

JAN 26 1988

84-166

The Honorable Fred Upton
House of Representatives
Washington, D.C. 20515

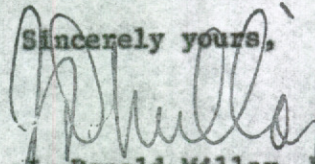
Dear Mr. Upton:

Thank you for your letters of December 11 to Mr. William Maroni and Mr. John Moran on behalf of Mr. William Moon 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 yours,



J. Donald Millar, M.D.
Assistant Surgeon General
Director

Enclosure

Page 2 - The Honorable Fred Upton

cc:

NIOSH/W

✓ NIOSH/Docket Office

CDC:NIOSH:LSparks

NIOSH #3163

Doc. 3160C

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LYNN S. SACHS
ADMINISTRATIVE ASSISTANT



Congress of the United States
House of Representatives

FRED UPTON
4TH DISTRICT, MICHIGAN

January 11, 1988

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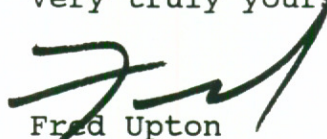
Mr. John B. Moran
Director
Division of Safety Research
NIOSH
944 Chestnut Ridge Rd.
Morgantown, WV 26505

Dear Mr. Moran,

The enclosed is of concern to one of my constituents, Mr. William Moon, President of Pro-Tech Respirators in Buchanan, Michigan. I would appreciate it if you would read his letter carefully and respond to his concerns. I would also appreciate it if you would address your response to my Washington office and I will forward your comments to Mr. Moon.

If I can provide any further information in this matter, please contact Henry Plaster of my staff at (202)225-3761.

Very truly yours,


Fred Upton
Member of Congress

FSU:hh
Enclosure

*Received
1-15-88 @ 1005am
ABM*

Pro-Tech
Respirators, Inc.

P.O. Box 192
107 E. Alexander Street,
Buchanan, MI 49107
Phone (616) 695-9663

December, 20, 1987

The Honorable Fred Upton
1607 Longworth
Washington, DC 20515

Dear Fred:

The National Institute for Occupational Safety and Health (NIOSH) has proposed a new standard for respirator certification, 42 CFR Part 84. This standard, should it become accepted in its proposed form, would have a profound negative impact on both end users and the respirator industry. This letter contains a brief summary of some of the changes which would occur if the proposal becomes law.

Under this proposal, few respirators currently available today, either maintenance-free or reusable, could pass the certification test requirements of the proposed new standard. Pro-Tech Respirators of Buchanan and Scott Aviation of South Haven manufacture such respirators.

Given state-of-the-art carbon and filtration technologies, product revisions required to meet the proposed standard would make these products so onerous to wear--bulky, hot, heavy, hard to breathe through, and generally uncomfortable, that workers would most likely refuse to wear them. (See enclosed artist's rendition.) Respirators offered by other safety manufacturers would be similarly affected.

Additional major problems in 42 CFR Part 84 include:

1. The workplace tests required for respirator certification may not be technically possible to conduct. Further, the costs associated with such workplace studies would add hundreds of thousands of dollars to development costs and end user costs for respirators.
2. Protocol and details concerning much of the workplace testing requirements are not included in the proposed standard, making timely comment on technical and economic feasibility issues impossible.
3. The workplace tests required for respirator certification must be conducted in mines, rather than in the general industrial workplace. This requirement is not only totally impractical, it avoids testing respirators in the industrial environment in which they are used.

Attached is an ISEA summary of the more abusive sections of the proposed standard. It outlines requirements on specific issues of the proposal. I invite you to review it and consider the impact this proposed regulation

will have on the workers who wear and depend on respiratory protection devices.

At the time of sending this letter, the public comment period is open for written statements from now until December 28, 1987. Public comments are to be sent to:

Director
Division of Safety Research
NIOSH
944 Chestnut Ridge Road
Morgantown, WV 26505

Other interested agencies are OSHA, OMB and EPA. If you can help us to persuade NIOSH to modify the proposed standard it will be very much appreciated.

