

Racal Health & Safety

August 16, 1996

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Dear Sir / Madam,

In response to the May 16, 1996 *Federal Register* notice published by the National Institute for Occupational Safety and Health titled 42 CFR 84, Racal Health & Safety is pleased to provide the following comments for the consideration of the Institute.

Racal believes that worker safety should be the first priority of NIOSH when considering modifications to safety equipment performance certification programs. In this regard, performance certification requirements in relationship to use applications and current technology should be the focus of updates to existing programs. Expediency by which an update can be implemented should also be considered. In addition, administrative and quality assurance components should be constantly reviewed to ensure the effectiveness and efficiency of the program. With these points in mind, Racal believes the first priorities of NIOSH regarding respirator certification rulemaking should be the Powered Air Purifying Respirator Performance Module and the Administrative and Quality Assurance Module. It is our belief that these modules could be handled simultaneously.

Racal applauds the efforts of NIOSH to update its respirator certification program in an ongoing effort to improve worker safety in today's diverse workplace. These comments are provided by Racal in our support of this effort. We appreciate this opportunity to provide input to NIOSH regarding respirator certification priorities, and will continue to support NIOSH's efforts to ensure state-of-the-art respiratory protection availability in the workplace.

Respectfully submitted,



Michael Cowell
Engineering Manager

Date: August 16, 1996

Subject: NIOSH Public Responses

I. PRIORITIES OF TECHNICAL MODULES

Issue 1, Question 1: What criteria should be used to rank the priority of each module?

The modules should be ranked based upon the affect on worker safety, protection provided, industries affected and available technologies. The affect on worker safety can range from the level of protection provided based on filter and respirator performance to the wearability and comfort of the respirator. The protection provided is based on both the efficiency of the filter and the protection provided by the headpiece. Advancements in technology must be addressed by the standard, by allowing new technologies to be introduced through updated performance requirements.

Other criteria for ranking the modules are the number of workers affected, the seriousness of hazards that would be addressed, the limitations imposed on respirator design through outdated performance requirements and the expediency by which new modules could be introduced. A module that affects more workers must be given greater weight than a module which affects fewer workers. This is common sense and will further support NIOSH's vision to protect the "safety and health at work for all people". The seriousness of hazards that would be addressed by a module revision must be given greater weight. This was evident with the new N-R-P classifications for negative pressure respirators which can all be used for protection against tuberculosis. The expediency for implementing change is an important consideration because modules that are technically feasible will be implemented sooner and have a stronger impact on worker safety.

Issue 2, Question 1: What changes to the current respirator certification requirements are needed in the modules identified in this notice?

Racal feels that the filter classes for PAPR's need to be aligned with the classes for negative pressure respirators under 42 CFR 84. In the preamble of 42 CFR 84, NIOSH indicated that PAPR's would be addressed in a future module. Different classifications for filters creates confusion for end users who are selecting respiratory equipment. In addition a range of PAPR's will be eliminated by the grandfathering provisions of 42 CFR 84 affecting workers in the mining, chemical, pharmaceutical, agricultural, metal processing and other related industries. Also PAPR performance requirements are incompletely defined in 42CFR84 currently.

Issue 2, Question 2: Are there any subject areas for improving current certification requirements that are not identified in this notice that should be considered in the prioritizing process?

No, all subject areas were identified in the Federal Register section: A. Priority Technical Modules, 1. Background.

Issue 2, Question 3: How should the modules be ranked and why?

The technical modules should be ranked in the following order with the Administrative and Quality Assurance Module being addressed separately at the same time.

1. Powered Air Purifying Respirator (PAPR) Module The PAPR needs to be the first module that NIOSH considers because PAPRs greatly affect worker safety and the module is technically feasible.

Worker safety is promoted by revising the PAPR module. First, upgrading PAPR filters to the N-R-P categories will eliminate confusion on filter selection. Second, PAPRs provide added comfort over negative pressure respirators because there is no additional stress on the wearer. Products with a high degree of comfort are more likely to be worn, will encounter less resistance from the worker and facilitate administering a respiratory protection program. Third, PAPRs accommodate facial hair and facial deformities thereby giving these wearers a respirator option. Fourth, the diversity of headpieces and filter types yields innumerable combinations that affect a wide number of industries and workers.

