January 1982 Recommendations from MHRAC

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Report of the Respirator Research Subcommittee of the Mine Health Research Advisory Committee

Respirator Certification, Fr. Leon Cander,
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I suggest you go through this package & see if it is "assembled" as it is supposed to be —

Respirator Certification

Dr. Leon Cander
Mr. John B. Moran
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Mr. Murray Jacobson
(Ex-officio Alternate, MSHA)

S-105

January 27, 1982

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INTRODUCTION

At the February 1981 meeting of the Mine Health Research Advisory Committee, the Director of NIOSH requested that the Committee establish a Respirator Research Subcommittee to provide the Director recommendations for the NIOSH Respirator Research Program. The Committee concurred with the Director's request and established the Respirator Research Subcommittee composed of the following Committee members:

Dr. Leon Cander

Mr. John B. Moran

Dr. Donald L. Werner

Mr. Murray Jacobson (MSHA; ex-officio alternate member).

The Subcommittee presented its Respirator Research Report at the next meeting of the Committee, held on October 13-14, 1981. The Committee formally adopted the Subcommittee's Report and passed the following resolution: "Resolved that the Respirator Subcommittee with the aid and support of Dr. Fleming and the NIOSH staff assemble a summary of data concerning advantages and disadvantages of in-house versus external testing of respirators and report this to the full Committee at its next meeting. The Subcommittee may, at its option, include in its Report a recommendation to NIOSH for the full Committee's consideration."

Pursuant to the resolution, the Subcommittee held a public meeting on January 4-5, 1982 (see Federal Register notice, Attachment 1). Meeting attendees are shown in Attachment 2. The meeting attendees focused not only on the advantages and disadvantages of in-house versus external respirator

testing as a procedure in the NIOSH/MSHA Respiratory Certification process, but also discussed and commented on the broader issue of Respiratory Certification as currently embodied in regulations contained in 30 Code of Federal Regulation, Part 11.

Public Meeting

As evidenced from the list of attendees (Attachment 2), a broad range of interests were represented during the public meeting, including labor unions, respirator manufacturers, independent testing organizations, trade associations, and the user community. The following is a summary of each presentation. Where written comments were provided, these are noted and attached to this Report.

Earle P. Shoub, Consultant

At the request of the Subcommittee chairman, Mr. Shoub prepared and presented a detailed analysis of the history of, and basis for, the current NIOSH/MSHA Respirator Certification Regulations (Attachment 3). Mr. Shoub, a retired Federal civilian employee, has had substantial experience in this subject area as a former official with both NIOSH and the Bureau of Mines. Mr. Shoub concluded that:

1. NIOSH/MSHA must be the certifying/approval authorities. Such authority may not be delegated to those outside the two departments involved (DHHS and DOL).

2. The intent of the statute concerning fees for respirator certification appears clear; i.e., the Government should endeavor to recover from the applicants the costs associated with processing applications, testing, and issuing approvals.

3. The enabling legislation appears to extend sufficient authority to the Secretary of Health and Human Services (DHHS) to permit respirator certification testing by non-Government entities.

Mr. Howard Walderman, General Counsel, OS/DHHS, concurred with Mr. Shoub's interpretation of the statutes and the conclusions he made.

Requirements for the use of NIOSH/MSHA-certified respirators in general industry are contained in a number of specific OSHA health standards embodied in 29 CFR 1910 and also generally within 29 CFR 1910.134. OSHA personnel who were present noted that an advance notice of Proposed Rulemaking regarding revisions to 1910.134 (originally published in 1971) is in final review now and will likely be published in the near future. The issue of specifically requiring use of NIOSH/MSHA-certified respirators will be discussed. The more specific language in recent OSHA health standards regarding the required use of NIOSH/MSHA-certified respirators was noted as a reference to the OSHA position on respirator certification; i.e., NIOSH/MSHA certification of respirators is desirable and will be required.

NIOSH: Testing and Certification Branch Activities (TCB)

Nancy Bollinger, acting Chief of the Testing and Certification Branch, provided an overview of current activities, the present certification process, changes in the approval process of the past few years to increase efficiency and expedite the approval process, and current activities and schedules associated with 30 CFR 11 revision activities (Attachment 4).

Attachment 5 provides a briefly outlined summary of proposed changes to 30 CFR 11 which NIOSH is currently considering. These were presented and discussed at the December 17, 1981 NACOSH meeting and are included in the Report since these were not discussed during the Subcommittee's meeting.

During discussion, Ms. Bollinger provided the following additional information:

1. NIOSH certification of Noise Measurement Devices and Detector Tubes, also conducted by TCB, has been placed on hold as a consequence of resource constraints.

2. TCB currently has approximately 30 personnel of which 13 are in the testing group.

3. In FY81, 99 new respirator approvals were issued; 344 applications were received and approximately 700 approvals were issued if extension of approvals are included. Approximately 80 new approvals were issued in FY80.

4. In FY81, $86,000 in fees for certification were collected. (Deposited to the Treasury.)

5. Current staff can handle 100-120 new approvals a year.

6. "Very few" new respirator manufacturers have sought certifications in the past 2 years.

7. TCB purchased from "retail" sources and tested approximately 40 gas and vapor and 13 self-contained respirators in FY81. FY80 audits were devoted nearly totally to gas masks. Reports of these audits have been written but have not been published.

IUD, AFL/CIO

Sheldon Samuels addressed three issues: new certification standards, the certification process, and respirator research.

The need for improved certification standards remains critical. A criteria document approach, which seeks to gain all the available information, should be pursued as a basis for developing new state-of-the-art respirator performance standards.

Respirator certification should remain a NIOSH/MSHA function, in Mr. Samuel's view, because preemption of an existing Government regulatory role should not be considered. The need for OSHA to pursue rulemaking regarding the use and application of NIOSH/MSHA-certified respirators was also emphasized, as was the need for OSHA to interface with the research program.

Respirator research should be expanded, focusing on workplace performance and examining human effects associated with respirator use, such as cardiopulmonary stress and neurological factors, such as sensory deprivation. Mr. Samuels felt that NIOSH suffers from the lack of senior respirator research personnel and should, therefore, increase their collaboration with such expert groups as the Los Alamos National Laboratory.

Safety Equipment Institute (SEI)

Mr. Frank Wilcher, President of the Safety Equipment Institute (a not-for-profit, independent, third-party certifying organization) presented an overview of SEI and its certification program which is now active in certifying industrial eyewear and hard hats. SEI recommendations are in Attachment 6. In effect, they are:

1. SEI certification of respirators
2. NIOSH concentration of its efforts in establishing respirator performance standards in cooperation with consensus standards organizations and on expansion of its respirator research program.

In discussion, Mr. Wilcher estimated that it would require about 1 year and perhaps $1 million to establish an SEI respirator testing and certification capability. Certification fees would be higher than those currently charged by NIOSH as applicants pay the full cost of certification.

Organization Resources Counselors, Inc. (ORC)

Darrell Mattheis presented a comprehensive view of both respirator research needs and respirator certification (Attachment 7). ORC recommends:

1. Respirator research be more appropriately funded
2. Some form of field testing be made part of the certification program
3. A mechanism be developed to permit certification of innovative devices keyed to field testing
4. Testing and certification technical and administrative groups be separated. NIOSH should administer the certification program and issue approvals, but the technical aspects (testing) should be conducted by laboratories capable of doing so since respirator "users have lost confidence in NIOSH's ability to properly conduct and interpret the scientific tests it conducts under the Part 11 requirements."
5. NIOSH, with the participation of non-Government centers of excellence, develop the research base required to properly revise the 30 CFR 11 test requirements.
6. Changes ultimately adapted by NIOSH be sensitive to the potential impact on respirator cost and the small respirator manufacturer.

3-M Company

Mr. Einar Horne, Technical Director of the Occupational Health and Safety Products Division of 3-M, gave an oral presentation, the highlights of which are as follows:

1. Changes to 30 CFR 11, while badly needed, have been discussed for several years. Substantial information and recommendations have been presented to NIOSH in public meetings and hearings but little has resulted.

2. The administrative aspects of certification by NIOSH have improved and significant progress is evident (to the manufacturers) during the last 18 months.

3. Certification of respirators should be provided by the following in order of decreasing preference:

   - Manufacturers self-certify (manufacturers are liable and responsible)
   - NIOSH/MSHA certify
   - Independent laboratories certify.

4. If NIOSH/MSHA continue to certify, the technical aspects of 30 CFR 11 must be revised and a means of certifying innovative devices must be developed.

5. 3-M is willing to have test data published and is willing to conduct field tests as a requisite to certification.

6. Certification by an independent laboratory is not a viable option as such would not result in improved respirator quality and such a laboratory would be without competitive pressures. Certification by SEI equates to self-certification as SEI is viewed as being controlled by manufacturers.

ANSI Ad Hoc Committee on Respirator Testing and Certification

Mr. Donald Wilmes, Chairman of the Ad Hoc Committee, discussed the committee's activities which are aimed at providing technical revisions, consensus input to NIOSH with regard to anticipated revisions to 30 CFR 11. The committee intends to provide its final report to NIOSH by January 29, 1982.

This committee's activities and subsequent report are directed specifically to the technical aspects of the testing requirements within 30 CFR 11, an issue not directly relevant to the subcommittee's report with regard to certification except in the following:

1. The Ad Hoc Committee was not able to achieve consensus on a number of important issues implying that technical improvements to 30 CFR 11 are not so clearly straightforward.

2. The Ad Hoc Committee is recommending establishment of permanent consensus committees that will focus on specific respirator classes. Preliminary efforts, however, indicate that participation by users and unions is a problem.

3. Mr. Wilmes agreed with the statement that all 30 CFR 11 tests can be improved, in a reasonable amount of time, with known methods.

Mine Safety Appliances (MSA)

Mr. Wayde Miller, Director of Product Planning, presented MSA's views regarding the advantages and disadvantages of in-house versus external testing of respirators (Attachment 8). MSA supports private sector certification of respirators based on a revised, 30 CFR 11-based consensus standard.

International Association of Fire Fighters (IAFF), AFL-CIO

Mr. Richard Duffy, Occupational Health and Safety Program Director, presented oral views of the IAFF position and provided the subcommittee with two IAFF documents: 1980 Annual Death and Injury Survey and A Fire Fighters Guide to Self-Contained Breathing Apparatus. Both documents underline the special hazards and needs of fire fighters with regard to respirators.

Mr. Duffy made the following comments:

1. NIOSH should be the sole certifier of respirators and the sole tester of respirators.

2. If others do the testing, NIOSH will lose expertise and quality will suffer. If more than one independent lab tested, interlaboratory comparability might be a problem. Auditing independent laboratories effectively may well assume more resources than are currently used in the present certification process.

