

MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
CENTER FOR DISEASE CONTROL
NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH

TO : Nelson Leidel, Chief, TERB, OECSP
Through: Dep. Chief, TCB, 1-14-80

DATE: January 10, 1980

FROM : Engineer, TCB
Division of Safety Research

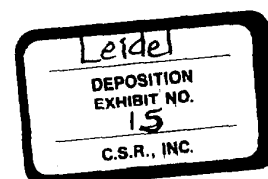
SUBJECT: November 27, 1979, Comments to Don Campbell on 3M 8710 Single Use
Dust Respirator (TC-21C-132)

We share your concern over the irregularities you observed in the extension of approval granted to these respirators on September 22, 1977. We went back to the data file and found that mask #513 was clearly identified (with a red marker) as failing final inhalation resistance. It is obviously impossible to defend that certification decision.

In your memo, you recommend that we reconsider the continued approval of the 3M 8710 respirator. If this were an isolated incident, I would wholeheartedly agree with you. Unfortunately, this incident represents only the tip of the iceberg. We have reason to believe that our certification files are well populated with similar irregularities. We have stumbled upon instances of approvals and extensions of approval being granted over the objections of the technical staff. Without initiating an intensive review of all certification files (which we don't have the resources to do), we have no way of knowing how prevalent this situation is.

We believe that inadequate or incomplete review of applications combined with problems such as those discussed above have contributed to some of the serious field problems we are now seeing. Although many of the failures can be attributed to fundamental flaws in the program defined by existing regulations, at least one case can be directly attributed to incomplete and inadequate review of the application.

The types of problems which have been reported during the past several months cannot be expected to diminish in frequency or severity for many years. The types of problems discussed above cannot be efficiently and effectively dealt with in any way but through termination of existing approvals. Even that approach would not solve the more fundamental problems posed by the present lack of viable performance criteria. We must continue to expect field problems to be reported until such time as existing respirators have been replaced by respirators approved under an adequate certification program.



Page 2--Nelson Leidel

We also agree with your comments dealing with the necessity of a statistical basis for certification decisions. We have been using such analysis techniques for several years in our PPE market surveys. Those techniques will be incorporated into our rewrite of the regulations.

William I. Cook

William I. Cook

cc:
JAOppold