Sincerely,


William F. Moon
President

- Enclosures: 1. ISEA Request for Recall of Proposed 42 CFR Part 84.
2. ISEA Summary of key issues of proposed 42 CFR Part 84.
3. Gas & Vapor Respirators as required by NIOSH under proposed 42 CFR Part 84-artist's rendition.

FOR YOUR INFORMATION
FROM ISEA

WICKENS, KOCHES & CALE
WASHINGTON SQUARE
SUITE 1111
1050 CONNECTICUT AVENUE, N.W.
WASHINGTON, D.C. 20036-5303

(202) 775-2400

September 21, 1987

Federal Express

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

Re: Request for Recall of
Proposed 42 C.F.R. Part 84

Dear Mr. Moran:

On behalf of the members of the Respiratory Protection Group of the Industrial Safety Equipment Association, Inc. ("ISEA")^{*} we hereby request the recall of 42 C.F.R. Part 84 as proposed on August 27, 1987 (52 Fed. Reg. 32402) for the following reasons:

*/ The members of ISEA's Respiratory Protection Group are:

- Airolife Safety Inc.
- American Optical Corporation
- Biosystems, Inc.
- E. D. Bullard Company
- Glendale Protective Technologies, Inc.
- Mine Safety Appliances Company
- Minnesota Mining and Manufacturing Co., Inc. (3M)
- Moldex-Metric, Inc.
- National Draeger, Inc.
- Parmelee Industries
- Pro-Tech Respirators, Inc.
- Racal Airstream
- Scott Aviation
- Sellstrom Manufacturing Company
- Siebe North, Inc.
- Survivair - U.S. Divers Company
- WGM/ Willson Safety Products

Under the Administrative Procedure Act, notice of a proposed rule must include "either the terms or substance of the proposed rule or a description of the subjects and issues involved." 5 U.S.C. §553(b)(3)(1982). This requirement exists to assure that interested parties are afforded the opportunity to offer informed criticism or comments on agency proposals. See, Ethyl Corp. v. Environmental Protection Agency, 541 F.2d 1, 48 (D.C. Cir. 1976). In the instant proposal NIOSH has failed to give the detailed notice required by the APA, thereby denying an opportunity for informed comment and full participation by interested parties in the rulemaking process.

As set forth at 42 C.F.R. §84.31 through §84.34, the proposed rule requires workplace or simulated workplace testing prior to certification. The preamble to the proposed rule states that NIOSH will provide applicants detailed model protocols to perform these tests upon request. The preamble further states that NIOSH "has begun to develop model protocols for performing such tests in a proven and reliable manner."

NIOSH notes that these protocols when and if developed would be too voluminous to be included in the Federal Register notice. The preamble states NIOSH's intention, however, to make the protocols available at the time of final rulemaking. NIOSH thereafter solicits comments on these unidentified model tests that will supposedly "assure reliability and reproducibility of mandatory workplace and simulated workplace test results."

The foregoing proposal for workplace testing protocols is insufficient and should be recalled for further development. The proposal as it currently exists fails to identify sufficiently the substance of the workplace testing and simulated workplace testing that will be required for certification. Without further specificity regarding the details of such testing, it is impossible for ISEA, or NIOSH for that matter, to evaluate and comment on the technical accuracy and feasibility of the proposed protocols.

While ISEA and its members generally support workplace testing, such testing can only assure reliability of the equipment when reliability of the test method itself has been established. Mandatory undefined workplace testing, as NIOSH now proposes, certainly does not advance reliability and it is thus premature to require such testing before reliable protocols have

Mr. John Moran
September 21, 1987
Page 3

been established. Accordingly, the proposed rule denies the opportunity for informed comment and criticism and the notice is therefore defective.

ISEA thus requests that NIOSH recall proposed Part 84 until it has developed protocols for workplace testing in sufficient detail to afford interested persons the opportunity to comment.

