



**AMERICAN
MINING
CONGRESS**

FOUNDED 1897

Suite 300
1920 N Street N.W.
Washington, D.C. 20036
202/861-2800
TWX 710/822-0126
Easylink: 62796020

Officers

Chairman:
Harry M. Conger

*Vice Chairman and Chairman,
Finance Committee:*
Milton H. Ward

Vice Chairmen:
Ralph E. Bailey
Robert H. Quenon
Frank A. McPherson
Allen Born
Richard de J. Osborne
Gordon R. Parker
G. Robert Durham
George D. Kennedy
M. Thomas Moore

President:
John A. Knebel

Vice President & Secretary:
Barbara Spillinger

Directors

Robert W. Hutton, Greenwich
Ralph E. Bailey, Stamford*
Thomas A. Holmes, Woodcliff Lake NJ
Robert H. Quenon, St. Louis
Frank A. McPherson, Oklahoma City
Calvin A. Campbell, Jr., Chicago
Harry M. Conger, San Francisco
Richard G. Miller, Chicago
Lord Clitheroe, London
Kenneth J. Barr, Englewood CO
A.W. Calder, Ligonier PA
Gino P. Giusti, Stamford
William G. Kegel, Indiana PA
Douglas J. Bourne, Houston
Milton H. Ward, New Orleans
Renold D. Thompson, Cleveland
G. Frank Joklik, Salt Lake City
Allen Born, Greenwich
B.R. Brown, Pittsburgh
R. Gene Dewey, Los Angeles
Gerard K. Drummond, Portland
Richard M. Holsten, Englewood CO
Robert A. Lothrop, Boise
George E. Nettels, Jr., Pittsburg KS
Richard de J. Osborne, New York
Gordon R. Parker, New York
Reuben Richards, New York
W.R. Stampler, Millersburg KY
G. Robert Durham, Phoenix
Richard W. Ince, Knoxville
George D. Kennedy, Northbrook IL
Terry A. Kirkley, Houston
M. Thomas Moore, Cleveland
Carl E. Nickels, Jr., Cleveland
John F. Schaefer, Orange CA
Robert T. Spitz, Charlotte NC
Arthur Brown, Coeur d'Alene
James T. Curry, San Francisco
H. L. Bilhartz, Denver
John D. Janak, Dallas
Sir Ian MacGregor, New York †
N.T. Camicia, Greenwich †
Charles F. Barber, New York †

* Immediate Past Chairman
† Honorary

(15)

84-081
RECEIVED

December 21 1987 DEC 30 PM 1:13

NIOSH

Mr. John Moran
Director
Division of Safety Research
National Institute for Occupational
Safety and Health
944 Chestnut Ridge Road
Morgantown, West Virginia 26505

Dear Mr. Moran:

The enclosed comments are submitted by the American Mining Congress (AMC) in response to the National Institute for Occupational Safety and Health Proposed Rule Revising Tests and Requirements for Certification of Respiratory Protective Devices Used in Mines and Mining, 42 CFR Part 84, published in the August 27, 1987, Federal Register.

The American Mining Congress represents the manufacturers and distributors of products that will be submitted for certification under the Proposed Rule, as well as the mining companies using those devices. The Institute's efforts in this area are, therefore, of vital concern to our members.

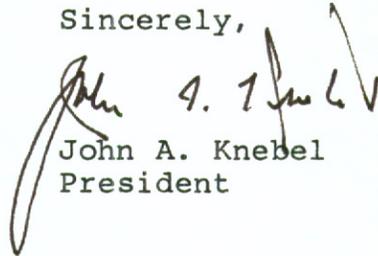
For many years, AMC has advocated the adoption of machinery and equipment approval criteria that ensure the introduction of safe products for use in mines, eliminate unnecessarily burdensome and time-consuming procedures, and incorporate performance-oriented requirements permitting the evaluation of new technologies. We recognize that sections of the Proposed Rule address these interests and commend the Institute for the effort.

