84-033

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December 2, 1987

NIOSH Docket Office
Mail Stop E-23
1600 Clifton Road NE
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Dear Sir:

Enclosed are comments prepared by National Draeger, Inc. in response to proposed rule 42 CFR, Part 84.

Sincerely,

Les Boord
Vice President
Safety Division

LB/kc

Enclosure

cc: R. Dangers
W. Kenneweg
Dr. Sieber

84.1 Purpose

While the Mine Safety and Health Act of 1977 requires NIOSH to approve and certify respirators for mines and mining, the Act does not prevent NIOSH from approving and certifying respirators for non-mining use. More than 90% of the respirators in use today are for non-mining use. NIOSH should expand the scope of its respirator certification program to address the needs of the vast majority of respirator users. For example, a SCBA with harness designed to meet the needs of the firefighter in mines would not most likely meet the needs of the nuclear industry where decontamination is a major factor, since the fireproof design would probably entail using a somewhat porous material that would trap radioactive material. Many other conflicts can be expected between the certification needs of the general respirator user and the miner wearing a respirator.

84.2

(a) Determination of certification by reviewing test reports as opposed to verifying test results could be biased and not ensure a safe respirator. National Draeger supports the testing of all respirators before certification is granted. Each manufacturer must be evaluated in a consistent manner. Even employee turnover at NIOSH can add to the inconsistency due to the subjectivity of the document review.

(b) Five years time will not be sufficient for manufacturers to make the necessary changes to their respirators and obtain certification. The users of these devices will have their programs interrupted because of unavailability of approved respirators.

Ten years would be a more appropriate time frame.

84.3

"Major Modifications"

This wording is extremely vague, and needs to be clarified.

"Respirator"

This definition denies the existence of situations other than mines where respirators are used. The definition should be expanded to read "any device worn by an individual designed to provide the wearer with respiratory protection against inhalation of a hazardous atmosphere."

"Simulated Workplace"

Simulated workplace must be expanded to other work situations and not only mines or mining work sites. Also, "reasonable representation" of any work site would have to be clarified as to what parameters should be evaluated to constitute a reasonable representation.

"Workplace"

"Workplace" should be expanded to any work site, not only "mine or mining work site."

84.11

(j) 45 CFR Part 46 Subpart A - Basic HHS Policy for Protection of Human Research Subjects is a regulation covering research performed or funded by HHS. This regulation should <u>not</u> be applied to specific testing which NIOSH is <u>requiring</u> the industry to perform.

The HHS approval procedure is extremely burdensome. All tests involving human subjects (fit test subjects, workplace test subjects) would be covered by this policy. The requirement is that an Institutional Review Board (IRB) be set up to govern human subject testing. The board must consist of members not having a conflict of interest with the research being conducted. This policy is normally applied to universities where volunteers from other departments can be used to make up the board. However, a manufacturer would need to hire outside consultants for every position. The board's function and procedure is governed by written guidelines and procedures that must be preapproved by the Secretary.

The policy requires the use of a lengthy informed consent requirement that must be both documented and witnessed informing the test subject of any possible risk that may occur. This appears to entail analyzing the worker's normal job and categorizing risks for field test. The consent form shall not contain any statements attempting to limit the manufacturer's liability should the testing in any way harm the subject.

In general, the requirements of this section are untenable and would appear to offer little, if any, added safety for field test subjects since workers are exposed to negligible incremental risk from the testing as opposed to risks normally present in their jobs.

84.20

(a) NIOSH states that the applicant, as part of his QA program, must "inspect or test, or both, the critical characteristics identified in the appropriate subparts of the part." It is difficult to comment on this rquirement because NIOSH has not defined the "critical characteristics" to which it is referring or which subpart is applicable. If NIOSH intends that the applicant conduct

workplace testing or anthropometric facefit panel testing on each lot of respirators, this would constitute an impossible burden on the applicant. NIOSH must identify "critical characteristics" before meaningful comments can be generated.

(b) "Critical characteristics" must be defined before meaningful comments can be made.

(d) Same as (b).

(e) NIOSH should conduct periodic plant audits, with advance notice, whether they have reason to believe the manufacturer is distributing non-conforming respirators or not. Periodic plant audits should be performed to assure compliance with good manufacturing procedures and, in effect, prevent distribution of non-conforming products.

84.21

Presently worded, a manufacturer would have to notify NIOSH of <u>any</u> respirator produced or assembled by him that fails compliance requirements. It would serve no purpose for NIOSH to be notified if such respirators did not leave the manufacturer's facility and would be disposed of so that they would not be used or sold to anyone.

(a) & (b)

This must be clarified so as to mean only respirators that have left the manufacturer's facility with the intent to be used or sold.