3. 30 CFR 11 requires revision, with emphasis on test methods, innovative devices, and special respirators for special needs such as the fire fighting environment.

Alan Hack, Los Alamos National Laboratory

Mr. Hack's oral comments are summarized as follows:

1. The Subcommittee should not focus solely on short-range issues that relate to current resource constraints and their consequences. Viable long-range solutions to the current certification issue are what is truly necessary.

2. A fundamental aspect of the current respirator certification issues is the low esteem held of the NIOSH certification program. The issue of alternates to Federal Certification would never have been raised when the program was run within the Bureau of Mines.

3. Abandonment of a Federal certification program to the private sector is without precedence.

4. Respirator certification should remain within NIOSH, but improvements are required in both the regulations and the personnel involved in the certification program.

Industrial Safety Equipment Association (ISEA)

Lou Rodenhouse, Chairman of the Respiratory Protection Group of ISEA, presented the ISEA position on the subject of the meeting (Attachment 9). ISEA recommends:

1. NIOSH concentrates its efforts on establishing recommended performance standards and expands its respirator research efforts.

2. Respirator certification should be conducted by an impartial third-party organization.

Subsequent discussion resulted in the following comments:

1. Even if 30 CFR 11 were updated, NIOSH would still have a problem

2. NIOSH needs better qualified personnel

3. An adversary relationship has been established that did not exist when the Bureau of Mines approved respirators

4. Manufacturers are willing to remedy "real" problems but not problems that they perceive as insignificant or unreal.

Underwriter Laboratories (UL)

Mr. William Hooper presented and submitted a statement regarding third-party testing and certification of personal protective equipment (Attachment 10).

The UL approach to product testing and certification was reviewed. UL currently tests and certifies products for the Federal Government, including the U.S. Coast Guard and OSHA. UL, based on its past experience, believes that third-party certification of respirators can be effective.

Mr. Hooper estimated that it would require about 1 year to establish such a program and would cost about $1 million in capital investment. As in the SEI certification program, actual device test data are kept confidential and not released.

E.D. Bullard Company

Mr. Robert Asbury made an oral presentation summarized as follows:

1. NIOSH has greatly improved the administrative aspects of the certification process in the last 18 months. Time for certification has been reduced and the new application checklist has been a big help in ensuring that the application is complete when first submitted.

2. The Bullard Company supports the certification of respirators by an independent third-party organization.

3. If other alternates are to be considered, Mr. Asbury suggested that the DOT safety helmet certification approach be examined. This approach involves establishment of standards/criteria by DOT, manufacturer self-certifying, and DOT product audits to ensure standards compliance.

United Steelworkers of America

Written comments were received from Mr. Mike Wright, an Industrial Hygienist with the Steelworkers Union (Attachment 11). Mr. Wright supports continued testing and certification of respirators by only NIOSH. Outside

testing may be acceptable for some tests if such were contracted for by the Government. NIOSH should bring 30 CFR 11 test criteria up to date and should change some of the current 30 CFR 11 administrative aspects, particularly the decertification process/procedures.

Advantages and Disadvantages of In-house Versus External Testing of Respirators

The following represents the Subcommittee's views with regard to the advantages and disadvantages of in-house versus external testing of respirators under the current NIOSH/MSHA respirator certification regulations.

The advantages of NIOSH performing respirator certification tests in house and, it is presumed, in the current Morgantown facility, are viewed as being the following:

1. Such testing within NIOSH facilities by NIOSH certification program personnel ensures the maintenance of existing personnel expertise and offers the opportunity to expand such expertise if new test criteria under revised 30 CFR 11 regulations are adopted and if such revised criteria incorporate procedures to permit a broader testing of innovative devices.

2. NIOSH respirator research scientists would have direct access to the testing experts and testing equipment. This assures that the research arena is intimately familiar with current respirator performance parameters, respirator problems, and respirator innovations that reach the testing stage.

3. Respirator testing, within a single Federal laboratory, which is keyed to a product certification program, offers the opportunity to establish a single, recognized, reference laboratory that all other respirator testing facilities could draw on for test validation, thus ensuring uniform, high-quality products and minimizing the potential for protracted regulatory-based disputes over product performance.

4. Direct and immediate access to test facilities and expert test personnel in the NIOSH reference laboratory would permit rapid, efficient, effective, and unchallenged commercial product audit testing in facilities upon which original certification tests were performed for the products under audit and, therefore, for which the original certification test data would be immediately accessible. This permits direct production product test data comparison with certification data on that same product.

5. Product test data, upon which certification or denial of certification was based, would be in the hands of the Federal certification authority, thus eliminating any potential concern with regard to access to such data, validity, or the failure to record and report data of uncertain or questionable quality.

6. Should it become necessary to publish respirator test data in the future, the generation, collection, and tabulation of such data at the NIOSH test facility would facilitate access and publication and would largely negate any potential concerns regarding the validity, accuracy, and completeness of the data.

7. Federal internal testing would ensure the timely, responsive, and reference laboratory-based confidence necessary in responding to user, manufacturer, and research scientists' requests for relevant information.

8. Presence of the testing facility and testing experts within NIOSH would minimize the problems that might be faced by a new manufacturer seeking entry into the market as compared to the need to seek basic detailed information from an organization outside the Federal Government.

9. Potential conflict of interest issues would not arise should testing be conducted by NIOSH in its own facilities by Federal employees.

10. The NIOSH reference test facility would serve as the reference laboratory for determining laboratory baseline data for respirators tested in the field environment in addition to providing the field test group with expert advise and counsel on test methods, analysis, and test procedures.

The disadvantages of NIOSH's performing respirator certification tests are viewed as follows:

1. Resource limitations or constraints may limit NIOSH's ability to procure advanced equipment in timely fashion when test criteria are advanced, for example.

2. Resource constraints may limit NIOSH's ability to staff the testing facility with appropriate senior personnel who can command the respect of their peers in the private sector. Further, such constraints may limit NIOSH's ability to keep truly competent senior, expert personnel on staff in career positions.

3. If viewed as a reference laboratory, increased effort will be required that may reduce a testing facility certification-related capacity on a fixed resources base assumption.

4. Respirator testing would be limited to that associated with an application for certification and would preclude the development testing often required by smaller manufacturers and which would be available from third-party testing organizations.

5. If the NIOSH testing activity remained isolated from respirator research, respirator field tests, and respirator quality assurance audits, it would quickly become isolated from the real world of respirator use, application, and need.

6. If the testing facility is insufficiently supported with monetary and human resources and is not adequately managed, problems with the certification process will continue to escalate regardless of technical and administrative revisions to 30 CFR 11.

7. If 30 CFR 11 is revised so as to encourage the development and marketing of innovative devices and devices with superior performance, the technical, administrative, and resource demands upon NIOSH will increase. If not managed appropriately at the outset, NIOSH will again be perceived as inhibiting rather than stimulating progress.

8. Test data are not, nor can they be, under present regulations, confidential to NIOSH and the submitting manufacturer only, which may be viewed as a negative factor to manufacturers.

9. Unless accepted as a competent reference laboratory, conflict will continue over test results and inter-laboratory test comparison issues. The problem is exacerbated by the fact that the NIOSH data are available to the public.

Subcommittee Recommendations

Basis:

While the Committee resolution focused on the issue of in-house versus external testing of respirators as an aspect of the respirator certification process, it has become evident to the Subcommittee that the testing issue alone cannot be examined out of context of the certification process itself. As a consequence, and based on a wide range of diverse input received by the Subcommittee during the public meeting held on January 4-5, 1982, the Subcommittee feels compelled to provide a number of recommendations regarding the testing and certification of respirators. The Subcommittee bases its recommendations on the following conclusions:

1. NIOSH and MSHA must continue to be the certifying authorities unless or until such requirements are legislatively changed. NIOSH and MSHA may not, it appears, delegate such authority to another authority.

2. The intent of the statute concerning fees for respirator certification is evidently that the Government should recover from the applicants the costs associated with issuing approvals. Present certification fees are insufficient in this regard.

3. On the basis of the Mining Acts and the OSH Act, it appears that NIOSH can contract for outside testing of respirators.

4. No evidence was presented during the public meeting that private laboratories are presently capable of assuming the respirator testing burden. While independent third-party laboratories expressed interest in doing such testing (and certifying), they indicated that it would require at least a year before such capability would be available. Others estimated that it would require 2-3 years and $3 million.

5. There is unanimous agreement that the fundamental problem is the absolute necessity to update 30 CFR 11 regulations that presently establish the testing criteria. Information discussed at the meeting suggest that performance criteria that meet the need to ensure that the tests more appropriately measure the ability of respirators to provide adequate protection are available.

6. The responsibility for developing new testing guidelines lies with NIOSH. NIOSH is pursuing that responsibility and is working closely with an ANSI Ad Hoc Committee from which a report on that criteria is expected by the end of January 1982.

7. While the recent administrative changes made by NIOSH in the Respirator Certification Program are seen as moves in the right direction by manufacturers, the technical aspects of the NIOSH program are viewed as unsatisfactory and are held in continually decreasing esteem by nearly all those present at the public meeting. Lack of senior scientific and technical personnel, the development of an adversary posture, and poor program management were voiced as particular concerns.

8. Support for many of the recommendations regarding updating 30 CFR 11 test criteria, determining respirator performance in the field, establishing a Respirator Research Fund, etc. contained in the Committee's Respirator Research Report was expressed by many of those present at the public meeting.

9. In the current setting and with no other changes, a decision to place the testing aspects of certification in private laboratories rather than continuing such testing within NIOSH would result in no clear benefit to the respirator user and would most likely have adverse results, would create chaos in the certification process due to the time required to get such laboratories up and running with verified procedures, and would likely not result in the application of new testing criteria. Due to the technical credibility problem that NIOSH now has, it is further unlikely that a meaningful audit program of private laboratories could be implemented by NIOSH.

The following recommendations of the Subcommittee are based on the premises that :

- The current respirator certification situation does not permit a simple recommendation with regard to whether NIOSH should or should not test respirators.
- The NIOSH Respirator Certification is necessary and essential to ensure the availability of appropriate protective devices for the American worker.
- The present NIOSH Respirator Certification Program is inadequate to meet the needs of the user community and that NIOSH is viewed with decreasing confidence to perform this essential function.
- Changes to the NIOSH Respirator Certification Program should be sufficiently comprehensive to ensure, with the maximum confidence, that users will be provided with better respirators in the future that are more appropriately suited to the use environment.
- Changes to the Certification Program can be made that will achieve the desired objectives.

Recommendations:

1. NIOSH and MSHA should continue to be the approving authorities for the certification of respirators.

2. NIOSH should revise its fee schedule so that the fees collected appropriately reflect the costs associated with product certification. As nearly all manufacturers support third-party certification, and the associated increased fees, this appears not to present an unacceptable burden to manufacturers.