Sincerely,


Paul A. Koches

PAK:mlr

cc: J. Donald Millar

KEY ISSUES ON NIOSH NOTICE OF PROPOSED
RULEMAKING FOR TESTING AND CERTIFICATION
OF RESPIRATORS FOR USE IN MINES AND MINING

The proposed new regulation for respirator certification (42 CFR Part 84, Federal Register, August 27, 1987) will have a disastrous impact on respirator users and their employers.

Worker safety will be compromised immediately by NIOSH's abandonment of its long-standing practice of certifying respirators for use in general industry and construction. In limiting its certification only to respirators for use in mines and mining, NIOSH purposely ignores the occupational safety and health needs of substantially more workers than it protects.

While ISEA and others have expressed concerns to NIOSH since many of the proposed changes were first drafted in 1982, most of these comments have been ignored. ISEA calls for a consensus standard activity to respond to the needs of all users of respiratory protection now and in the future.

Few, if any, of the respirators now on the market, which currently provide adequate protection, will meet the requirements of the proposed standard. Employers will be required to revise their respirator programs to accommodate those few respirators which satisfy the new requirements. These respirators will be, in many cases, larger, bulkier and more costly.

Contrary to NIOSH's opinion, these proposed rules will have significant economic impact on both the user community and respirator manufacturers.

The problems arising from the new proposed regulations can be divided into two categories: those dealing with general respirator requirements, and those dealing with the technical requirements for specific types of equipment.

I. General Requirements

A. Workplace Testing of Respirators - While workplace testing of respirators is desirable, the proposal contains the following deficiencies:

1. The proposed regulation contains the requirement that the performance of all respirators be tested in the workplace. The proposed rule states that the protocol and details for performing these field studies will be available at the time the final rule is promulgated. This represents a denial of due process of law by not allowing affected parties to comment on feasibility, cost and validity of requirements before they go into

effect. If NIOSH is going to proceed with a rulemaking hearing, then another hearing on the detailed requirements for field testing protocols should be held before the final rule is promulgated. For example, the proposal does not stipulate how many workplaces need to be included in the tests nor how many subjects in each workplace need be studied. A better alternative would be to recall the proposed rule until complete details are developed by NIOSH.

2. The proposed rule requires that during analysis of the workplace protection factor data, 95% of the test subjects must achieve a workplace protection factor in excess of the stated assigned protection factor with 95% confidence. There is too much variability in the test methods to require the use of confidence intervals. When the confidence interval is added to the prediction, no field test performed to date indicates any tested respirator can meet its assigned protection factor. For example, a half mask respirator with a minimum workplace protection factor (WPF) of 22 in the DuPont asbestos study would have a WPF of 6 using the NIOSH methods.
3. The proposed rule allows the use of simulated workplace testing in lieu of workplace testing if a good correlation can be established between the two types of tests. However, because the variables involved in workplace testing are so large, establishment of such correlations cannot be accomplished. To date, no lab tests have correlated to any workplace tests.
4. The proposed rule allows certification of respirators for use at protection factors greater than the assigned protection factor listed in the table if evidence is provided that the equipment performs at the higher protection level. Furthermore, an even higher confidence interval than the unachievable 95% confidence level for the base line protection factors must be met. NIOSH does not state what that confidence level should be. In effect the ultimate decision will be up to NIOSH, however, it is not stated what criteria must be met.
5. NIOSH is requiring all workplace testing be done with mines or mining operations as the workplace. Not enough mines exist to accommodate the number of tests required. NIOSH has stated unofficially that non-mining worksites may be used if correlations with mining worksites is established. Such correlations are not possible given the high variability intrinsic to these test methods. With all respirator manufacturers attempting to test several respirators per year with typical test periods a month, this would result

in test situations at virtually all the existing mines 100% of the time. Obviously mines would refuse to cooperate. In addition, while most types of respirators may at some time be used in mines, subjects wearing organic vapor or paint spray respirators, for example, would be hard to find.

