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NEOTERIK

NEOTERIK HEALTH TECHNOLOGIES, INC.

December 28, 1987

Niosh Docket Office
Mail Stop E-23
1600 Clifton Road, N.E.
Atlanta GA 30333

Re: proposed rulemaking: 42 CFR part 84

Gentlemen:

These comments are sent to you as a participation in the proposed rulemaking.

We are a small business, located in Maryland. We design, manufacture and sell products, including respirators which need NIOSH certification.

These are our comments:

1. We are pleased that NIOSH is proposing to keep its role in a certification program for respirators. We strongly believe that an effective NIOSH program will provide protection for users of respirators.
2. The proposed 42 CFR 84 relates explicitly only to respirators used in mines and mining. This does not address the certification requirements for the majority of respirators, those used in non-mining applications. Is it NIOSH'S objective that only mining respirators be re-assessed? Or, does NIOSH intend to recommend that the proposal of 42 CFR 84 apply to all applications for respirators? Or, is NIOSH preparing another proposal for respirators used in non-mining applications?
3. The proposal includes a requirement for so-called "workplace or simulated workplace test" (para. 84-32) to be performed before certification is assured.

These tests are therefore a crucial new requirement, a requirement which we oppose absolutely!

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- (a) It will not, as claimed, assure logical and repeatable analysis of test data. The statistical methods used are not appropriate because they are based upon assumptions which do not apply in the circumstances of evaluation. The method only works if the test samples are from a normally distributed population which is free to take any of its values. In practice, the test samples are a small number of discrete items and the assumption of normality is not true.
- (b) The method attempts to make a prediction of the spread of values of test results. However, the method simply ignores the quality control program which is needed. This Q.C. program will reduce the spread of values by removing unacceptable values. For example, suppose a process produces values of 8,9,10,11, and 12. Further, suppose the values 8 and 9 are rejected by the Q.C. program, leaving only 10,11 and 12. Any statistical analysis of values 10,11 and 12 which predicts the presence in the accepted product of the values 8 and 9 is clearly worthless. The methodology of section 84-229 ignores the fact that a Q.C. program is required.
- (c) Section 84-229 is actually an argument for the abolition of quality control, an argument which we reject utterly! Mathematics must never replace quality. An effective Q.C. program will help to protect the wearers of respirators. The invalid approach of Section 84-229 will not.
5. We reserve the right to comment further at the public meetings.

Yours sincerely,



Kenneth Vaughan
President

vph

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The reasons for our opposition are:

- (a) This requirement is devastatingly unfair to small business. One of our respirators can be as good or better than one produced by a large manufacturer and yet not be certified because we might be unable to organize a field test. Clearly, giants of the industry like 3M and MSA can wield enormous commercial influence and are far more likely to receive willing cooperation from user companies than we are. This is a built-in bias against small business.
 - (b) Certain large companies will be able to perform field tests within their own company or within their own conglomerate.
 - (c) Certain large companies will be able to perform field tests within the locations of their current major customers. There will be an opportunity to offer commercial benefits to these customers and so the results, including subjective comments, may be influenced to be favorable and to gain certification. This is a built-in bias against small business.
 - (d) Certain large companies will perform their own sample analysis or use laboratories within their own organizations. This is a built-in bias against small companies.
 - (e) The field test protocols are not included for comment. How can a crucial, new test be considered by us if the test procedure itself is not available until the time of final rulemaking. We must oppose a requirement which is, in the words of the rulemakers, "the most significant of the new requirements", when we do not understand the procedures. These procedures will directly effect our ability to stay in business. As a small company, we must oppose this open-ended approach to certification. When the procedures are available, we will comment on them.
 - (f) The field test protocols are not known, and so their cost impacts cannot be determined. However, the new costs will be biased against small business. The incremental expenses will be more burdensome for us than for the big companies.
 - (g) The field tests will introduce large elements of variability, subjectivity and lack of control into the certification process. In other words, the lucky ones will get approved.
4. The proposal includes a procedure for statistical analysis of performance test results. We oppose this requirement because: