

DEPARTMENT OF HEALTH AND HUMAN SERVICES

84-162

Docket

JAN 25 1988

The Honorable Paul S. Sarbanes
United States Senate
Washington, D.C. 20510

Dear Senator Sarbanes:

Thank you for your letter of December 17 also signed by Senator Barbara A. Mikulski and Representative Beverly Byron 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.

A similar letter is being sent to Senator Barbara A. Mikulski and Representative Beverly Byron.

Sincerely,

Otis R. Bowen, M.D.

Otis R. Bowen, M.D.
Secretary

Enclosure

FILE
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CDC

Page 2 - The Honorable Paul S. Sarbanes

Similar letter to: Senator Barbara Mikulski and Rep. Beverly Byron

cc:

OD

NIOSH

FMO

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H Official File

CDC Official File (Return to CDC, Atlanta)

OS No. 8712280023 (Sarbanes)

OS No. 8712280024 (Mikulski)

OS NO. 8712280025 (Byron)

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Contact Karen Lindauer, CDC, FTS 236-3322

United States Senate

WASHINGTON, DC 20510

December 17, 1987

Honorable Otis R. Bowen
Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Bowen:

It has come to our attention that the National Institute for Occupational Health and Safety (NIOSH) has proposed regulations to modify the process by which respirators used in general industry and construction are certified.

Having reviewed the proposed changes, we have several major concerns about this proposal. Our chief concern is the impact of the proposed rule on worker safety. By requiring manufacturers to "self-certify" their products, NIOSH is abandoning its long-standing practice and responsibility for assuring the reliability of these devices, presenting a serious threat to quality assurance and the safety of respirator users.

Secondly, we are concerned that industry, and ultimately workers' safety, are denied due process when they have been asked to respond to a proposal which is so incomplete that it doesn't include a protocol nor the details necessary for a responsible comment.

Thirdly, we are concerned that the proposal was considered a "minor rulemaking" under Executive Order 12291 having an impact of \$100 million or less. Industry and worker representatives have informed our offices that they estimate the initiative will cost the industry up to \$700 million. It seems that the case for the proposal may have been misstated.

Finally, it is our understanding that the proposal is actually substantively infeasible in that it calls for workplace testing for which the technology has not yet been developed.

On the basis of these concerns, and the impact this proposal could have on the industry and worker safety, we request that you consider having NIOSH and the Office of Management and Budget recall this proposal.

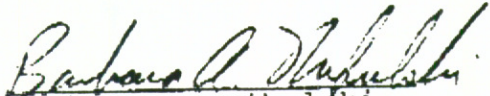
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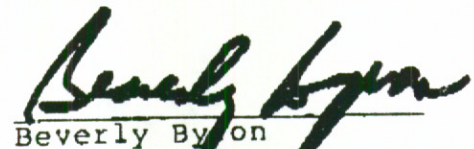
We look forward to hearing from you as soon as possible on this matter.

With best regards,

Sincerely,


Barbara A. Mikulski
United States Senator


Paul S. Sarbanes
United States Senator


Beverly Byron
Member of Congress