WILLSON™
SAFETY PRODUCTS

P.O. Box 622 • Reading, PA 19603 • 215/376-6161

December 21, 1987

Dr. Nelson Leidel
Docket Officer
NIOSH Docket Office
Mail Stop E-23
1600 Clifton Road, NE
Atlanta, GA 30333

Dear Dr. Leidel:

Willson Safety Products, a Division of WGM Safety Corp., has been active in the field of respiratory protective devices for many years. We recognize the need to provide the end user with the highest level of protective equipment possible and therefore support any activity to ensure the workers continued safety. We concur that 30 CFR Part 11 is obsolete and needs updating; however, the proposed revisions outlined under 42 CFR 84 do not improve the situation, and in fact, may reduce the actual protection afforded to the workers.

Our detailed review and comments concering 42 CFR 84 are attached. In general, however, our concerns and objections are summarized as follows:

1) Technically, the proposed revisions are ambiguous, contradictory, and overly burdensome in both intepretation and execution. Statistically valid studies to support certain areas of the document have neither been cited nor published, and leads us to suspect that changes are being made politically and not scientifically. The proposed revisions will, in effect, eliminate certification of certain types of existing respirators. Not one shred of medical evidence has been offered to support the need for this change.

2) Administratively, the proposed revision is a blend of regulatory and legislative sections which are neither consistent nor unbiased. We believe the document in itself not only restricts the due process afforded to a manufacturer, but also is in direct violation of both Executive Order 12291 and The Freedom of Information Act in various subparts of the proposal. The proposed revisions would permit biased and inconsistent activities on the part of NIOSH with little or no regard to the use of scientific methods.

3) Philosophically, 42 CFR 84 allows NIOSH to back out of the main picture and wash the government's collective hands of responsibility in the non-mining area. The proposal to remove 30 CFR Part 11 Subchapter B (Reference: Federal Register, August 27, 1987, pgs. 32313, 32314) states "Both rulemaking activities will be coordinated to ensure that the level of protection afforded to miners and other effected workers is maintained at all times during the development and transition period". 42 CFR Part 84 is for certification of respirators used only in the mining industry and ignores "other effected workers".

In the past NIOSH has approved respirators for which there were no provisions in the regulation. It is evident that NIOSH approved these devices with the understanding that the contaminants in question were not found in mines. Over the years NIOSH has published reports on subjects which pertain to the non-mining general industry and has been an important force in the safety of the worker. Their certification branch has insured that only the best respiratory equipment will be certified. Injury Prevention and Surveillance has researched and developed protocols ranging from firefighter's helmets to quantitative fit testing of respirators. The legislative restriction might be to mining, but NIOSH has shown by their actions their moral commitment to general industry.

Our position on 42 CFR 84 is as follows:

1) Willson supports the need to update 30 CFR Part 11. The proposed 42 CFR 84 does not, at this time, offer an improvement to the existing procedures.

2) Willson supports the continuation of NIOSH as the certifying agency for respiratory devices and does not support any concept of self - certification or third party certification.

3) Willson recommends that the proposed 42 CFR 84 be retracted, rewritten, and resubmitted with the appropirate corrections and supporting background data included.

If there are any questions concerning our position on 42 CFR 84 please let us know.

Very Truly Yours,

James P. Kline
Director of Operations

JPK/kmp

84-050

Willson Safety Products

Comments on the Proposed 42 CFR Part 84

Regulatory Impact Analysis

(1) The proposed rule is incomplete and unclear. It does not include field test protocols which are one of the major changes in the standard. Because of this, manufacturers can only estimate the significant costs which will be incurred. Certification costs are also yet to be determined. The cost for certification must be stated beforehand.

NIOSH has stated that it will determine whether or not to verify submitted test results. This is inconsistent and may lead to biased determination. Either NIOSH should or should not verify test data for all submittals; maybe is ambiguous.

A proper economic impact analysis has not been performed due to Part 84 being incomplete. The impact on the economy cannot be established when the effects on respirator manufacturers are undetermined. Therefore, it cannot be assumed that the rule will not have an "annual effect on the economy of $100 million or more."

(2) Due to the necessity of purchasing new test equipment, redesigning products, recertifying products, and the paperwork involved in such, the cost of manufacturing a respirator may increase dramatically. Based on the information in the proposal, the cost for recertifying products will be significant. This cost increase must be absorbed in some way.

(3) Small respiratory manufacturers may suffer if this proposal becomes final. The small manufacturers that cannot absorb this cost will no longer be able to offer certified respirators. This will result in less competition between manufacturers and a reduced selection for respiratory users.

The person who is required by OSHA regulations (29 CFR Part 1910) to use an approved respirator will find it difficult to comply. At this time we do not know what OSHA will require of end users when the revised 1910.134 is published. The respirators on the market will be approved for use in mines and tested accordingly. This will result in confusion and inconvenience to the end user and safety professionals alike.

Subpart A - General Provisions

84.1 Purpose

Reference is made only to certification of respirators for use in mines and mining. There are no provisions to offer protection to users in, or certify respirators, for, general industry, construction, and small business. Over 90% of the respirators in use today are for non-mining use. Willson supports NIOSH as the government certification agency for all respirators regardless of industry. NIOSH as part of the Department of Health and Human Services, Public Health Service, is responsible for the health and welfare of the entire public, not ony miners. Therefore, in order to protect the health of all workers, NIOSH must continue to certify respirators as in the past.

The proposal for removal of Subchapter B from 30 CFR Part 11 (reference Federal Register, August 27, 1987, pgs 32313,4) conveys no implication that future certifications will be for respirators used only in mines. Reference is made to MSHA consultation for certification of respirators used in mines. It does not state that this will be for all respirators. In the last paragraph of section II, it states "Both rulemaking activities (Removal of 30 CFR Part 11 and enacting 42 CFR Part 84) will be be coordinated to ensure that the level of protection afforded to miners and other affected workers is maintained at all times during the development and transition period." It is obvious that this is not the case. 30 CFR Part 11 Subchapter B is being removed based on the new regulation (42 CFR Part 84) protecting all workers. 42 CFR Part 84 is only for certification of respirators used in mines.

84.2 Certified Respirators

(a) Determination of certification by reviewing test reports as opposed to verifying test results could be biased and not ensure a safe respirator. Willson supports the testing of all respirators before certification is granted. Each manufacturer must be evaluated in a consistent manner. Employee turnover at NIOSH can add to the inconsistency of the expectations during documentation review.

In addition, it is stated that the respirator is to meet the "requirements set forth in this part". Many requirements are not included and others are vague and open for interpretation. There is no provision to ensure consistent interpretation of the NIOSH requirements from manufacturer to manufacturer.

(b) Without knowing the complete test protocols, it is impossible to determine if five years is sufficient time for recertification of current respirators. Willson supports the need for updated certification tests; however, respirators certified under 30 CFR Part 11 should maintain their certification. There is no research or medical evidence to support decertifying the respirators approved under 30 CFR Part 11. If NIOSH has such information to support this decertification it must be made available for public comment.