3. NIOSH and MSHA should proceed with plans to revise the adminstrative and technical aspects of 30 CFR 11 as soon as possible. These amendments should be estabished as the basic certification criteria for the next many years. This Subcommittee is willing to assist in this process, if NIOSH desires.

4. NIOSH, with consensus group participation and with the assistance of recognized consulting experts, should propose an additional aspect to the 30 CFR 11 amendments discussed under (3) above which establishes more stringent levels of required performance for respirators as voluntary alternatives to basic certification. Such an approach would provide, over the years and without the time constraints associated with rules promulgation, the option for manufacturers to obtain certification of superior performance devices that offer the opportunity to develop performance-based marketing practices, thus providing the potential for enhanced return for a more expensive, superior, certified product. For such advanced devices, a means for comprehensive field testing, conditional approvals while additional special field tests are conducted, and the like should be required.

   Such an approach could also be applied to innovative devices that cannot be clearly identified as belonging to a particular 30 CFR 11 respirator category for testing and certification purposes.

   The recommended approach also ensures that the smaller manufacturers are not forced out of the market, that their products do comply with minimum performance requirements, and provides a more appropriate time frame for them to upgrade their products as the superior-category products capture more and more of the market.

5. NIOSH should establish a vigorous field product audit program aimed at ensuring the continued performance to certification standards of production products. In-plant quality assurance audits of certification holders should be terminated.

6. The NIOSH Respirator Research Group should be co-located with the testing and certification groups.

7. NIOSH should publish the results of respirator certification testing and audit testing in a form useful and meaningful to users and purchasing authorities.

8. NIOSH should develop, as part of the administrative aspects of the proposed revision to 30 CFR 11, an official, effective, efficient, and acceptable appeals process that ensures timely resolution to test or audit conflicts and that ensures that products which fail field audit tests in particular that may result in serious health consequences to users are withdrawn from sale and promptly remedied. The existing MSHA "revision of approval" procedures should be examined as an example of one such effective approach.

9. NIOSH should begin to explore the feasibility of "approving" independent laboratories to conduct respirator tests using the NIOSH testing facility as the reference laboratory. Should a laboratory be approved by NIOSH to conduct one or more specific respirator tests, NIOSH could use the laboratory under contract to perform tests as it deems necessary and to support field audit programs, for example. Manufacturers could use such laboratories for verification tests, prior to submission of an application to NIOSH. In the future, NIOSH could use such laboratories to do selected certification tests and, as fees would be more appropriate to the cost, could perhaps require the applicant to pay the laboratory instead of NIOSH, thus easing NIOSH resource constraints.

10. NIOSH should immediately seek to strengthen its certification program, using all means available in the following areas:

    a. Personnel. Senior scientific, technical, and management personnel should be sought for the Morgantown, West Virginia, facility

    b. Administrative. NIOSH needs to provide firm direction to the certification program with an evident resolve to improve the program and establish a policy of fairness and firmness without suggesting favoratism to labor or management

    c. Consultants. NIOSH should have a roster of available consultants from the academic, industrial, and medical communities available for assistance in pursuing this mission.

STATEMENT OF

EARLE P. SHOUB

CONSULTANT

CONCERNING GOVERNMENT

RESPIRATOR

CERTIFICATION

PROGRAM

I am pleased to have this opportunity to respond to Mr. Moran's invitation to present this abbreviated chronological history of the testing and certification by our Government of respiratory protective devices for civilian, industrial purposes. I will also provide as requested some observations about the circumstances in which the certification program originated, was first carried on, fees were charged, and the past advantages of testing only against minimum performance standards.

From the time of the Civil War, bills had almost regularly been introduced into the Congress to establish an agency of the Federal Government to be responsible for the mineral industries of the United States. Although hearings were held on some of the bills and many were passed by one or the other house of the Congress, none passed both houses until 1910. Public pressure which arose out of a series of dramatic mine disasters, especially in underground coal mines, finally provided sufficient encouragement so that, in 1910, the Bureau of Mines was established in the Department of the Interior. The Act establishing the Bureau was amended in 1913 to clarify the duties of the Bureau, the relationship between the Secretary of the Interior and the Director of the Bureau, and the publication of reports of the Bureau's findings.

In its work in health and safety, the Bureau expended much of its efforts in rescue and recovery operations subsequent to mine accidents. These activities were frequently delayed or made additionally hazardous because mine atmospheres, at such times, were often irrespirable. Attention was therefore turned toward obtaining equipment which could overcome these hazards.

By the time, during World War I, when the Axis powers began to use warfare gases, the Bureau had accumulated a considerable fund of knowledge concerning respiratory protection and a staff of chemists and engineers with special interests in the subject. Cooperation between the Bureau and the military produced various simple air-purifying respirators which were effective protection for the Allied military forces.

After the war, it was a logical step for the Bureau to rely upon its Organic Act which directed it ".....to conduct inquiries and scientific and technologic investigations concerning mining, and the preparation, treatment, and utilization of mineral substances with a view to improving health conditions, and increasing safety.....in the mining, quarrying, metallurgical, and other mineral industries;.....,and to disseminate information concerning these subjects in such manner as will best carry out the purposes of this Act" to put its knowledge to practical use.

The respirator testing and approval or certification program began in 1919 with the publication of Schedules 13 and 14 dealing with Permissible Self-Contained Mine Rescue Breathing Apparatus, and Permissible Gas Masks, respectively. In each case, the schedule set forth the procedure in which a manufacturer of a qualifying device could apply to the Bureau to have it examined and listed among the certified or approved devices. The Act stated, "For tests and investigations authorized.....under the provisions of this Act.....a fee sufficient in each case to compensate the Bureau of Mines for the entire cost of the services rendered shall be charged.....".

At the time the program was initiated there was no widespread requirement making mandatory the use of certified respiratory protective devices in industrial or other settings. With the exception of coal mining and a few other relatively small industries, it wasn't until the promulgation of regulations in 1974 under the Occupational Safety and Health Act of 1970 that the use of approved respirators became mandatory. Thus, at the outset, the program was almost entirely voluntary. Moreover, only two of the present five classes of protective devices were included. It was felt by the Bureau personnel, however, that certified devices, where available, were more likely to provide reliable continuing protection than many of the unapproved devices being sold. Manufacturers and employers, it was feared, would ignore any system which inordinately raised costs. Nevertheless, standards had to be set high enough and improved from time to time so as to identify acceptable quality products.

These conflicting goals required some compromise. Fees were kept to a minimum. Testing was carried out in confidence and only after a product passed the required tests was it publicly known it had been examined. Test data for this and other compelling reasons was on a pass-fail basis. Thus, lists of approved devices were published but did not indicate that any certified device was superior to competitive devices. In addition to serving to encourage voluntary participation, not attempting to rank devices recognized that the test procedures could represent only generalized workplace conditions and that, depending on circumstances of use, one might find after more intensive testing that one or two devices might be slightly more desirable than some of the others. Small changes such as a variation in humidity or in a trace contaminant below the hazard level might alter the order by rank.

The evidence is that reliance on this voluntary approval of devices to protect workers was fostered by the policy and practices mentioned above. It is also probable, but not as easily shown, that the less satisfactory devices were discontinued or withdrawn from sale.

The appended partial chronology should give one a general impression of the administrative environment and rate of change in the program. For the main purposes of this document, however, one can skip to 1951 when under the Act of August 31, 1951, the Congress again stated the fees collection requirements. At 31 USC 483a, one finds:

> "It is the sense of the Congress that any work, service, publications, report, document, benefit, privilege, authority, use, franchise, license, permit, certificate, registration, or similar thing of value or utility performed, furnished, provided, granted, prepared, or issued by any Federal agency.....to or for any person.....shall be self-sustaining to the full extent possible, and the head of each Federal agency is authorized by regulation.....to prescribe therefor such fee, charge, or price, if any, as he shall determine.....to be fair and equitable.....Provided further, that nothing contained in this section shall repeal or modify existing statutes providing basis for calculation of any fee.....".

The Federal Coal Mine Health and Safety Act of 1969 included some significant items affecting or potentially affecting the program of testing and approving respirators. Among these were:

1. Sec. 202(h):

> "Respiratory equipment approved by the Secretary (of Interior) and the Secretary of Health, Education, and Welfare shall be made available to all persons whenever exposed to concentrations of respirable dust in excess of the levels required to be maintained under this Act. Use of respirators shall not be substituted for environmental control measures in the active workings. Each operator shall maintain a supply of respiratory equipment adequate to deal with occurrences of respirable dust in the mine atmosphere in excess of the levels required to be maintained under this Act."

2. Sec. 317(n):

> "A self-rescue device approved by the Secretary (of Interior) shall be made available to each miner by the operator which shall be adequate to protect such miner for one hour or longer. Each operator shall train each miner in the use of such device."

3. Sec. 317(o):

> "The Secretary (of Interior) shall prescribe improved methods of assuring that miners are not exposed to atmospheres that are deficient in oxygen."

4. Sec. 318(i):

> "'permissible' as applied to electric face equipment means.....and the other features of which are designed and constructed, in accordance with the specifications of the Secretary (of Interior), to prevent, to the greatest extent possible, other accidents in the use of such equipment; and the regulations of the Secretary (of Interior) or the Director of the Bureau of Mines in effect on the operative date of this title relating to the requirements for investigation, testing, approval, certification, and acceptance of such equipment as permissible shall continue in effect until modified or superceded by the Secretary."

5. Sec. 501(b):

> "Activities under this section in the field of coal mine health shall be carried out by the Secretary of Health, Education, and Welfare, and activities under this section in the field of coal mine safety shall be carried out by the Secretary." (of Interior)

6. Sec. 501(g):

> "The Secretary of Health, Education, and Welfare is authorized to make grants to any public or private agency, institution, or organization, and operators or individuals for research and experiments to develop effective respiratory equipment."

For carrying out the joint respirator testing and certification program envisioned by the Federal Coal Mine Health and Safety Act of 1969, the Secretary of the Interior relied upon the Bureau of Mines, and the Secretary of Health, Education, and Welfare upon the Bureau of Occupational Safety and Health of his department.

A year later when the Occupational Safety and Health Act of 1970 was enacted, the Bureau of Occupational Safety and Health was replaced in the joint endeavor by the newly created National Institute for Occupational Safety and Health (NIOSH). This Act contained some potential sources of additional funds to further the development of an improved testing and certification program. None focus directly on this purpose. For example:

1. Sec. 2(b) (A declaration by the Congress of its purposes and policy.)

2. Sec. 2(b)(5):

> "By providing for research in the field of occupational safety and health, including the pychological factors involved, and by developing innovative methods, techniques, and approaches for dealing with occupational safety and health problems."

