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January 28, 1988

Department of Health and Human Services
National Institute for Occupational Safety and Health

Gentlemen:

Ocenco, Incorporated is the largest provider of self-contained self-rescuers to the underground mines of America. Our collective years of experience in underground mining, coupled with our understanding of respirator manufacture and design, provide us with a unique and practical perspective on the proposed rulemaking for 42 CFR Part 84. With concern for the safety of underground miners, and understanding of the needs of the coal industry we submit our comments on the subject rulemaking.

Ocenco, Incorporated fully supports the formal transfer of responsibility for respirator testing from the Department of Labor, MSHA, to the Department of Health and Human Services, NIOSH. For years NIOSH has performed the service of respirator testing without clear mandate. Transferring these responsibilities from 30 CFR, Mineral Resources to 42 CFR, Public Health, is appropriate. Our objections are to the content of the proposed 42 CFR Part 84.

The proposed changes to the test and certification requirements will have a severe detrimental economic impact on our already depressed coal industry, and offer no increase in safety to underground miners.

Given the number and severity of objections which have been voiced against these proposed changes, it is obvious that finalization of 42 CFR Part 84, as written, is premature and ill-advised. We, therefore, propose the following actions be undertaken:

- The content of 30 CFR Part 11, exactly as written, be transferred to the Department of Health and Human Services under 42 CFR. This will officially mandate NIOSH testing without disrupting industry, and possibly endangering human life.

- NIOSH and MSHA should complete the "Memorandum of Understanding" which will define the consultive role of MSHA in the process of certifying respirators targeted for use in mines and mining. The unique conditions of underground mining dictate that MSHA continue its role in approving devices for this severe environment.

- Changes to the existing requirements for certification of respirators should be made with cognizance of the environment in which those respirators will be used. For example, NFPA standards should be considered when drafting requirements for respirators used in firefighting.

Our specific objections to the contents of the proposed changes are addressed in the attached written commentary. We ask that these concerns be addressed prior to any rewrite of the existing certification standards.

Very truly yours,
OCENCO, INCORPORATED

J. P. Droppleman
President

attachments

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OCENCO, INCORPORATED
COMMENTS ON PROPOSED RULEMAKING
42 CFR PART 84

January 27, 1988

SUBPART A-

84.1

- The stated purpose is not copacetic with the intent of this proposal. As stated the proposed requirements and procedures will apply only to respirators used in mines and mining. The "Supplementary Information:" given on pages 32402, 32403 and 32404 of the Federal Register / Vol. 52, No. 166 states that MSHA will only be involved in the approval of respirators for use in mines and mining. NIOSH certification of respirators affects the selection and use of respirators in all American workplaces. The scope of this certification process should be defined.

84.2 (b)

- This paragraph provides for the expiration of current certifications five (5) years from the effective date of the proposed rule. As pertains to self-contained self-rescuers deployed in underground coal mines, the differences in performance requirements between the existing 30 CFR Part 11 and the proposed 42 CFR Part 84 will necessitate the replacement or reconstruction of the 100,000 self-rescuers presently deployed in American mines. At an average cost of $550.00 per self-rescuer, this translates to a $55 million economic burden to the coal industry for the replacement of self-rescuers alone. Other respiratory devices used by the coal industry will also be similarly affected, thus serving to further increase the economic burden placed on the American coal industry.

- The provision to withdraw existing certifications pursuant to provisions of Subpart H effectively allows NIOSH to withdraw certification of any device which does not meet the proposed performance standards. (see also comments on Subpart H)

SUBPART B-

84.11 (d)

- The requirement for submitted respirators to be made on "production tooling" is unreasonable. Production tooling is very costly, and few, if any, manufacturers could afford to invest in production tooling for a device which has not yet received NIOSH/MSHA approval.

84.11 (e)

- The requirement for a sample of packaging materials is unnecessary. Packaging for interstate transport is already regulated by the Department of Transportation (DOT), and additional regulation by NIOSH will be a costly duplication of effort.

84.11 (j)

- The cost of complying with 45 CFR Part 46, Subpart A may prove prohibitive to small businesses. The cost impact cannot be estimated without the publication of protocols and requirements for workplace testing.

- Under 30 CFR Part 11 human subject tests are conducted at NIOSH, and the cost of compliance is not carried by manufacturers. Under the proposed rules NIOSH laboratories will continue to provide human subject testing, thus the cost of compliance will not be transferred to manufacturers, but rather duplicated by manufacturers.