84.3 Definitions

"Major Modification" - as defined in the proposal is vague, unclear and open to various interpretations. A major modification should be a modification affecting only fit or performance.

"Respirator" only pertains to respiratory protection worn in mines. This must be changed to include all respiratory protective devices, regardless of where worn.

"Simulated Workplace" and "Workplace" refer to mines. This evaluation in a mining environment is of no value to the worker using a respirator in a non-mining situation. Willson is opposed to workplace/simulated workplace testing requirements as part of certification. There are no published protocols or research to justify workplace testing as part of certification. If evidence exists supporting the accuracy, reliability, and reproducibility of such testing, it should be published for review and comment. Effective comment cannot be made without this information.

Subpart B - Application Procedure

84.11 Required contents for an application to NIOSH for certification

(d) When submitting a new respirator for certification, prototypes representative of the intended production product should be acceptable. Requiring the expense of production tooling is unacceptable considering the possibility exists that the respirator will not be approved due to undefined test requirements. At this time we do not yet know what all of the test protocols will entail and NIOSH states that they can require "additional tests" (Reference 84.30 (d) after the product is accepted for evaluation.

(g) NIOSH has recently reduced the paperwork (letter to respirator manufacturers, September 15, 1987) requiring parts lists only for components listed on the approval plate. This requirement is a complete reversal of current policy.

(i) The actual cost for submittal should be known by the appplicant beforehand. Small companies could develop a new product and realize after submittal they can not afford to certify it. An accurate economic impact analysis cannot be performed when the cost for certification is unknown.

(j) Basic HHS Policy for Protection of Human Research Subject (45 CFR Part 46 Subpart A) is a regulation covering research performed or funded by HHS. This regulation should not be applied to specific testing which NIOSH is requiring the industry to perform. If NIOSH is concerned about the impact on workers by the proposed testing, NIOSH should submit their field test and fit test protocols to HHS for approval. It is unacceptable for NIOSH to require a type of testing that HHS may later determine is unsafe to perform.

Subpart C - Quality Assurance

84.20 Quality Assurance

(a) The term, "critical characteristic" must be clearly defined. As it is, the term is vague and open to arbitrary interpretation by each individual manufacturer.

General: Since the proposed ruling appears to be applicable only to the certification of respirators for use in mines, does that mean that the Quality Assurance portion of this document must be met for only those respirators sold to mines?

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

"Produced or assembled" should read "shipped". There is no need for notification when a product discrepancy is discovered before shipment or before which time the manufacturer is no longer in control of the product.

(b) There is no justification for reporting to NIOSH product discrepancies that do not detract from the levels of protection afforded to the user. The manufacturer's resources would be better spent correcting the problem as opposed to doing unnecessary paperwork.

"Reasonable time" is vague and left open to interpretation by each manufacturer.

(c) This notification should be required only when defects detract from the level of protection afforded to the user.

84.22 Notification by the Manufacturer to NIOSH

(b) Production of occasional non-conforming material is normal to any manufacturing process. The purpose of implementing quality control plans is to assure the material is not released for sale and distribution. The sentence should be modified to read "The total number of respirators distributed, and no longer in the possession of the manufacturer".

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

(a) (4) and (b) "Reasonable amount of time" needs to be defined. This statement is vague and unclear.

(c) Notification to distrubutors and end users should only be required when defects may detract from the level of protection afforded by the respirator.

Subpart D - Respirator Testing by Applicant

84.30 Lab testing by applicant and interm certification

(a) The second sentence should be modified to read "In addition... performs as required...". The word "expected" is based on someone's subjective belief and not on published performance requirements. The word "may" should be removed from the last sentence to make this a more objective determination.

(b) (2) Change to read "A detailed description or reference to ...". An unnecessary amount of paperwork is being generated if standard test methods routinely used are required to be reproduced in this document.

(c) The decision by NIOSH to test or not to test could be biased and inconsistent. Each manufacturer must be evaluated in a consistent manner. Employee turnover at NIOSH can add to the possibility for inconsistent decisions. Willson supports the testing of all respirators before certification is granted.

(d) "Additional tests" must be defined at this time, not after a product is submitted. Requiring "additional tests" in only certain instances is arbitrary and subjective. The determination to require additional testing can be biased in favor of or against certain manufacturers. At this point, there has been no determination as to what the additional tests may be.

If there are additional tests which are of significance in evaluating the effectivness or quality of a respirator, then they should be included as part of this standard and applicable to all manufacturers.

(e)(2) Change to read "performs as required". "Expected" is a subjective response and not based on the requirements of this part.

(e)(3) The word "may" should be deleted to make this a more objective determination.

(f) Ninety days is too long for interim certification. For final certification thirty days should be sufficient when no testing is required and sixty days where testing is necessary. Allowing ninety days for interim certification would have a negative impact on a manufacturers ability to compete. This conflicts with statements made under Regulatory Impact Analysis.

At what point is the test report accepted? "Acceptance" must be defined or limited to a time frame.

(f) (1) This evaluation in a mining environment is of no value to the worker using a respirator in a non-mining situation. Willson is opposed to workplace/simulated workplace testing requirements as part of certification. If evidence exists supporting the accuracy, reliability, and reproducibility of such testing it should be published for review and comment.

(f)(2) Implies that an interim certification can be rejected based on the applicants report without verifying the results. The burden of proof of failure to comply should rest with NIOSH.

84.31 Guidelines for workplace or simulated workplace testing.

(a) Workplace/simulated workplace testing is unclear, undefined, vague, burdensome, and open for interpretation. The protocols will not be made available until final ruling (Reference Preamble). This constitutes a major part of the regulation and is stated that the regulation will become law without the protocols being made available for public comment. This is a violation of our rights under the Administrative Procedures Act.

It is stated in the preamble that NIOSH does not yet have these protocols developed, yet this section states that these tests are to adequately determine respirator performance. This cannot be stated unless there is evidence supporting that this is possible. Meaningful comment cannot be made when the protocols are not available.

Worksite testing will be uncontrollable and inconsistent from site to site and manufacturer to manufacturer. Since the manufacturers, not NIOSH, will be doing the testing there will be different interpretations of the protocols. There is no correlation between workplace testing and the actual protection the user achieves. Therefore, the inconsistent and uncontrollable data will have no significance to the end user.

(b) Correlation to workplace testing cannot be made (Reference Preamble) when this workplace test protocol is nonexistent. Worplace testing will be uncontrollable and inconsistent from site to site and manufacturer to manufacturer. Since the manufacturer, not NIOSH, will be doing the testing there will be different interpretations of the protocols.

The manufacturer has no control over the end user's respirator usage. It is overly burdensome to expect the manufacturer to anticipate unusual and nonstandard usage and test accordingly.

(c) Who qualifies as an "expert"? What are the requirements used to determine the effectiveness and safety of the respirator? The paragraph must be more specific.

