Racal Health & Safety, Inc.
7305 Executive Way
Frederick, MD 21701-8368
(301) 695-8200 (800) 682-9500
FAX (301) 695-4413

July 22, 1994

NIOSH Docket Office
Docket Office Manager
Robert A. Taft Laboratories
Mail Stop C34
4676 Columbia Parkway
Cincinnati, Ohio 45226-1998

Comments on the Proposed Rule 42 CFR Part 84

Dear Ms. Manning:

Racal Health & Safety, Inc., is pleased to offer comments on the proposed rule for Respiratory Protective Devices, 42 CFR 84.

In general terms, Racal Health & Safety supports the recommendations and proposals from the ISEA which have been submitted to the Docket and also presented at the public meeting.

Without repeating all the issues raised by ISEA, we would like to comment further on the PAPR issues and also on the role of electrostatic filter media in respiratory protective devices following the comments made during the public meeting.

Our comments are attached in the following six pages.

Yours sincerely,

M. R. Bennett
Technical Director

JUL 28 1994

RACAL

1) POWERED AIR PURIFYING RESPIRATORS (PAPRs)

For a complete representation of Racal's views on PAPRs, reference should be made to the ISEA presentation on PAPRs at the public meeting. Racal supports all of the issues raised in the presentation. There may, however, have been some confusion as to whether ISEA were recommending the continuation of the 30CFR11 regulation or just the tests in its proposal.

Discussions between Racal and NIOSH, noted to the record, clarified Racals concern that PAPRs would be disadvantaged against other types of APR if not approved under 42CFR84 during the proposed interim period. NIOSH expressed its concern that the dust/mist and dust/fume/mist categories could be perpetuated beyond the Grandfather period.

Three options to meet these concerns were identified as follows:

1) Stay with the original ISEA position of no 42CFR84 certification.
2) Bring the 30CFR11 tests forward into 42CFR84 to allow certification under the new regulation but with two conditions:
   a) that this interim certification process only be allowed for a finite time, no longer than the Grandfather period at most.
   b) that only HEPA based products be submitted for certification during this period.
3) Define interim tests that could be included in 42CFR84.

Discussion.

Option 1) is unacceptable for the reason given above. Even option 2) only goes halfway in meeting the market's expectations for newly approved product in that the new classes of filter could not be specified. This would be particularly true in the Health Care sector. However, it is thought to be possible to explain to users of HEPA based PAPRs that the old HEPA filters are almost identical to the future class A type filters and will probably be capable of being recertified in that category. This is because all known PAPR HEPA filters are of the mechanical type with well known characteristics under the new tests.

Option 3) is attractive, but as presented at the public meeting, we feel

that it would not be possible to define meaningful tests in the coming weeks with all the other pressures on NIOSH to complete module one. The subject deserves proper attention hence the proposal for a separate module.

Option 2) is a route forward that allows PAPRs that are acceptable to NIOSH to be certified during the interim period. Racal Health and Safety is prepared to accept the proposal that only HEPA based PAPRs be put forward for certification during the interim period. We understand that the non-HEPA based products will continue to be sold for the duration of the grandfather period. We believe that our existing non-HEPA based PAPR products are capable of being classified under the new filter penetration classes but this cannot be confirmed until the tests and performance levels are finally known.

Bringing forward the 30CFR11 tests into 42CFR84 is as unattractive to the manufacturers as it is to NIOSH but it allows the certification process to continue without the risk of introducing hurriedly prepared tests. To ease the burden, NIOSH may wish to consider dropping the dust loading tests for the HEPA filters during the interim period recognizing that HEPA filters are designed for use against toxic or harmful particles that are generally small and in low concentrations. The European tests for the equivalent filter do not include dust loading for this reason.

On timescales, we are committed to the rapid development of suitable tests to allow the new module to be completed as quickly as possible and incorporated into 42CFR84. We would be disappointed if the interim period were to extend as far as the grandfather period. We would not be prepared to support this proposal if PAPRs were not included within 42CFR84 by the end of the grandfather period.

Recent discussions within ISEA have clarified the ISEA position on PAPRs. The final position contained within the written comments of July 22nd, 1994 confirms that ISEA are also seeking the inclusion of 30CFR11 test within 42CFR84 for an interim period. The ISEA has not been able to address the 'HEPA only' proposal on a full membership wide basis because of limited time. We would encourage NIOSH to continue the dialogue with ISEA to enable this proposal to be fully explored.

Recommendation.

