

Our Ref: JWF/JJ

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Dear Sirs,

## **CODE OF FEDERAL REGULATIONS** **PART 84 (42 CFR 84)**

We are ISO 9001 approved manufacturers of a range of state of the art Respiratory protection products where the enhanced comfort and safety of the wearer has been the No.1 design priority, rather than "what do we have to do to satisfy the standard". Many of our products are not only approved for use throughout Europe but have now gained approval much further afield. Some of our products have undergone experimental evaluation in the United States of America and are being well received. Having taken our design priority it is not surprising therefore that there are various factors in the above code of which we now fall foul. We are certainly aware that technology will always outstrip standards development and are conscious that this is the case with respect to NIOSH. We would like to take this opportunity to try and influence the rule making proposals in your future deliberations.

### **Policy**

Unfortunately the Code of Federal Regulations Part 84 in our view has been developed from a military protection perspective and not an industrial safety perspective. In our view this means that NIOSH has arrived at performance requirements which are based on the compulsory wearing of respirators in environments where the wearing is mandatorily necessary to survive. In the industrial environment this is not the case, since industrial contaminants are covered by other mandatory regulations. To this end the wearing of respiratory protective equipment is not necessary to survive in the short term. (However, most employers with a social conscience are happy to make protection available, certainly in areas where there are queries in the long term effects of low level contaminants). We would therefore propose that our pieces of equipment for our respiratory products are not immediately life conserving but are certainly enhancing wearer comfort and safety.

Most of our products, since they are aimed specifically at the industrial safety market place do not fall within classes currently covered within the Code of Federal Regulations Part 84. However we understand that they could be evaluated under the authority of § 84.60(b). We therefore believe a policy mechanism has to be invoked which would allow approval of respirators which are not deemed to be within current classes. Whilst it is difficult to stipulate which performance criteria ought to apply,

and which performance criteria could be deleted or amended, I believe it would depend on a respirator by respirator comparison. The over-riding principle however should be that the respiratory protection offered to the wearer has to be recognisably enhanced over the non wearing of that equipment.

### **Performance Criteria**

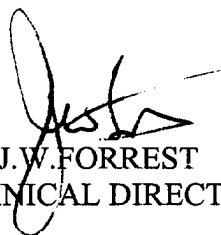
Notwithstanding the above, there are certain inconsistencies within the Code of Federal Regulations Part 84 which I think need to be addressed in the future revision. I set these out below in no particular order of importance:-

1. Industrial respiratory protection problems are at a basic level identical throughout the World. To this end it is likely that the solutions to industrial respiratory protection problems will be similar throughout the World. We believe this begs the question that ultimately there will be harmonised performance criteria throughout the World, and would suggest that in the future review cognisance is taken of both the similarities and differences between European and Australasian respiratory protection performance criteria.
2. More and more wearers are interested in the performance of the “whole respiratory system”. Because of this manufacturers are more and more utilising “whole respiratory system testing” for evaluation of both theirs and competitors products. Again we would respectfully suggest NIOSH takes “whole respiratory system testing” into account when reviewing their performance criteria.
3. Currently there appears to be a dichotomy between tight fitting respirator performance requirements and PAPR performance requirements. It would make a great deal of sense for the categories currently acceptable within the Code of Federal Regulations Part 84 for half masks and half mask filters to be applied to PAPR’s where the performance requirements would be evaluated on the complete system, not just on the filters. Furthermore in carrying out this performance evaluation the subjective face seal fit IAA test, which at best can be considered to be subjective, could be replaced by a much more objective test. In addition the utilisation of DOP as a penetrating particle size change is outlawing some extremely effective below .1 micron filter medium. These filter medium in the rest of the World are being used as protection against sub-micron particles from both workplace contaminants and combustion gas pollutants. There are many industrial environments where these latter are risks, and there is no likelihood of any oil droplet spray. The particle size of DOP is very similar to the particle size that can be generated from sodium chloride droplets, and therefore we would recommend challenge materials such as these should be adopted.

Whilst there are other specific performance criteria that we could challenge (such as the minimum 170 l/min criteria for loose fitting head pieces where it is known that certain product designs at this flow rate can lead to loss of facial body fluids and long term stress and other damage) these pale against the points I have made above.

If you require any further input or support for this document, please do not hesitate to contact me.

Yours faithfully,

A handwritten signature in black ink, appearing to read 'J.W. Forrest', is written over the typed name and title.

J.W. FORREST  
TECHNICAL DIRECTOR.