Statement of

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I am Dr. John F. Finklea, Director of the National Institute for Occupational Safety and Health (NIOSH), administered by the Center for Disease Control within the Department of Health, Education, and Welfare. Accompanying me are Mr. John B. Moran, Special Assistant for Safety and Testing and Certification, Dr. Donald Campbell, Chief, Safety Equipment Section, and Mr. William Cook, Electrical Engineer, Safety Equipment Section. We appreciate the opportunity to discuss our experience in testing and certifying products against standards established by consensus standards producing organizations.

NIOSH was established by the Occupational Safety and Health Act of 1970 to conduct programs of research, standards development, technical assistance and manpower development. One of our Institute's most important responsibilities under this act is to transmit recommended standards to the Occupational Safety and Health Administration (OSHA) in the Department of Labor. The NIOSH recommendations are intended to serve as the basis, along with other available information, for assisting OSHA in revising the approximately 1200 consensus safety standards and 400 consensus health standards that were promulgated when the act was passed.

NIOSH has devoted its primary effort toward developing recommended health standards. Since 1972, NIOSH has transmitted more than 60 criteria documents recommending new health standards to the Department of Labor. These recommended health standards are transmitted to OSHA in the form of criteria documents which include an environmental

limit, as well as recommendations on the use of labels and other forms of warning, type and frequency of medical examinations, sampling and analytical methods, procedures for technological control of hazards, and suitable personal protective equipment. In addition, we have developed additional information on measurement of employee exposure, medical surveillance, compliance, training, recordkeeping and work practices for most of the 400 existing consensus health standards.

To meet our responsibilities for conducting safety research, NIOSH has recently consolidated that program in Morgantown, West Virginia. An important part of that program is the Testing and Certification Branch, which evaluates and reports on a wide range of personal protective equipment. We also conduct research to establish performance requirements for equipment to protect workers from defined health and safety hazards. This research has resulted in regulations certifying respirators, sound level meters, and devices to sample gas, vapor, and dusts. A NIOSH program for certifying head protective devices is in the final stages of promulgation by the Department of HEW.

Before we discuss our program in greater detail, we would like to review the present roles which OSHA, employers, employees and protective equipment manufacturers play with regard to personal protective equipment.

OSHA has adopted or referenced a large number of standards for personal prtoective equipment which employers under jurisdiction of

the Occupational Health and Safety Act must comply with. The majority of these standards were developed by the American National Standards Institute (ANSI). Although manufacturers assert that their products meet these standards, most employers, especially small businessmen, have no way to determine whether a welder's filter plate, for example, actually meets the required performance standards. All too often it is only after a tragic accident that the employer discovers that the equipment he relies on is inadequate to protect his employees. To afford the American worker some degree of protection until new Federal standards and improved personal protective equipment are developed, NIOSH tests currently available products against currently available consensus standards. The adequacy of these consensus standards is the primary subject of our testimony today.

THE CONSENSUS STANDARDS PROCESS

Voluntary consensus standards are developed by committees representing various interest groups. These committees usually include: Manufacturers, trade associations, users, and representatives of government and academia.

The selection of individual members of these committees is the option of each standards organization. The procedures for this selection process varies widely among the many standards producing organizations in the United States. In general, most claim that the selection

process is designed to ensure a committee that is "balanced" by including representatives of all concerned groups. The standards produced by these committees are "voluntary" in the sense that the committee itself has no legal authority to require compliance to the standard it develops.

In contrast to voluntary standards are "mandatory" standards that carry the force of law -- either Federal, state, or local. Voluntary standards may become mandatory when they are adopted by law as was the case when OSHA adopted the ANSI standards. There is, however, one pitfall associated with the consensus standard system that, in our opinion, is commonly overlooked. And, that problem concerns the very last step involving the conversion of a voluntary standard to a mandatory standard. The problem is this: Standards are developed as if they will be voluntary standards. In fact, they often are intended to be, and only have meaning as, mandatory standards. The two types of standards generally differ in their requirements for documentation, justification, and public comment. If a consensus standard is considered for adoption by a regulatory agency, the agency generally needs to review the technical basis of the standard. Unfortunately it is not the general policy of consensus standard groups to include such supporting documentation with the standards they develop.