We are, however, concerned that the Institute has failed to release for comment the protocols to be followed in performing the proposed workplace and simulated workplace tests. As stated in our comments, we believe that before proceeding to promulgate this Proposed Rule, the Institute should make such protocols available for comment by all interested parties.

RECEIVED
 84-081
 DEC 23 AM 10:10
 ODP, NIOSH

The American Mining Congress appreciates the opportunity to participate in this important rulemaking procedure. We trust that the enclosed comments will be helpful in your effort to revise the tests and requirements for the certification of respiratory devices used in mines.

Sincerely,

A handwritten signature in black ink, appearing to read "John A. Knebel", with a large, sweeping flourish extending downwards and to the left.

John A. Knebel
President

Enclosure



**AMERICAN
MINING
CONGRESS**

FOUNDED 1897

Suite 300
1920 N Street N.W.
Washington, D.C. 20036
202/861-2800

TWX 710/822-0126
Easylink: 62756020

John A. Knebel
President

INTRODUCTION

The American Mining Congress (AMC) welcomes the opportunity to comment on the Proposed Rule Revising Requirements and Tests for Certifying Respirators, 42 CFR Part 84, developed by the National Institute for Occupational Safety and Health (NIOSH).

AMC is an industry association comprising the producers of most of the nation's coal, metals, industrial and agricultural minerals; the manufacturers of mining and mineral processing machinery, equipment and supplies; and the engineering and consulting firms and financial institutions serving the mining industry.

Subsequent to publication in the August 27 Federal Register, the proposed rule revising technical requirements and test procedures for the approval of respirators was reviewed by representatives of AMC's manufacturer and producer member companies. The same company representatives concurrently considered the Mine Safety and Health Administration (MSHA) proposal revoking 30 CFR Part 11.

The following comments set forth the AMC position in response to NIOSH-proposed 42 CFR 84. Our comments primarily address the procedural aspects of the proposed rule. Detailed comments on specific tests will be submitted by the manufacturers and users of the diverse respiratory devices employed in our nation's mines. We, however, reserve the right to address these provisions and to expand upon the enclosed comments at any public hearings on this subject scheduled by NIOSH.

AMC has long advocated that government regulatory bodies adopt requirements reflective of existing technologies and existing mining conditions. We commend NIOSH for its commitment to promulgate approval requirements for new types of respirators and to revise existing requirements in order to address more completely existing mining conditions.

GENERAL COMMENTS

The American Mining Congress supports the efforts of the National Institute for Occupational Safety and Health to revise the tests and requirements for the certification of respiratory devices used in mines. We do, however, believe that 42 CFR

Part 84 should be modified to address broad industry concerns, including those identified below.

We concur with the MSHA proposal to revoke 30 CFR Part 11 upon promulgation of 42 CFR Part 84. We believe that adoption of 42 CFR 84 is consistent with the established program under which MSHA and NIOSH currently approve respirators. This program assigns responsibility for the approval of respirators to NIOSH, which is recognized as a leader in the area of respirator approvals. We also support MSHA's continuing to test the electric components of respirators for in-mine use as well as the consultive role retained by MSHA in the approval of all respirators. MSHA's role in regulating mines and products used therein mandates that there be close cooperation between the two government bodies.

AMC member companies have assisted NIOSH and MSHA in the evaluation of respiratory protection devices since such efforts began in 1972. We fully support the Institute in its efforts to ensure the continued use of safe and reliable respirators in mines. We commend the Institute for replacing design-oriented approval criteria with performance requirements that will permit the use of respirators incorporating current and future safe technologies.

Such action by NIOSH will assure flexibility in the certification process, while at the same time enhancing safety in our mines.

SUBPART A

84.1--Purpose.

As stated previously, AMC supports efforts to assign to NIOSH the lead responsibility for the establishment of procedures and requirements for the certification of respirators used in mines. We urge that the Institute periodically review this part so that the requirements and tests at no time hinder efforts to introduce new and safe technologies into our mines.

84.2--Certified Respirators.