Racal Health and Safety recommends that NIOSH considers option 2), allowing the incorporation of 30CFR11 tests into 42CFR84 for HEPA based PAPRs, for an interim period of time pending the rapid incorporation of the results of a new module specifically aimed at the needs of PAPRs.

Other PAPR issues.

These are listed in the last page of the presentation from the public meeting. We would particularly like to see consideration given to the possibility of introducing PAPRs of duration less than the current four hours to enable more compact and lightweight systems to be developed, particularly for the Healthcare sector. Current battery packs,typically containing four 'D' cells are heavy and bulky. We anticipate working through the ISEA to develop specific recommendations on this and many other areas raised in the public meeting.

We are particularly concerned that the proposed new regulations ignore the functional aspects of the wide variety of headtops (respiratory inlet coverings) that are available from PAPR manufacturers. This aspect must be addressed as soon as possible in the interests of giving workers a choice of effective systems in the workplace. Naturally these systems will give a variety of protection factors in the laboratory as well as in the workplace. A means for addressing this aspect within US regulations must be developed.

2) Electrostatic Filter Media

Racal Health and Safety would like to comment on issues raised during the presentation made by Mine Safety Appliances Company (MSA) at the Public Meeting.

Racal Health and Safety has been designing and selling respirators internationally for over 15 years. Although principally known for our Powered Air range of products, we manufacture a broad range of respirators from disposable half masks through to SCBA equipment. We

are continuously seeking new filter media and manufacturing techniques to advance the state of respiratory protection in the workplace.

From the beginning, we have employed a wide range of filtration media in both our filters and our integrated systems. We have extensive experience of how various filter media behave both in the laboratory under test and in the field. We have no particular allegiance to one type of media over another and have featured both mechanical and electrostatic media in a wide range of products for many different applications.

With this background, we would wish to state our opinion that while the MSA presentation raised very genuine issues concerning the potential misuse of electrostatic based filter media in respiratory filters, it gave an unnecessarily negative view of the performance of such materials and may have raised unnecessary concerns in the minds of users. We do not believe that a more balanced consideration of the properties of electrostatic media would lead to the extreme conclusions proposed by MSA.

Elimination of the 'solid only' class and testing of filters containing electrostatic elements to their end-point with 'hot' DOP would have the twin effects of eliminating most single use disposable half masks and forcing all other filters to be considerably thicker and hence more expensive than at present - or be mechanical. In our opinion, this is not in the best interests of users who would be denied the choice of many effective types of respirator.

Effective filter design is a balance of the strengths and weaknesses of the different media available. Again, the filter is only one element in a complete respirator and its properties have to be considered as part of the whole. For example, pressure drop through the filter effects the leakage round the faceseal. As a mechanical filter loads, so the faceseal leakage increases.

It would be helpful to consider some of the positive attributes of electrostatic media to see why they have found a role in filter construction. Most notably they offer an extremely low pressure drop for an equivalent level of filter efficiency. The pressure drop does not

increase as rapidly as with mechanical media, allowing the user to breathe more easily through the filter and also reduce the faceseal leakage. The media can often be formed into useful, flexible shapes without additional support leading to complete products constructed from the filter media. Finally, electrostatic filters are particularly efficient against small particles which can only be filtered by high pressure drop mechanical filters with small pores.

The graphs and data presented by MSA were arrived at in the context of assessing laboratory tests based on DOP. The relationship to the workplace was implied but no data was presented on the performance of electrostatic filters in the workplace. What is the relevance of a 200mg load to workplace levels? It is a severe test.

In fact there is a lot of workplace experience to show that effective electrostatic filters can be constructed to stand up to real workplace conditions. In the UK, the Health and Safety Executive performed early field trials in foundries as part of the approval process for electrostatic filters, assessing this to be a most penetrating challenge, with a lot of success.

The graphs from MSA are presented in a form that indicates that the filters start out at an acceptable level and then fail. In reality the filter is designed so that it reaches the required level at the end of the test.

It would be easy to gain the impression from the presentation that electrostatic filters come in one variety and that they all behave the same way. It is important to recognize that the term electrostatic media embraces a broad range of media types with a varying degree of electrostatic versus mechanical filtration. Some offer almost pure electrostatic filtration whereas others feature only 5% of electrostatic filtration. Most complete filters in practice are manufactured from a combination of layers featuring a combination of properties. This will continue to be the way forward.

The concerns expressed by MSA are most valid when considering HEPA type filters and challenges. It is in this area that the risk to the wearer is highest. The tests proposed by NIOSH for the class A Solid and Liquid

filter do mean that it would be virtually impossible and certainly not cost effective to produce such a filter with a major electrostatic element. The mechanical filter is the natural consequence of the test as specified, with cold DOP. To specify hot DOP is to overspecify the test. More flexibility in designing filters for the other classes is,in our opinion, desirable.