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

NIOSH is not a regulatory agency and should not be assigning protection factors. It is up to the end user to perform fit testing to determine they meet assigned protection factors. OSHA, or the agency recognized by OSHA, should set forth the protection factors which must be obtained by the end user. Willson supports quantitative fit testing by NIOSH only to ensure that respirators have the capability to meet existing protection factors accepted by OSHA.

The respirators are required to meet protection factors at a 95% confidence level in workplace or simulated workplace testing. At this time these test protocols are non-existent. We cannot effectively comment until these protocols are available.

(a) & (a)(1) " Substantial evidence" must be clarified. This is an unclear and vague requirement.

(a)(1) The word "expected" should be changed to "required" and the word "may" deleted. This is a more objective evaluation.

(a)(2) This section is vague and the requirements are undefined. Comments cannot be made without more specific information.

(b)(1) What determines if a respirator is "properly fitted"? This must be defined.

(b)(2) The proposed rule requires that during analysis of the workplace protection factor data, 95% of the test subjects must achieve a workplace protection factor in excess of the stated assigned protection factor with 95% confidence. There is too much variability in the test methods to require the use of confidence intervals. When the confidence interval is added to the prediction, no field test performed to date indicates any tested respirator can meet its assigned protection factor. For example, a half mask respirator with a minimum workplace protection factor (WPF) of 22 in the DuPont asbestos study would have a WPF of 6 using the NIOSH methods.

Protection Factor Table

The protection factors in the table are extremely low in some cases and extremely high in others in comparison with the numbers accepted by OSHA. There is no substantial data included to justify these numbers.

(d) What defines "acceptance" of the test report? This must be defined before comment can be made.

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

This entire section should be deleted. NIOSH is not a regulatory agency and should not certify respirators to protection factors. There is no correlation between workplace testing and the actual protection the user achieves. Therefore, the inconsistent and uncontrollable data will have no significance to the end user. Higher certification will only be supported relative to performance and not fit characteristics.

84.34 Availability of Respirator test results and protocols

The way the paragraph is stated it is unclear if NIOSH is stating their intention to make test protocols available to us or to make the manufacturers test results available to the public.

As for the manufacturers test results, Willson considers information submitted, and results obtained, to be trade secret and/or commercial or financial information which is privileged or confidential within the meaning of the Freedom of Information Act, 5 USC 552.

Test protocols must be made available to the manufacturers. Without these protocols we cannot make meaningful comment.

Subpart E - NIOSH Certification Label

84.40 Required contents of a certification label

(a)(3) The lot number or date code should appear on the packaging and not the certification label. This will cause confusion when labels are located in the instructions or literature and not kept with the respirator with which they were obtained. Most respirator instruction books contain multiple approval labels to cover all respirator configurations. The requirement limits the feasibility of the manufacturer to quickly convey the proper information on the products. The assumption is made that "labels" are the only means by which respirators are marked.

(a)(8) The word "may" should be substituted for "should". There is no reason to require the end user to forward complaints to NIOSH. Most problems can be resolved easily without putting an extra burden on NIOSH. Willson does support informing the end user that they "may" contact NIOSH.

(a) (9) Marking the fully charged and discharged weight permanently and legibly on each SCBA is not a feasible requirement. It is not possible to meaningfully comment on this paragraph since NIOSH has not stated why they have included this requirement. However, as stated, this requirement would be virtually impossible to comply with. Respirators are approved for use with many accessories or options. Each time an accessory or option is added or removed, weight changes occur. Some can be very significant, such as switching from a steel to an aluminum cylinder. In addition, the components themselves vary a great deal in weight from one to another. For example, one steel cylinder might vary 2 pounds from another of the same type.

84.41 General label and marking requirements

(b) This requirement is burdensome and unclear. "Major Component" needs to be defined in order to determine NIOSH's intentions. Not all component parts are large enough to be labeled in a legible manner. Packaging should be labeled as indicated, not the respirator and components. Components should be labeled to only identify component part or identified in the instructions when labeling is not feasible.

Subpart F - Maintenance, Informational and Instructional Materials

84.50 Operation and maintenance manuals

(a) Manuals are not always necessary to contain all the information required for proper use of a respirator. Some types of respirators, such as disposable respirators, do not require maintenance and have operating instructions that are simple enough to be placed on the packaging.

Many disposable respirators are multiple-packed in a single box and providing instructions for each is not necessary since the user has access to the box.

Wording should be changed to read "operation and maintenance instructions shall be provided with each respirator container and shall..."

(1),(2) and (b) The word "manual" should be replaced by the word "instructions" for the reasons stated above.

Subpart G - Modification of Certified Respirators

84.60 Major modification of certified respirators

The section covers the procedure NIOSH will follow if the recertification is denied. It does not include any provision for granting recertification.

(a) It is unclear what NIOSH will require in this part since the definition for "major modification" is so vague. Without clarification of the definition this section cannot be commented on.

84.61 Minor Modification of Certified Respirators.

This section has no significance without a clear definition of "major modification".

Subpart H - Withdrawal of Certification

84.70 Withdrawal of certification for cause.

(c) This should only be justified as a reason for withdrawal of certification if 84.21 through 84.25 as reference in this part are changed as recommended.

(g) The word "produce" should be replaced with "release for use". A manufacturer should not lose certification due to a production problem.

(h) The manufacturer should not lose certification because NIOSH has not determined a proper test method. If NIOSH means that the tests contained in this regulation may now or in the foreseeable future prove to have no validity and are not meaningful, then the whole regulation should be recalled and held until such time as valid and meaningful tests and requirements can be proposed. If in the future such information becomes available, new rulemaking can be initiated. Every other government agency must proceed through rulemaking process before imposing new requirements. NIOSH has shown no need for abandoning due process provided under law in the Administrative Procedures Act.

(i) Change to read "A determination ... certified respirator deviates from the requirements of this part or from its design in a manner making it defective...".

This change is necessary to remove subjectivity from such a determination. Therefore, both the design of the product and the requirements of this part must be referenced here.

Subpart I - Appeals

84.80 Appeal Procedure

This section allows for appeals of a NIOSH decison, but the NIOSH director is not bound by the judges ruling. This is not a fair appeals procedure. The director of NIOSH must be bound by the Administrative Law Judges ruling to revise, reverse, or affirm the original NIOSH determination. This is a violtaiton of our right to due process.

Subpart J - Fee Determination

84.90 Fees

Undetermined fees are unacceptable. An applicant must know exactly what fees will be charged for a submittal before an application is made. The fee schedule must be open for public comments. An accurate economic impact study cannot be performed if the cost of certification is undefined. Open ended cost could cause small respirator manufacturers to be unable to certify respirators.

(c) It is stated that NIOSH will publish a notice of the availability of the current fee schedule each January in the Federal Register. This implies that the fee schedule itself will not be published. The fee schedule is part of the rule and should be open for public comment.

Subpart O - Technical definitions

84.200 Definitions as used in this part

- "IDLH" needs clarification

(1) The word "delayed" should be moved so it reads "... immediate or delayed threat of loss of life or irreversible effects ...". Metal fume fever is an example of a delayed effect that is reversible and not life threatening.