(a) Consistent with our position in support of the MSHA-proposed rule 30 CFR Part 7, AMC advocates product-testing by the respirator manufacturer or third party with NIOSH review and approval of test results prior to issuance of a certification. Permitting an applicant or a third party retained by that applicant to test a respirator will allow NIOSH to focus its resources on implementation of the quality assurances provisions of this part that are designed to monitor compliance.

(b) AMC strongly disagrees with the Institute's proposal that certifications issued under existing requirements expire five years from the effective date of 42 CFR 84. AMC believes that

NIOSH's proposal would place an unwarranted burden on the industry when, in fact, there is no reason to believe that respirators in the field at that time are not safe for continued use.

Under the NIOSH proposal, thousands of MSHA/NIOSH approved respirators would require recertification within five years. The Institute's focus would necessarily be centered on the recertification efforts not the responsibilities assigned under other provisions of the part. Manufacturers would expend time and effort on recertification, not the development of new products, thereby inhibiting the introduction of advanced, safe technologies. In addition, product users could conceivably encounter work stoppages as a result of the unavailability of certified respirators.

AMC strongly urges that respirators approved under existing 30 CFR 11 be grandfathered and that no recertification program be instituted.

84.3--Definitions.

"Major modification." Use of words such as "other qualities affecting respirator use" and "elementary" render the proposed definition vague, unclear and, in fact, applicable to any change in a product.

AMC recommends that the proposed definition be revised to read:

"Major modification" is a change from the documentation on file at NIOSH that affects the technical requirements or critical characteristics established by this part.

"Simulated Workplace." AMC finds the reference to "varying contaminant exposures" confusing. Does the Institute mean to imply that respirators will be certified for specific applications, i.e. coal, metal, or industrial minerals operations? Does the Institute contend that varying contaminant exposures will limit the certification to specific types of mines?

We also believe that the term "reasonable representation" must be more clearly defined. Does the Institute intend that testing take place only at workplace sites or will tests conducted in a laboratory be accepted?

We strongly suggest that the Institute provide a clearer definition if, in fact, it requires that such testing be accomplished.

SUBPART B

84.10(b)--Submission of an application.

(b) For purpose of clarification, it is suggested that the reference to "this chapter" read "...Part 18 of 30 CFR...."

84.11--Required contents of an application to NIOSH for certification.

(e) AMC recommends that the word "informational" be deleted from this provision. "Informational" materials may be construed to mean advertising or sales literature. Certainly it is not intended that a manufacturer should notify NIOSH of changes in such materials. A requirement of this type would not enhance safety in the mine but would be an unnecessary burden on manufacturers.

(g) This provision appears to rescind the September 15, 1987, NIOSH letter requiring parts lists covering only those components listed on the approval plate. We request that the Institute explain why the established policy is being reversed.

SUBPART C

84.20--Quality Assurance.

(a) AMC commends the Institute for focusing its quality assurance program on an examination of identified critical characteristics. We recommend that the following definition of a "critical characteristic" be incorporated into the Sec. 84.3 of this proposal:

A feature capable of adversely affecting product safety and for which testing or inspection is required to assure conformity with the technical requirements specified in the appropriate subpart of this part. The critical characteristics of the products addressed shall be specified in each subpart.

(c) AMC seeks a statement from the Institute that the required drawings and specifications may employ the use of computer aided design and manufacturing systems.

(e) To ensure the effectiveness of this provision, the Institute should incorporate language stipulating that the visit of the NIOSH representative to a manufacturing site will be at a time mutually agreeable to the manufacturer and Institute personnel.

(f) The proposed language seems to allow NIOSH to request multiple products for the audit and, as such, is of concern to AMC members. To demand and examine an excessive number of respiratory devices could be very costly to both manufacturers and the Institute. Absent a restriction on the number of units that can be requested without a clearly defined statement as to need, the provision will prove unnecessarily burdensome.

84.21--Discovery of defect or failure of compliance by manufacturer; notice requirements.

AMC recommends that the provision state clearly that the manufacturer is required to notify the Institute only if the failure to comply is discovered relative to products having left his control. The manufacturer should not be required to inform NIOSH if such problems are discovered and corrected while all affected units are in his control.