Current PAPR's approved with Dust, Dust / Mist, and Dust / Mist / Fume filters are grandfathered and cannot be sold after July 1998 under the current standard. End users must be given PAPR options that are equivalent to the D, DM and DMF categories that are being eliminated. Otherwise, employers will incur unnecessary costs or compromise safety as they will be forced to replace their PAPRs with negative pressure respirators reducing the protection level provided or upgrade to a HEPA-based PAPR adding an undue cost burden. Note that some employees are unable to wear a negative pressure respirator due to a poor fit or health limitations.

PAPRs were included in the original 42 CFR 84 proposal but later removed to expedite the negative pressure particulate module. The intent, as mentioned in the preamble to 42 CFR 84, was and still is to address this class of respirators in a follow-up module.

A revised PAPR module will allow for the introduction of new and better technology by the respirator manufacturers to provide PAPR's that closely matches the intended application. Lighter weight, shorter duration and higher performance PAPRs are only some of the innovative ideas that can be realized by a revised PAPR module to incorporate state of the art performance parameters. This module is technically feasible and specific details are contained in our written comments.

2. Supplied Air Respirator (SAR) Module The Supplied Air Respirator current test methods do not adequately access the performance of these respirators. New criteria and test methods need to be developed. A breathing machine should be used to conduct performance testing on all SAR's. SAR's must maintain positive pressure inside the respiratory inlet covering during the test to indicate adequate performance. Respirators could then be classified according to the work rate at which they are tested.
3. Self Contained Breathing Apparatus (SCBA) Module The SCBA testing should be upgraded to include portions of the NFPA 1981-1992 standards that would improve the performance of SCBA units that are used in other applications other than fire fighting. The sections that should be considered are the airflow requirements (103 lpm), lens abrasion resistance and communication sections. That other sections of the NFPA standard should continue to be approved under the NFPA program, as not to increase the cost of SCBA's that are not used in fire fighting.
4. Respiratory Protective Escape Devices (RPED) Module RPEDs are non-traditional respiratory device. However, minimum performance levels must be established for these devices so that users can properly select these respirators for their application. The RPED must be tested against minimum performance levels to ensure that they provide the expected level of respiratory protection. Users of RPEDs are unlikely to have daily experience with them. It is important for a user to quickly understand how an RPED is worn for the device to be effective.

Issue 2, Question 2(A): Are there existing national or international standards that could be adopted by NIOSH to replace current certification requirements pertaining to a given module?

There are existing standards from Europe, Australia and the United States that could be adopted by NIOSH either in whole or in part for inclusion in the technical modules.

The US standards are:

1. NFPA 1981-1992 : Open-Circuit SCBA for Fire Fighting.
2. ANSI Z88.8-199x (draft) : Performance Criteria and Test Methodologies for Air-Purifying Respirators.
3. ANSI Z88.2-1992 : American National Standard for Respirator Protection.
4. ANSI RPED standard - this standard is currently under development.

The European standards are:

1. prEN146 : Respiratory Protective Devices, Powered Filtering Devices incorporation Helmets or Hoods Requirements, testing, marking
2. prEN147 : Respiratory Protection- Power assisted filtering devices incorporating full facemasks, half masks or quarter masks - Requirements, testing, marking

The Australian / New Zealand standards are:

1. AS/NZS 1715 : Selection, use and maintenance of respiratory protective devices
2. AS/NZS 1716 : Respiratory protective devices

Issue 2, Question 3(A): How would potential changes to current requirements achieved through a proposed module affect public health?

The proposed changes in the PAPR module would allow for the use of a PAPR in wider range of uses and provide multiple levels of filter efficiencies for different applications. This would provide a greater range of products to be available to the users, enhancing comfort, protection and compliance options of air-purifying respiratory protection.

Issue 2, Question 4: Which industries and how many workers would be affected by potential changes achieved through a proposed module?