(2) Should be removed. It is not valid to include eye irritation levels as IDLH.

A statement should be added to include an oxygen deficient or oxygen level outside the range of 19.5% to 23% atmosphere as IDLH.

- "dBA" needs clarification.

Must specify the type of sound level meter to be used. This will ensure reproducibility from manufacturer to manufacturer.

- "Face Seal Leakage" is vague.

It is not stated if the leakage is instantaneous or an average. Furthermore, there is no indication as to the instrumentation used.

-"Particulate Respirator"

Recommend changing to read ". . solid and/or liquid.."

Solid particulates are a more commonly encountered respiratory contaminant. Most liquid and oil mist contaminants require the use of a HEPA filter due to the PEL for those substances. The HEPA media used today does remove solid and liquid aerosols. Therefore it is not necessary for all filters to remove both olid and liquid particles.

- "Loose fitting facepiece" and "tight fitting facepiece" A respirator is not referred to as having a gas tight seal. This is contradictory with the allowance for inward leakage during facefit testing or filter penetration. Recommend removing the words "gas-tight".

Subpart P - Classification

84.210 Classification of certified respirators

(a)(2) Implies that a PAPR can be approved with a low efficiency filter. This is not consistent throughout the document. Reference 84.210 (c) - medium and high; 84.235 - low, medium and high; and 84.270 (d) - medium and high

(a)(2) and (c)

Willson recommends that particulate respirators be classified as "solid and/or liquid aerosol removing". Solid particulates are a more commonly encountered respiratory contaminant. Most liquid and oil mist contaminants require the use of a HEPA filter due to the PEL for those substances. The HEPA media used today does remove solid and liquid particles. Therefore, it is not necessary for all filters to remove both solid and liquid particles.

(b)(2) This section is vague and very unclear. The words "in terms of the regulator type" should be removed. The wording implies that a continuous flow air-line respirator must include a regulator. 84.251-3 (c) states that a regulator on a continuous flow respirator is optional.

The words "or continuous flow air-line respirator" should be removed. this implies that a continuous flow respirator is not positive pressure. Another option to alleviate confusion would be to add the words "positive pressure" before "continuous flow" or to categorize air-line respirators as such: 1 Pressure Demand 2) Demand and 3) Continuous Flow. If it is felt that the airflow requirements for continuous flow respirators are not sufficient, then those requirements should be changed.

Abrasive blasting respirators have been approved in the past and are not included here. This deletion must be justified or else the category should be included.

(c) Refers only to a medium and high efficiency approval for a PAPR. This is inconsistent throughout the document. Reference: 84.210 (a) unclear; 84.235 - low, medium and high; 84.270 (d) medium and high.

84.211 Combination Respirators

Provison for combination escape respirators should be included. NIOSH has allowed for these types of approval in the past. An air-line respirator, used in an air-purifying mode only for escape, should not have to meet resistance requirements as an air-purifying respirator.

Subpart Q - General Construction and Performance Requirements

84.220 General Construction Requirements

(e) The ANSI Z87.1-1979 standard has no provision for testing impact and penetration resistance of respirator lenses. A specific test method for performing this test must be provided.

(f) Only half-mask respirators, or hoods and helmets with lenses not meeting impact and penetration requirements should be designed so as to allow the manufacturer's recommended safety glasses. There is no need to require safety glasses under a full-facepiece respirator which has an impact and penetration resistant lens. Full-facepiece respirators should only be required to provide for the use of corrective eyewear.

(h) This is a subjective evaluation. A specific test method and requirement must be provided.

(i) If NIOSH desires a degree of corrosion and deterioration resistance a specific test method and requirements must be provided.

84.221 Test Requirements: General

Provision for combination escape respirators should be included. NIOSH currently approves these products. An air-line respirator, used in an air-purifying mode only for escape, should not have to meet resistance requirements as an air-purifying respirator.

84.222 Breathing Tubes

(c) Must be removed. "Interference" is undefined making this a subjective requirement.

(d) This is a vague statement and must be more specific.

84.223 Body harnesses

(c) Recommend changing to read "Body harnesses for self-contained breathing apparatus certified for fire fighting shall remain functional..."

The type of harness meeting this heat resistance requirement is not suitable for many industry uses such as the nuclear industry where decontamination of this type of harness is not possible.

84.224 Respirator Containers

(a)(b) & (d)

These requirements are not performance oriented and should not be included in a certification standard.

(a) The word "durable" is undefined and should be removed.

(b) Is vague and unclear, should be removed.

(c) Should be required only for escape respirators.

(d) Test requirements are necessary.

84.225 Head Harnesses

(a) This is a vague and undefined requirement. Should be removed.

(b) Mouthpiece respirators do not have or need adjustable or replaceable harnesses. The neck strap is not intended to hold the mouthpiece in place. This requirement should be removed.

(c) This is a design limitation and must be removed. A disposable respirator with elastic headbands does not need provisions for adjustments. Elastic headbands are adjustable by their very nature.

84.226 Inhalation and exhalation valves

(a) "Distortion" is undefined. The manufacturer cannot comply when requirements are vague.

(c)(1) Must be clarified as to what conditions and what "external influence" includes.

(c)(2) Contradicts 84.227 (b) which allows 30 ml/min inward leakage at 25mm water column height suction.

84.228 Air velocity and noise levels; Hoods and helmets

The title of the section is air velocity and noise levels, however, nothing is said about air velocity. A test method should be defined to eliminate ambiguity.

84.229 Procedure for sequential analysis of performance test results using one-sided tolerance limits.

(d) and (e) This requirement is burdensome, unreliable absolutely unscientific, and conducive to inaccuracy. The sample size is too small to obtain an accurate and reliable statistical analysis. The method for data analysis must be revised.

84.232 Negative pressure respirators, either air purifying or atmosphere supplying respirators.

This section covers fit testing of respirators as a requirement for certification. NIOSH has published the NIOSH Respiratory Decision Logic which contains reference to the unreliability of fit testing. Other studies have been performed showing the variability of data obtained when fit testing. The following information is quoted directly from the NIOSH Respiratory Decision Logic.

"No qualitative or quantitative fit tests have been demonstrated to be capable of effectively identifying inadequately fitting respirators (i.e., respirator-wearer combinations that provide less protection than the APF). The presently used fit test (e.g., ANSI-recommended, OSHA-approved) may fail to identify individual wearers with inadequate respiratory protection. Thus fit tests should be used with caution and with recognition of their possible deficiencies. As appropriate, periodic evaluations of the of each respirator during use in the workplace should be conducted to ensure that each wearer is being provided with adequate respiratory protection."

