94-207

NEOTERIK

NEOTERIK HEALTH TECHNOLOGIES, INC.

July 14, 1994

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 concerns the proposed effective date of the rule.

Paragraph III on page 26852 contains the following:

"2. Sale and distribution of respirators listed as certified under the provisions of 30 CFR Part II, subparts K or M will no longer be authorized effective 2 years from the date of publication of this rule as final."

We object to this, and propose that it be deleted and replaced with

"2. Manufacture of complete respirators listed as certified under the provisions of 30 CFR Park II, subpart K, will no longer be authorized effective 10 years from the date of publication of this rule as final."

The reasons for this are as follows:

JUL 22 1994

NEOTERIK CENTER, BOX 128 • WOODSBORO, MARYLAND 21798
(301) 845-2777 • Fax (301) 845-2213

(a) Manufacturers of respirators cannot dictate the abrupt cessation of sale and distribution. This will be determined by distributors and by end-users. It serves no purpose to suddenly ban products that are effective. This is contrary to the purpose of the Proposed Rules, which is to increase the choices available to end-users. It is unnecessarily burdensome to suddenly ban the use of effective products simply because other products become available. End-users have established, effective programs in place. Before it is agreed that a Rule change will void these programs shortly, the consequences need to be known. We believe that the consequences could be enormous, and that this timetable as proposed will most certainly bring the proposed rule into the "economically significant" category. This aspect of the proposal is not known or appreciated by end-users generally, and before it is resolved it must be more broadly advertised so that end-user comments can be obtained.

(b) Even if it is decided to ban effective respirators from some future date, there is every reason for end-users with effective programs to continue to use their effective respirators. Respirator manufacturers will certainly be asked to provide replacement respirators, replacement filters and replacement parts. The proposed Rule as now presented forbids manufactures to provide respirators, replacement filters, and parts, except perhaps as non-Approved items. This would force the end-user either to use non-approved parts and so violate OSHA regulations, or to disband a perfectly good program and start again, with all the expense of purchasing new items, training, fit-testing and so on that would be involved. This is a complete waste of money.

(c) This part of the Proposed Rule is made very complex by the "modular" approach adopted by NIOSH. For example, an end-user is very likely to have half-masks and different cartridges for different applications. Under this Proposed Rule, the end-user will find that for some of his present applications the half-mask will meet OSHA requirements while for others it will not. For example, OV cartridges approved under 30 CFR II will be fine, but fume filters under 30 CFR II will not.

(d) It is not reasonable to believe that NIOSH can perform the testing from all the manufacturers who will need re-approvals within a two year period. The Proposed Rule justifies this two year period in two ways:

(i) "NIOSH believes that six months provides ample time for manufacturers to assemble the information necessary for application for certification under the new part 84" (See page 26852). We do not agree. We were not asked by NIOSH to provide any estimate of the time required. We have no knowledge of any respirator manufacturer being asked. We therefore believe that this statement is without foundation, and we assert that six months is not sufficient time. It is

not possible to estimate how long this would really take, because the Proposed Rule needs to be clarified. Our estimate is that it would take us at least one year, and depending on the final form of the Rule, perhaps as long as two and a half. This is because there is much more to each submission than merely, as the Proposed Rule states, assembling information. We must source likely materials, evaluate materials, test prototype filters, test the filters in respirators, establish production methods, acquire test instruments, prepare Q.C. plans, implement Q.C. procedures, and then submit for approval. This is no six month exercise for manufacturers with a number of different configurations involved.

(ii) "NIOSH believes that this time frame (i.e. two years from the date the rule becomes final) will provide ample time for manufacturers to have respirators approved and manufactured to meet the demand" (see page 26852).

The Supplementary Information presented does not provide any information to support this. Our experience is that it takes between four and eight months to get a product approved by NIOSH. It is no secret that NIOSH personnel are not able to keep up with the normal rate of submissions. Our experience is that it takes longer to obtain an approval now than it did three years ago. This is a work-load problem. The NIOSH personnel are highly skilled and professional, but they cannot complete tasks any faster because of the volume of approval requests. This existing difficulty would be severely aggravated by the approximately 35 manufacturers rushing in to get products re-approved under Part 84.

Has NIOSH made any attempt to quantify this work load? How many submissions for re-qualification will this Proposed Rule generate? It must be at least ten from each manufacturer, and the average could be as high as thirty. Will there be 350 submissions? Or will there be 1050 submissions? How long will it take for the labs at Morgantown to turn around these submissions? Has NIOSH made any estimates? Certainly, we have not been asked to estimate how many submissions we would need to make. This interval of two years in clearly unrealistic.

As well as believing that all the new Approvals can be issued in two years, NIOSH also states the belief that manufacturers can manufacture the new respirators within two years. Again, there is no evidence to support this view, and we know of no attempt to obtain information from manufacturers to evaluate the time needed. Without this information, neither NIOSH nor anyone else can estimate how long it would take.

Sincerely,

Kenneth V. Vaughan
President