3. Sec. 2(b)(7):

> "By providing medical criteria which will assure insofar as practicable that no employee will suffer diminished health, functional capacity, or life expectancy as a result of his work experience."

4. Sec. 6(b)(7):

"Any standard promulgated under this subsection shall prescribe the use of labels or other appropriate forms of warning as are necessary to insure that employees are apprised of all hazards to which they are exposed, relevant symptoms and emergency treatment, and proper conditions and precautions of safe use or exposure. Where appropriate, such standards shall also prescribe suitable protective equipment and control or technological procedures to be used in connection with such hazards and shall provide for monitoring or measuring employee exposure at such locations and intervals, and in such manner as may be necessary for the protection of employees....."

5. Sec. 8(g)(2):

"The Secretary (of Labor) and the Secretary of Health, Education, and Welfare shall each prescribe such rules and regulations as he may deem necessary to carry out their responsibilities under this Act....."

6. Sec. 20(a)(1):

"The Secretary of Health, Education, and Welfare, after consultation with the Secretary (of Labor) and with other appropriate Federal departments and agencies, shall conduct (directly or by grants or contracts) research, experiments, and demonstrations relating to occupational safety and health,.....and relating to innovative methods, techniques, and approaches for dealing with occupational safety and health problems."

7. Sec. 20(c):

"The Secretary (of Labor) is authorized to enter into contracts, agreements, or other arrangements with appropriate public agencies or private organizations for the purpose of conducting studies relating to his responsibilities under this Act. In carrying out his responsibilities under this subsection, the Secretary (of Labor) shall cooperate with the Secretary of Health, Education, and Welfare in order to avoid any duplication of efforts under this section."

8. Sec. 22(e):

> "In addition to any authority vested in the Institute (NIOSH) by other provisions of this section, the Director, in carrying out the functions of the Institute, is authorized to:
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> * * * * *
>
> "(2) receive money and other property donated, bequeathed, or devised, without conditions or restrictions other than it be used for the purposes of the Institute and to use, sell, or otherwise dispose of such property for the purpose of carrying out its functions;
>
> "(3) receive (and use, sell, or otherwise dispose of, in accordance with paragraph (2)), money and other property donated, bequeathed, or devised to the Institute with a condition or restriction, including a condition that the Institute use other funds of the Institute for the purposes of the gift;
>
> * * * * *
>
> "(7) enter into contracts, grants or other arrangements, or modifications thereof to carry out the provisions of this section, and such contracts or modifications thereof may be entered into without performance or other bonds, and without regard to section 3709 of the Revised Statutes, as amended (41 U.S.C. 5), or any other provision of law relating to competitive bidding;....."

The various Bureau of Mines schedules and regulations dealing with respirators were consolidated, amended, and promulgated in 1972 in Title 30, Code of Federal Regulations, Part 11, which provided for joint certification by NIOSH and the Bureau of Mines. In 1974, when the Secretary of the Interior created the Mining Enforcement and Safety Administration (MESA) in his department, these responsibilities of the Bureau of Mines were assigned to the new organization and the program became a joint endeavor of NIOSH and MESA. Very shortly thereafter, also in 1974, the Secretary of Labor promulgated the General Industry regulations of the Occupational Safety and Health Administration, 29 CFR 1910. For the first time, a regulation of wide application specified that only approved respirators were to be used (if available), and the manner of their selection. Subparts 1910.134(b)(11) and 1910.134(c) said:

"(11) Approved or accepted respirators shall be used when they are available. The respirator furnished shall provide adequate respiratory protection against the particular hazard for which it is designed in accordance with standards established by competent authorities....."

"(c) Selection of respirators. Proper selection of respirators shall be made according to the guidance of American National Standard Practices for Respiratory Protection Z88.2-1969."

These and other requirements made it necessary for respirator manufacturers to obtain NIOSH/Bureau of Mines or NIOSH/MESA approvals in order to have their products accepted in the workplace. The testing and approval facility and staff received more applications than anticipated. To place all manufacturers on an equal footing and allow employers an opportunity to secure NIOSH approved devices, it was necessary to modify the 1972 regulations (30 CFR 11) to provide additional time before the approvals of respirators approved only by the Bureau would expire.

The 1969 Act to which reference has been made applied to coal mining and coal miners as well as to any persons or industries who came in contact with coal mining or coal miners or who were affected by them. Another Act, the Federal Metal and Nonmetallic Mine Safety Act, which had been passed in 1966 applied to non-coal mines and miners.

In 1977, Congress enacted the Federal Mine Safety and Health Act of 1977. This law combined most of the provisions of the 1969 and 1966 acts and transferred MESA and its functions from the Department of the Interior to the Department of Labor. A new agency, the Mine Safety and Health Administration, was created in the Department of Labor for this purpose. Accordingly, the Secretary of Labor, through an Assistant Secretary for Occupational Safety and Health, and an Assistant Secretary for Mine Safety and Health, was required to cooperate with the Secretary of Health, Education, and Welfare in matters involving mining and other industries.

In most ways the 1977 Act did not amend the portions of the 1969 Act applying to respirators. It is noteworthy that in the 1977 Act, a subsection dealing with warning labels, and protective equipment which did not appear in the 1969 Act was added. This addition is very similar to Sec. 6(b)(7) of the OSHAct quoted above. The provisions of the 1969 Act described above were unchanged except that NIOSH was included as part of the Department of Health, Education, and Welfare.

To reinforce the impression I wish to convey about the program in the past, I would like to make a personal observation and relate one or two anecdotes.

For perhaps 40 or 45 years when it was not mandatory to use approved devices when available there were only a few manufacturers of approved respiratory protective devices. After a trade association was organized, all the manufacturers were members. Frequent, amicable meetings were held. There was a free exchange of information. The Government and the manufacturers were never adversaries. For example, in about 1966, the Bureau learned that the respirator filters being sold by one or more manufacturers contained a potentially harmful ingredient which possibly could be inhaled by the user. The Bureau official who met shortly thereafter with representatives of the manufacturers in connection with another matter described the findings and the potential hazard. He asked the manufacturers voluntarily to cease using the substance so that a regulation would not be required. An informal agreement resulted.

The manufacture and sale of respirators has now become economically more attractive. There are large and small manufacturers of approved devices who do not belong to the trade association; some do not attend general meetings. New companies are entering the field from time to time. In order to treat all persons equitably, NIOSH must rely upon its promulgated regulations to communicate with its clientele. No other form of communication will suffice. Researchers, investors, and others have a right to expect a full disclosure in the regulations.

The intent of the statute concerning fees appears clear, the Government should endeavor to recover from the applicants the cost of receiving and processing applications, testing, and issuing approvals. Whether the cost of developing and publishing regulations should be included is conjectural. More important is whether funds thus received by NIOSH must be covered into the Treasury as miscellaneous receipts or may they be used to augment the funds available to NIOSH. I believe this could be done if it is really advisable and am prompted to this conclusion for the following reasons:

1. Although the program is presently authorized by the Federal Mine Safety and Health Act of 1977, it is equally being carried out in support of the avowed purposes and regulations promulgated under the Occupational Safety and Health Act of 1970. Authority to accept funds for deposit to the credit of the Government and to expend them in support of authorized programs is contained in the latter Act.

2. The Secretary of Labor, acting through the Assistant Secretary for Mine Safety and Health, is a party to the respirator testing and certification program. The Secretary of Labor, acting through the Assistant Secretary for Occupational Safety and Health, is responsible for enforcement and other operations under the Occupational Safety and Health Act of 1970 which, like the mining law, assigns to the Secretary of Health, Education, and Welfare joint responsibility.

3. I am informed that moneys received by NIOSH from coal mine operators as repayment for coal miner medical examinations required under the Federal Coal Mine Health and Safety Act of 1969 have been disbursed by NIOSH to further its programs. The current (1977) Act contains the same provisions as the 1969 Act.

The final item about which I've been asked to comment is whether the testing of respirators must be conducted by NIOSH on an in-house basis. Section 501(g) which was included in both mining acts, and sections 20(a)(1) and 22(e)(2),(3), and (7) of the OSHAct appear to me to extend sufficient authority to the Secretary of Health, Education, and Welfare (now Secretary of Health and Human Services) to have the testing performed for him in non-Governmental facilities. I doubt, however, that persons outside the two Departments involved, Health and Human Services, and Labor, may be authorized to exercise either or both the Secretary's authority to issue the approval document.

CHRONOLOGY: TESTING and CERTIFICATION

1910	Organic Act of Bureau of Mines, Department of the Interior.
1913	Revision of Organic Act of Bureau of Mines, Department of the Interior.
1913-1918	Bureau of Mines engaged in rescue and recovery operations, especially in underground coal mines where toxic gases (CO), and oxygen deficiency were frequent hazards which severely interfered with rescue.
1917-1918	World War I research into gas masks for military use by Bureau of Mines.
1919	Bureau of Mines Schedule 13 promulgated, Procedure for Establishing a List of Permissible Self-Contained Mine Rescue Breathing Apparatus, Fees, Character of Tests, and Conditions Under Which Mine Rescue Breathing Apparatus Will be Tested.
1919	Bureau of Mines Schedule 14, Procedure for Establishing a List of Permissible Gas Masks, Fees, Character of Tests, and Conditions Under Which Gas Masks Will be Tested.
1920	Supplement to Schedule 14.
1923	Bureau of Mines Schedule 14A (Revision of Schedule 14).
1925	Executive Order of President of the United States. Transferred Bureau of Mines to Department of Commerce.
1927	Bureau of Mines Schedule 19, Procedure for Testing Hose Masks for Permissibility.
1930	Bureau of Mines Schedule 13A (Revision of Schedule 13).
1930	Bureau of Mines Schedule 14B (Revision of Schedule 14A).
1934	Executive Order of President of the United States. Transferred Bureau of Mines back to Department of the Interior.
1934	Bureau of Mines Schedule 14C (Revision of Schedule 14B).

