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NEOTERIK HEALTH TECHNOLOGIES, INC.

July 13, 1994 /A

NIOSH Docket Office
Robert A Taft Laboratories, Mail Stop C34
4676 Columbia Parkway
Cincinnati, OH 45226

Gentlemen:

We are a small business manufacturing, among other items, respirators which are NIOSH approved. We are submitting this comment on 42 CFR Part 84, Respiratory Protective Devices; Proposed Rule.

This comment is on para 84.184, sub-part (j) on 26885, and para 84.170 on 26883.

This paragraph proposes that a certain statistical calculation shall be performed in order to assess the result of filter penetration tests.

We oppose this proposal, and recommend that it be deleted and replaced by the following:

(j) The maximum filter penetration for each of 20 filters shall be determined and recorded. The particulate respirator filter shall meet the requirement of this subpart if:
for type A, no filter exceeds 0.0003 penetration
for type B, no filter exceeds 0.01 penetration
for type C, no filter exceeds 0.05 perpetration

Our reasons for this recommendation are as follows:

(1) The proposed statistic U=M+2.22s is not explained or justified. We have assumed that because M is the mean penetration and s is the standard deviation, then U is intended to be an estimate of the extent of the variability in the penetration through filters. U attempts to predict the highest value for penetration through all future filters which will be manufactured. This approach is in error in two important ways. First, it confuses Type Approval with Quality Control. Second, it is an incorrect application of statistics to the assessment of the results of the testing.

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(2) Type Approval and Quality Control should not be confused. 42 CFR Part 84 correctly presents the Proposed Rule as a system for Type Approval of respirators. It also, in Subpart E, includes requirements for Quality Control. This results in a total approval system which uses Type Approval to establish that the product will in fact satisfy specific tests, and then uses Quality Control Approval to ensure that future production items are manufactured in the same, consistent manner. These are clearly different requirements, and Part 84 correctly requires both. However, in 84.184 (j) these two requirements are confused.

In this one paragraph, and only in this one, there is an attempt to go beyond the purpose and capability of the testing. The penetration tests will show whether these particular filters meet the standard or not. If they do, they should be approved. If not, they should not be approved. The data collected cannot, and should not, be used to estimate the limits of future production variability. The whole purpose of the distinct Quality Control program is to combat this production variability. The test results obtained from 30 filters provide no useful information on the future performance of the Quality Control program.

The factor 2.22 S in the statistic U is derived from some assumed distribution. Before any meaningful use can be made of U, it must also be assumed that these 30 observations are a random sample from that distribution. Both these assumptions are false. These 30 filters are not a random sample, they are the result of a series of operations, inspections and tests, all of which truncate and skew the many distributions involved. Since it is a mistake to assume that a regular distribution of any kind does exist, it is a further and greater mistake to assume that such a non-existent distribution will repeat in the future. Suppose that a manufacturer makes a batch of filters, some of which he accepts, and some of which he rejects because they fail. If 30 good filters are checked as part of an approval program, the variability in these 30 will not be related to the variability in the full batch in a way which can be estimated from knowledge of the variability in the sample. Any conclusions based on such an assumption are technically and statistically incorrect. Because NIOSH is concerned about variability in the manufacture of future batches of filters, then NIOSH must ensure that the Quality Control tests used by the manufacture are adequate

The statistic U=M+2.22s is inconsistent with the Quality Control plan in Subpart E, which recommends MIL-STD-105D or MIL-STD-414. The statistic U, which for a Gaussian distribution would yield a single-sided interval of 0.013, cannot be achieved with any of the many plans in these two widely used standards.

(3) The Proposed Rule does not explain why the statistic U should be used only for interpreting tests of filter penetration; and why U is not proposed to be used for interpreting the other tests. For example, other performance tests appear in Subpart K. The requirement in each case is that the item shall pass the test. Only in 84.184 is there a requirement that the item shall pass a test and then be subjected to a statistical calculation to see if the item has really passed or not. These following paragraphs are tests without the statistic U, even through U could indeed be calculated for each one, if it was useful:

| | |
|---|---|
| 84.183 | Airflow Resistance Test |
| 84.185 | Flow Requirements |
| 84.186 | Exhalation Value Leakage Test |

The Proposed Rule does not require U to be calculated for the results of these tests.