The PAPRs on today's market encompass a broad range of products used in many industries. Major industries utilizing powered-air respirators include:

- chemical
- pharmaceutical
- agricultural
- steel mills and steel processing
- transportation equipment manufacturers
- ship and boat building
- welding
- mining
- contracting
- environmental / remediation

In traditional industry, we estimate that there are over half a million workers using PAPRs.

PAPRs are finding increased use in non-traditional industries. There is a growing need for PAPRs in the medical and dental community for protection against multiple drug resistant infectious disease (such as

tuberculosis). Within the medical arena are an estimated nine million health-care workers in various professions including physicians, nurses, emergency medical technicians, and home-health care workers. In addition, federal and state government employees are utilizing PAPR protection in environmental security and other applications. These workers would also benefit by updating the PAPR module.

Issue 2, Question 5: What would be the technical feasibility of suggested change?

The PAPR Module will allow the use of the PAPR to be expanded into all of the filter classes in the current 42 CRF 42 module on particulate filters. This will allow for user to have additional choices of respirators to meet their requirements. Because a PAPR is easier to fit and wear and is more comfortable, the protection provided by this device will be at a higher level because the users will wear it longer. The headpieces types and the APF assigned to the headpiece types will need to be expanded to accommodate the additional filter classes as well as new technology.

The PAPR module is technically feasible. ANSI Z88.8 may be used as a guide for some of the testing. The following is an outline of the requirements that should be included.

A. Facepiece Types

- 1. Tight Fitting
- 2. Loose Fitting

Notes:

- 1. Should not be design restrictive.
- 2. Use ANSI Z88.2 as a basis for the APF table but modified with respect to filter efficiency.
- 3. APFs are based on headpiece type and filter efficiency.
- 4. We feel that the APF for a loose fitting headpiece using a “100” class filter should be raised to 50.

APFs Tight fitting vs Loose fitting by Filter Class

Type	TF, 1/2 Facepiece	TF, Full Facepiece	TF, Helmet / Hood	LF, 1/2 Facepiece	LF, Full Facepiece	LF, Helmet / Hood
N95	15	20	20	10	15	15
N99	25	100	100	25	25	25
N100	50	1000	1000	50	50	50
R95	15	20	20	10	15	15
R99	25	100	100	25	25	25
R100	50	1000	1000	50	50	50
P95	15	20	20	10	15	15
P99	25	100	100	25	25	25
P100	50	1000	1000	50	50	50

Definitions

Respiratory inlet covering - that portion of a respirator that connects the wearer's respiratory tract to an air-purifying device or respirable gas source, or both. It may be a facepiece, helmet, hood, suit, or mouthpiece/nose clamp.

Tight-fitting facepiece - a respiratory inlet covering that is designed to form a complete seal with the face.

Loose-fitting facepiece¹ - a respiratory inlet covering that is designed to form a partial seal with the face.

Hood - a respiratory inlet covering that completely covers the head and neck and may cover portions of the shoulders.

Helmet - a hood that offers head protection against impact and penetration.

Tight-fitting half facepiece - a respiratory inlet covering that is designed to form a complete seal with the face, and covers the nose and mouth.

Loose-fitting half facepiece² - a respiratory inlet covering that is designed to form a partial seal with the face, and covers the nose and mouth.

Tight-fitting full facepiece - a respiratory inlet covering that is designed to form a complete seal with the face, and covers the nose, mouth and eyes.

Loose-fitting full facepiece - a respiratory inlet covering that is designed to form a partial seal with the face, and covers the nose, mouth and eyes.

Tight-fitting hood - a respiratory inlet covering that is designed to form a complete seal with the face or neck, and completely covers the head and neck and may cover portions of the shoulders.

Loose-fitting hood - a respiratory inlet covering that is designed to form a partial seal with the face or neck, and completely covers the head and neck and may cover portions of the shoulders.