1934	Bureau of Mines Schedule 21, Procedure for Testing Filter-Type Dust, Fume, and Mist Respirators for Permissibility.
1934	Supplement to Schedule 19.
1935	Bureau of Mines Schedule 14D (Revision of Schedule 14C).
1935	Bureau of Mines Schedule 13B (Revision of Schedule 13A).
1936	Executive Order of President of the United States. Transferred Bureau of Mines back to Department of the Interior.
1937	Bureau of Mines Schedule 19A (Revision of Schedule 19 and Supplement, enlarged to include special hose masks without blowers, air-line respirators and abrasive blasting helmets, hoods, or masks).
1941	Bureau of Mines Schedule 14E (Revision of Schedule 14D).
1944	Bureau of Mines Schedule 23, Procedure for Testing Nonemergency Gas Respirators (Chemical Cartridge Respirators) for Permissibility.
1946	Bureau of Mines Schedule 13C (Revision of Schedule 13B).
1948	Amendment to Bureau of Mines Schedule 19A (As amended on March 13, 1948, to include Type C, demand-class supplied-air respirators).
1951	31 USC 483a Services as self-sustaining; uniformity; regulations; deposit in Treasury; effect on other laws.
1955	Bureau of Mines Schedule 19B (Revision of Schedule 19A).
1955	Bureau of Mines Schedule 21A (Revision of Schedule 21).
1955	Bureau of Mines Schedule 14F (Revision of Schedule 14E).

1955	Bureau of Mines Schedule 23A (Revision of Schedule 23).
1956	Bureau of Mines Schedule 23B (Revision of Schedule 23A).
1963	Amendment to Schedule 19B (As amended on November 6, 1963, to include pressure-demand Type C supplied-air respirators, to increase the maximum allowable length of air hose for Type A supplied-air respirators from 150 to 300 feet, and to permit the use of motor-operated as well as hand-operated blowers to furnish air for Type A supplied-air respirators).
1965	All Schedules, Revision of Fees.
1965	Bureau of Mines Schedule 21B (Revision of Schedule 21A).
1968	Bureau of Mines Schedule 13E (Revision of Schedule 13D).
1968	Amendment to Schedule 19B.
1969	Federal Coal Mine Health and Safety Act of 1969 signed into law.
1970	Occupational Safety and Health Act of 1970 signed into law. NIOSH created.
1972	Part 11 of Title 30, Code of Federal Regulations (30 CFR 11) promulgated. Respirator certification jointly administered by NIOSH and Bureau of Mines.
1974	Bureau of Mines Functions transferred to Mine Enforcement and Safety Administration (MESA) of Department of the Interior. Joint program now NIOSH/MESA.
1974	OSHA Safety and Health Standards, 29 CFR 1910, promulgated.
1977-1978	Federal Mine Safety and Health Amendments Act of 1977 (Federal Mine Safety and Health Act of 1977) enacted. Mine Safety and Health Administration (MSHA), Department of Labor, created. MESA functions transferred to MSHA.

Earle P. Shoub
Consultant

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NIOSH Respirator Research Program

Presented to

Respirator Subcommittee

of

The Mine Health Advisory

Committee

by

James A. Oppold, Ph.D, PE, CSP

Director, Division of Safety Research,

NIOSH, CDC, PHS, DHHS

August 13 and 14, 1981

One goal of NIOSH, through the Division of Safety Research, (DSR) is increasing worker protection through improved personal protective equipment (PPE) and hazard measuring instruments. Today I will devote my time to a brief explanation of NIOSH's Respirator Research Program which is a part of DSR's PPE research effort.

Prior to 1979 the Institute's respirator research effort was conducted by the Division of Physical Sciences and Engineering in Cincinnati, but in May of that year a decision was made to move all protective equipment research to the Division of Safety Research, Morgantown, West Virginia. Currently, the respirator research staff of DSR is located in the Testing and Certification Branch.

In order to better focus the scarce resources available for respirator research, it was decided that we should attempt to first determine what should be the primary objectives for the program. In pursuit of that end, we participated in the 1979 International Symposium on Personal Protective Equipment in Spain and then sponsored the First International Respirator Research Workshop in September, 1980 in Morgantown. Based on the learned opinion of the participants in both meetings and the research efforts of our own staff, we concluded that the ideal respirator research program should be striving to develop a respirator with the following qualities:

First, the respirator should be a light-weight full face type which workers would find comfortable and desirable to wear;

Second, it should fit the contours of any adult face so as to make a perfect seal with the skin at all times;

Third, it should protect against any hazardous gas, vapor, mist, fume, particulate, aerosol, and also supply breathing air in an oxygen deficient environment, and;

Fourth, it should be inexpensive, simple to operate and maintain, and highly reliable.

Such a respirator would be a safety equipment manufacturer's dream and would have virtually unlimited marketability. As a result, it is just such a device that respirator manufacturers are attempting to develop from the expenditure of millions of dollars. Since NIOSH-DSR was not established for the purpose of being the research and development arm of safety equipment manufacturers, we intend to leave the production of the ideal respirator to the private sector. Our research efforts will be directed, rather, at the development of respirator performance criteria which will subject respirators to performance standards that assure users of the maximum protection possible according to the current state of the art. We will also strive to assure that NIOSH-promulgated performance criteria are not only technologically feasible

but also provide an incentive for technological innovation. Hopefully, such an effort by NIOSH, if undertaken with reason and discretion, will spur manufacturers to continually strive toward the production of the ideal respirator.

A major factor which complicates our efforts in this area is the fact that currently the standards and criteria used by NIOSH to evaluate respirator performance are written as formally promulgated regulations in 30 CFR Part 11. Because the standards and criteria therein are part of the Federal regulations; their revision, amendment or deletion is - while theoretically possible - an exceedingly cumbersome and time-consuming process. This fact along with the lack of agreement on an alternative method for promulgating performance standards and criteria, has resulted in 30 CFR Part 11 going substantially unchanged for many years. Such static regulations in a very dynamic field have resulted in performance criteria and standards that in some instances are simply irrelevant, and in others dangerously antiquated.

In order for any program to be responsive to current needs, the program must be sufficiently flexible in its structure to accomodate changes on a dynamic basis. To alleviate some of the problems cited as a result of the relative rigidity of the current respirator approval regulations, modifications are being considered for incorporating a "feedback" mechanism which could continually provide program input on needed changes and serve to monitor program impact. NIOSH recently established a Field Investigation Group, whose mission is to study problems with MSHA/NIOSH approved respirators in actual field use. This group acts as a conduit to funnel end user concerns into program priorities. Another element under consideration for inclusion in the approval process would be to place responsibility for verifying performance in the field on the manufacturer of the device. Such dual input could enhance the responsiveness of the respirator approval program to current concerns.

By the first of the year, we hope to have a set of recommended revisions to 30 CFR Part 11, which will address the current problems and hopefully avoid similar problems in the future. We believe it is essential that both efforts must be successful if we are to have a first rate respirator research program.

Now, let me elaborate on the present status of our respirator program activities and attempt to establish a perspective for our future directions in this area.

Presently, NIOSH of the Department of Health and Human Services has a joint mandate with MSHA of the Department of Labor to approve respirators according to the requirements of 30 CFR Part 11. Considering that these requirements were established primarily for applications in the mining industry, in many instances they lack the versatility of applicability to the broad spectrum of industrial environments in which such devices are relied upon today. Adherence to the specific tests as required in Part 11 requirements rather than on performance requirements, has served to restrict program responsiveness. This has contributed to a false sense of assurance that conformance with Part 11 requirements implies applicability in a wide variety of situations not in fact addressed by the Part 11 tests.

The NIOSH respirator research program , if it is truly to be meaningful, must be a program that concentrates its resources on applied research. Such research should be primarily directed at the development and continual monitoring of scientifically validated performance criteria which represent a wide variety of field use conditions. Because of the static nature of the existing performance requirements which are incorporated in Part 11, actual field use conditions are frequently not duplicated in the NIOSH respirator approval tests.

During the time when many of the existing performance criteria included in Part 11 were developed, dust was the major source of concern. As a result, many of the performance tests required for approval under Part 11 were aimed at meeting requirments for dust filtration. Today, many other chemical agents have been identified, which are in some cases even more hazardous than dusts. Many substances, thought to be safe yesterday, are known hazards today; and substances thought to be safe at certain levels yesterday may be found to be hazardous in much smaller quantities tomorrow. Unfortunately, the performance criteria to which we are bound by Part 11, while quite reliably predictive of respirator performance against most dusts, can seldom be relied upon to be equally predictive of respirator performance when challenged by other chemical agents.

Another example of the problems we confront as a consequence of having to utilize the specific tests mandated by Part 11 involves the testing of organic vapor respirators against carbon tetrachloride. We have learned that there are many compounds that a user may encounter in the workplace that have sorbent breakthrough times that are much shorter than carbon tetrachloride. Yet, because our test criteria are mandated in Part 11, an organic vapor respirator that performs satifactorily against carbon tetrachloride is approved by NIOSH even when we have reason to believe that the respirator may be used in environments contaminated by substances with significantly shorter sorbent times. The difficulty may be even further compounded by the fact that Part 11 makes no provision for evaluating respirators under a variety of environmental conditions. Our experience has shown that temperature and humidity variations, for example, can also significantly affect the performance of respirators. It is this kind of information and knowledge that is frequently acquired through our respirator research program. This knowledge must be incorporated into our performance criteria. However, our current ability to do so, as indicated earlier, is severely restricted.

We are convinced that the revision of Part 11 so as to permit easier revision and updating of performance requirements is essential, and we are currently in the process of writing recommended revisions which we intend to have completed for public review and comment by the first of the year. A number of these revisions were discussed at a Testing and Certification Public Meeting held in Gaithersburg, July, 1980.

Meanwhile, our respirator research program is forging ahead. We assume that if our research results indicate the need for changes in respirator performance requirements that our efforts to revise Part 11 to permit the incorporation of such changes with a minimum of effort will have been successful.

More specifically, our respirator research program will involve four major projects in addition to the Part 11 revision. The first project involves research on the sorbent performance of air purifying respirators. As indicated above, the existing Part 11 provisions appear to be seriously deficient in evaluating sorbent performance against actual use conditions. We are working on the development of new methods for evaluating sorbent efficiency over a much wider range of organic compounds and for evaluating the effects of multiple compound exposures on sorbent efficiency. We also intend to look at environmental factors, storage and handling, breathing resistance, end of service life indicators, durability and reliability.

Our second research thrust involves the self contained breathing appraratus (SCBA). We intend to examine the adequacy of SCBA performance in special circumstances, such as in the fire fighting service and in mine self rescue. In addition we intend to examine the ways in which the operational integrity of an SCBA is affected by temperature variations, moisture, flames, etc. We also intend to examine the issue of the approval of closed circuit positive pressure breathing apparatus, the role of weight of an SCBA as a factor in user performance, and the issue of service life duration and warning alarm sound levels. We also hope to eventually address other performance issues associated with demand, pressure demand, and continuous flow breathing systems.

The third project involves the human response to use of respirators. We plan to examine such issues as the possible adverse psychological response to respirator use, human behavior factors involved in a worker's refusal or reluctance to wear a respirator, and the degree of work impairment that may result from use of various types of respirators. The Division of Safety Research is cooperating with NIOSH's Division of Training and Manpower Development as well as other agencies, including MSHA, to assure that effective training programs are implemented. Such training will accentuate the proper use, care, and maintenance of respirators.