In summary, we believe that the better way forward is to offer both 'solid' and 'solid and liquid' types of filter and to promote the clear labelling of these products combined with education in the workplace. The cheaper 'solid only' filters will be more widely used because they are more generally appropriate. If this potentially popular mask is eliminated and only the more expensive higher performance solid and liquid version allowed because of the risk of misuse of the solid mask, then the consequence will surely be that fewer masks will be issued to the workforce or that they will be encouraged to use the product past its proper life. This is clearly not in workers interests.

The proper use of electrostatic media should be encouraged in the light of the benefits that they bring to filter and system design as a whole. We believe that the proposed cold DOP test will be sufficiently stringent to ensure that the 'solid and liquid' type filters that will result will be capable of withstanding real workplace challenges even when constructed from electrostatic elements where appropriate. We support NIOSH's proposed test.

Racal Health and Safety
22nd July,1994

POWERED AIR-PURIFYING RESPIRATORS (PAPRs)

Issues arising from Proposed Regulations 42CFR84

- PAPRs not adequately covered.
- Proposed regulations don't reflect workers needs or modern designs and technology.
- Proposed tests not consistent with Module 1 objectives (filter penetration).
- Proposed tests unclear in intent and execution.

Consequence: Proposed tests are inadequate and design restrictive.

PAPRs

Why are PAPRs different?

In terms of the product design and certification process there is a unique interaction between:

- **filter penetration**
- **air flow**
- **face fit**

Variation of one affects the others.

Consequence: Measurement of one aspect cannot be made in isolation of the others. The system must be taken as a whole.

PAPRs

SPECIFIC ISSUES TO BE ADDRESSED FROM 42CFR84

- FILTER EFFICIENCY LEVELS — Values
- FILTER OR SYSTEM TESTING — Module 1
- PEAK OR CONTINUOUS FLOW
- MULTIPLE FILTER TESTING
- TEST EQUIPMENT — Specification, Design, Use, Supply
- AIRFLOW — When, How?
- FILTER LOADING — Airflow, Duration
- FIT TESTING — Test Inadequacies, New Categories

PLUS CONSEQUENCES OF ABOVE ON FUTURE MODULES
(e.g., APFs)

PAPRs

Consequences of immediately adopting Module 1 tests

1. No system testing equipment is specified or generally available. For filter testing, the TSI 8130 (a suitable test rig) has too low airflow and salt density for sensible PAPR filter measurements.

   ∴ **Modifications to test rig + long tests.**

2. Preliminary data show that, after loading with 2000 mg of 'penetrating' salt, the increase in pressure drop of four types of common filtration media ranged from 2:1 (mechanical) to 7:1 (90% electrostatic), 10:1 (30% electrostatic), and 30:1 (90% electrostatic). Anomalous caking effects were also evident unless the tests were interrupted.

   ∴ Salt loading tests are arbitrary and bear no relation to work-place filter loading. More research is required.

PAPRs

- All the technical issues raised can be resolved by discussion and interaction with
    1) the manufacturers
    2) other national test and certification bodies

- The formal process must be supplemented by an informal interaction from the earliest stage.

- Manufacturers require reproducible and relevant tests to ensure proper use of the resources of the Certification Body.

- ISEA proposes **a new module** be established to address the specific requirements of PAPRs leading to a coherent set of test and certification requirements, reflecting modern PAPR design practice.

Proposal for PAPRs

1] ISEA recommends the urgent addition of **a separate PAPR module.**

2] **No new tests** or test criteria for PAPRs to be included **in Module 1.** The existing 30 CFR11 tests to remain as an interim.

PAPRs

Suggested Contents for a New Module:

- **New Categories**
  - higher protection category (positive pressure, > 6 cfm, etc.)
  - lower protection category ("loose fitting," nuisance dusts, etc.)
  - review headpiece categories ("loose fitting" vs. "hoods")
- **Breath-responsive systems** - how classify; how measure?
- **Appropriate Fit Tests**
- **New APFs** reflecting new categories
- **New Durations** - user related
- **Test Equipment** - specification, design, supply
- **Test Protocols** - clarification
- **Filter Compatibility** with APRs
- **Airflow Indicators** - cost/performance trade-offs
- **Chemical Cartridge** respirator compatibility

POWERED AIR-PURIFYING RESPIRATORS (PAPRs)

Issues arising from Proposed Regulations 42CFR84

- PAPRs not adequately covered.
- Proposed regulations don't reflect workers needs or modern designs and technology.
- Proposed tests not consistent with Module 1 objectives (filter penetration).
- Proposed tests unclear in intent and execution.

