BENDIX EPID PRESENTATION
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NIOSH PUBLIC MEETING
U.S. Bureau of Standards
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Our feelings on a revised NIOSH Certification Program are similar to those presented by Frank Wilcher of ISEA. We believe that a significant change in the approval process is necessary, both to expedite the process and to permit NIOSH to spend more of its resources in administering and improving the quality of safety product standards. Like ISEA, we would like to suggest a variation of the fourth alternative listed in the June 18, 1980 notice in the Federal Register; however, our suggested variation would be somewhat different from that presented by ISEA.

We question whether testing by an independent third party would resolve any of the present problems, or would actually add to them. As mentioned several times in presentations yesterday afternoon, the burden of engineering design, quality assurance, and product liability lie with the manufacturer, not with NIOSH. The role of NIOSH should be to establish certain performance standards in safety equipment. The role of the manufacturers should be to meet these requirements (as a minimum), and to certify that his product meets them -- with the definition of "certification" being a "guarantee, or pledge of conformance", as generally associated with the word. It would seem that reference to a NIOSH certification makes no sense since NIOSH cannot guarantee the quality of a product. It can only certify that it tested samples supplied by the manufacturer, and they met the minimum standards.

We should also point out that 30 CFR 11 requires the manufacturer to perform complete testing of equipment prior to submittal, meaning that manufacturers must either procure test equipment or locate an independent testing laboratory to perform the necessary tests before NIOSH submittal. Does it not follow that if a manufacturer has a complete, descriptive specification and has the facilities to perform the required tests that he should be able to certify whether his equipment meets the approval requirements.

We believe that manufacturers are capable of performing their own tests and determining whether their products meet published standards, provided that the standards are sufficiently descriptive and complete. We do not feel, however, that NIOSH must be, nor necessarily should be, divorced from the initial introduction of a new product to the market. The design of a new device could be reviewed briefly and a representative of NIOSH could be present during the final "qualification testing" as a witness.

We envision an approval process which would take several days and might be handled as follows:

1. The manufacturer, upon completion of his own testing, notifies NIOSH of his design, test results, and planned qualification test program. (The test program would be set up to cover all required testing in a minimal time).

2. A NIOSH representative (or group of representatives) would travel to either the manufacturer's facility or to an independent testing facility (at the manufacturer's option) to witness the testing.

3. The manufacturer would supply or make available all test equipment, test units, refills, recharges, and test subjects. NIOSH could specify that all testing be completed in a specified period of time based on the type and duration of the apparatus (e.g., within a three day period for an SCBA having a duration of 60 minutes or less).

4. Under this plan, the testing facility at Morgantown would remain as the test facility for field audits and development studies. Hopefully, TCL would eventually become the master reference laboratory by incorporating the best of the testing technology used at the various manufacturer's test facilities.

Advantages

This plan should have several advantages over the existing program:

1. It would permit streamlining of the approval procedure without requiring additional NIOSH resources or federal allocations.

2. It would permit NIOSH to concentrate the use of its personnel and facilities toward advancing the state of the art, rather than confirming the manufacturer's test results.

3. It would eliminate pressure from NIOSH test personnel, and place the burden of compliance demonstration on the manufacturer.

In review, we believe that a self-certification program by the manufacturers, coupled with witnessing of the tests by NIOSH representatives, offers a desirable alternative to the current approval method.

Comments on Other Points

We would like to futher add that we agree with the ISEA position on the 14 issues requesting comment in the June 18, 1980 Federal Register with the following additions:

1. We believe that a failure mode analysis describing results of component failure would be a helpful tool to both manufacturers and NIOSH and should be submitted to NIOSH on a voluntary basis.

2. Witnessing of approval tests would not be an issue if testing were performed by the manufacturers.

3. The duration of approval should be indefinite so long as no change is made to the approved apparatus affecting form, fit, or function. The problem of having different devices which carry the same approval number should be rectified by requiring a new approval number for any change affecting form, fit, or function.

4. We would like to emphasize the ISEA statement concerning testing of prototypes. NIOSH should not act as an independent testing laboratory for the development of new products. But NIOSH should not expect manufacturers to invest in tools and make production runs for the purpose of running qualification tests.

Additional Comments

We would like to add in our statement that we too feel a need exists to provide regular updating of the 30 CFR 11 requirements. New concepts cannot be approved

because the specifications do not exist. Older, out-of-date requirements remain in the schedule. An example of this is in the case of positive pressure requirements for self-contained breathing apparatus. For years, the only available positive pressure devices were open-circuit. The approval requirements are quite liberal in that exhalation resistance is measured at a very low flow and the allowable resistance is rather high. When closed-circuit, positive-pressure devices came into existence, they were required to meet existing requirements for closed-circuit, non-positive-pressure devices on exhalation (which are considerably more stringent than for open-circuit, positive-pressure apparatus) without going negative on inhalation. Although new requirements for closed-circuit, positive-pressure devices have been developed, these resistance requirements are completely different from open-circuit devices. It would seem that resistance requirements for positive-pressure devices should be the same, regardless of system design and that references to particular types of system design should be eliminated in favor of acceptable parameters regardless of system design.

We appreciate this opportunity to express our views on these points.