84.22

(b) Production of occasional non-conforming material is normal to any manufac-

turing process. The purpose of implementing quality control plans is to assure the material is not released for sale and distributed. The sentence should be modified to read "The total number of respirators distributed and no longer in the possession of manufacturer."

84.30

(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.

(b) (2) Change to read "a detailed description or reference to...." An unnecessary amount of paperwork is being required if standard test methods that are incorporated by reference must be reproduced in this document.

(c) The decision by NIOSH to test or not to test could be biased. National Draeger supports the testing of all respirators before certification is granted. Each manufacturer must be evaluated in a consistent manner.

(d) Change last sentence to read "NIOSH will...stating specifically the reasons...." If NIOSH is imposing additional requirements, it must state specifically, not generally, what is required.

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

84.31

The proposed regulation contains the requirement that the performance of all respirators be tested in the workplace. The Preamble to the proposed rule states that the protocol and details for performing these field studies will be

available at the time the final rule is promulgated. This represents a denial of due process of law by not allowing affected parties to comment on feasibility, cost and validity of requirements before they go into effect. If NIOSH is going to proceed with a rulemaking hearing, then another hearing on the detailed requirements for field testing protocols should be held before the final rule is promulgated. For example, the proposal doesn't stipulate how many workplaces need to be included in the tests, nor how many subjects in each workplace need to be studied.

The tremendous expense of field testing will put a severe burden on the respirator user since these costs will be passed on to the product.

The proposed rule also allows the use of simulated workplace testing in lieu of workplace testing if a good correlation can be established between the two types of tests. However, because of the variables involved in workplace testing are so large, establishment of such correlations cannot be accomplished. To date, no lab tests have correlated to any workplace tests.

NIOSH is requiring all workplace testing to be done in mines or involving mining operations. Not enough mines exist to accomodate the number of tests required. NIOSH has stated in conversation that non-mining work sites may be used if correlations with mining work sites are established. Such correlations are not possible given the high variability intrinsic to these test methods. Furthermore, with all respirator manufacturers attempting to test several respirators per year and considering a typical test takes a month to perform, testing would be in progress at virtually all the existing mines 100% of the time. In addition, while most types of respirators may at some time be used in mines, subjects wearing organic vapor or paint spray respirators, for example, would be hard to find.

Technology does not exist today to perform workplace testing against most hazardous substances found in the workplace. Analytical methods do not have sensitivity sufficient to make meaningful measurements of performance, especially with those respirators having high assigned protection factors.

(b) It is impossible to comment because NIOSH has not specified the conditions one needs to consider in order to determine if the workplace or simulated workplace is representative of where the respirator will be used. There are thousands of conditions and environments in which respirators are used.

84.32

(a) The assigned protection factors, found on page 32409, are very low for certain types of respirators such as continuous flow airline and low efficiency respirators (see discussion under 84.232 (j) regarding low efficiency respirators), but are very high for positive pressure SCBA. There is no justification given for NIOSH's assigned protection factors.

It is impossible to comment without knowing NIOSH's reasoning behind the proposed numbers.

(a) (1) Change the word "expected" to "required by this part." Expected is a subjective response. Also, delete "which may make" and replace with "which make."

(2) This section is too vague to comment on. For example, for which observations are methods to be provided, which results are to be recorded, which variables measured, which subjective responses measured, which biases measured? This sections provides the commenter with no basis to form comments.

(b) This section is also vague. It is impossible to comment on. For example, how many workplaces need measuring, how is one to determine which workplace is representative of another, which conditions must be measured?

(1) This section is too vague to comment on.

(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.

84.40

(a) (3) The requirement for placing "the lot number or other appropriate designation of date of manufacture" on the approval label is unnecessary and unworkable. This information is already required in section 84.41 (b) to be "placed on each respirator, major respirator component and respirator container." Most certification labels are printed on the respirator or component package or inserted into the carton containing the respirator as a booklet or placed in the operating and maintenance manuals for the device.

To change these booklets on a daily basis would be prohibitively expensive and, since this information is already on the packaging and on the respirator, redundant and unnecessary.

(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 two pounds from another of the same type.

84.41

(b) It is very difficult to comment on this paragraph since NIOSH has not defined what a major component is. Some components of respirators such as valves and gaskets will have their performance adversely affected by the marking requirements, making such a requirement infeasible.

It is the manufacturer's responsibility to determine what components are to be traceable in his QC plan.

84.60

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

NIOSH needs to modify its definition of "major modification." See definition section 84.3.

84.80

The proposed rule sets up an appeals procedure, but the outcome of the proceeding is not binding on the director of NIOSH. This must be changed, or in effect no appeals procedure exists.

Change by dropping the last sentence and add "The decision of the administrative law judge will be binding pending further appeals as determined by the Administrative Procedures Act."

84.90

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.

84.223

(c) "...shall not melt" should be replaced with "shall remain functional."