(a) AMC recommends that "significant threat of serious injury" be defined. The proposed language is vague and ambiguous and, therefore, it does not clearly define the responsibilities of a manufacturer.

(b) AMC recommends that the term "reasonable time" be deleted and suggests that a manufacturer be required to notify NIOSH 10 working days after discovery of a failure not posing an immediate or significant threat of serious injury or death.

84.22--Notification by the manufacturer to NIOSH.

AMC recommends that the Institute specify the office within NIOSH to be contacted. The failure to do so will weaken the effectiveness of the provision.

(b) The products subject to the reporting requirement should be the number known to the manufacturer to be in the field. The program need not be concerned with products still within the control of manufacturers.

(c) AMC seeks clarification as to the precision expected in a manufacturer's statement regarding "expected usage." A failure to more clearly define the term will confuse those attempting to comply.

84.23--Notification by manufacturer to affected persons.

(b)(1) Since the manufacturer cannot be expected to know the location of all products having left his control, the provision should be revised to read "...to subsequent transferees, where known to the manufacturer."

84.25--Determination by NIOSH that a respirator fails to comply or has a defect.

(a)(4) The term "reasonable period of time" is vague and could result in unnecessary conflict between the Institute and a manufacturer. AMC recommends that, on a case-by-case basis, there be discussions between NIOSH and a manufacturer to determine a mutually acceptable time for the presentation of views.

SUBPART D--Respirator Testing by Applicant

84.30--Laboratory testing by applicant and interim certification.

- (a) To eliminate unnecessary vagueness, AMC recommends that in the second sentence the word "required" be substituted for "expected."
- (b)(2) AMC recommends that the Institute allow manufacturers to reference standards test procedures i.e. ANSI, ASTM, rather than requiring the submittal of unnecessary paperwork.
- (d) AMC recommends that the language be revised to require that NIOSH state "with specificity" not "generally" its reasons for mandating additional tests.
- (e)(2) To prevent unnecessary confusion, AMC believes that the word "expected" should be changed to "required."
- (f) AMC suggests that NIOSH issue its letter of notification 90 days after "receipt" of the laboratory test results, not 90 days after "acceptance" of such data. The incorporation of this language will provide more certainty to manufacturers and will assist the Institute in its effort to process applications efficiently.
- (f)(i) AMC believes that the granting of an "interim certification" may be unwise as it could result in increased liability for all parties. This concept should be closely examined in greater detail before proceeding.

84.31--Guidelines for workplace or simulated workplace testing.

AMC believes that NIOSH must release for comment the protocols to be followed in performing workplace or simulated workplace tests. We are very concerned that NIOSH does not clearly state that such information will be available in advance of the promulgation of this rule. Any comments relative to the need for specific tests and/or the number of each required must necessarily await review of the specific proposed protocols.

AMC strongly recommends that NIOSH publish proposed protocols in the Federal Register and invite public comment before proceeding with this rulemaking.

84.32--Workplace or simulated workplace testing by applicant; Certification of minimum performance level.

- (d) The word "acceptance" should be changed to "receipt." This change is designed to provide more certainty for all involved in the program.

**84.33--Workplace or simulated workplace testing by applicant;
Certification of higher performance level.**

AMC believes the Institute should more carefully examine the consequences and implementation of a dual level certification program before proceeding. The benefits to manufacturers, end-users and the Institute have not been clearly identified in the proposal.

84.34--Availability of respirator test results and protocol.

The lack of information regarding the content of the protocols prevents our responding fully. However, we caution the Institute to take appropriate action to prevent the release of confidential data.

SUBPART E--Withdrawal of Certification

84.70--Withdrawal of certification for cause.

(h) AMC cautions the Institute that, should it determine that a test used to certify a respirator is no longer valid, specific reasons must be given to explain the Institute's decision.

SUBPART I--Appeals

84.80--Appeal procedure.

AMC commends NIOSH for providing manufacturers with an appeals procedure to be used in challenging a decision not to issue a certification. However, the language should be clarified to ensure that the decision of the administrative law judge is binding pending any further appeals in accord with the Administrative Procedures Act.