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REMARKS PRESENTED AT PUBLIC MEETING
HELD BY NIOSH ON RESPIRATOR TESTING
AND CERTIFICATION PROGRAM
(AT NBS, JULY 28, 29, 30, 1980)

My name is Jerrold L. Caplin. I am a health physicist, employed by the Federal government, in the Occupational Health Standards Branch of the Nuclear Regulatory Commission's (NRC) Office of Standards Development. The NRC staff welcomes this opportunity to offer its comments on the NIOSH-MSHA respirator testing and certification program.

The NRC has a regulatory responsibility for the protection of workers against airborne radioactive materials that are used in NRC-licensed activities. This responsibility is carried out, in part, through our regulations which require the NRC's licensees to provide occupational respiratory protection that may include the appropriate use of respirators where engineering controls are not practicable. The NRC, therefore, has an important need to be able to assure that the respirators utilized by its licensees are capable of protecting the people who wear them against the various respiratory hazards that might be encountered in nuclear facilities.

The NIOSH-MSHA respirator testing and certification program is one of the NRC's chief means of assuring the reliability of the respirators that its licensees use. Our regulations generally require our licensees to use only NIOSH-MSHA tested and certified respirators in NRC-approved programs. Thus, the continuation of the respirator testing and certification program is important to the NRC's interests in carrying out its regulatory responsibilities. This program provides an authoritative, relatively unbiased, governmental source to which we can refer for assuring the availability of acceptable respiratory protective equipment. If such a program were not in

place, appropriate action would have to be taken to establish an equivalent program.

The NIOSH-MSHA testing and certification program has generally been very useful and has certainly resulted in the availability of reliable equipment for use in many situations. However, the program can, and should, certainly be made more useful from the NRC's point of view. It does not provide everything that the NRC needs from such a program for regulating the use of respirators, and the NRC has developed some of the additional information that it requires through the support of research and technical assistance contracts. Some of the areas that should be strengthened in the NIOSH test and certification program are: the provision of quantitative performance requirements; broader coverage of the testing schedules, for example, for equipment such as supplied-air suits, or for air-purifying respirators for use against radio-iodines; more complete and specific test procedures for various filters, sorbents and combinations thereof; better specifications for differential pressure between inhalation and exhalation resistance and for minimum and maximum air-flow limits for atmosphere-supplying equipment; and better means for identifying certified devices as they go through various model changes.

However, we believe that it would be wrong for each governmental agency that has responsibilities for some aspects of respiratory protection to have to set up a completely independent program for testing and certifying respirators. Such a course would obviously be inefficient and might very well degrade rather than improve the overall quality of occupational respiratory protection that is provided.

Of the alternatives presented in the notice for this meeting, we favor alternative 2 which would focus the responsibility both for the performance criteria and the testing procedures for certification in a single agency, NIOSH, and by which action would be taken to revise and strengthen the current requirements. Alternative 1, which would include both NIOSH and MSHA as the certifying agencies would also be acceptable. However, alternative 3, in which NIOSH would certify private laboratories to perform testing and certification of respirators, would be much less acceptable for this sort of certification. This alternative might be useful where a less complex set of tests on less diversified equipment were involved; it does not seem suitable for respirator testing and certification where an elaborate scheme would have to be developed and maintained for monitoring the private laboratories and for keeping track of multiple sources of tests, approvals, and changes to approvals. Those jobs are difficult enough when you're dealing with just one organization. Another important consideration regarding alternative 3 is that the granting of certification would be under the control of several private laboratories rather than that of the Federal Government. This approach would abrogate and diffuse responsibility, provide less confidence to workers and to other agencies in the assurance of the quality of protection provided, and thus might be considered unsatisfactory by some individuals and organizations.

The fourth alternative, which would allow the industry to "self-certify" respirators is the least preferable, and, in our view, would entail costs that would outweigh any likely benefits. For example any initial savings in time or manpower would, very likely, be more than offset by the need for increased regulatory activity by the various responsible agencies.

As to the performance specifications, perhaps too much has been made of the supposed distinction between "performance criteria" and "test procedures." In practical application these terms are closely linked; there is little meaning to a criterion for performance unless there is some reasonable way to test whether or not that criterion has been met. We believe that 30 CFR Part 11 should be updated with respect both to the performance requirements and to the testing requirements that have to be met before certification is granted. As we mentioned previously, the updating should include quantitative performance requirements that would provide estimates of how much protection a respirator provides and should also include more realistic testing procedures.

As to quality control, we believe that the changes suggested in the notice on the method for assuring quality control should be reconsidered. The suggested changes would result in checks on quality control only by after-the-fact methods such as field surveys. Although such surveys are useful adjuncts to a quality control program, it seems to us that there should be a more positive method of assuring the quality of these important safety devices before they are marketed. This is a more difficult course to pursue, and it would require a considerable commitment in staffing and other resources; but we believe that it is preferable to the alternative of allowing the distribution of unreliable safety equipment.

In these brief remarks we will not attempt to deal with all of the important topics addressed in the meeting notice. Most of these are the detailed procedural matters of an on-going program. The main points that we wish to emphasize today are that we believe that the current program

is very useful to us, that there should continue to be such a governmental program, and that it should be strengthened to assure the availability of reliable respiratory protective equipment.

One other topic that we feel is important, but that was not addressed in the notice, is the need for closer coordination of the interests of the various governmental agencies that have responsibilities in occupational respiratory protection. The need for such coordination has been recognized before, but no formal mechanism has yet been established to meet this need. NIOSH's planned revision of the testing and certification program presents an opportunity to initiate action to provide such a mechanism. One way to establish a coordinating group might be by agreement between agencies at appropriate management levels. This approach has proven to be effective in the test and certification program for personnel radiation dosimetry processors, for which a group of this type was formed and chaired by the National Bureau of Standards.

Whatever the form of the group, we believe that it would have a beneficial effect in enabling the testing and certifying agency and the "user" agencies to better understand each others' needs and to take coordinated action for improving the quality of occupational respiratory protection. We would like to work with NIOSH and the other agencies toward that goal. And, for now, we thank NIOSH for this opportunity to present our views.