THE NIOSH PERSONAL PROTECTIVE EQUIPMENT STANDARDS PROCESS

The NIOSH Testing and Certification Branch has a staff of 40 with an

annual budget of somewhat less than $1 million. It tests equipment against ANSI standards and reports on the results of those test, defines unacceptable failure rates for each performance attribute develops quality control plans, and develops regulations to permit certification of personal protective equipment and measuring devices.

The NIOSH certification process contains the essential elements needed to assure that personal protective equipment performs as required in the workplace. Those elements are:

- Performance criteria based upon a sound technical and scientific basis.
- Regulations promulgation process which ensures full public review and comment and requires NIOSH justification of criteria, procedures, and need.
- Certification of devices meeting both the performance criteria and quality control criteria. Certification permits the manufacturer to affix an appropriate NIOSH approval label on each certified piece of equipment.
- In-plant quality control inspections to verify that devices actually meet performance requirements.
- Confirmatory testing on an unscheduled basis of certified products obtained from the open-market.
- Authority to de-certify any device which is not in compliance with the regulations of either the performance regulations or quality control requirement.

MAJOR ISSUES

Does Existing Personal Protective Equipment Comply With OSHA-ANSI Standards?

To determine whether existing personal protective equipment meets existing standards NIOSH tests a large number of helmets, goggles, and spectacles, safety toe shoes and other equipment.

These tests are performed on equipment purchased on the open market in accordance with the ANSI standards adopted by OSHA. Prior to performing the tests, we discuss our procedures with equipment manufacturers, OSHA, users, and union representatives. After completing the tests, the results are discussed with the same persons and, subsequently, the results are distributed in a report. The objective is to provide unbiased test results to all parties so that workers may be adequately protected. I would like to summarize some of the results.

Our Report on the Performance of Men's Safety-toed Footwear confirmed our earlier preliminary report that one-third (1/3) of the models randomly selected failed to meet the ANSI Z41.1 requirements. This standard provides for 3 classes or levels of protection, and the test results indicated that, where failures occurred, in models were usually overrated in degree of protection by one level.

Even more disappointing were the results of our tests on Women's Safety-toed Footwear. Only one-fourth (1/4) of the 20 models tested

passed the criteria we used. Our criteria were very lenient since it was obvious from the outset that these shoes would not meet the requirements of the only women's footwear standard available, the obsolete ASA war standard Z41.21944, nor would they meet the requirements for the protection level for men's safety-toe footwear in ANSI Z41.1. This is one case, however, where the manufacturers did not claim their products met any standard. Nevertheless, it is apparent that the number of women in the workplace has significantly increased and that they do not now have adequate foot protection in those occupations where it is necessary.

In the area of eye and face protection tested for compliance with the ANSI Z87.1 standard, some of the devices available appear to be very well made. Our report, Tests of Flexible Fitting Safety Goggles, showed these devices to do a very good job of protecting the eyes of the wearer. There were no failures in the important impact and penetration tests.

Tests of Glass Plano Safety Spectacles (nonprescription) found the group also to be in general compliance with the standard. These devices had lenses of high optical quality with no models failing the requirements in this area. As a group, these devices also did well in the lens and frame impact tests and were found to do a good job of preventing eye damage. One of the more interesting developments discussed in this report is the flatfold side shield - a new type of side shield currently on the market but which is not specifically

covered by the standard. The flatfold design appears to be a useful alternative to bridge the gap between no side shield and full side shields.

In the Industrial Face Shield Performance Test report, we found that as a group, the devices generally exceeded the more important test requirements for impact, penetration, and flammability. It was noted, however, that 28 of the models allowed eye exposure from the side. Although this is not a requirement of the standard, we felt that this is an important feature that users should consider.

Our Report of Tests on Welding Filter Plates showed some serious deficiencies. Eleven models failed one or more of the 3 critical tests: impact, infrared transmittance, and ultraviolet transmittance. Since other models easily passed all 3 tests, there appears to be no reason for even marginal performance. Deficiencies causing failures in these 3 tests are particularly significant since they are not apparent to the user. Also, one-half (1/2) of the 26 models which passed the 3 tests were not made of glass which had been heat treated for impact resistance, and therefore, did not comply with the ANSI standard.

The Report on Tests of Class B Industrial Helmets showed only 3 of 21 models passing the performance requirements of ANSI Z89.2. The type of suspension used appears to affect the test results.