Consequence: Proposed tests are inadequate and design restrictive.

PAPRs

Why are PAPRs different?

In terms of the product design and certification process there is a unique interaction between:

- **filter penetration**
- **air flow**
- **face fit**

Variation of one affects the others.

Consequence: Measurement of one aspect cannot be made in isolation of the others. The system must be taken as a whole.

PAPRs

SPECIFIC ISSUES TO BE ADDRESSED FROM 42CFR84

- FILTER EFFICIENCY LEVELS — Values
- FILTER OR SYSTEM TESTING — Module 1
- PEAK OR CONTINUOUS FLOW
- MULTIPLE FILTER TESTING
- TEST EQUIPMENT — Specification, Design, Use, Supply
- AIRFLOW — When, How?
- FILTER LOADING — Airflow, Duration
- FIT TESTING — Test Inadequacies, New Categories

PLUS CONSEQUENCES OF ABOVE ON FUTURE MODULES
(e.g., APFs)

PAPRs

Consequences of immediately adopting Module 1 tests

1. No system testing equipment is specified or generally available. For filter testing, the TSI 8130 (a suitable test rig) has too low airflow and salt density for sensible PAPR filter measurements.

   ∴ **Modifications to test rig + long tests.**

2. Preliminary data show that, after loading with 2000 mg of 'penetrating' salt, the increase in pressure drop of four types of common filtration media ranged from 2:1 (mechanical) to 7:1 (90% electrostatic), 10:1 (30% electrostatic), and 30:1 (90% electrostatic). Anomalous caking effects were also evident unless the tests were interrupted.

   ∴ **Salt loading tests are arbitrary and bear no relation to work-place filter loading. More research is required.**

PAPRs

- All the technical issues raised can be resolved by discussion and interaction with
    1) the manufacturers
    2) other national test and certification bodies

- The formal process must be supplemented by an informal interaction from the earliest stage.

- Manufacturers require reproducible and relevant tests to ensure proper use of the resources of the Certification Body.

- ISEA proposes **a new module** be established to address the specific requirements of PAPRs leading to a coherent set of test and certification requirements, reflecting modern PAPR design practice.

Proposal for PAPRs

1] ISEA recommends the urgent addition of **a separate PAPR module.**

2] **No new tests** or test criteria for PAPRs to be included **in Module 1**. The existing 30 CFR11 tests to remain as an interim.

PAPRs

Suggested Contents for a New Module:

- **New Categories**
  - higher protection category (positive pressure, > 6 cfm, etc.)
  - lower protection category ("loose fitting," nuisance dusts, etc.)
  - review headpiece categories ("loose fitting" vs. "hoods")
- **Breath-responsive systems** - how classify; how measure?
- **Appropriate Fit Tests**
- **New APFs** reflecting new categories
- **New Durations** - user related
- **Test Equipment** - specification, design, supply
- **Test Protocols** - clarification
- **Filter Compatibility** with APRs
- **Airflow Indicators** - cost/performance trade-offs
- **Chemical Cartridge** respirator compatibility

TEST STATISTICS

Sub Part 84.184 (j)

For a sample of 30 filters

Test Statistic $\mathbf{U} = \mathbf{m} + 2.22\,\mathbf{s} \leq$ A, B, C

m = mean maximum penetration
s = standard deviation

Issues
* validity of parametric testing
* increase in acceptable quality level (AQL)

Test Statistics 84.184 (j)

Issue 1. Validity of parametric testing

Concerns:

- not all filter types follow normal distributions
- instrument resolution can distort the distribution
- 100% testing meets the spirit of the regulation but can fail the statistical test

Recommendation: NIOSH to modify the decision rule logic to include non-statistical criteria

Test Statistics 84.184 (j)

Issue 2. Increase in Acceptable Quality Level (AQL)

$U = m + K s$

Concerns: The new penetration tests will significantly increase filter efficiency because

a) the test aerosol is highly penetrating

b) the efficiency levels (A, B, C) are set high

c) a multiplier **K** has been introduced

Given that the sample has been increased to 30, **K is too high.**

Effect: Filters will be over designed with excessive sampling and testing regimes, leading to expensive and bulky filters. The B and C types in particular will be affected.

Recommendation: Reduce **K** to a lower value (1.778).