6. Technology does not exist today to perform workplace testing against most hazardous substances found in the workplace. Analytical methods do not have sensitivity sufficient to make meaningful measurements of performance, especially with the respirators which have high assigned protection factors. Additionally, no methods exist for gas and vapor respirators.
7. The assigned protection factors, found on Page 32409, are very low for certain types of respirators such as continuous flow airline respirators, but are very high for positive pressure self-contained breathing apparatus. There is no justification given for NIOSH's assigned protection factors.

B. Modifications

All major modifications to a respirator will require repeat field testing of a respirator. A major modification is defined as one that "might appreciably affect weight, balance, strength or other qualities affecting respirator use or is not done according to accepted practices or cannot be done by elementary operations". This would be any change by definition. This will create another undue burden on the manufacturer and increased costs to the users.

C. General

42 CFR 84 eliminates general industry needs by certifying respirators for use in mines and mining. While OSHA and others may accept this certification for their use, general industry will not have respirators reflecting their needs.

II. Technical Requirements

A. Particulate Filter Efficiency

1. All respirator filters will be required to meet a loading filter efficiency test with both a liquid oil and solid aerosol 0.2-0.3 micron in diameter. Nearly all non-high efficiency respirators will fail the liquid oil requirements. Yet, workplaces having liquid oil contaminants are in the minority and are easily distinguished from workplaces having solid aerosol contaminants.

2. The oil mist loading test will eliminate all electrostatic filter media from respirators. This type of filter offers lower breathing resistance.
3. NIOSH has not responded to both the American National Standards Institute (ANSI) and ISEA requests that separate approvals be given for liquid and solid particles.

B. Chemical Cartridge Respirators

1. The proposed rule requires that gas and vapor respirators be equilibrated at 85% relative humidity, then tested at 85% relative humidity with a 50-minute service life requirement. No organic vapor chemical cartridge currently available in the U.S. today will meet this requirement. Organic vapor chemical cartridges will have to be made at least four times bigger to meet this requirement with today's technology. Respirator users have not expressed the need for longer service life for organic vapor cartridges.

C. Fit Test Panel

1. NIOSH is requiring the use of an anthropometric panel to size and assure fit of respirators. Manufacturers will be required to state the anthropometric size faces that their respirators will fit. No one to date has established a correlation between face length and face width and size of the respirator needed. Los Alamos National Labs, which developed the panel as a research tool, opposes the use of anthropometric panels in respirator certification.
2. The proposed rule implies to the user that since the respirator is certified to fit workers of a certain face size, and identified as such, that fit testing is not necessary.
3. The proposed rule requires 95% of the test subjects to exceed a fit factor of 50 for half masks and 100 for full facepiece respirators on a 25 person panel with a confidence level of 95%. Because of test variability most respirators will not meet this requirement. For example in one test on a 25 person panel a minimum fit factor of 120 was achieved on a half mask respirator. Using NIOSH's methods this would yield a fit factor of 31 and would not meet the requirements.

D. Tolerance Limits

1. NIOSH is using a three or six sample method of analyzing data to assure compliance with test requirements. Because of the normal variability in product

performance and test methods, many respirators will not meet the proposed requirements when compliance is based on such a small sample size. Thus many acceptable respirators in use today will be eliminated.