Tight-fitting helmet - a respiratory inlet covering that is designed to form a complete seal with the face or neck, and is a hood that offers head protection against impact and penetration

Loose-fitting helmet - a respiratory inlet covering that is designed to form a partial seal with the face or neck, and is a hood that offers head protection against impact and penetration

1. The ANSI Z88.2 definition of loose-fitting facepiece is "a respiratory inlet covering that is designed to form a partial seal with the face, does not cover the neck and shoulders, and may or may not offer head protection against impact and penetration". We propose that the definitions of loose-fitting only address the seal with the face. The definition, as worded above, parallels the tight fitting definition. Doing this allows us to accommodate different headpiece styles (half, full, helmet, hood) in both a tight-fitting and a loose-fitting configuration.

2. This is a new facepiece category that is not covered in ANSI Z88.2

B. Duration

1. Minimum duration 1 hour.
2. Maximum duration to be specified by manufacturer, in 1 hour segments.
3. Testing to verify minimum airflow (4 / 6 cfm) at the end of the rated duration.

C. Airflow

1. Tight Fitting 4 cfm, 115 lpm
2. Loose Fitting 6 cfm, 170 lpm

Notes:

- a) Airflow to be measured as a complete system with headpiece in place.
- b) Variable speed units to meet minimum airflow requirements and lowest speed setting.

D. Workrate

1. Standard workrate 40 lpm, measured using NIOSH breathing machine

E. Noise

1. 80 db measured at both ears with PAPR running on fully charged battery

F. Facemask pressure

1. Greater than 0 inches water on 40 lpm breathing machine

G. User interface

1. Design considerations should take in account human elements of the interface with the user.
 - a) Breathing tube
 - b) Unit support
 - c) Facepiece

H. Filtration

1. The classification of filters for use on Powered Air-Purifying Respirators should be the same as allowed on Non-Powered Air-Purifying Respirators.
 - a) N, R, P classes
 - b) 95, 99, 100 efficiencies
2. The testing for PAPR filters should be by component and not the system.
3. N series filters
 - a) Condition filters at 85 \pm 5% relative humidity at 38 \pm 2.5 degrees C for 25 \pm 1 hours.
 - b) Test challenge sodium chloride (NaCl) solid aerosol at 25 \pm 5 degree C and relative humidity of 30 \pm 10% neutralized to the Boltzmann equilibrium state.
 - c) Particle size distribution with count median diameter of 0.075 \pm 0.020 micrometer and a standard geometric deviation not exceeding 1.86.
 - d) Measure the maximum free flow of air from the PAPR after the unit has been running for 30 minutes. Then divide this value by the number of filters and use this value to test the filter.
 - e) A 200 mg challenge will be divided by the total number of filters and this value applied to the filter.
 - f) Only the filter will be tested to the airflow and challenge levels established in d and e.
 - g) Test series, 6 sets of filters.

4. R series filters

- a) Condition filters at 85+/-5% relative humidity at 38+/-2.5 degrees C for 25+/-1 hours.
- b) Test challenge cold-nebulized dioctyl phthalate (DOP) aerosol at 25+/-5 degree C neutralized to the Boltzmann equilibrium state.
- c) Particle size distribution with count median diameter of 0.185+/-0.020 micrometer and a standard geometric deviation not exceeding 1.60.
- d) Measure the maximum free flow of air from the PAPR after the unit has been running for 30 minutes. Then divide this value by the number of filters and use this value to test the filter.
- e) A 200 mg challenge will be divided by the total number of filters and this value applied to the filter.
- f) Only the filter will be tested to the airflow and challenge levels established in d and e.
- g) Test series: 6 sets of filters.

5. P series filters

- a) Condition filters at 85+/-5% relative humidity at 38+/-2.5 degrees C for 25+/-1 hours.
- b) Test challenge cold-nebulized dioctyl phthalate (DOP) aerosol at 25+/-5 degree C neutralized to the Boltzmann equilibrium state.
- c) Particle size distribution with count median diameter of 0.185+/-0.020 micrometer and a standard geometric deviation not exceeding 1.60.
- d) Measure the maximum free flow of air from the PAPR after the unit has been running for 30 minutes. Then divide this value by the number of filters and use this value to test the filter.
- e) A 200 mg challenge will be divided by the total number of filters and this value applied to the filter.
- f) Only the filter will be tested to the airflow and challenge levels established in d and e. If the filter efficiency is decreasing when the challenge level is reached, the test shall continue until there is no further decrease in efficiency.
- g) Test series: 6 sets of filters.