"Regarding quantitative fit testing (QNFT), no studies are available to indicate what fit factor value (i.e., screening level) will ensure a high probability of identifying inadequately fitting respirators. That is, there are no studies demonstrating what fit factor values are adequate accept/reject criteria for QNFT fit screening. When QNFT is used for fit screening, the fit factor screening level should be chosen with caution and with recognition of the uncertainty of its effectiveness. As appropriate, periodic evaluation of the effectiveness of each respirator during use in the workplace should be conducted to ensure that each wearer is being provided with adequate respiratory protection".

A study by Patricia M. Holton and Klaus Willeke discusses the variability of face fit data due to the diameter of the leak and the use of different test aerosols.

Myers, Allender, Plummer, and Stobbe have published a study showing the variability incurred by probe location and depth.

Myers and Hornung performed a study funded by the EPA which discusses the bias resulting from using various sampling methods.

The information shows that even NIOSH does not have the technological capability at this time to perform accurate, reliable, face fit testing. The manufacturers can not be expected to perform testing for which established protocols and technology do not exist.

(a) Sizing method and designation means should be up to the manufacturer, and not be based on the Menton-Nasal Root Depression Length and Bizygomatic Breadth. Los Alamos National Laboratories developed the panel structure in which these measurements are used, and which shows the percentage of the population that can be expected in each category. The panel is used for selecting subjects for face fit testing and ensuring there is good coverage of the population. It is important to realize that the study was performed on white, male servicemen. This is not representative of the population. Los Alamos does not support the use of Menton-Nasal Root Depression Length and Bizygomatic Breadth for sizing respirators.

(d) Recommend changing wording to read ..."shall be fit tested with the test subject properly fitted with safety spectacles designated by the respirator manufacturer and ..."

(e) The particle size for fit testing is stated as 0.6 + or - 0.2 micrometer. This conflicts with the particle size at which the filters are evaluated (0.2-0.3 micrometer, Reference 84.273 (g)). In 84.231 (b), the filter leakage may be eliminated from the fit test leakage. This would result in an inaccurate evaluation, and Willson does not support this elimination. We do however recommend using the same particle size for fit testing and filter penetration. This would be much more practical.

Quantitative fit testing using probed respirators is biased and not reproducible. The probe location, probe depth, and respirator design affect the results. Warren Myers, while working for NIOSH, was involved in a study of probe placement which showed these effects. This testing cannot be a certification requirement when it has proven so unreliable. If NIOSH has studies or evidence supporting a reliable, consistent evaluation, it must be made available at this time for public review and comment.

(f) The exercise regimen contains exercises not used in a standard fit test. Raising arms while looking upward and bending forward while touching the toes are new exercises that must be justified with supporting data. Grimacing and frowning is for the purpose of determining the respirators ability to reseal itself. This has no purpose in determining the protection factor and must be deleted.

(h) The method used for data analysis results in lower protection factors than those we calculate today.

(h) (2) Needs clarification. The volumetic flow through the face seal leak is not possible to determine.

(i) Size marking should be up to the manufacturer to determine and mark or so designate as appropriate. If masks were designated as stated, the workforce would require extensive training to interpret.

(j) The fit factors to be met are excessively high, conflict with the protection factors in 84.32 and are inconsistent with published and recognized protection factors (OSHA,ANSI).

The leakage units must be defined. It is not accurate to state a leakage without using units of measure.

References

1. U.S. Department of Health and Human Services, "NIOSH Respiratory Decision Logic", May 1987.

2. Holton, Patricia, M., Willeke, Klaus, "The Effect of Aerosol Size Distribution and Measurement Method on Respirator Fit", AIHA Journal, Volume 40, 1987, pp. 855-860

3. Myers, W.R., Allender, J., Plummer, R., Stoble, T., "Parameters that Bias Measurement of Airborne Concentrations Within a Respirator", AIHA Journal, Volume 47, 1986, pp 106-114.

4. Myers, Warren, R., Horning, Richrad, W., "Evaluation of New In-Facepiece Sampling Procedures for Field Facepieces", EPA, May 1987.

Subpart R - Faceseal Leakage

84.230 Applicability

A more accurate and reproducible method would be to measure total inward leakage as opposed to face seal leakage.

84.231 General

(a) The assumption that exhalation valve leakage is negligible is contradictory to the allowable exhalation valve leakage of 30 ml per minute. (Reference 84. 227).

(b) In the proposed standard, filter penetration and face fit leakage are not measured using the same equipment. Therefore, the filter penetration cannot be eliminated from the data. Even if the same particle size were used, this alteration of the data would produce unreliable results. The filters are challenged at different flow rates, configurations and environments. It is recommended to measure total inward leakage.

(c) This is assuming that all gas and vapor respirators will have elements interchangeable with particulate elements. Previous sections (84.11 (d)) require production tooling for submitted respirators. Manufacturers may have to produce parts only for the purpose of fit testing. This requirement is unacceptable.

84.233 Positive pressure atmosphere supplying respirators.

(a) Fit testing a positive pressure respirator in the negative pressure mode would not comply with 45 CFR Part 46, Subpart A - Basic HHS Policy for Protection of Human Research Subjects. The exercise regimen calls for nine exercises for a minimum period of one minute each. It is not humanly possible to subject oneself to a nine minute routine without air and still maintain consciousness. It would also be impossible to perform the 1) Normal breathing and 2) Deep breathing exercises.

(a) & (b) The requirements to be met are not only excessively high, but conflict with the protection factors in 84.32. The respirator is expected to perform to a much higher level than which NIOSH accepts for use. The leakage units are undefined and must be stated throughout.

84.234 Continuous flow atmosphere supplying respirators.

By listing this section separately, it is implied that a continuous flow respirator is not positive pressure. If NIOSH feels the flow requirements are not sufficient for a continuous flow respirator, then the flow requirements should be changed.

The requirements to be met are not only excessively high, but conflict with the protection factors in 84.32. The respirator is expected to perform to a much higher level than which NIOSH accepts for use. The leakage units are undefined and must be stated.

84.235 Powered Air-Purifying respirators.

This states that a particulate PAPR can be approved with high, medium and low efficiency filters. This is inconsistent with sections 84.210(a), 84.210 (c) and 84.270.

The fit factors to be met are not only excessively high, but conflict with the protection factors in 84.32. The respirator is expected to perform to a much higher level than which NIOSH accepts for use. The leakage units are undefined and must be stated.

84.236 Mouthpiece Respirators.

These respirators are for escape only and there is no justification for fit testing. Furthermore, it is not technologically feasiable to probe the respirator.

84.237 Reduced Panel Size

This section should be removed. Willson does not support fit testing as described within as a requirement for certification. A panel of ten in an extreme facial size would be difficult to obtain.

Subpart S - Self Contained Breathing Apparatus

84.242 Interchangeability of oxygen and air prohibited; use of 100% oxygen in open flames and high heat.

(b) This is a performance standard and NIOSH should not be making recommendations. The use of products is regulated by other agencies (OSHA, MSHA).

84.243 Compressed breathing gas and liquefied breathing gas containers.

(d) CGA has recently issued its new version of this standard CGA V-1, 1987. The 1965 version is now outdated.

