DEPARTMENT OF HEALTH AND HUMAN SERVICES

84-161

JAN 25 1988

The Honorable John C. Danforth United States Senate Washington, D.C. 20510

Dear Senator Danforth:

Thank you for your letter of December 17 regarding the proposed regulations governing the certification of respirators. Please excuse the delay in responding.

The current regulations under which the Mine Health and Safety Administration and the National Institute for Occupational Safety and Health test and certify respirators (30 CFR Part 11) were originally promulgated in 1972. During the last several years, there has been a growing consensus among the respirator manufacturers and user community that these requirements need revision to reflect the technical advances in the field and the increased knowledge regarding environmental factors in the workplace. Some of the steps taken to develop the proposed rule are outlined in the enclosed preamble (52 FR 32402).

We are, of course, anxious to receive comments on both the technical and policy elements of this proposed rule. Toward that end, in October we extended our original comment period and announced two public hearings (52 FR 37639). The first took place in San Francisco on January 20, 1988, and the second is scheduled for January 27-28, 1988, in Washington, D.C. We look forward to hearing from all parties concerned, and I assure you that all comments received will be placed into the record and will be carefully considered in any final rulemaking decision.

> Sincerely, Otis R. Bowen, M.D.

> > Otis R. Bown, M.D. Secretary

Enclosure

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cc:
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United States Senate

COMMITTEE ON COMMERCE, SCIENCE, AND TRANSPORTATION

WASHINGTON, DC 20510-6125

December 17, 1987

The Honorable Otis R. Bowen, M.D. Secretary
Department of Health and Human Services
Hubert Humphrey Building
200 Independence Avenue, SW
Washington, D. C. 20201

Dear Secretary Bowen:

It has come to my attention that the National Institute for Occupational Safety and Health (NIOSH) has proposed to modify the process by which respirators are certified (CFR 84, August 27 Federal Register).

I am concerned that, should this proposed rule change be approved, the quality of respiratory equipment could decline and the respirator industry may face unnecessarily increased costs.

The proposal suggests that the change comes under the category of "minor rulemaking." According to Executive Order 12291, the economic impact of a minor rulemaking must be limited to \$100,000. Yet the respirator industry has estimated the cost of this rule change to be \$700,000.

Further, neither complete guidelines nor a validated protocol for respirator certification is provided in the proposal. Industry officials and workers whose safety is at risk are put in a difficult position when asked to comment on information which has not been provided to them.

Finally, it is my understanding that it is not technically feasible to execute workplace testing as outlined in the proposal. The technology does not yet exist for workplace testing and is projected to take considerable time and funding to be developed.

The Honorable Otis R. Bowen, M.D. December 17, 1987
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Given these concerns and the impact this proposal may have on worker safety and the respirator industry, I believe it would be prudent for you to have NIOSH and the Office of Management and Budget recall this proposal.

Thank you for your attention to this matter.

Sincerely

John C. Danforth