I. Airflow indicator

1. The accuracy of the airflow indicator should be assessed for its ability to measure and indicate the minimum airflow.

J. Breath Responsive Systems (tight fitting only)

1. The use of a breath responsive unit to extend the filter life will be accepted.
2. European Standard EN147 should be used as a guide.

K. System Integrity Test

1. Test complete PAPR on a breathing machine for 15 minute with fresh batteries. Place complete PAPR system in a chamber with sodium chloride or DOP to measure the performance based on the filter efficiency of 95, 99, 100. All sampling to be taken inside the facepiece. Sample at the beginning and at the end of the test to verify that the system integrity is at least the filter efficiency.

L. Exhalation Valves

1. Same requirements as negative pressure respirators (see 84.182).

M. Chemical Cartridges

1. Chemical cartridges will be tested to the current requirements of 42 CFR 84, Subpart L.

Issue 2, Question 6: What would be the economic impact to respirator manufactures, purchasers, and users resulting from the suggested changes?

The current requirements for PAPR certification under 42 CFR 84 limit innovation and advancements in design. In turn, these limitations reduce the availability of innovative products that can enhance the comfort and protection provided to respiratory protection users. Through advancements in technology and design, powered air respiratory protection products can be designed to meet the specific requirements of varied workplaces and industries. Through variations such as duration, headpieces, configuration, and filter efficiency and design, PAPR's can be designed to meet specific user requirements and protection levels within the respiratory protection programs of various industries and applications. This added range of designs will provide user options that should reflect a reduction in equipment and program cost. This would occur through enhanced equipment selection options that may provide the user a respiratory protection device that more closely relates to the application requirements. The closer the product relates to the application parameters, the more cost effective it would become in relation to purchase price, added worker comfort, enhanced worker efficiency and reduced worker downtime. (For example, should an application require a bearded worker with limited lung capacity to work in a low level dust environment for an hour on a regular basis, a two hour rated powered air purifying respirator with N95 filtration would provide the worker a more cost effective and lighter weight alternative to an 8 hour HEPA PAPR available under current standards.) In addition, although there is the up front development costs incurred by the manufacturer, the development of new products provides new revenue stream opportunities for the manufacturing community. This reflects a regulatory adjustment that would provide a positive impact on economic factors.

Issue 2, Question 7: What other factors relate to the priority ranking of the proposed module?

The original proposal updating 30 CFR part 11 to 42 CFR part 84 included certification requirement modifications to particulate filtering powered air purifying respirators. Due to technical difficulties and equipment limitations at the time of the initial draft, and in an effort to expedite the negative pressure particulate module, powered air purifying respirators were removed from the initial draft with the intent of being addressed in a follow up module. By removing particulate filtering powered air purifying respirators from the first module, two problems have been created at the user and manufacturer level.

1. Different classifications for filters relating to powered and non-powered air purifying respirators. This causes confusion in user selection and application for particulate filtering respirators, and creates a perceived devaluation in powered air filtration "as it is tested to an old standard".
2. A grandfather period is in place reducing the future availability of dust/mist and dust/mist/fume powered air purifying respirators while a compatible replacement design certification option has not been established. This will cause the future (under two years) elimination of an effective respiratory protection option, potentially adding cost to workers in industries such as woodworking, mining, agriculture, grain handling, and construction where these products have provided worker protection and comfort for many years.

These two points, in conjunction with the technical feasibility of updating the PAPR certification requirements should add weight to the priority level given to the PAPR module.

Issue 3, Question 1: How should NIOSH notify respiratory purchasers and users of revised priorities?