84.229

(e) "If the initial sample of three fails to demonstrate performance at the required level of confidence, additional samples shall be tested and m, s and UTL or LTL shall be recalculated for the total sample using K from the following table:

n	K	n	K
3	6.158	11	2.275
4	4.163	12	2.210
5	3.407	13	2.155

n	K	n	K
6	3.006	14	2.108
7	2.755	15	2.068
8	2.582	16	2.032
9	2.454	17	2.001
10	2.355	18	1.974

If at any point, acceptable performance is demonstrated, the performance test may be terminated.

If the additional samples fail to demonstrate acceptable performance at the 95 percent confidence level after 18 samples, the respirator under evaluation shall be considered unacceptable."

NOTE: This table is taken from Juran, "Quality Control Handbook," Third Edition, Appendix 11, Table V.

84.232

(a) Sizing, (b) Panel Selection, (i) Marking

NIOSH is requiring the use of an anthropometric panel as developed by Los Alamos National Laboratory to test and size respirators. The panel is composed by selecting and assigning individuals to sizes or grids on the basis of two facial measurements, length and width. The 25 people are selected to obtain a distribution of facial sizes as defined in the Los Alamos panel. NIOSH is requiring manufacturers to specify which contiguous grids of the panel their respirators are designed to fit. The 25 people are then proportioned accordingly among the designated grids. After compliance is demonstrated, the manufacturer is required to mark each facepiece to indicate the range of facial sizes the mask is intended to fit, based on the panel structure.

While the relationship between facial size and respirator size may be reliable for the extremes, i.e., very large faces need large respirators and very small faces need small respirators, it is a poor predictor of fit for the majority of faces that fall in between the extremes. This is because the two facial measurements don't account for differences in facial shapes and contours, which will have a great effect on the size and shape of respirators needed to achieve a good fit. Therefore, the NIOSH proposal forcing manufacturers to arbitrarily specify grids, and fit faces within those grids with a designated size of respirator to achieve certification, is burdensome and meaningless.

Furthermore, the NIOSH statement in (h)(5) of this section, that the panel testing confers with 95% confidence that 95% of the population represented by the test panel can achieve leakage values less than the maximum allowed leakage, is misleading. The reason it is misleading is because the population "represented" by the test panel is in no way well described by the only available facial measurements, length and width.

An alternate scheme for sizing respirators and testing respirators' fit capacity on human subjects is proposed:

I. Single or multiple sizes designed to fit the general workforce.

1. Compose a 25 person panel per the Los Alamos grid.

2. If more than one size is available, the subject shall choose the size that is most comfortable. NIOSH shall assist in the process of selecting the size of respirator that is most likely to fit the subject. If that size fails to fit, other sizes will be tried. The value from the best fitting size will be used.

3. Respirators available in a single size shall employ fit values for 20 out of the 25 panel members for determining compliance with the requirement. The five worst fit factors shall be deleted before calculating maximum allowed faceseal leakage.

4. Respirators available in multiple sizes shall fit the specified proportion of the panel for calculations for compliance determination, as follows:

Number of Sizes	Proportion of Panel
4 or more	24/25
3	23/25
2	21/25

5. Marking, Single Size: The following shall appear on the respirator use instructions: "This respirator is designed to fit many facial shapes and sizes. However, face shapes vary widely, so the fit of this respirator cannot be certified. The fit must be verified on each individual respirator wearer with a fit test."

   Marking, Multiple Sizes: The following shall appear on the respirator use instructions: "This respirator comes in multiple sizes designed to fit many faces. Use of all sizes will help to fit more faces. However, face shapes varly widely, so fit of any respirator cannot be certified and the fit must be verified on each individual respirator wearer with a fit test."

6. Sizing: Manufacturers are at liberty to size their products in any logical manner they choose, such as small, medium, large; medium/large,

medium/small; 1,2,3,4; etc.

II. Single or multiple sizes designed to fit a particular segment of the population.

If a manufacturer chooses to develop a mask for a specific segment of the population, such as orientals, people with small faces, etc., the manufacturer shall so specify on the application for certification the facial attributes the respirator is designed to fit.

1. Based on the manufacturer's specified attributes, a 25 person panel shall be composed by selecting members having those attributes specified by the manufacturer.

2. See sections 2-4 above, for the general population, for assigning sizes of multiple sized respirators to panel members and for methods for determining compliance.

3. Marking, Single Size: The following shall appear on each respirator: "This respirator is specifically intended to fit (fill in the target population, i.e., small or oriental, or female, etc.) faces. Although this mask is designed to fit _____ faces, facial shapes vary widely. The fit of any respirator on an individual cannot be certified and must be verified by a fit test on the respirator wearer."