(4) In particular, U must be completely inapplicable in the case of type A (Hepa) filters. NIOSH requires that all these filters be tested and certified. Therefore, process variability is not an issue. Every single filter is tested. Therefore, the statistic U serves no purpose with Hepa filters.

(5) NIOSH may find it helpful to recommend sequential sampling plans as part of the Quality Control system for Type B and Type C filters, because such filters will not be 100% tested. Sequential plans have the advantage of requiring more testing as the batch average quality tends towards the unacceptable.

(6) NIOSH may also consider changing the test parameter, if there is a concern over variability based on past experience. For example, even though Type C may be theoretically acceptable as 0.05, perhaps the Type Approval requirement should be 0.04.

(7) Paragraph 84.170 contains definitions of the three filter types, and when 84.184 is revised then 84.170 should also be revised. We assume that the use of the term "shall demonstrate a minimum efficiency of" is somehow related to the application of the statistic U. We recommend that 84.170 read as follows:

(c) (1) Type A filters shall be tested for an efficiency of 99.97 percent

(2) Type B filters shall be tested for an efficiency of 99 percent.

(3) Type C filters shall be tested for an efficiency of 95 percent.

(d) (1) Type A filters shall be tested for an efficiency of 99.97 percent.

KV Vaughan

Kenneth V. Vaughan
President

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Gentlemen:

We are a small business manufacturing, among other items, respirators which are NIOSH approved. We are submitting this comment on 42 CFR Part 84, Respiratory Protective Devices; Proposed Rule.

This comment is on 84.170 (c) and 84.170 (d) on 26883.

84.170 (c) proposes that non-powered particulate air purifying respirators be classified according to the efficiency of the filter as Type A, Type B or Type C.

84.170 (d) proposes that powered respirators be classified as Type A or Type B.

NIOSH does not explain why there are three categories of air purifying respirators and two categories of powered air purifying respirators. We believe that the reason must be that a 95 percent filter fitted to a powered respirator could easily be misused. The user is likely to believe that the protection is greater than it really is. We endorse this, and agree that Type C filters should not be approved with powered respirators.

We recommend that Type B filters also not be approved with powered air purifying respirators. We believe that users can readily overestimate the protection received. We recommend that powered air purifying respirators be approved with only the highest grade of particulate filters, Type A / LxS (Hepa filters).

We recommend that 84.170 (d) (2) be deleted.

KV Vaughan

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Gentlemen:

We are a small business manufacturing, among other items, respirators which are NIOSH approved. We are submitting this comment on 42 CFR Part 84, Respiratory Protective Devices; Proposed Rule.

This comment concerns Section V, Executive Order 12866, on 26859.

As part of the discussion under this heading the following statement is made (beginning on line 44 of column 1).

> "respirators already using high efficiency filters meeting class A requirements will not be affected by this proposal."

We endorse this comment, and agree with its technical basis. Clearly, respirators meeting class A requirements should not be affected. As a small company, the burden of obtaining re-approval for identical configurations would be onerous and disproportionately punishing. We are pleased that it is the intent of the Proposal not to affect respirators which meet class A.

However, the Proposed Rule does not address the procedure for bringing such conforming class A respirators under 42 CFR 84.

We recommend that manufacturers with existing NIOSH approvals for respirators with Hepa cartridges submit revised Approval Certificates and labels to NIOSH for review. There should be no fee charged by NIOSH for this review. When this review is completed, such respirators will be in compliance with 42 CFR 84.

This procedure is clearly in accordance with the intent of the proposal, as explicitly stated in the commentary on Executive order 12866.

Kenneth V. Vaughan
President

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