A Report on the Performance of Firefighters' Helmets found 3 of 6 models tested failing to meet the requirements of ANSI Z89.1. Two of these were due to failing the impact test.

In upcoming reports on devices for which testing programs have recently been completed, we will be discussing the commendable performances of Linemen's Rubber Insulating Gloves and Plastic Plano Safety Spectacles. At the same time, we will be reporting on the very poor performance of Eyecup Goggles in which one-half (1/2) of the models tested failed the lens impact test.

It is obvious, therefore, that some of the devices we have tested have complied with the applicable OSHA-ANSI standard while others have not. The deficiencies noted with regard to Class B Industrial Helmets were tragically brought to our attention by an OSHA Field Compliance Officer in Toledo, Ohio, earlier this year. On January 4, 1977, a worker was injured when a frozen ball of sand struck the top of his safety helmet. He died 11 days later from apparent complications due to severe head and brain injuries. Although NIOSH had not previously tested samples of the exact helmet model worn by this man, we had tested another model from the same manufacturer in 1976, and observed and reported its failure to meet the ANSI impact test requirement. We could not check the helmet worn by the worker because it was badly damaged. However, we purchased new helmets of the same model worn by the fatally injured worker and obtained used helmets of the same model worn by his fellow employees. These were tested in Morgantown and

found to be barely acceptable. Of the new helmets purchased by NIOSH 28 out of 50 failed to meet the ANSI standard impact requirements. Many of the helmets transmitted forces in excess of 5,000 pounds, or 4,000 pounds greater than the maximum force of 1,000 pounds allowed by ANSI Standard Z89. All the helmets concerned were labeled as meeting the ANSI Z89.1 standard specifications.

In another case, fortunately not resulting in serious injury, the Medical Director of a well known brewery sought our assistance in regard to the failure of a lens in a pair of prescription safety glasses which was impacted by a nail. This failure caused the Medical Director to collect 20 pair of prescription safety spectacles and subject them to the impact test. All 20 failed.

How Many Workers are Injured Because They are Using Defective Personal Protective Equipment?

The answer to this question is that we simply do not know. Cases, such as the two noted above, are brought to our attention by OSHA inspectors, unions, employees, and employers. The OSHA First Report of Injury Form (OSHA 101), the primary reporting vehicle for State workers' compensation programs and Federal national injury and fatality statistics, contains no information whatsoever with regard to the use of, misuse of, lack of, or failure of personal protective equipment.

A major initial commitment of the expanded safety program is the development of a more pertinent and useful National Injury Surveillance Network, which will also address the issue of personal protective equipment. It is our hope that we will be able to learn what role inadequate personal protective equipment plays in injuries and that we can learn more about the in-use durability and performance of such devices, data which simply does not now exist.

Are the OSHA Adopted ANSI Standards for Personal Protective Equipment Adequate?

Another important issue is the adequacy of the standards themselves and the mechanism by which they are developed. Based on our experience with personal protective safety equipment there are several problems with the present ANSI standards.

1. They are often unclear and require a great deal of interpretation.
2. The technical justification for each of the specific requirements is not presented. As a result, there are requirements that appear to have no technical basis.
3. Little effort has been made to validate the test procedures and ensure that they produce consistent results that can be reproduced from one laboratory to another. This is in marked contrast to the commendable effort that is apparently made in the development of standards by the American Society for Testing Materials (ASTM) standards. Detailed description of

the methods often used to validate test procedures are included in the ASTM manual for conducting an interlaboratory study of test methods.

4. Statistically significant sampling requirements necessary to evaluate the continued production compliance of a product line are usually not specified. When a sampling plan is specified, it is all too often inadequate.

I believe that in order to clarify the nature of these problems, it is appropriate to consider several examples from the present ANSI standards. As an example of a test requirement that is quite vague, let us consider the water absorption requirement presented in the ANSI standard Z87.1-1968 for eye and face protective equipment. Section 6, which covers safety spectacles and safety goggles, specifies that "Plastic parts shall be tested for water absorption and the results calculated in accordance with Test Method Number 7031 of Federal Test Method Standard 406." Superficially, this would appear to be a very specific requirement. However, the strict application of this method to these safety devices is not possible. Samples to be tested are required to be in the form of discs, sheets, rods, or tubes -- none of which occur naturally on the finished product of these devices. Furthermore, the dimensions specified for the samples are unobtainable since they exceed the dimensions of the components to be tested. The only three devices covered by the entire ANSI Z87.1 standard from which these dimensions are easily obtainable (face shields, welding helmets, and hand shields) are, strangely, not required to be tested

for water absorption. In addition, this method specifies no less than seven procedures for immersing the samples in water, without any guidance whatever as to which one should be used.

There is another problem associated with this water absorption requirement. There is no obvious relationship between this test and the performance of the device. This question has been discussed with several members of the present ANSI Z87 Committee and the origin of this requirement is a mystery. The original purpose of this requirement may have been quite appropriate, but since there was no supporting documentation produced with this ANSI standard, that purpose is unknown.

Another example from the ANSI Z87.1 standard relates to the requirement for corrosion resistance. The Z87.1 standard requires certain devices to be tested for corrosion resistance in accordance with the test procedure of ANSI Standard Z118.1 (ASTM B117), "Standard Method of Salt Spray (Fog) Testing." The referenced standard, ASTM B117, does not specify any of several basic criteria needed to do the test properly. In fact, the scope of the standard plainly states "the method does not prescribe the type of test specimen or exposure periods to be used...nor the interpretation to be given to the results". This lack of specificity results from the failure of the ANSI Z87.1 standard to provide these specifications along with the reference to the ASTM corrosion test method.

American National Standards Institute (ANSI) Standard Z87.1-1968

requires face shields to pass an impact test. This test is a good illustration of an inadequate performance test due to a weak technical basis. The list of typical intended uses for face shields in the standard clearly indicates that this device is intended to provide protection in the more hazardous situations. Yet to comply with the standard, a face shield need only withstand a one and one-half (1-1/2) ounce steel ball dropped from 50 inches. This test could obviously not be justified by the level of protection the face shields are expected to provide.

Does the Consensus Standard Process Encourage Product Innovation?

The ANSI Z87 standard contains requirements for a large number of personal protective devices including: faceshields, safety spectacles, welders' helmets, welders' filter plates, and safety goggles. Therefore, all eye and face safety items purchased for use in the industrial environment must comply with that standard. One of the problems associated with this and similar standards is restrictive design requirements. As an example, I would like to now consider some of these design requirements associated with safety spectacles. And, as an even more specific example, I would like to discuss a pair of safety spectacles that does not comply with several of these design requirements and therefore cannot be marketed in the United States for industrial use.

The ANSI Z87.1 standard for (nonprescription) spectacles requires, for

example:

1. The lens curvature must be of a specified value (6.0 diopter).
2. The lens is to have a minimum thickness of 3.0 mm.
3. The left and right lens must be interchangeable.

Here is a pair of spectacles that does not comply with these design requirements--among others. They are Fitrite Safety Spectacles manufactured by Safemaster, Incorporated, of McKeesport, Pennsylvania. These spectacles incorporate several innovative design features:

1. Increased lens curvature that creates a "wrap-around" effect which tends to decrease the hazards associated with exposures to the eye from the side while the design simultaneously increases the unobstructed field of view for the wearer. However, because the lens curvature is greater than the 6.0 diopter specified by the ANSI standard, this and similar designs cannot be purchased for use in the industrial environment.

2. High strength polycarbonate lenses that are far more impact resistant than required by the standard. Because of the strength of the material used, the lens can provide the required impact resistance with lenses that are much lighter and thinner than the more conventional tempered glass lens. The lenses are, nevertheless, not allowed by the present

Federal regulation because the lens thickness is less than the 3 mm required by the ANSI standard.

3. Contoured lens edges which fit closely the contour of the face and thereby minimize direct exposure of the eye. This is also not allowed since the left and right lenses are not interchangeable.

Since the ANSI standards are not developed with a supporting document that provides the technical rationale and justification for the specific requirements of the standard, the basis for the requirements just discussed are unknown. This is a very awkward situation for Federal agencies who must either enforce the standard or make recommendations based on it. Both OSHA and NIOSH must tell Safemaster that their product cannot be approved but when asked for the technical basis for this denial, we cannot give a satisfactory answer.