   Marking, Multiple Sizes: The following shall appear on each respirator: "This respirator comes in multiple sizes designed to fit _____ faces. Use of all sizes will help to fit more faces. However, face shapes vary widely, so fit of any respirator cannot be certified and must be verified on each individual wearer with a fit test."

4. Sizing Respirators: Same as section 6 above for the general population.

Justification for Alternate Proposal

The alternate proposal accomplished the goal of assuring that masks with poor fitting capability are not certified. In addition, the alternate proposal has the following benefits not present in the NIOSH proposal:

1. The alternate protocol optimizes use of the Los Alamos panel. The panel is used to select people with the same variety of face shapes, as determined by length and width, as occurs in the general population. However, the panel concept is not used beyond its applicabilty as was the case in the NIOSH proposal. For example, NIOSH was assuming just two facial measurements will always be a good predictor of the size of respirator needed. NIOSH even implies that they have great confidence that 95% of the people in the general population falling within the grids will also achieve a fit on the certified respirator if the NIOSH proposal were adopted.

   The many other features of people's faces that will occur at random in any panel or in the general population prevent respirator sizing or prediction of fit based only on length and width measurements. For example, jaw line or shape, prominence of cheek bones, width and depth of nose bridge, chin prominence, etc., could have a greater effect on a respirator's fit on an individual than length and width.

2. The alternative proposal assigns and tests sizes of multiple size respirators in the same manner they are assigned in the workplace, i.e., the size that looks and feels like it will fit the worker is

tested first, followed by other sizes. In addition, the NIOSH proposal fails to address the issue of special training that would be necessary for each and every employer before accurate measurements of respirator wearer's faces could be made.

3. The alternate proposal allows manufacturers to target and design their respirator to fit a certain segment of the market (not necessarily based on size), that might otherwise have a difficult time finding good fitting respirators. For example, a recent report demonstrated that men and women of the same facial size have different jaw lines. A manufacturer could design a respirator with a narrower chin cup specifically to fit women. Likewise, it may be possible for a manufacturer to design a respirator with a flatter nose bridge that would better fit oriental faces.

84.232

(f) Exercise Regimen

We feel exercises of 30 second duration provide the same assurance of fit measurement as do one minute exercises. Reducing the exercise duration to 30 seconds also greatly reduces the testing burden associated with evaluating facepieces on 25 individuals for a faceseal capability determination. Reducing the exercise duration reduces the testing time per person from approximately 12 minutes down to 6½ minutes. For a 25 person panel, this results in a savings in use of valuable test equipment and technician time of over 2½ hours.

We also feel it is inappropriate to include "grimacing or frowning" as one of the test exercises. It is difficult to comment on this since NIOSH provides no explanation or justification for its inclusion anywhere in the Preamble or the

proposed rule. In the past, this exercise was used by Los Alamos National Laboratory and others as a means of purposefully inducing a faceseal leak, then checking for ability of the mask to reseat and reseal on the wearer's face. It is an impossible exercise to standardize or perform repeatedly in the same manner by the same person.

84.232

(h) Analysis

NIOSH is proposing to require manufacturers to first compute the lower fifth percentile of the average inward leakage during nine exercises, for the 25 people comprising the panel, then apply an added factor of statistical conservation in the form of 95% confidence limits, before they can demonstrate compliance with the requirement for allowable faceseal leakage. Measuring fit factors on a 25 person panel is too highly variable to suggest application of statistical confidence limits. An estimate of a value which 95% of the people on the panel would exceed, based on results from 20-24 out of the 25 people (see discussion in section (a) above) is a very rigorous test of acceptable fitting capability of a respirator. NIOSH's proposal penalizes manufacturers for variability in the test that has little to do with the inherent fitting capability of the respirator. For example, in addition to choosing a very wide range of face sizes by the two dimensions of length and width in selecting people for the panel, the multitude of other dimensions affecting fit will also vary randomly. Thus, you would <u>expect</u> a large range in fit values. In addition, the well documented variability in fit for repeated donnings of the same facepiece by the same individual and the variability in the test methods add considerably more variability to the test.

NIOSH appears to be implying with their approach to this test that the test will be a useful predictor of fit on a given individual. But no test on a panel can ever take the place of performing a fit test on each individual for every respirator they will wear. This requirement should be aimed at preventing respirators with inherently poor fitting capability from being certified, i.e., those respirators that can be expected to consistently fail to provide an acceptable fit to most wearers.

84.248-4 Weight Marking

It is impractical to mark each apparatus with the fully charged and discharged weight. This requirement would require that each apparatus be weighed in each configuration at the time of assembly.

84.248-6 (b) (4) Gas Flow

The last sentence of this paragraph implies that positive pressure units must have a constant flow. This sentence should be revised to state "For positive pressure apparatus employing a constant flow, the constant flow shall be greater than one liter per minute for the entire rated service time.