pro forma procedure up to this time. As consultants, we question its usefulness and look to the views of those appearing at this Hearing to shed light on the value of the concept. Of course, our view is based on NIOSH putting in place an effective testing schema for units in the field and an associated system for rapid communication to users of test results for field units. In this way, inadequate design changes will be rapidly detected; the product manufacturer will be responsible for any untoward effects stemming from design changes. Any notification of change forwarded by the manufacturer to NIOSH should be viewed, we

believe, as a courtesy procedure, and nothing more.

It is conceivable, but not likely, that with the increased presence of large organizations in this business area, that PPE and HMI product manufacturers will require some assistance to set up to duplicate NIOSH testing protocols. We believe that this is a legitimate request by manufacturers and that NIOSH should respond accordingly. NIOSH might also coordinate inter-organization testing comparisons to be sure that test results performed by NIOSH and the companies are compatible. Several years ago I was involved in a case of results of PPE test discrepancies between a manufacturer and NIOSH and can attest to the vexing nature of the situation. The manufacturer in good faith believed his product met NIOSH specs, but upon submission, it repeatedly failed one dust challenge test. Presumably, the tests were run the same way at both sites. My point is that these are technical areas of performance. Each manufacturer must invest in or purchase for usage the facilities and technical competence to document performance. If assistance is needed, NIOSH should provide some to an earnest product manufacturer. The recognition by manufacturers of PPE that investment in technical capabilities and facilities is required has been slow and some major manufacturers are still poorly equipped and staffed in this area. The system we are suggesting to NIOSH would demand a high level of technical skills of the manufacturer -- and it is fitting and proper to do so because lives depend on the product quality.

As consultants we discussed the longevity of individual product certifications. Some comment is appropriate. Barring a major advance in state-of-the-art, 3 or 5 years for a valid certification seems appropriate. In the case of state-of-the-art major advance, NIOSH

should recall all certifications pending retest and adherence to new test protocols. Only in this way can the ultimate potential beneficiary of all this effort gain from new materials technology, design improvements, etc. While this short-term assurance to a product manufacturer may seem to some "unfair" considering large potential investments in product development, it cannot be any other way, in our opinion. This is not a game; lives literally depend on the quality of PPE and HMI devices and their proper usage.

Of course, the establishment of new performance criteria by NIOSH would not be arbitrary or capricious, but would occur under the rule-making procedures of the Administrative Procedures Act.

Quality Control

Under the recently curtailed NIOSH procedures, NIOSH engaged with manufacturers in a process designated as "quality assurance", which was differentiated from "quality control". Quality assurance involved direct NIOSH personnel involvement in manufacturers' product manufacturing procedures. NIOSH analyzed and literally approved of quality assurance aspects of the manufacturing process. Quality control was considered the output function, e.g., how many units were unsatisfactory, as differentiated from the quality assurance procedures to minimize unsatisfactory units. As Consultants we think the distinction drawn by NIOSH between quality assurance and quality control is meaningless; it is all quality control, the only test is the final product, and it is the manufacturers' duty to take all steps to assure that product quality is in accordance with product performance tests. We recommend that NIOSH withdraw from all activities related to manufacturer quality assurance or quality control. NIOSH rationalized its involvement in this area because of small manufacturer inability to mobilize quality

control programs. This may be a valid reflection of manufacturer inadequacies. In our opinion, satisfactory product quality control is part of the price of doing business in this product market. Manufacturer inability to compete in this regard should, in our view, disqualify a manufacturer from marketing his or her products when human lives depend on their usage.

User Reporting System for PPE and HMI

Even if the system proposed operates at a high degree of efficiency, there will be equipment defects which become apparent only after extended field usage. NIOSH must develop a feedback system which permits users to communicate such defects in a timely manner and with particularity, so that NIOSH can take effective action. Malfunctions must be reported to other potential users as quickly as possible to avoid repetition of the unfortunate event(s). Such a system will require a great deal of initial and continuing NIOSH effort. It is an essential component of a testing and certification program, not merely an addendum ingredient. At present, mechanisms for PPE and HMI equipment failures does not exist. We suspect that only the most spectacular and tragic failures of such equipment are ever reported back to NIOSH. Development of this feedback system will include an educational component in order to sensitize users to the most probable failure modes of PPE and HMI. Also, an information distribution system to notify potential users of PPE and HMI potential problems must be developed. Views on how to do this in an effective and efficient manner are solicited by NIOSH at this Hearing. In our report we refer to this feedback system as a PPE and HMI Field Surveillance System.

User Information System for Available PPE and HMI

In addition to information related to malfunctions of PPE and HMI in the field, we believe NIOSH can play a meaningful role as the source of information related to the availability of, and performance of individual PPE and HMI. The issuance of a NIOSH report was not, in our opinion, a highly effective means of informing a potential user population of 100 million of the availability and characteristics of PPE and HMI. We do not believe that NIOSH should advertise for manufacturers, but between the role of advertiser and the publication of technical reports of performance, there is a spectrum of activities available to NIOSH to promote the knowledgeable utilization of these devices by potential users. NIOSH is soliciting views on this role at this Hearing.

NIOSH Systems Manual

It was a relatively difficult task for the Consultants to determine current responsibilities and procedures used in the PPE and HMI certification program. A large effort was devoted to gathering and then digesting materials in memos, Federal Register publications, laboratory procedures, etc. We believe the government agency charged with testing and certification has an obligation to explicitly state its procedures and that these procedures should be readily available to the public. Therefore, we have recommended that NIOSH prepare a Systems Manual for testing and certification procedures and that the Manual or parts thereof be available to the public upon request. We envision the Manual as a very detailed compendium of materials which, taken together, explain all facets of NIOSH Testing and Certification Program operations.

Approval Testing

NIOSH should engage only in testing of devices formally submitted for approval, that is submitted according to the published procedures governing such submission and testing. Informal submissions, unpublished test results, prototype testing -- in our opinion, all are inappropriate to a publicly financed agency concerned with assuring the availability of satisfactory PPE and HMI to users. The product manufacturer has the responsibility for bringing a product to the stage of development where it can be submitted for testing. If NIOSH decides to exploit new and novel ideas and/or technology to foster new examples of PPE and HMI, it should do so by sponsoring research by capable investigators, with the results of such research subsequently available to the public. Prototype unit testing and unpublished results of such testing was, in our view, NIOSH underwriting of individual manufacturer research. NIOSH has solicited public views on this issue at this Hearing. Other views are certainly possible; I have reiterated the consensus of the Consultants on this subject.