A further example of inhibiting innovation is the ANSI Safety-Toe Footwear Committee which has perpetuated the antiquated test methods developed in 1944, complete with all the vagaries associated with the original wartime standards. The standard is so vague that agreement of test results could well be the exception rather than the rule. In fact, of the three newest standards issued by this Committee in 1976, none of the manufacturers present at the committee meeting in November 1976 had been able to manufacture footwear in compliance with all aspects of each of the new standards. The manufacturers' response has been to ignore the new standards and, in some cases, continue to use

standards withdrawn in 1965 until the standards could be revised to their satisfaction. The question of whether or not the new test methods simulate the real world was not considered; only whether footwear currently being produced could "pass a test."

What Do We Conclude About the Consensus Standards Process For Personal Safety Equipment?

1. Writing a standard and the rationale for that standard is a very small part of the total effort. The real effort is the research that forms the technical basis of the written standard. If the research effort has not been made, it will still be possible to write a standard, but it will not be possible to support that standard. The usual Federal approach to standard setting is time consuming, requires technical support, and involves extensive public review and comment before such standards can be promulgated as regulations. This is as it should be as our responsibilities are universal -- to the workers, the employer, the manufacturer, and the public in general. Consensus standards do not reflect this "public" responsibility, rather many of the ANSI standards we have discussed here today appear to be written by persons who primarily represent the business interests of their own company or industry.

2. All the time, resources, and effort that are spent in developing a standard are useless if there is no compliance with that standard.

Simply adopting a consensus standard, however good it might be, cannot assure that products are, or will continue to be, in compliance with that standard. This means that additional steps to develop an effective compliance program are necessary.

3. Test procedures incorporated into standards should be validated to minimize the variability between different manufacturers, production lots, testing laboratories, etc.

4. Adequate quality control procedures for production line products must be established to assure continued conformance with the applicable standards. Such procedures must establish the number and source of representative samples required for quality control testing and determine acceptable failure rates commensurate with the hazard due to failure.

5. Manufacturers whose products fail to meet applicable standards must bear the direct burden for that failure to comply. With the exception of NIOSH certified equipment, it is generally the employer not the manufacturer who bears the burden if equipment fails to meet the applicable consensus standard.

What are We Doing About the Personal Protective Equipment Issues?

NIOSH is currently active in three significant areas with regard to personal protective equipment and consensus standards.

- The personal protective equipment evaluation program is continuing. We will complete testing and will issue reports on police riot helmets, lineman's gloves, and plastic lens spectacles this fiscal year. We are devoting some of our limited resources in the new safety initiative to personal protective equipment research programs which will provide the technical basis for future standards.

- NIOSH has recently instituted a new policy with regard to participation in consensus standard setting bodies. One aspect of the Institute's policy is that no NIOSH employee may serve as a member of a non-Government committee if that committee cannot satisfactorily assure that its meetings, minutes, and membership records are open to the public.

- NIOSH has been working with OSHA since November 1976 toward the development of a national personal protective equipment sampling and testing program for selected devices. The objective of this program, an extension of the NIOSH testing program, is to determine which equipment may not comply with applicable OSHA-ANSI standards. In the event such failures are observed, OSHA will take appropriate regulatory action.

Mr. Chairman, I will be pleased to answer any questions you or members of your Subcommittee may have.

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15. Supplementary Notes

16. Abstract (Limit: 200 words) This testimony concerned the NIOSH experience in testing and certifying products against standards established by consensus standards producing organizations. One NIOSH responsibility under the Occupational Safety and Health Act of 1970 was to transmit recommended standards to OSHA to assist OSHA in revising consensus safety standards. The Testing and Certification Branch was engaged in testing equipment against American National Standards Institute (ANSI) standards. The roles of OSHA, employers, employees and manufacturers of protective equipment with regard to personal protective equipment were reviewed. The consensus standards process and the NIOSH personal protective equipment standards process were described. Some results of the personal protective equipment tests for compliance with OSHA/ANSI standards were summarized. Some of the equipment tested did not comply with the applicable standards. It was not known how many workers were injured because of the use of defective equipment. The adequacy of the standard and the mechanisms for standards development were discussed. Problems with ANSI standards included: a lack of clarity; the necessity for interpretation; absence of technical justification; lack of validation for test procedures; and the lack of statistically significant sampling procedures. The tendency of the consensus standard process to discourage product innovation was discussed. NIOSH activities in the area of consensus standards for personal protective equipment were described.

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