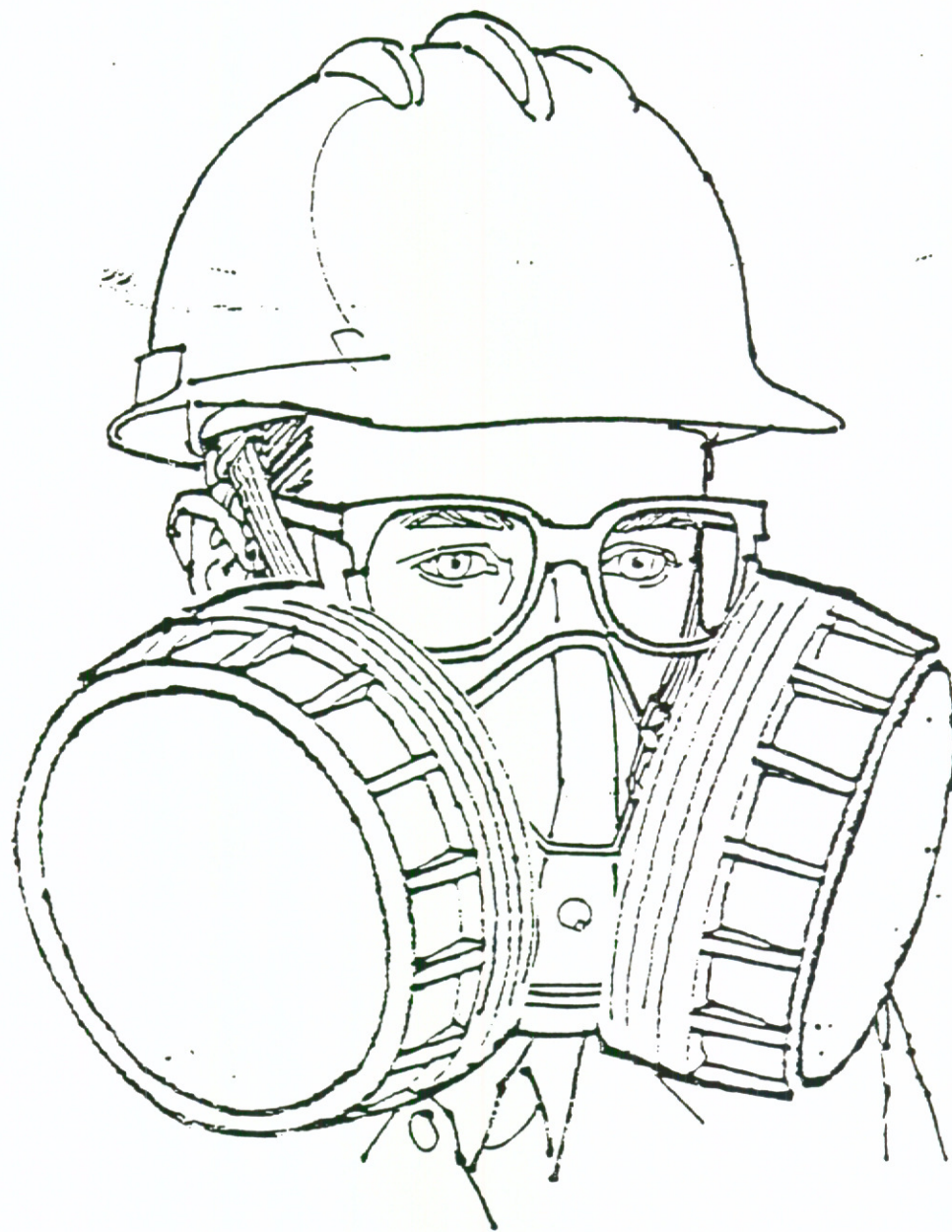
Recommendations:

- A. 42 CFR 84 must not become final as proposed.
- B. NIOSH must clarify or recall its proposed rule before the scheduled hearing. Information in the proposed rule is far too incomplete or in some cases nonexistent to allow adoption.
- C. We urge all interested parties to submit detailed comments, due at this writing by December 28, 1987, on the proposed rule to:

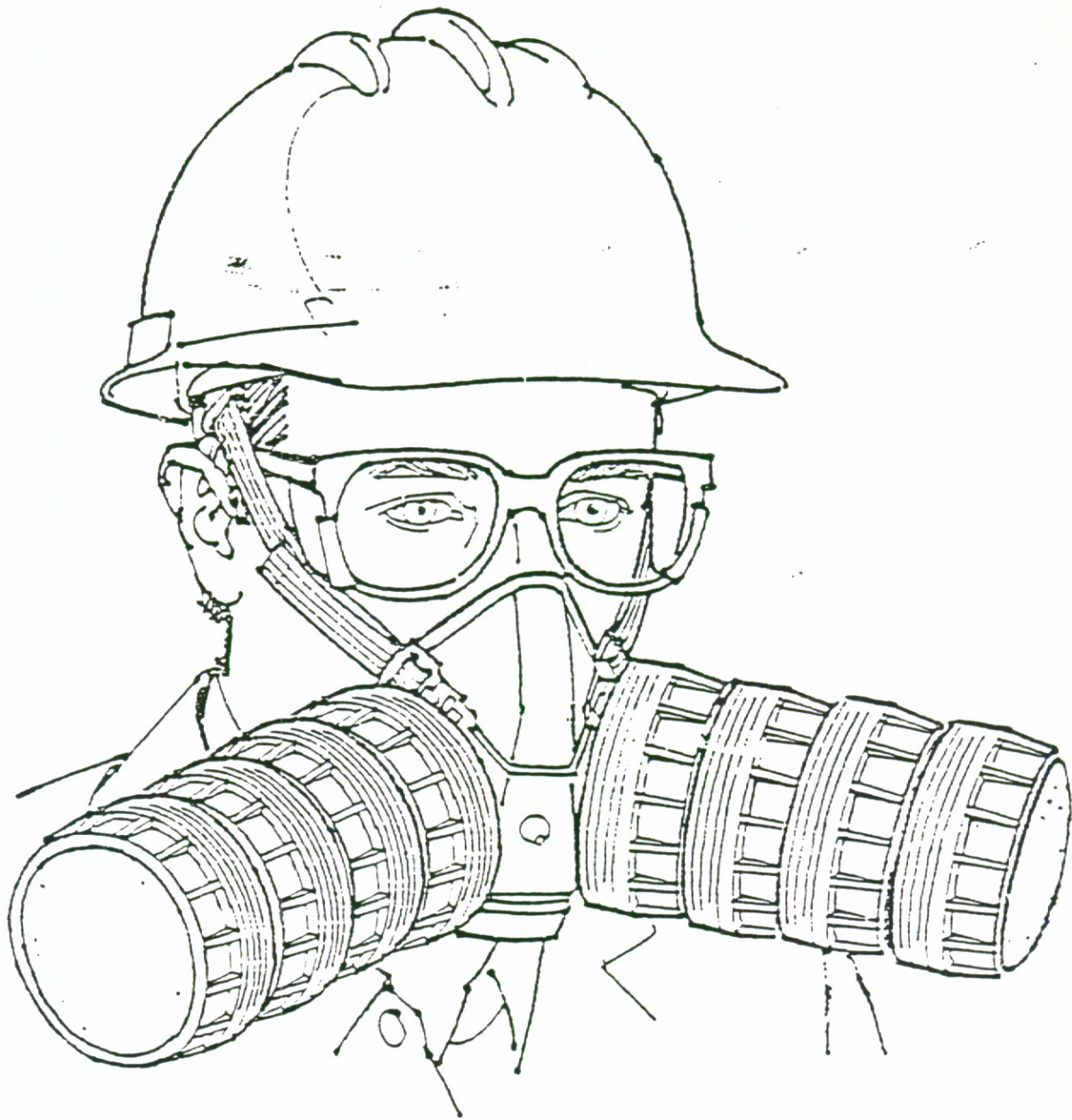
Director, Division of Safety Research
NIOSH, 944 Chestnut Ridge Road
Morgantown, WV 26505
- D. Resources must be committed to develop a consensus standard for respirator certification for use in all industrial applications. Such a standard should be developed through an accredited ANSI Committee, and made available to OSHA and other government agencies.
- E. A non-governmental third-party certification program must be established to show compliance with respiratory protection standards developed through a consensus committee.

* * * * *

GAS AND VAPOR RESPIRATOR
AS REQUIRED BY NIOSH
UNDER PROPOSED 42 CFR PART 84



GAS AND VAPOR RESPIRATOR
AS REQUIRED BY NIOSH
UNDER PROPOSED 42 CFR PART 84



Business Investment is Federal government

12/31

By JOHN CUNNINGHAM
AP Business Analyst

NEW YORK — If you don't mind fiscal irresponsibility, you might advise your friends and neighbors that, in the aggregate, the surest investment in these risky times is the federal government.