The fourth project involves the funding of a contract effort to develop a statistical method for prediction of face fit characteristics of a respirator as applied to the general population through the use of a small number of measurements.

What are the obstacles to the accomplishment of our goal of establishing the effective respirator research program which we have described? The first obstacle has already been discussed. That is, the revision of 30 CFR Part 11. As indicated we are currently attempting to remedy that problem.

The second problem is certainly not a new problem but is nevertheless a very real one. The problem involves staffing. The current respirator research staff includes five people. We have been seeking additional staff positions and have finally been awarded five positions, but are likely to have difficulty in filling those positions because of the current hiring and personnel freeze. Adequate funding generally is, as might be expected, a continuing problem.

However, we are confident that these obstacles can and will be overcome and that NIOSH can achieve its goal of becoming a world leader and supporter of scientific respirator research. To achieve this goal we are striving to establish a core of highly qualified and motivated respirator research personnel at NIOSH and to provide them with sufficient resources and laboratory facilities to accomplish the goal. In addition, we wish to serve as a stimulus to the conduct of respirator research by others, a clearinghouse for materials relevant to this field, a coordinator and sponsor of conferences and symposia on respirator research and a source of support for the training of professional personnel in the proper selection, use and maintenance of respirators.

Board of Governors of the Federal Reserve System, July 20, 1981.

D. Michael Manies,

Assistant Secretary of the Board.

[FR Doc. 81-21858 Filed 7-24-81; 8:45 am]

BILLING CODE 6210-01-M

Sherburn Bancshares, Inc.; Formation of Bank Holding Company

Sherburn Bancshares, Inc., Sherburn, Minnesota, has applied for the Board's approval under section 3(a)(1) of the Bank Holding Company Act (12 U.S.C. 1842(a)(1)) to become a bank holding company by acquiring 100 per cent of the voting shares, less directors' qualifying shares, of Farmers State Bank of Sherburn, Sherburn, Minnesota. The factors that are considered in acting on the application are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

The application may be inspected at the offices of the Board of Governors or at the Federal Reserve Bank of Minneapolis. Any person wishing to comment on the application should submit views in writing to the Reserve Bank, to be received not later than August 20, 1981. Any comment on an application that requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.

Board of Governors of the Federal Reserve System, July 21, 1981.

D. Michael Manies,

Assistant Secretary of the Board.

[FR Doc. 81-21859 Filed 7-24-81; 8:45 am]

BILLING CODE 6210-01-M

Tri-State Investment Corp.; Acquisition of Bank

Tri-State Investment Corporation, Pensacola, Florida, has applied for the Board's approval under section 3(a)(3) of the Bank Holding Company Act (12 U.S.C. 1842(a)(3)) to acquire at least 55.5 percent of the voting shares of the West Florida Bank, Pensacola, Florida. The factors that are considered in acting on the application are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

The application may be inspected at the offices of the Board of Governors or at the Federal Reserve Bank of Atlanta. Any person wishing to comment on the application should submit views in writing to the Reserve Bank to be received not later than August 21, 1981. Any comment on an application that requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.

Board of Governors of the Federal Reserve System, July 22, 1981.

D. Michael Manies,

Assistant Secretary of the Board.

[FR Doc. 81-21873 Filed 7-24-81; 8:45 am]

BILLING CODE 6210-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control

Machine/Presence Sensing Device Performance Studies; Open Meeting

The following meeting will be convened by the National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and will be open to the public for observation and participation, limited only by space available:

Machine/Presence Sensing Device Performance Studies

Date: August 25, 1981.

Time: 9 a.m. to 4 p.m.

Place: Ramada Inn, VIP Room, Route 119 South and U.S. 48, Morgantown, West Virginia 26505.

Purpose: To discuss and critically evaluate scientific content of recent studies of presence sensing machine safeguards, particularly R-F type machine safety devices.

Additional information may be obtained from: John Etherton, Division of Safety Research, National Institute for Occupational Safety and Health, Centers for Disease Control, 944 Chestnut Ridge Road, Morgantown, West Virginia 26505, Telephone: (305) 599-7454.

Dated: July 21, 1981.

William H. Foege,

Director, Centers for Disease Control.

[FR Doc. 81-21827 Filed 7-24-81; 8:45 am]

BILLING CODE 4110-87-M

Mine Health Research Advisory Committee, Respirator Research Subcommittee; Meeting

In accordance with Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease Control announces the following National Institute for Occupational Safety and Health (NIOSH) Committee meeting:

Name: Respirator Research Subcommittee of the Mine Health Research Advisory Committee.

Date: August 13-14, 1981.

Time: 8:30 a.m. to 4:30 p.m.

Place: Conference Room M, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857.

Type of Meeting: Open.

Contact Person: Jon R. May, Ph.D., Special Assistant to the Director (for Testing and Certification), National Institute for Occupational Safety and Health, Centers for Disease Control, 5600 Fishers Lane, Room 8A-53, Rockville, MD 20857, Telephone: (301) 443-3680.

Purpose: To discuss and obtain comments relevant to the development of the NIOSH respiratory research program.

The Mine Health Research Advisory Committee (MHRAC) was established by the Federal Mine Safety and Health Act of 1977. This legislation also provides the basis for the NIOSH/MSHA Respirator Certification Regulations under 30 CFR Part 11. The subcommittee, composed of members of the MHRAC, will provide to the Director of NIOSH, recommendations appropriate to the NIOSH respirator research program particularly with regard to respirator research objectives and priorities. Resource personnel from among the users of respirators will be invited to assist the subcommittee.

Viewpoints and suggestions from manufacturers and users of respirators, industry, organized labor, academia, other government agencies, and any other interested parties are invited. Interested parties wishing to address the meeting are requested to contact Dr. Jon May at the address above in order to be assured appropriate time for presentation. Presentations by interested parties must be accompanied by four copies of the text of the presentation to be made before the subcommittee. Such test should be provided to the subcommittee chairperson, John B. Moran, Post Office Box 42, Boyds, MD 20841, prior to or at the subcommittee meeting.

The subcommittee will prepare and present its report on this subject to the MHRAC at their next meeting currently schedule for October 13-14, 1981. The final subcommittee report, as approved by the MHRAC, will be available subsequent to the October meeting.

Dated: July 21, 1981.

William H. Foege,

Director, Centers for Disease Control.

[FR Doc. 81-21826 Filed 7-24-81; 8:45 am]

BILLING CODE 4110-87-M

Public Health Service

National Council on Health Care Technology; Meeting

Pursuant to the Federal Advisory

Attendees at the NIOSH Respirator Research Subcommittee of the Mine Health Research Advisory Committee meeting on August 13, 1981, in Conference Room M, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland.

Committee members:

Cander, Leon, M.D.
Jacobson, Murray (MSHA ex officio alternate)
Moran, John B., M.S., Chairperson
Werner, Donald L., M.D.

May, Jon R., Ph.D., NIOSH, Executive Secretary

Resource individuals:

Duffy, Richard - International Assn. of Fire Fighters, AFL-CIO, DC
Hendricks, Lynette - Nuclear Regulatory Commission, Rockville, MD
Mattheis, Darrell K. - Organization of Resource Counselors, DC
Miller, Wayde B., Jr. - Mine Safety Appliances, Pittsburgh, PA
Oppold, James A., Ph.D. - NIOSH - Morgantown, WV
Walker, Thomas J. - Kaiser Aluminum & Chemical Corp., Oakland, CA
Wilmes, Don - 3M Company, St. Paul, MN
Zdroek, Joseph Z. - American Optical Corp., Southbridge, MA

Others present:

Campbell, Donald L., Ph.D. - NIOSH - Morgantown, WV
Dobbin, Ronald D. - NIOSH - Rockville, MD
Fishman, Sheldon A. - NIOSH - Rockville, MD
Fleming, Roy M., Sc.D. - NIOSH - Rockville, MD
Harris, Elliot S., Ph.D. - NIOSH - Rockville, MD
Johnson, Mary Jane - Pall Corporation, Alexandria, VA
Myers, Melvin L. - NIOSH - Rockville, MD
Shapiro, Steve R. - NIOSH - Rockville, MD
Turcic, Peter M. - MSHA - Arlington, VA
Wilberger, Margaret - NIOSH - Rockville, MD

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A STRATEGY

FOR THE

RESPIRATORY PROTECTION

RESEARCH PROGRAM

Developed by

DIVISION OF SAFETY RESEARCH

October 21, 1980

MISSION STATEMENT AND PROGRAM LOGIC

The mission of the Respiratory Protection Research Program is to eliminate ineffective respiratory protection, encourage innovation in respiratory protective devices or systems and stimulate alternative, more acceptable methods of minimizing respiratory exposures to workers through a sound program of research; incentives for users and manufacturers of respiratory protective equipment; and regulatory leverage; all of which will help create an environment that will motivate industry to profit in accordance with their ability to design, manufacture, distribute, and insure effective use of respiratory protective equipment.

There are two fundamental ways to achieve this mission: (1) create an environment to stimulate improved performance and acceptability of available respirators, (2) improved methods for selection, and use of respirators. The first is a question of respirator hardware, while the second is one of software. A complete program must consider both.

Consider now the first of two fundamental questions, "What can NIOSH do to improve respirator performance and acceptability?" It is proposed that there are three ways for NIOSH to stimulate the development of improved respirators.

1. Provide incentive for respirator manufacturers and users to pursue improved performance and acceptability of respirators. An environment will be created in which it will be in the self-interests of both manufacturers and users of respirators to constantly strive to produce or acquire improved innovative respirators. This is one of the most important elements of this program because it encompasses the essence of "feeding back" acceptability and performance information to the users and manufacturers of respirators.

   The activities involved in this element of the program cross the activities associated with several other program elements and include: (1) publish findings on the performance ratings of commercially available respirators; (2) include state-of-knowledge performance standards in the respirator cerification program to assure a minimum level of performance; (3) develop a "Certified Respirator Selection Manual" to expand the role of our present "List of Certified Equipment" and to emphasize the use of joint NIOSH/OSHA decision logic; (4) conduct field consultation similar to health hazard evaluation activities to develop

and provide field experience concerning the selection and use of respirators in particular work situations; (5) develop a work practices document for employer's respiratoar programs; and (6) provide technical support and recommendations for standard setting activities

2. Define respirator performance through technically sound performance standards. This is another key element of the program. Accordingly, the development of respirator performance standards will receive emphasis in this program.

   In order to design and build a better respirator it is first necessary to know what a better respirator is. Performance standards are the means to define a better respirator.