As NIOSH develops and promulgates revisions to its respirator certification standard, it is obviously critical that the user community be kept informed as to the updating process and effectively of future modules. Through the utilization of current information technologies, along with the networking capabilities of manufacturers, industry and trade associations, and other Government agencies, NIOSH should coordinate a planned informational process with which the user community is informed as new modules are published and become effective. The NIOSH, CDC and OSHA Web pages should all be structured and maintained to provide easy access to current certification updates and user's notices. This Web page information should include up-to-date information on product certifications. NIOSH should also continue to work in conjunction with industry associations such as the American Industrial Hygiene Association to coordinate workshops for the development of "user friendly" user's guides in an effort to help support user comprehension. These workshops should allow interested parties from the user, manufacturer, regulatory, academic and "industry expert" segments to participate as in the previous AIHA sponsored 42 CFR 84 User's Guide Workshop. In addition, NIOSH should work closely with the Industrial Safety Equipment Association and respirator manufacturers in the effort to inform the user community as the manufacturers are in contact with users on a daily basis.

II. ADMINISTRATIVE / QUALITY ASSURANCE MODULE

General

Racal H& S wishes to support the initiative taken by NIOSH in investigating new ways of carrying out the certification procedures relating to Respiratory Protective Equipment (RPE). This process consists of three elements: **certification** - the legal and final step allowing the manufacturer or agent to place the product on the market; **product assessment** when a product is submitted for certification - a process involving an assessment of a manufacturer's design documentation, his test data and a physical evaluation of the product against agreed test criteria; and thirdly, a process to **monitor ongoing production** to ensure that product supplied to the market is in conformance with the design as originally submitted. This can be done by checking on the product itself on a regular or random basis or by auditing the production process of the manufacturer and his Quality system (or a combination of these).

NIOSH is currently in the position, following the implementation of 42 CFR 84, of carrying out all three aspects internally, against a background of a rising demand for these services combined with conflicting pressures to reduce operating budgets and use the same resources in other more pressing areas. The possibility of employing private sector resources to carry out some or all of these activities is being actively considered along with the need to maintain the very high level of integrity and public credibility that a NIOSH certification enjoys both in the USA and abroad. Both users and manufacturers wish to see this position maintained.

NIOSH has given notice that it wishes to retain the certification aspect of the process and maintain ultimate responsibility for the process as a whole. This is welcomed and is a key aspect underlying any changes. NIOSH seeks guidance on how and whether the testing and on-going production monitoring aspects could be more efficiently carried out using other organizations and resources. Racal H & S believes that the answer to both parts is yes and all parties (manufacturers, NIOSH and end users) would benefit if NIOSH recognizes and takes advantage of two important trends in the US. First is the emergence of frameworks within which independent

test houses can operate and be accredited to carry out specialist technical tests. These are guided by various ISO standards for laboratory operation and accreditation by third parties which lead not only to high standards of competence but to international mutual recognition agreements and the generation of major export opportunities. Secondly, on the manufacturing side, there has been a widespread adoption of the ISO Quality Standards by US manufacturers - particularly in the RPE supply industry - and the infrastructure to grant the ISO 9000 certifications is in place and functioning in the US. More importantly, this implies that the accreditation process for auditing the QA systems should also be in place to some extent. This is essential if the system is to maintain credibility in the US and abroad.

Both of these aspects have to be promoted and regulated by the appropriate branch of the US Government. It is not possible or reasonable for NIOSH to have to establish these general aspects itself but rather for NIOSH to consider which of the various systems in place or under development in the US are most appropriate and to actively promote and employ them after selection. Other Government agencies such as the FDA, MSHA and OSHA are already using or considering using equivalent processes for similar reasons. Electrical safety and communications related bodies are in the forefront of establishing parallel schemes.

To maintain the integrity of the NIOSH certification it will be necessary for NIOSH to involve itself in both the setting up and maintenance of these systems. This will in the short term place extra burdens on NIOSH as the most senior and experienced staff will be needed to steer the process through to completion. Racal believes that this process is both desirable and achievable as it will result in a streamlined and responsive certification process that relieves the burden on NIOSH while at the same time allowing for rapid product certification and efficient production monitoring in line with the audit processes already selected by manufacturers and recognized by other government agencies.