84.244 Pressure indicators

Wherever "gauges" is used it should be "gauge(s)". It is design restrictive to require two gauges.

(d)(1) "Accurate" would be a better word than "reliable".

84.245 Timers; Elapsed time indicators; Remaining service life indicators

(a) (2) "Gauges" should be replaced with "gauge(s)".

(b) Delete "remaining service life" and insert "or elapsed time". Remaining

(h) Delete reference to "normal hearing". The requirement for the audible alarm of end-of-service indicators should be measured in dBA at the wearer's ear. We are also concerned about restricting the use of non-audible alarms. This is a design requirement and restricts innovation.

84.246 Hand-operated valves

(a) This is a design requirement and "normal usage" is not defined. If this is a necessary requirement, then a specific test method is required.

(b) "External forces" must be defined.

(c) This should be reworded to say "... be readily operated...". These valves are not for the purpose of making adjustments.

84.247 Breathing Bags

This entire section is vague and the requirements are not defined. "Sufficient volume", "adequate reserve", "flexible", "resistant", "damage", and "external forces" are all subjective requirements. Design restrictions should not be included in a certification standard. Performance requirements must be specific in order for the manufacturers to comply with the standard and to comment on the proposal.

84.248-1 Component parts exposed to oxygen pressures.

If this is a requirement, it must be defined.

84.248-2 Compressed gas filters.

"Effectively remove" is not defined. To what degree?

84.248-4 Weight markings.

Marking the fully charged and discharged weight permanently and legibly on each SCBA is not a feasible requirement. It is not possible to meaningfully comment on this paragraph since NIOSH has not stated why they have included this requirement. However, as stated, this requirement would be virtually impossible to comply with. Respirators are approved for use with many accessories or options. Each time an accessory or option is added or removed, weight changes occur. Some can be very significant, such as switching from a steel to an aluminum cylinder. In addition, the components themselves vary a great deal in weight from one to another. For example, one steel cylinder might vary 2 pounds from another of the same type.

84.248-5 Breathing resistance test

(a)(2) Recording instrumentation sensitivity, accuracy and response time must be specified in order to provide uniformity and repeatability of test results between NIOSH and the manufacturers.

(c) The breathing resistances are listed without significant figures. It is current policy at NIOSH to measure to 0.1 figures. If this is the intent, it should be stated.

84.248-7 Bypass gas flow test.

(a)(4) "In paragraph (e)" should refer to paragraph (5).

84.248-9 Service time test; Closed-circuit apparatus

(a) & (b) The technology exists to perform these tests using machine tests (metabolic simulators) which would give more consistent results.

84-248-11 Test during low temperature operation.

(e) (1) "Function satisfactorily" must state requirements.

(e)(3) "Undue discomfort" is a subjective requirement.

(e)(4) "Proper functioning" must state requirements.

(f) The end user should not be able to use any commercial parts, only those recommended by the manufacturer.

84.248-12 Shock and vibration tests

The current MIL-STD 810 standard is at Revision D as of July 19, 1983 and there is no callout for rubber-tired vehicles. Therefore, the protocol for the vibration test is not specific. A method and category should be specified. It is not clear if the apparatus is to be operated during the vibration test. A respiration rate or tidal volume must be specified for the machine test if required.

How the apparatus is to be mounted should be specified as most manufacturers cannot provide this information due to the wide variety of industries the equipment goes into. The mounting is normally determined by the user.

Why 60 LPM? It should either be 40 LPM on a breathing machine or 300 LPM constant flow to be consistent with 248-6(a)(2) or 243-8(b). The requirements should be brought in line with NFPA 1971, self-contained breathing apparatus for fire fighters.

(b) The shock test should be eliminated due to inherent variability of such tests.

(d) "The vibration test shall be performed..." should be reworded to cover deletion of shock test. Recommend the testing to be performed on a metabolic simulator not on human test subjects.

84.248-13 Use tests; Purpose and requirements; general

(b) We recommend the use of metabolic simulators instead of human test subjects.

84.248-15 Use Transfer test

(b) A person using a respirator is required to be trained for such use. Expecting a person to operate this respirator just after reading the instructions is a bias evaluation.

84.248-16 Use tests; Requirements.

(b) "Undue discomfort" is a subjective requirement. The evaluation for fogging must be defined to be more objective.

84.248-17 Flammability

The proposed standard includes a test which exposes a respirator facepiece to the action of flame while sealed to a mannequin head.

This test is unrepresentative of respirator use conditions and is potentially design restrictive. Self-contained breathing apparatuses (SCBA) are not intended for flame contact. However, if a respirator were briefly to come in contact with flame there is no logical way to predict which part of the respirator may be contacted by the flame. Therefore, a flame test of the respirator should be designed to expose the entire respirator uniformly to flame contact. Accidental contact with flame is primarily of interest while the respirator is being used. The flame test should be arranged so that the respirator is attached to a head and torso mannequin in approximately the use condition of an upright user. A flame array of the nature described in the proposed test should be arranged to encircle the torso and pass slowly from bottom to top of the mannequin. The respirator should be operated by a breathing machine during this exposure. The criteria should be continued operation of the respirator, non-separation of the respirator from the mannequin and no after flame of the respirator. The current test is potentially design restrictive because it does not require the respirator to continue to operate during and after the flame exposure. This may encourage respirator designers to locate components which they believe to be sensitive to flame contact on portions of the respirator remote from the facepiece in an effort to avoid failing this test.

Figure 2, Detail 1 and Detail 2

This figure illustrates each component with a label for each part.

The burner size or a brand must be specified to allow duplication of test results. We would also require additional dimensions to allow accurate positioning of each facepiece.

Subpart T - Air-line Respirators

84.250 Air-line respirators; Description

The entire paragraph is unclear and must be rewritten. The words "stationary", "compressed" and "high pressure" restrict design and should be removed. The reference to air requirements should only specify Grade D breathing air as prescribed in 19 CFR 1910.134 (d)(1)(ii). The wording of the paragraph implies that continuous flow respirators are not positive pressure and require an air regulator as part of the respirator (conflicts with 84.251-3(c).

84.251-3 Air-Supply line tests.

(b)(1) The information could be conveyed in a much clearer manner. Ex. The respirator assembly, with specified hose length shall maintain a minimum of 4 cfm and a maximum of 15 cfm at the specified pressure range.

(c) On what research data or protocol is the test requiring actuation of the regulator 20 times per minute for a total of 100,0000 inhalation level based? Is there some justification for these particular requirements or are they just arbritrary?

The purpose of an air control valve is to adjust the air flow. It is absurd to require it to remain at a specific adjustment.

84.251-4 Harness Test

(f) This should not be required to be attached to a part of the wearer's clothing. The degree of comfort, whether or not it disturbs the wearer or restricts movement is very subjective.

84.251-5 Breathing Tube Test

(a) The words "or disturb the wearer" should be removed. It is ambiguous and subjective. The other requirements must also be defined to be more objective.

(b) and (c) should be together, not separating continuous flow respirators. This is implying that a continuous flow respirator is neither positive or negative pressure.