   As indicated in the accompanying chart, there are two basic program activities necessary to develop a performance standard: (1) the development of performance levels that are based on the physiological needs of the wearer, a knowledge use environment, and the present state-of-the-art; and (2) the development of relevant, documented, validated test procedures.

3. Provide the "tools" for a manufacturer to meaningfully evaluate the performance of its respirators. Having defined the "goal" (performance standards) and having provided the "incentives", it is also possible for NIOSH to provide many of the "means" by stimulating (1) the availability of commercial test equipment and (2) the development of competent private laboratories to do respirator testing. This is the last step in the cycle. After having completed the background necessary to develop performance standards this last step will be an easy one for NIOSH.

   As an added benefit of these activities, the NIOSH certification program will be able to utilize private labs in its routine testing program. In order for the certification program to use private labs both "validated" test procedures and "competent" private labs must be available. The program presented here will develop both.

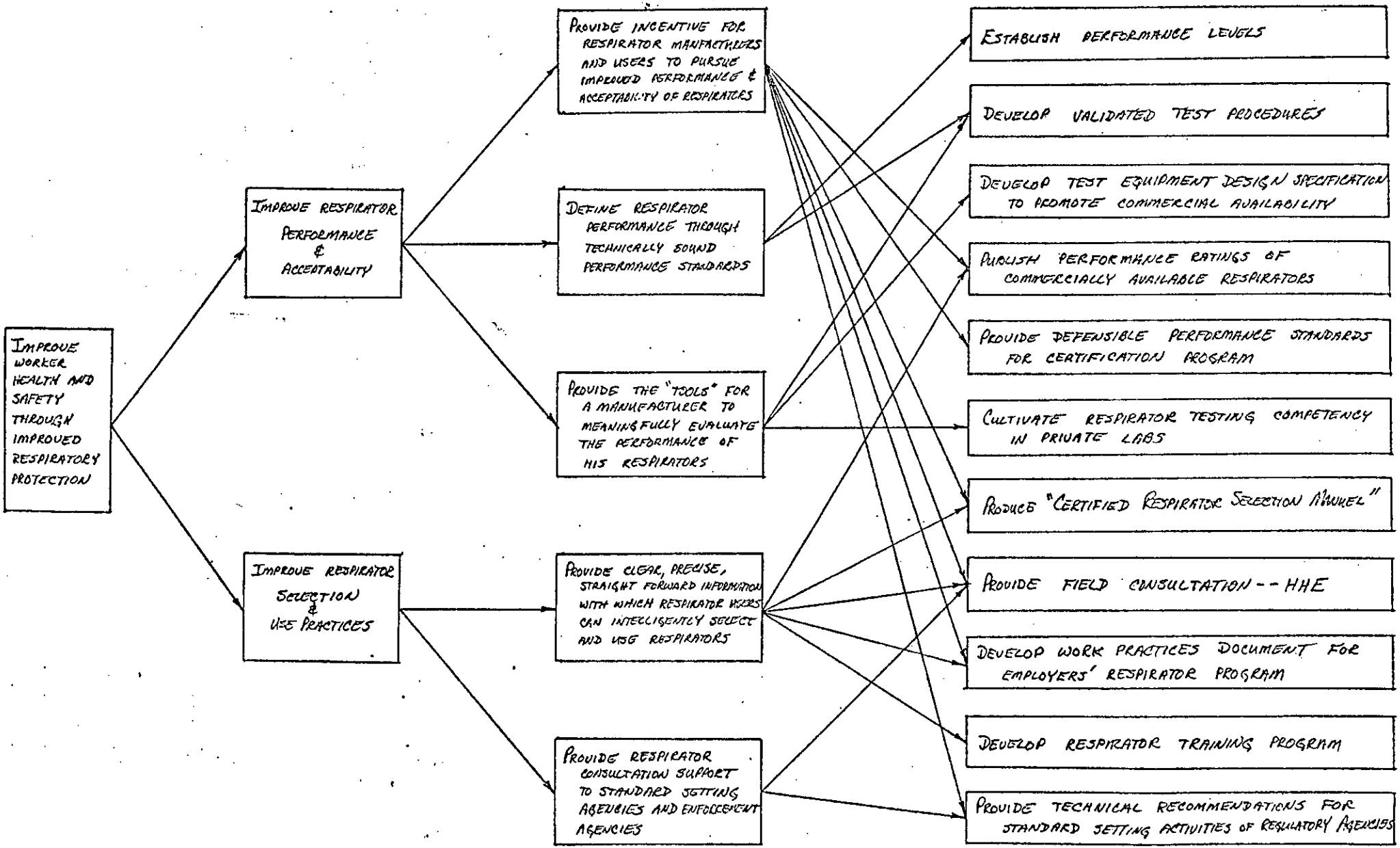
   As shown in the accompanying chart there are three contributing activities. When they are complete it will be possible, and relatively easy, for a conscientious manufacturer to evaluate, for example, a new respirator design.. Relevant, reproducible test methods will be available. Test equipment is designed and available. Evaluation can be done either in-house or by private laboratories. (See "Program Activities" section for a detailed description of each activity.)

Consider now the second fundamental question, "What can NIOSH do to improve respirator selection and use practices"? It is proposed that there are two basic means for NIOSH to improve selection and use practices.

1. Provide clear, precise straight-forward information with which respirator users can intelligently select and use respirators. To achieve this, five activities are proposed: (1) publish performance ratings of all commercially available respirators, (2) develop "Certified Respirator Selection Manual" to expand the role of our present "List of NIOSH Certified Equipment" and to emphasize the use of the Joint NIOSH/OSHA Decision Logic, (3) Conduct field consultation similar to health hazard evaluation activities to develop and provide field experience concerning the selection and use of respirators in particular work situations, (4) develop a work practices document for employer's respirator programs, and (5) develop training program on proper selection and user of respirators.

2. Provide respirator consultation and support to standard setting and enforcement agencies. Contributing to this end will be the program activities of (1) providing respirator selection and use consultation and assistance on an "as needed" basis to field staff of regulatory agencies, and (2) provide technical support for standard setting activities.

CHART I. -- PROGRAM MISSION to PROGRAM ACTIVITIES



PROGRAM ACTIVITIES

This section describes each of the program activities to be undertaken in the proposed respirator research program.

Incentive Producing Activities

Underlying the "Program Activities" described in this section is the very important concept of implementation of the necessary incentives that will result in (1) respirator manufacturers designing respirators with continually improved performance and worker acceptance; and (2) respirator purchasers (i.e., the purchaser is not usually the actual user) buying respirators with continually improved performance and worker acceptance.

As a result of the knowledge and experience gained from the recent Respirator Research Workshop; the major needs identified in response to the Workshop theme of "Respirator Research, Where It Needs To Go" include: (1) the often overlooked but very important fact that most workers, 80 - 85%, who should have respiratory protection do not have it nor are they aware of needing it; (2) where respirators are used, they are often not selected or used properly; (3) when respirators are selected and used properly, the respirators are often unreliable, inadequate or otherwise unacceptable to the worker.

It is the intent of the activities associated with this "incentives producing" element of the program to create "feedback" from the worker on the acceptability of respirators and "feedback" from the purchasers on the overall performance of respirators.

Presently, respirators are manufactured to meet certification standards based on test procedures which may or may not apply to the hazards in the work place. This situation causes the purchaser to buy the lowest price respirator that is "NIOSH certified". There is no feedback whatsover from the worker concerning acceptability or from the purchaser concerning performance.

The publication of "performance ratings", establishment of state-of-knowledge "performance standards" and the "Certified Respirator Selection Manual" will provide the purchasers with reliable information for selection of respirators based on performance. The "Field consultation" activities and the "Work Practices Document" will define the characteristics of a good respirator program and a method for allowing the worker to have a voice in the selection of the most "acceptable" respirator.

Finally, the technical support and recommendations for standard setting activities will, if implemented, provide the regulatory leverage or incentive to establish the requirement for "feedback" from workers and purchasers.

The situation which will result should reflect back to respirator manufacturers the demand for devices with greater acceptance and performance. This reflected demand will in turn effect sales and profits. Ultimately, the free market forces, with a little regulatory incentive, will reward those respirator manufacturers (through greater sales and profits) who perform best (i.e., provide the respirators that are selected by workers for greater acceptability and by purchasers for greater performance and competitive prices).

Performance Levels

The proposed program will establish the acceptable level of performance for each significant attribute of the respirator. The attributes to be considered are numerous: inhaltion resistance, impact resistance of the facepiece, protection factor, exhalation resistance, reliability, durability, weight, service life, corrosion resistance, facepiece optics, comfort, field of vision, flammability, mechanical integrity, maintainability, simplicity of operation, storage life, etc. This list is long even though it is quite incomplete.

The first step of the research program must be to simply list and define, for each basic type of respirator, the attributes to be considered in a performance standard. The next step would be to prioritize the list of terms of importance to the user. And finally, in the established order of importance, set out to develop a performance standard for each.

That first step should be done with a small working group established for that specific purpose. That group should not be limited to NIOSH personnel.

The respirator attributes can be grouped into four basic categories: (1) those that relate to the primary protection provided by the device, (2) those relating to the ability of the device to reliably provide that protection in the full variety of use situations, (3) those attributes that relate to the compatibility of the device to the physiological needs of the wearer, and (4) those that relate to the inherent safety of the devices (the respirator itself must not be a hazard). Certain of these categories are fundamentally more significant than others. Also, within a category, certain attributes are more important than others. In thinking through these categories, it seems that the most important is the first, the category containing

the attributes that relate to the primary protection provided by the respirator. Within that group of attributes there is one that seems to be the most significant. That is the attribute of a protection factor. It is disappointing to realize that this most important attribute is not considered in this nation's respirator performance standards.

Once the program has established a prioritized listing of relevant attributes, the following coordinated activities will be conducted in parallel. For each attribute:

1. Establish performance levels considering each of the following:

   A. The level of protection required.

   B. The physiological needs of the wearer.

   C. The environment and conditions in which the device is to be used.

   D. The current state-of-the-art for respirator design.

2. Develop test procedures in accordance with the principles presented in the following section.

Test Procedures

The development of performance levels and test procedures is the heart of this research program. They are the foundation upon which the remainder of the program is built. It is, however, important to define the basic terms used here. As used here a "performance standard" consists of two parts: a "test procedure" and a "required performance level". The test procedure is the "meterstick" and the required performance level is the required "length".

The development of performance levels and the development of test procedures are presented separately to emphasize the difference between the two. It is quite common for standard setting activities to lose sight of this difference and thereby compromise the integrity of the performance standard. There is, for examaple, a tendency to modify the test procedure in order to adjust the severity of the test. That is a mistake that results in the test procedure being less realistic. Instead, the severity of a performance standard must be controlled by manipulating the performance level, not the test procedure.