Year after year the federal government demonstrates a way with money that few institutions can match. Last year, for example, it was able to return to the public nearly \$1,000 more per capita than it collected in taxes.

Nothing frightens old Uncle Sam. He spends, but he always has more, which is something no other smart money man has been able to do. The good uncle, big-hearted, kindly old man, seldom says no.

That's one view.

Another is that he is a rogue, impostor, spendthrift, ne'er-do-well — an incompetent, dissolute and debauched character who has performed his "miracles" by running up a debt of nearly \$40,000 for every family of four.

In this view he is a panhandler without a decent job, a Robin Hood at best and a common thief at worst. While creating the notion that he gives more than he receives, he actually receives a great deal more than he gives.

Uncle Sam, hero or bum? Benefactor of the downtrodden or destroyer of future generations? The issue seldom is stated that way, but that's what all the talk about budget deficits and tax revisions is about.

The only viable solution to all this is to end his ability to spend without limit, says Daniel Mitchell of the Citizens for a Sound Economy. In his view, the Constitution must be amended to stop the old codger's spendthrift ways.

Mitchell, director of tax and budget policy at the non-profit, Washington-based foundation, has written a pamphlet titled "Federal Spending in Crisis," which puts the issue in a perspective that some people might find horrifying.

He points out that deficit spending, which Uncle Sam has practiced

peace-time aberration rather than custom. Only within the past two decades has it become the general practice rather than the exception.

Wars produced debts, of course, but following them the country went on binges of saving.

When the Civil War ended, the national debt was \$2.7 billion. But 28 consecutive surpluses brought it down to \$961 million in 1893. It rose to \$1.4 billion after the Spanish-American War, but was back down to \$1.2 billion by 1914.

World War I pushed it up to \$25.5 billion, but 11 straight surpluses brought it back down to \$16.2 billion by 1930, before a once-in-a-lifetime depression caused it to rise again.

Salvage firm says it has found wreckage of sunken luxury liner

12/31

By Booth News Service
and Associated Press reports

ST. JOSEPH — A Kalamazoo salvage company says it has found the wreckage of a luxury steamship that sank during a violent storm in 1895 and figures prominently in Great Lakes folklore.

Louis Wayne Simpson, an owner of Breakwater Marine Salvage Co., has applied to the state Department of Natural Resources for permits to salvage wreckage from the SS Chicora.

KENNETH POTT, curator of the Lake Michigan Maritime Museum in South Haven, said the ship's sinking was one of the major marine disasters off the southwestern Lower Peninsula shore.

Pott said if the vessel is the SS Chicora, the find would be valuable because of what could be learned about shipbuilding of the period.

"The significance of it being found is that it does represent in a

to be capable of withstanding powerful Great Lakes storms.

THE LUXURY ship, which ran a regular route from the Twin Cities to Chicago in the summer, was taken out of winter storage to pick up the load of flour from Milwaukee.

Its sinking was a "traumatic event in Michigan's history," said Larry Masse, a Michigan historian who lives in Allegan.

"It was so mysterious . . . all they ever found was wreckage that washed up on the coast around South Haven," Masse said.

At least one song, "The Sinking of the Chicora," was written about the incident. A small town in southwestern Allegan County also was named after the ship, Masse said.

Residents near South Haven, where the ship was believed to have gone down, reported seeing or hearing the ship the night it disappeared. Earlier sightings of the wreckage have been reported, but no efforts were made to salvage

U.S. Department of Labor

Occupational Safety and Health Administration
Washington, D.C. 20210



Reply to the Attention of:

JAN 21 1988


Dr. J. Donald Millar
Director
National Institute for Occupational
Safety and Health
Centers for Disease Control
1600 Clifton Road N.E.
Atlanta, Georgia 30333

Dear Dr. Don:

Enclosed are comments from a constituent of Congressman Fred Upton concerning the National Institute for Occupational Safety and Health (NIOSH) proposal 42 CFR 84.

Please review his comments and respond directly to Congressman Upton.

Sincerely,


Edward J. Baier
Director
Directorate of Technical Support

Enclosure