84-062

Glendale Protective Technologies, Inc.

130 Crossways Park Drive • Woodbury, N.Y. 11797

December 15, 1987

NIOSH Docket Office
Mail Stop E-23
1600 Clifton Road NE
Atlanta, GA 30333

Re: Comments on 42CFR84

Dear Sirs:

Glendale Protective Technologies, Inc., a manufacturer of NIOSH/MSHA approved respirators, has the following comments on 42CFR84, Revision of Tests and Requirements for Certification of Permissibility of Respiratory Protective Devices Used in Mines and Mining; Notice of Proposed Rulemaking:

1. The standard only applies to respirators used in mines and mining and "the issuance of certificates for respirators is limited to only those respirators used in coal or other mines." This new policy totally ignores the needs of general industry, which accounts for 90% of the respirators in use today.

2. Workplace or simulated workplace testing is required for approval. "Workplace" is defined as a mine or mining work site. Protocols for conducting workplace or simulated workplace tests have not, as of yet, been developed and the costs of such studies would add substantially to the cost of respirators and have a major economic impact on the manufacturer. In addition, not enough mines exist to accomodate the number of tests that will be required.

3. The proposed rule requires statistical analysis of the results of the workplace study to determine, with a high degree of confidence, the fifth percentile protection factor. There is too much variability in the field test methods to require the use of confidence intervals.

4. The proposed rule does allow the alternative of conducting simulated workplace tests instead of workplace tests if a correlation can be established between the two types of tests. However, no such correlation has ever been demonstrated.

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5. The technology necessary to perform workplace testing against hazardous substances found in the workplace does not exist today. The analytical methods available do not have enough sensitivity to allow for highly precise measurements of performance, especially with respirators which have high protection factors. In addition, there are no accepted methods for workplace testing of gas and vapor respirators.

6. The proposed rule does not contain a protocol outlining the requirements, rules, details and procedures for conducting the workplace test. This omission denies us due process by making it impossible for us to comment on this aspect of the proposal in a meaningful way.

7. The assigned protection factors for continuous-flow airline respirators have been lowered to 50 for a half mask or full facepiece. This change is not supported by any research study on these devices.

8. All major modifications to a respirator will require that repeat workplace testing be performed. "Major modification" is defined in the proposal in such a way that NIOSH could require workplace testing for practically any change. This puts a further burden on the manufacturer and will further increase respirator costs.

9. All respirator particulate filters will be tested against both a liquid and solid aerosol 0.2-0.3 micrometer in diameter. Nearly all non-high efficiency filters will not pass this new requirement. Electrostatic filters will definitely not be able to pass the liquid aerosol test. NIOSH has ignored previous comments from the American National Standards Institute to issue separate approvals for solid and liquid particulates and to therefore conduct only the solid aerosol test on filters designed for solids and the liquid aerosol test on filters designed for liquids (mists).

10. The proposed rule stipulates that gas and vapor respirators be conditioned at 85% relative humidity and then tested at 64 liters per minute and 85% relative humidity. The current standard requires testing at 32 liters per minute and 50% relative humidity after conditioning. All currently approved organic vapor cartridges in the U.S. today will fail this new requirement. The cartridges would have to have about $2\frac{1}{2}$ to 3 times more volume to pass the new test. This will result in much larger and heavier cartridges. The need for longer service life cartridges has not been established and this change will penalize the wearer by greatly increasing the weight and bulk of the respirator.

11. NIOSH is requiring the use of tolerance limits with a sample size no larger than 6 in the analysis of performance test data. This means that performance test results will be quite difficult to pass and many respirators approved today will not be able to meet this requirement. Larger sample sizes should be allowed which can overcome this problem without sacrificing any performance levels.

12. In the appeals procedure in the proposal rule, the outcome of the proceeding is not binding on the Director of NIOSH. The ruling by the Administrative Law Judge to revise, reverse or affirm the original NIOSH determination should be binding on the Director of NIOSH.

13. NIOSH should remove the requirement for manufacturers to label organic vapor respirators with a list of chemicals having good warning properties and for which the respirator is effective. This would place an impossible burden on the manufacturers to test the respirator against all conceivable organics. The best method for evaluation of cartridges is to run tests in the work-place against the mixtures and concentrations of organics for which the respirator will be used.

In the foregoing comments I have restricted myself to what I consider to be the major problem areas of the proposed rule. I strongly recommend that 42CFR84 be withdrawn and be reissued at some future date with full consideration given to the comments above. Once a workable document is achieved, attention can be given to the fine points which at this time are not worth commenting on because they are so overshadowed by the major changes in the proposed rule.

Sincerely,

Jay A. Parker

Jay A. Parker
Product Manager
Respiratory Protection

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