The following steps in the development of a test procedure will be followed:

1. Identify the attribute to be measured.

2. Develop written test procedures and test apparatus.

3. Determine single operator consistency.

4. Conduct intralaboratory test validation.

5. Conduct interlaboratory test validation, if possible.

The result of this program will be test procedures with the following main characteristics:

A. The test procedures must be realistic in that they simulate the conditions of use.

B. The test procedures must yield consistent results.

C. The test procedures must be reproducible from laboratory to laboratory. To demonstrate this reproducibility, validation of the test procedure is necessary.

D. The test procedures must produce a figure-of-merit. That is, they must produce a quantitative result which is a measure of performance.

E. The test procedure must be relevant. That is, it must measure an attribute that is truly significant to the user of the respirator.

F. The test procedure must be complete. They must define the number of samples, test equipment and statistical analysis of data.

G. The test procedure must obtain the maximum information from smallest number of samples. Therefore parametric tests are preferred over non-parametric tests.

Test procedure development will be conducted under contract to the maximum extent possible. Initial development will be conducted in-house and then followed through by the contract effort. Contracts will be used as an extension of the resources available to staff researchers--not as a replacement for staff researchers.

Several individual test procedures will be developed simultaneously. The development of individual test prcedures will be conducted nearly independently of one another. The number being developed at any one time will therefore be limited only by program resources.

A performance standard is incomplete if it does not include both a specific performance level and a test procedure. The only exception is an attribute that can be defined from "first principles" (such as length, optical density, mass, etc.). In these cases no test procedure need by developed.

The above discussion applied to test procedures that are to be used by testing laboratories (NIOSH's, manufacturers, or private). There is also a need for "field" test procedures. The face-fit test is an example. The test procedure suitable for laboratory testing may not be suitable as a field test. When different tests are found to be necessary, the program will develop both.

Test Equipment Specifications

The test procedures developed as previously described will have the most impact if they are widely used. Wide spread usage is most likely to occur when the test instrumentation is commercially available. After a test procedure is developed, this proposed program will take the final and relatively easy step to encourage the commercial availability of test systems.

We have in the past done this for other types of personal protective equipment. As a result, there is a commercially available test system for safety shoe impact testing. There is also a commercially available, state-of-the-art safety helmet impact test system, complete with force transducers and instrumentation. The commercial cost of both of these systems is only a fraction of the cost, if a manufacturer, say, were to design and build their own individual system. Both of these systems in the hands of manufacturers have turned out to be far more important than simple testing tools; they are also very powerfully design tools.

Performance Reports

The program will evaluate currently available respirators in terms of newly developed test procedures. The results will be included in the performance reports that will be published by the Certification Program.

Consider the following example. Suppose that through other activities of the program three new test procedures have been developed for a particular class of SCBA's. These three consider important respirator attributes which, at that time, are not considered in the certification program: A flammability test, a field of vision test, and a ballistic impact facepiece test. Also, suppose that two improved test procedures are developed to replace those already in the certification program. These two are improvements in that they produce information more relevant to the health and safety of the respirator wearer. These five tests would serve as the basis of a testing program to evaluate all commercially available respirators of that class. The results of that testing program would be integrated with the test data produced by the certification program and then published in a single report.

The benefits of this program activity are threefold:

A. It will provide information important to the selection of the most suitable respirator. Or, more importantly, the information would indicate that some, or perhaps all, commercially available (and certified) equipment may be unsuitable in certain work situations. For example, the flammability of respirators is not considered in our present certification requirements. However, some respirators are quite flammable, while others are quite flame resistant. The worker who may be exposed to open flames or other source of ignition, needs to know one from the other.

B. It will stimulate healthy competition among manufacturers to improve their respirators. If the program is successful, it will lead and encourage innovation rather than follow innovation as so many standard setting activities unfortunately do.

C. It will also set the stage for the addition of these new tests into the formal certification program.

The testing could be performed either in-house or by private labs under contract. Since the staff will have an intimate understanding of the test procedures, by virtue of having developed them, it will be relatively easy for them to effectively monitor testing conducted by a private laboratory.

The analysis of test results and the preparation of reports for publication should be performed by the in-house staff. If private labs are used, they would only produce test data. All reports for publication would be prepared by the in-house staff.

Certification Criteria

The development of respirator performance standards is the primary means for this research program to support the certification program. These activities have already been discussed. But it is insufficient to simply "develop" performance standards. It is also necessary to support the certification program through "due process" of the rulemaking procedures. This support should take the form of:

(1) Insuring that respirator performance standards are in a format suitable for incorporating into certification regulations, and of

(2) Providing the technical rationale for all new respirator performance standards so that they are defensible in the public review forum.

Private Lab Testing

The purpose of this activity is to develop the competency of private laboratories to test respirators. NIOSH will then be able to contract much of the testing now done in-house by the certification program. Manufacturers will be able to have product development testing done in private testing laboratories rather than by NIOSH.

The use of private testing labs by NIOSH will be essential to the respirator certification program, if it is to conduct the substantial testing required of a meaningful field evaluation program.

Private labs cannot now be used by NIOSH. The necessary documented and validated test procedures have never been developed.

One-by-one, as appropriate test procedures are produced, the development of the competency of a private lab to do the testing is simply a matter of NIOSH hiring the lab and absorbing the start-up costs of the laboratory. Once done, the testing service would be available to all, NIOSH, as well as manufacturers.

Manufacturers will be able to use these private labs, rather than NIOSH, to do their product development testing and thereby further reducing the in-house workload of the certification program.

Certified Respirator Selection Manual

This manual will serve as a comprehensive selection guide for respirators. To that end it will be an expansion of the role and scope of the "List of Certified Respirators" as now produced by the certification program. Production of this manual will remain the responsibility of the certification group with the research group providing input as appropriate.

This manual will be based primarily on the test data generated by both the certification program and the research program. It will indicate how that and other information is to be used in respirator selection. That information must be presented in a format that is clear and useful to the reader.

It is important for the user of this manual to understand whatever limitations exist in the scope of the certification program. To that end, it will include:

- A list of the attributes evaluated in certification program for each type of respirator;
- A brief, but instructive, outline of the tests used to evaluate these attributes and the required performance levels;
- A discussion of all significant attributes not considered by the certification testing

Field Consultation

The program will provide a field consultation service similar to our existing Health Hazard Evaluation, HHE, program, but for the specific purpose of evaluating an employer's respirator program. The expertise of the staff will be in respirators and the activities will be limited to that area. This activity can be conducted independently or, when appropriate, as a part of a more comprehensive HHE.

This program activity falls under the Institute's mandate to perform Health Hazard Evaluations. The Institute's experience with the HHE program will be a tremendous aid in establishing this program's activities. For example, the protocol established for the existing HHE program will also be applicable to this respirator program.

As this program is proposed, field consultation will not be a large effort. Once this element of the program is functional, approximately 2.0 man-years of effort will be devoted to this activity. If a much larger demand develops, a separate group should be established to provide this service on a large scale. Such as expansion of the consultation program would be best achieved after the "work practice document" is completed.

The responsibility for these field consultations will not be limited to 2 or 3 individuals, instead, the responsibility will be spread among the entire staff. All researchers in this program will be expected to participate in at least one field investigation per year. All researchers will thereby have direct exposure to the real problems of the worker and it will, therefore, be unlikely that anyone will loose sight of the true purpose of their individual research efforts.

Work Practices Document

The work practices document will present practices and procedures for an employer to establish and maintain an effective respirator program. The document will be complete and cover all aspects of an employer's respirator program.

The work practices document will complement the "Certified Respirator Selection Manual" discussed elsewhere in this paper. The selection manual presents current information about available respirators that is necessary for intelligent respirator selection. The work practices document, on the other hand, is concerned with the employer's program in which the respirator is used.

The development of this document will not begin until after the research team has field experience through the "Field Consultation" activity discussed elsewhere in this paper.

The document can be presented in either one of two formats. It can either present "recommended practices" or a recommendation for an enforceable standard. The most appropriate choice will be determined at a decision point just prior to beginning the document and after we have field consultation experience.

Respirator Training

A training program to instruct in the proper selection and use of respirators will be developed and updated as necessary. Once developed it will be implemented by the Division of Training.

Even though the routine training program will be the responsibility of the Division of Training, all professionals in the respirator research program will be competent to teach the training course and will do so periodically. Teaching the course will be a necessary step in developing the course curriculum. It will also tend to insure a well-rounded staff.

Since the heart of the respirator research program will be a team of respirator authorities competent in all areas of respirator technology, use and selection, it would be illogical for any other group to write the "textbook" for the respirator training course.

Regulatory Agency Support

The best support we can give OSHA and MSHA is to do the previous activities well, and to do these with the needs of OSHA and MSHA in mind.

There will, however, be situations where OSHA or MSHA needs information or support that is beyond the normal program activities. The program must be able to respond to these situations.

Our ability to respond to these situations will be in direct proportion to the competency and experience of our research team. Accordingly, in the early years of the program, our responsiveness to the issues of the day will have a large positive derivative.

Personnel Requirements

The projected level of effort for each of the activities previously described is presented in Chart 2. The numbers shown in that chart represent the number of professional researchers, in man-years, committed to each activity for each year. The numbers shown do not include support personnel such as clerical personnel and laboratory technicians. For optimum efficiency it is estimated that (1) there should be one secretary for each of four researchers and (2) there should be one technician for each of two researchers. Therefore, the numbers shown in Chart 2 can be multiplied by 7/4 to get total personnel figures. Also, two positions should be added to that total to represent Branch level management support.

CHART II -- Number of Research Positions Per Activity Per Year

	FY82	FY83	FY84	FY85	FY86	FY87	FY88
Establish Performance Levels	3.5	4.0	3.0	3.0	3.0	3.0	3.0
Develop Test Procedures	6.0	5.0	4.0	3.0	3.0	3.0	3.0
Develop Test Equipment Specifications	0.5	0.5	0.5	0.5	0.5	0.5	0.5
Publish Ratings		1.0	1.5	2.0	3.0	2.0	2.0
Certification Requirements	1.0	1.0	1.5	2.0	1.0	1.0	1.0
Private Lab Tests			0.5	0.5	0.5	0.5	0.5
Selection Manuel	0.5	0.5	0.5	0.5	0.5	0.5	0.5
Field Consultation-HHE	3.0	3.0	3.0	3.0	3.0	3.0	3.0
Work Practices Document		2.0	2.0				
Training Program	1.0	2.0	2.0	0.5	0.5	0.5	0.5
Support Regulatory Agencies	1.0	1.0	1.0	1.0	1.0	1.0	1.0
Total Research Positions	16.5	20.0	19.5	16.0	16.0	15.0	15.0
Total Positions	31	37	36	30	30	28	28