



July 19, 1994

NIOSH Docket Office
Robert A. Taft Laboratories
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Columbia Parkway
Cincinnati, Ohio 45226

LOUIS M. GERSON CO., INC.
Comments On The NIOSH Proposed 42CFR Part 84
Respiratory Protective Devices - May 24, 1994

Introduction

Louis M. Gerson Co., Inc. is a major manufacturer and supplier of respirators world wide. We market respiratory protective products which are NIOSH certified and also supply a variety of respirators which meet FDA requirements for the health industry. Some of our respirators are also manufactured to meet European, Australian and Japanese Standards.

The Gerson Company is in agreement with NIOSH that the current regulation is outdated and test methods need to be revised. We have a considerable amount of experience, knowledge and technology in the field of respiratory protection. Since our products and users will be impacted significantly by the proposed regulation (42CFR84), we would like to take the opportunity to offer our comments to NIOSH.

1. Solids and Solids and Liquid Approvals

Gerson fully supports NIOSH with their intention to certify respirators for use against solids and solids and liquids. At the NIOSH hearings on July 23 and June 24, comments were offered to eliminate the solids classification. The European respirator community has been successful with their solid and solids and liquids certification for many years. The European concept should be used as a benchmark for the industry. The suggestion to proceed with a solid and liquid only approval because of possible confusion in the industry is merely a speculation without merit. By offering the type of classifications proposed by NIOSH, it will greatly benefit the user since the cost of respirators which will meet the solids and liquids requirements will be significantly higher.

The majority of respirator users require protection against solid particulates. Those users who encounter solids and liquids usually are water based. Present dust/mist filters and respirators easily meet the water base silica mist challenge and are not degraded to the extent which DOP can do to non-mechanical filters. It would not be fair to the majority of users to be burdened with the cost of filters and respirators which can meet a severe DOP test but unnecessary for their specific application.

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2. Isoamyl Acetate Tightness Test

We believe that fit testing should be performed on the individual user. Using a surrogate respirator to pass a vapor test like isoamyl acetate does not benefit the end user. The use of a particulate fit test in the field however, would be of value to the end user. Gerson recommends that the Bitrex Qualitative Fit Test submitted by ISEA be used for this purpose.

3. Filter Loading

Gerson believes the proposed loading tests are too severe and unnecessary. The 200 mg. loading level is very time consuming, burdensome and expensive. A 50 mg. loading level would be more reasonable. Current high efficiency filters are challenged with a much lower loading level and are recognized as the "best" filter available in the U.S. Gerson questions the value of increasing this loading level when there are no indications that high efficiency filters and respirators need a more severe test.

4. Test Statistics

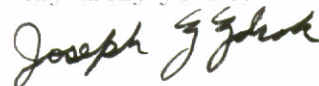
The statistical treatment of test data is very severe and will add greatly to the cost of filters and respirators. The new classification and higher efficiency levels of filters and the new method of testing will require some learning and experience. Variability from test site to test site will definitely be experienced. Adding a new statistical treatment of test data appears to be unreasonable at this time. We therefore request that this section and proposed method of data treatment be re-evaluated.

5. Summary

Gerson supports the need for an upgraded regulation. We do not however endorse any of the proposals which are unreasonably severe, expensive to implement or of no value to the end user.

Thank you for this opportunity to offer our comments.

Very truly yours,



Joseph Z. Zdrok
Technical Director
Respiratory Protection