Docket

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

84-160

JAN 25 1988

The Honorable John H. Chafee United States Senator Washington, D.C. 20515

Dear Senator Chafee:

Thank you for your letter of December 18 regarding the proposed regulations governing the certification of respirators. Please excuse the delay in responding.

The current regulations under which the Mine Realth 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. Bowen, M.D. Secretary

Enclosure

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H Official File
CDC Official File (Return to CDC, Atlanta)
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Prepared by Larry Sparks, CDC, FTS 236-3061, 12/29/87
Contact Karen Lindauer, CDC, FTS 236-3322

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JOHN H. CHAFEE

CHAIRMAN, REPUBLICAN

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## United States Senate

VASHINGTON OFFICE:

Washington, DC 20510 (202) 224-2921

PROVIDENCE OFFICE:

301 JOHN O. PASTORE FEDERAL BUILDING KENNEDY PLAZA PROVIDENCE, RI 02903 (401) 528-5294

> TOLL FREE NUMBER IN RHODE ISLAND 1-800-662-5188

December 18, 1987

The Honorable Otis R. Bowen, M.D. Secretary
The Department of Health and Human Services Room 615F
Hubert H. Humphrey Building
Washington, DC 20201

Dear Otis:

It has recently come to my attention that the National Institute for Occupational Safety and Health (NIOSH) has proposed new regulations to modify the process by which respirators are certified.

Having reviewed 42 CFR 84, as released in the August 27th Federal Register, I am concerned about three major factors of the proposal.

First, I am troubled that NIOSH is treating this proposed change in regulations as a "minor rulemaking" -- defined by Executive Order 12291 as limited to an impact of \$100,000,000. The manufacturers of the respirators believe that this change will cost them up to \$700,000,000 and that many manufacturers will end up out of business due to the provision.

Second, the proposed regulations call for self-testing and workplace testing and for re-certification -- but do not include, in any section, the protocols to use to implement such testing. This uncertainty, at the very least, constitutes a denial of due process in the "notice and comment" stage of administrative rulemaking; and at the very most could result in an even costlier impact than the industry is now predicting.

Finally, both the industry and the unions, including the AFL-CIO feel that self-certification and testing could result in lowered and unpredictable safety levels. I find this possibility deeply troubling.

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The Honorable Otis R. Bowen, M.D. December 18, 1987
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On the basis of these concerns, and the impact I know this proposal will have on worker safety and the respirator industry, I urge you to have this proposal withdrawn. Surely there must be an alternative to such a troubling situation.

I look forward to hearing from you on this matter.

Sincerely,

John H. Chafee

United States Senator

JHC/tlf