- "Workplace testing", as described in 84.32 and 84.33, appears to depend on the intentional exposure of human subjects to hazardous materials. This exposure is contrary to the criteria for approval of research as noted in 45 CFR Part 46, 46.111 (a) (1) "Risks to subjects are minimized:", and (2) "Risks to subjects are reasonable in relation to anticipated benefits,...".

SUBPART C-

84.20 (f)

- The intent of this requirement is not clear. Will NIOSH be auditing respirators which have been deployed in workplaces, or are newly manufactured repirators to be provided?

- The cost impact of annually providing an unspecified number of free respirators cannot be estimated.

84.21

- The scope of this notification program is not well defined. Does the phrase "any respirator produced or assembled ... [which] fails to comply..." apply only to newly manufactured respirators, or is it to include respirators deployed by end users? If this requirement is intended to cover deployed respirators the requirement is unreasonable. Due to aging of materials and components deployed respirators cannot be expected to meet all the requirements of newly manufactured devices.

84.25 (a)

- The paragraph as written does not specify whether compliance is expected of deployed respirators as well as newly manufactured apparatus. Again, deployed respirators cannot be expected to perform "as new".

SUBPART D-

84.30 (f) (1)

- Final NIOSH certfication is to be based on results of workplace or simulated workplace tests. Protocols for such tests, and pass/fail requirements for respirators deployed in these tests are not published. It is not possible to evaluate the economic impact of workplace testing without published protocols and performance requirements.

- As stated in the "Supplementary Information:" preface to the proposed rules, (page 32402, Federal Register / Vol. 52, No. 166) the proposed workplace and simulated workplace testing is "The most significant of the new requirements in the proposed 42 CFR Part 84 ...". To proceed with this rulemaking prior to the publication of, and subsequent commentary on, workplace testing protocols and performance requirements is to neglect the manufacturers and end users who will be seriously affected by this requirement.

84.32

- The workplace protection factors (WPF) given in this subpart are the only published pass/fail criteria for the required workplace testing. Infiltration of ambient atmosphere is only one of many factors affecting the successful use of a respirator.

84.33

- The philosophy of certifying respirators to a higher performance level is a significant departure from the pass/fail standards of 30 CFR Part 11. What advantage is presented to the end user by this higher level of certification? A certification to a higher performance level based solely on protection factors could serve as a disservice to the end user. An apparatus with a lower protection factor could provide superior overall service to the end user than one certified as "high performance". Such levels of NIOSH approval could easily be misinterpreted by end users as NIOSH endorsement of one respirator over others in the same classification.

SUBPART E-

84.40 (a) (9)

- The requirement for marking the assembled and discharged weight on all self-contained breathing apparatus is undesirable. The discharged weight of a closed-circuit breathing apparatus will vary dependent on the time and conditions of use. Marking of these weights could be misinterpreted by end users as sanction to continue use of a spent unit until the stated discharge weight is acheived. Clearly this requirement could result in the endangerment of lives.

SUBPART H-

84.70 (h)

- Certification withdrawal based on a determination by NIOSH that previous tests did not provide assurance of "reasonable protection" is essentially a mandate for NIOSH to withdraw the certification of any respirator which was approved under 30 CFR Part 11, but which does not meet the performance requirements of 42 CFR Part 84. The term "reasonable protection" must be more clearly defined.

SUBPART O-

84.200

- The definition of "Facepiece" should not include mouthpieces and oral/nasal masks. The subsequent flammability tests for facepieces (84.248-17) are not appropriate for mouthpieces and oral/nasal masks. A user's face would be seriously burned if exposed to flames while he was using a mouthpiece type apparatus. Facepieces are designed to provide face protection and optimum respiratory fit; mouthpieces and oral/nasal masks are utilized to provide optimum respiratory fit independent of facial features.

SUBPART S-

84.248-4

- The requirement for marking assembled and discharged weight must not apply to closed circuit respirators. This requirement could result in endangerment of human life as described in our comments for 84.40 (a) (9).

84.246-6 (b) (2)

- The requirement for regulators to be in the fully open position at -4" water column and to deliver a minimum of 60 liters of gas at that pressure is severe and unnecessary. Breathing patterns of subjects using proven closed-circuit devices often show negative pressures in excess of 4" water column. To waste oxygen at a minimum rate of 60 lpm every time this negative pressure occurs is contrary to the purpose of closed-circuit devices: to conserve oxygen, thus extending service life of the device.

84.248-17

- Mouthpieces and oral/nasal masks should be noted as exempt from the reqirements of this section. Users of mouthpieces and oral/nasal masks would be seriously burned if exposed to flames as described in this test. Mouthpieces and oral/nasal masks are not intended to provide protection to the face, and therefore should not be subjected to these extreme tests. (see also our comments on 84.200)