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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control
National Institute for Occupational
Safety and Health – ALOSH
944 Chestnut Ridge Road
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July 19, 1994

Mr. David W. Crosby
Vice President and General Manager
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11403 Cronridge Drive
Owings Mills, Maryland 21117-2247

Dear Mr. Crosby:

I am writing in response to your letter of May 31, 1994, and as a follow-up to our telephone conversation on this subject. As you are aware, the National Institute for Occupational Safety and Health (NIOSH) is currently in the comment period for the proposed rule for certification requirements for respirators. Your letter will be placed in the rulemaking docket for consideration with the other comments received.

In reviewing your concerns and questions, it is obvious that a great deal of confusion, misinterpretation, and misinformation surrounds our current rulemaking efforts. I am providing some appropriate background material in an attempt to clarify the situation.

On August 27, 1987, NIOSH published a Notice of Proposed Rulemaking (NPRM) in the Federal Register (52 FR 32402) to revise the tests and requirements for the certification of respirators. These revisions were proposed to be codified under Part 84 of Title 42, Code of Federal Regulations (42 CFR 84). A particulate filter penetration test was included in that proposal under section 84.273 (52 FR 32435). On May 24, 1994, NIOSH published a NPRM in the Federal Register (59 FR 26850) as the first in a series of regulations to upgrade existing procedures for testing and certifying respirators. The current proposal includes a particulate filter penetration test under section 84.184 (59 FR 26885). The particle size and distributions contained in the present proposal remain essentially unchanged from those proposed in the 1987 NPRM. Both proposals contained tests using dioctyl-phthalate (DOP) and sodium chloride (NaCl) aerosols. Neither NIOSH document requires the use of a cold or hot generated aerosol to meet the proposed test requirements.

The new testing methodology is intended to demonstrate the filter's efficiency level against particulates in the most penetrating particle size range throughout the test period. The Institute believes that the semi-polydispersed aerosols described in the subject documents provide an adequate assessment of the filter's efficiency in the most penetrating particle size range. This will benefit users by providing filters that have better demonstrated efficient filtering characteristics against the challenge aerosol. The benefit to manufacturers would be the removal of the current particulate tests of 30 CFR 11 that they have perceived as an impediment to the introduction of improved filters. The Institute believes that an understanding of the philosophy behind the criteria contained in the proposal will provide insight that the proposed criteria does, in fact, represent a more stringent test than currently performed under 30 CFR 11. In testing at the most penetrating particle size range with continuous efficiency monitoring throughout the test, not just initially or averaged, this criteria represents a more stringent test for ALL particulate filter respirators to be certified.

The Institute testing experience indicates that, when properly conducted, the results obtained with the DOP aerosol as specified in the proposed Part 84 are essentially identical to results obtained on the same product using the thermally generated DOP aerosol of 30 CFR for high-efficiency filters. However, you should be aware that our testing experience indicates that heating of the DOP causes chemical changes, diminishing the purity of the DOP. Similar chemical changes occur as the DOP ages. The rate at which some filter media degrades appears to be a function of the DOP purity.

The Institute disagrees with your contention that the proposed criteria requires the purchase of any particular manufacturer's equipment. The Institute has equipment from both TSI and ATI that we believe are capable of performing the subject tests. All of these instruments have been purchased through appropriate procurement procedures. The regulations are designed to define the critical parameters for testing performance. Since, as described above, testing experience by NIOSH on both manufacturers' equipment has been positive, there is no rationale for precluding the use of any instrument that meets the regulation's specifications. No manufacturer's name or equipment model numbers were ever included in any of the drafts in the rulemaking effort.

Additionally, a draft Standard Test Procedure (STP) reflects the current planned protocol by NIOSH for conducting a particulate filter instantaneous-penetration test for negative-pressure respirators against liquid particulates. This STP, dated December 15, 1993, is entitled "Particulate Filter Instantaneous-

Penetration Procedure to Test Negative-Pressure Respirators Against Liquid Particulates." The draft STP was distributed to respirator manufacturers and others who requested information as to the testing protocol that the Institute considered as appropriate if a penetration test similar to that proposed in the 1987 NPRM were instituted. The TSI, Inc. company name and model numbers were included in the draft STP. It should be noted that in 1993, NIOSH considered instituting such a test as a voluntary program, in addition to the certification standard. The Institute did not assemble a "task group" in the rulemaking effort or in development of the protocol.

As always, related reports, memos, and correspondences are available, if requested. Copies of publications related to DOP and NaCl testing procedures, along with copies of the current 42 CFR 84 NPRM, the 1987 42 CFR 84 NPRM, and our draft test protocol were previously sent to Mr. Benner on your staff. At no time has NIOSH endorsed or indicated a preference or bias toward any manufacturer.

I trust that this information will clarify the current situation in regard to the proposed instantaneous filter penetration tests of the NPRM.

Sincerely yours,

Richard W. Metzler, Chief
Certification and Quality
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