Racal would be pleased to suggest detailed ways in which these goals can be accomplished. In the interest of conciseness, we offer the following general principles in response to the detailed questions raised.

Issue 1 Independent Testing.

Clearly there are no external or private sector laboratories currently available in the US to perform the tests carried out by NIOSH. Several manufacturers have invested in the equipment to perform the tests carried out by NIOSH to ensure a speedy and successful certification process. This is partly successful and Racal welcomes the steps taken by NIOSH to make these tests reproducible by the use of widely available equipment and consistent test methodologies.

Successful implementation of independent testing relies upon three main elements:

- Properly run test houses from the point of view of equipment and staff. These aspects are covered in ISO 25.
- Agreed tests and test protocols that are reproducible and minimize the elements of subjective assessment.
- The existence of independent auditors who can oversee the proper running of the test house on a regular basis. This is covered by ISO Guide 58.

The availability of such resources is governed by market forces. There must be sufficient demand to ensure continuity of work and a proper return on investment for the organization running it. The normal market forces will regulate the supply of these facilities and the level of test fees levied. The experience from Europe, which has undergone the whole scale accreditation of test (and certification) houses to ISO standards, has shown that test houses do become available and that although the rates charged do increase a little over the government set rates of before, the choice and availability of these specialized resources lead to reduced turn around times and hence a speedier time to market that benefits the manufacturer and the user. Targets of 90 days can be regularly met.

NIOSH should ensure that their own standards of performance are met by assisting in the regular audits of the proposed bodies. In the early stages this can be a matter of guidance and training as much as in auditing. Two years of high level monitoring should be anticipated to ensure the proper running of the new center(s). The auditing party should comprise experts in the procedural side of running a test house alongside experts in the particular disciplines of respiratory testing. These latter will have to be supplied by NIOSH.

The need for agreed and consistent tests and test protocols will place another short term burden on NIOSH as it will almost certainly be the NIOSH tests that have to be transplanted as these are the only tests available. This can only be achieved if NIOSH fully document the tests and protocols that are employed on a daily basis and at a working level, to ensure reproducibility. This is a minimum requirement. Consistency between test houses then follows and has to be addressed by more effort applied to monitoring and cooperation. As a first step it may be of value to NIOSH to submit itself for accreditation under ISO 25 (General requirements for the technical competence of testing laboratories) as a first step in generating the procedures that could be exported to potential test houses.

Despite the major hurdles that have to be overcome, the experience from Europe over the last five years has shown that it can be done and that there are benefits to be gained all round. Racal believes that the same benefits could be obtained in the US both within North America and internationally as mutual recognition agreements are established.

Issue 2.

Racal encourages NIOSH to make use of the growing use of ISO accredited quality systems that are adopted by choice and increasingly by customer decree in American manufacturing industry.

The use of ISO accredited auditors should be encouraged to prevent needless duplication of effort by the manufacturer and NIOSH. Other agencies already are moving towards using ISO as part of a production qualification process. ISO 9002 meets all of the basic requirements.

NIOSH could look at selecting auditors who meet the ISO Guide requirements for ISO 9000 accreditation (ISO 48 and some of 40) overlaid by a willingness to address the additional items that NIOSH wish to add to a basic ISO audit. Provided these requirements are made clear to manufacturers, so that they were aware of what to expect on a dual ISO/NIOSH audit, the system could be implemented within a year. Again NIOSH quality auditors should be involved alongside the senior auditors of the selected parties to ensure a proper understanding of NIOSH requirements. These would only be small additions to the basic ISO 9000 requirements and should not be as demanding as the test house training requirements proposed above.

It should be noted that in Europe it was recognized that not all companies wished to operate to ISO standards of quality. To avoid additional burden on these companies, they have the option of electing for annual product testing (selected at random by the auditing body) as an acceptable alternative. This may give small companies a real alternative while recognizing that larger companies will want to promote the use of accredited quality systems.

Racal would be pleased to submit further information to support these main points at a future time if this is required.