84.251-8 Air flow resistance test; Airline respirator, positive pressure class

(b) This is a very confusing statement and should be clarified to alleviate misinterpretation.

Subpart U - Air-Purifying Respirators; General Requirements

84.261 Cartridges, canisters and filters in parallel; Resistance requirements.

"Essentially equal" needs to be replaced with an exact requirement. What is the definition for "essentially equal"?

84.262 Filters used with canisters and cartridges; Location; Replacement.

(a) Suggest wording be revised as follows: "Particulate filters used with a gas and vapor canister or cartridge shall be located so that a gas or vapor removing element is located downstream of the particulate filter". In some cases it is necessary to place an additional gas or vapor removing element at the inlet to protect the filter.

Subpart V- Particulate Air-Purifying Respirators

84.270 Particulate Air Purifying Respirators; Description

Without specific approval it will be confusing for end users to determine appropriate filters. Until the new 1910.134 is made public, it is difficult to comment on how filter selection will be affected.

Willson does support eliminating the particulate tests in 30 CFR Part 11 due to the lack of reproducible results. The changes that are made must be consistent with the regulations of the agency that regulates respirator use. (OSHA 29 CFR 1910)

(a) Solid particulates are a more commonly encountered respiratory contaminant. Most liquid and oil mist contaminants require the use of a HEPA filter due to the PEL for those substances. The HEPA media used today does remove solid and liquid aerosols. Therefore it is not necessary for all filters to remove both solid and liquid particles.

(b) Add a statement about further classification as per removal of solid and/or liquid particulates.

(c) & (d) The requirements for filter efficiencies must be supported by research. To the publics knowledge, there has been no testing to justify these numbers and determine the technological feasibility and economic viability of the stringent requirements. Without the supporting research and test data, we have no basis for the particular efficiencies chosen.

European standards that classify filters by efficiencies do not have such stringent requirements. The British Standard, BS6016.1980, challenges the filters against NaCl at 30 lpm. The efficiencies for this challenge agent are 90%, 95%, and 97.5%. The CEN draft standard pr EN 143 which is already adhered to in some countries has flow requirements for Paraffin oil and/or NaCl test at 95 lpm. The efficiencies for the NaCl are 80%, 94% and 99.5%. The efficiencies for paraffin oil are 98% and 99.9%.

(d) A PAPR low efficiency filter approval is not included. This conflicts with 84.235 and 84.210.

84.271 Performance requirements; Particulate air-purifying respirators; general

(b) This section must be modified to reflect the recommendations in 84.270.

84.272 Airflow resistance tests

(b) The breathing resistances are listed without significant figures. It is current policy at NIOSH to measure to 0.1 figures. If this is the intent, then it should be stated.

84.273 Particulate instantaneous penetration filter test.

NIOSH has not published evidence supporting the use of both oil and solid particulates to determine all filter efficiencies. This information must be available for public comment if it justifies the test requirements. We recommend a solid and/or liquid particulate respirator certification.

(b) "Immediately after conditioning" must be changed to a specific amount of time. It is not feasible to perform the tests immediately.

(d) The low flows of 32 and 16 lpm are unnecessary and serve no purpose in evaluating respirator filters. Low test flows are used for detecting holes in large clean room HEPA filters. Filter paper efficiency is evaluated by higher test flows. This type of challenge is not necessary for respiratory filters which cover a much smaller area. The higher flow will always result in a higher leakage when testing respirator HEPA filters whether the leakage is due to a hole or to filter efficiency.

(e) The filter elements only should be required to meet the penetration requirements of this part using the flows for which the blower will operate. The blower itself is evaluated in 84.263 which is sufficient.

(e)(1) Needs clarification. The word "cycled" implies that the air is not inhaled and exhaled through the respirator.

(f) & (h) Instantaneous penetration should be measured to alleviate this long duration test (15 to 20 minutes per filter).

(g) "...Aerodynamic mean diameter..." does not exist. Should this be "... mass mean aerodynamic diameter..."?

Subpart W - Gas and Vapor Air-Purifying Cartridge Respirators

84.280 Gas and Vapor air-purifying respirators; description

Maximum use concentration for Methylamine has been lowered from 100 ppm to 75 ppm. The justification for this must be available for public comment. The current NIOSH Respirator Decision Logic, May 1987, states the Methylamine maximum use concentration as 100 ppm. NIOSH should be consistent in its publications.

Specific approvals for Vinyl Chloride and Formaldehyde etc. for which NIOSH has test protocols, have not been included. Subpart Z does allow for approval of gases which are not specifically listed, but since the protocols are already developed they should be included.

Approvals are for specific gases which eliminate "acid gas" approval. Where the OSHA/NIOSH Pocket Guide recommends acid gas respirators, these cartridges cannot be used.

(c) NIOSH is not a regulatory agency and should not be determining respirator use. MSHA is the only agency listed in this proposal as being able to approve administrative controls. NIOSH has ignored the responsibility of OSHA in regulating respiratory use and administrative contols. Adhering to the provisions in this part would eliminate the use of cartridges in cases where OSHA allows for their use. An example would be the Benzene Standard.

84.283 Breathing Resistance Test

(a) There is no need for a final resistance test and requirement Testing cartridges against gases does not increase breathing resistance.

(b) The breathing resistances are listed without significanct figures. It is current policy at NIOSH to measure to 0.1 figures. If this is the intent, it should be stated.

84.284 Gas and vapor cartridge service life test

(c) Testing equilibrated cartridges within 8 hours is too time constraining. Testing within 24 hours would be more reasonable and it would still maintain the same level of performance. If there is supporting evidence for this change, it should be published for review and comment.

(f) Willson recommends that the HCl test be eliminated. Cartridges that pass Chlorine and/or Sulfur Dioxide will always pass HCl.

Minimum life requirements are too stringent for equilibrated cartridges if they are to be tested at 64 lpm. The public has not stated the need for respiratory protection exceeding the current performance levels. The result of these requirements will be larger, bulkier respirators which will not be conducive to the end users' comfort. The technical justification for the change in required performance level must be stated. This information must be made available for comment.

Test concentrations and penetrations require tolerance limits. There is a certain amount of error in these tests which should be defined.

Subpart X - Gas and Vapor Air-Purifying canister respirators

84.290 Description and classification

(a) In the last sentence, "escape" needs clarification. "Escape" from what is not defined.

(b) Approvals are for specific gases which eliminate "acid gas" approval This is contradictory to current approvals for gas masks. Where the OSHA/NIOSH Pocket Guide recommends acid gas respirators these canisters will not be permitted.

(c) This restricts innovation by eliminating the possibility of all other contaminant approvals.

(d) NIOSH is not a regulatory agency and should not be determining respirator use. MSHA is the only agency listed in this proposal as being able to approve administrative contols. NIOSH has ignored the responsibility of OSHA in regulating respirator use and administrative controls. Adhering to the provisions in this part would eliminate the use of cartridges in cases where OSHA allows for their use. An example would be the Benzene Standard.

84.293 Breathing resistance test and 84.294 Particulate Test; Canisters containing filters.

(a) There is no need for a final resistance test and requirement. Canister tests against the challenge gases do not increase breathing resistance.

(b) The breathing resistances are listed without significant figures. It is current policy at NIOSH to measure to 0.1 figures. If this is the intent, then it should be stated.

84.295 Canister Service life test.

(c) Testing equilibrated canisters within 8 hours is too time constraining. Testing within 24 hours would be more reasonable and it would still maintain the same level of performance. If there is evidence supporting this change, it must be published for comment.

(d) and (e) Minimum life requirements are too stringent for equilibrated canisters if they are to be tested at 64 lpm. The public has not stated the need for respiratory protection exceeding the current performance levels. The result of these requirements will be larger, bulkier respirators which will not be conducive to the end users comfort. The technical justification for the change in required performance level must be published for comment.

The test concentrations and penetrations require tolerance limits. There is a certain amount of eror in these tests which should be defined.

Table 6

The carbon monoxide test at 20,000 ppm has two contradictory conditions on it.

(f)(1) and (f)(3) The requirement that the indicator change within 80 + or - 10% of the service life is in conflict with Section 84.314(a) of Subpart Z "...the indicator shall change or afford such warning less then or equal to 90% of the total service life." The -10% tolerance should be dropped since a change at less than 80% of the service life gives a greater safety factor.

Subpart Y - Organic Gas and Vapor Air-Purifying cartridge and canister Respirators

84.300 Description and limitations.

(c) NIOSH is not a regulatory agency and should not be determining respirator use. MSHA is the only agency listed in this proposal as being able to approve administrative controls. NIOSH has ignored the responsibility of OSHA in regulating respirator use and administrative controls. Adhering to the provisions in this part would eliminate the use of cartridges in cases where OSHA allows for their use. An example would be the Benzene Standard.

84.302 Organic gas and vapor air-purifying canister respirators

(a)(2) In the last sentence, "escape" needs clarification. "Escape" from what is not defined.

84.303 Labeling requirements

(a) Labeling requirement is unacceptable:

-When the list is printed and is in the hands of the end user there is no protection for the manufacturer if OSHA changes a PEL, thereby redefining the warning properties of the substance.

- In OSHA's new Benzene Standard, the use of an organic vapor respirator is accepted even though Benzene is recognized as having poor warning properties. In this case, the manufacturer would be implying that the respirator cannot be used, but OSHA allows such use.

- A substance cannot have adequate warning properties if there are not PELs or TLVs set for it. This limits respirator usage to only regulated substances. A person desiring to wear protection for a non-regulated substance, possibly for an allergy or irritation, cannot legally do so.

- Including a list as part of the label would turn the label into a book 29 CFR Part 1910.1000 Table Z-1 and Z-2 includes an alphabetical listing of airborne contaminants including organic vapors. The first page, almost half of which is not devoted to Table Z-1, contains 64 chemicals, starting with Acetaldehyde and ending at Chlorodiphenyl. Of these chemicals: 11 are not gases, 5 are not organic vapors, 14 have inadequate warning proporties or sufficient information is not available to determine warning properties, 32 have adequate warning properties! This is only the first page of the table. Tables Z-1 covers an additional 3 pages, table Z-2 covers half a page. The result will be an extraordinarily long approval label which may change when OSHA regulations change.

Section 84.41 calls for an abbreviated label to be on all cartridges and canisters. Does this include this listing of chemicals?

84.306 Breathing resistance test and 84.307 Particulate tests; canisters and cartridges containing filters.

(a) There is no need for a final resistance test and requirement. Cartridge and canister testing against CCl_4 does not increase breathing resistance.

84.308 Service Life Test

Testing equilibrated cartridges and canisters within 8 hours is too time constraining. Testing within 24 hours would be more reasonable and it would still maintain the same level of performance. If there is supporting evidence for this change it should be published for review and comment.

Minimum life requirements are too stringent for equilibrated cartridges and canisters if they are to be tested at 64 lpm. The public has not stated the need for respiratory protection exceeding the current performance levels. The result of these requirements will be larger, bulkier respirators which will not be conducive to the end users' comfort. The technical justification for the change in required performance level must be stated. This information must be made available for comment.

Test concentrations and penetrations require tolerance limits. There is a certain amount of error in these tests which should be defined.

Subpart Z - Gas and Vapor Air-purifying Respirators for Unlisted Contaminants

84.312 General test requirements.

(a) All of the requirements that are to be included in the certification application must be stated here.

(a)(6) There are not always studies or data available on the warning properties of all chemicals. If there are no PELs or TLVs for the substances,it is not possible to have adequate warning properites.

34.314 Requirements for end-of-service-life indicators.

(a) This contradicts cases where MSHA or OSHA allows the use of a respirator without end of service life indicators against a contaminant without adequate warning properties.

(b)(1) There must be guidelines for contaminant concentrations if no TLVs or PELs exist.

(b)(3) The manufacturer cannot anticipate all use conditions in the workplace. This requirement must be removed because it is not feasible to comply.

(b)(4) Toxicity data is not available for all substances.

(c) Requirement should be removed. If a person is color blind, that is a physical impairment preventing their use of this type of respirator, not a reason for restricting design. The requirement for the ESLI to be visible to the wearer restricts innovation.

(e)(4) This restricts innovation by eliminating disposables.

(e)(7) The manufacturer cannot anticipate all use conditions in the workplace. This requirement must be removed because it is not feasible to comply. The requirement for the labeling should be reworded to add a statement about "where known to the manufacturer".

(e) (9) This would be be a physical limitation restricting a persons' use of a respirator. This is not a reason for restricting the design of a respirator.

(f) This section is confusing and must be clarified. It is describing respirators without ESLIs - Why is it in this section?

Appendix A - Assumed Conditions of Use

It is stated that these respirators referenced in Part 84 are governed by MSHA. This means that they are certified for mine use only. This does not offer any certification mechanism for respirators for general industry, and therefore no guaranteed protection for those users.

(d) NIOSH is not a regulatory agency and should not be determining respirator use. MSHA is the only agency listed in this proposal as being able to approve administrative controls. NIOSH has ignored the responsibility of OSHA in regulating respiratory use and administrative controls. Adhering to the provisions in this part would eliminate the use of cartridges in cases where OSHA allows for their use. An example would be the Benzene Standard.

(e) The definition of adequate warning properties not only subjects the wearer to exposures above the PEL, but is inconsistent with the logic used in the recommendations made in NIOSH Pocket Guide to Chemical Hazards.

(f) "Gas and vapor cartridge respirators will be used in concentrations in excess of the maximum use concentration". It is unclear why NIOSH should make this assumption when such use is prohibited by regulation.

(j)(1) This paragraph is redundant with Section (g) which covers air quality of atmosphere supplying respirators.

(j) (2) This paragraph refers to paragraph (c), but (c) does not seem to apply