Review of Respirator and Mask Protection Levels

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Summary

The paper assesses the intended or presumed protection factors provided by typical FFP3 and N99 fit tested respirators and disposable masks against exposure to harmful substances. The focus is on the general acceptance that established and usually encountered hazardous substances have permitted exposure levels and that mask/respirator leakage or filter failure is acceptable to certain limits. The paper sets out to prove that these International standards cannot be used when bacterial, viral agents or toxic industrial chemical (TIC) agents are present. The paper rationalises the accepted mask/respirator protection against known protection failures and assesses the public use of respirators against professional use where engineering controls are demanded. Overall the paper identifies the public and general misplaced reliance on this type of protection and points towards alternative solutions.

Hypothesis

This paper reviews the current performance standards of masks and respirators and investigates their assumed protection factors against realistic expectations. The hypothesis is that most respiratory protection equipment (RPE) and personal protective equipment (PPE) generally provide almost no defence against infectious or biological agents to any personnel others than those in the highest level of laboratory (Level A) type protection.

Foreword

Masks and respirators are generically known as PPE, or more specifically RPE and as such are regulated by national or international standards. PPE is universally recognised as a last choice if the hazard cannot be removed or reduced and is rarely relied upon as stand alone protection with engineering controls usually required. Engineering controls can broadly be said to involve the control or dilution of the hazard and this usually takes the form of dilution either by focused source control or air exchanges.

These standards and the equipment fulfilling these legislative requirements have been designed for professional use by trained and competent workers. The general use of RPE by anyone who has not been fit tested, trained in fitting, maintenance, storage, or indeed limitations can be expected to result in seriously deficient protection. More importantly, the equipment and standards generally available today have been developed for industrial use at the workplace where occupational exposure limits or (the maximum allowed) inhalation or exposure to a substance has been measured and accepted as a minimum risk over a specific period usually defined as time weighted average (TWA) (8hours) or short term exposure limit (STEL) usually 10 minutes.

These standards and, more importantly, reliance must now come under scrutiny as RPE is increasingly becoming a first choice and engineering controls are not available to reduce exposure levels; the threat from biological and viral infections (Bird Flu) have relatively no safe level of exposure. The failure to accommodate new hazards and increasing risks within RPE may result in serious protection shortfalls.

Review

RPE level of protection is defined by the following levels:

A. The highest level includes totally-encapsulating, chemical-protective hermetically-sealed suit with positive pressure air supply or SCBA used in laboratories or where the highest hazard is expected.

B. The highest level of respiratory protection is necessary but a lesser level of skin protection is needed. Standard protection where full face (fit tested) filter respirators are worn with outer garment.

C. The concentration(s) and type(s) of airborne substance(s) are known and the criteria for using air purifying respirators are met. Full-face or half-mask, air purifying respirators (fit tested). Protective clothing as required, usually disposable suits, gloves etc.

D. Lowest level of protection, dust or nuisance dust mask, overalls, toe protection, gloves, goggles etc.

These different levels of protection were designed to reduce or eliminate the risk to workers engaged in hazardous work or likely to be exposed to risk. Each of the protection levels has benefits and shortfalls, and typically the level A requires substantial training, physical and mental fitness, but more importantly it has a very short working life as heat stress or limitation of air supply (SCBA) or length of air-line limits the area or time of use.

From level (A) we note that the next relevant and usually accepted level of RPE for the workforce or general public would be level C and we will therefore concentrate on this.

Usually accepted Level C protection

It can be seen that in this protection level the main emphasis is on the respirator and its known filtering capabilities coupled to its protection factors. These are assessed from:

- Filter efficiency
- Mask or respirator leakage.

Filter efficiency

The filter efficiency is the easiest of all assessments as these can be scientifically evaluated in laboratories. This is usually undertaken with NACL sodium chloride or di-octyl phthalate (DOP) oil which is measured as leakage through a filter with a maximum filter loading of 200mg.

For simplicity, filtration takes three forms as follows;

- Normal filtration 95% down to 2.5 micron
- HEPA filtration 99.97% down to .3 micron
- Electrostatic 99.999999 all particulates (.027) micron

The following table shows typical dust or particulate challenges and size of risk. These are internationally recognised as Particulate Matter (PM) and the smallest PM2.5 can be the most hazardous as it can be adsorbed into the deep lung and the alveoli where blood oxygen exchanges take place which can magnify the pathogen or hazard present as it may transfer directly into the blood stream.

Typical filter challenges

Table 1

PM Size	**Route**
<10 micron	Respiratory channel Nose sinus
<7.5 micron	Thoracic
<2.5 micron	Alveloic Deepest lung tissue

Challenge material	**Size range**
Dust	2.5-10 micron
Mould	7-20 micron
Bacteria	> 0.3 micron
Virus	< 0.027 micron

Table 2

Type or Model	**Protection Percentile**
FFPI	**95**
FFP2	**99**
FFP3	**99.7**
N95	**95**
N99	**99**
N100	**99.7**
Filter hood electrostatic filtration	**99.999999**

It can be seen from these tables that electrostatic filters provide the most efficient protection where not only size and percentage of particulates stopped is absolute.

Filter Housing

Filters are fitted to masks or respirators either as an integral part of construction as in FFP1-2-3 (N95-98-99) fabric disposable masks, or as screw-on cartridges. The protection factor of the filter is now accepted and our view is now on the housing or mask/respirator.

The following table shows typical international protection factors. These are classified as Nominal and Assigned protection factors.

Nominal Protection Factor (NPF)

The NPF of the full face mask was developed by manufacturers from laboratory testing. The test involves the use of a rubber head where the mask is securely strapped onto the rubber face. A hole is drilled through the back of the rubber head into the face mask and air is extracted from within the mask and contamination ingress or leakage is measured.

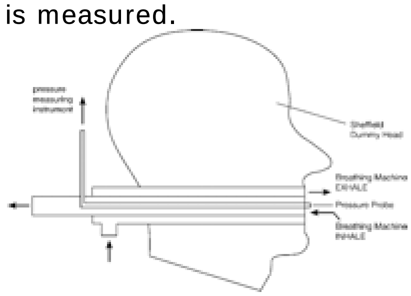

Fig 1 The 'Sheffield' test head

The mask provided a satisfactory seal around the edges and the filter performed as designed. A NPF of 1000 was awarded and professionals around the world relied upon this test for their safety.

Unfortunately the mask design was tested but the mask was not tested in use. The rubber head does not move, flex or have a jaw which moves around. Sweat and beard growth (stubble) result in mask edges moving and leaking.

It was clear that a new 'Fit' and use test needed to be developed and this now forms part of all RPE assessments and indeed is a mandatory legal requirement where RPE is issued to workers where risk assessments have recognised the need for PPE.

Table 3

Standard	Description	Filter class	Nominal PF	Assigned PF
EN149	**Filtering face piece for particulates**	**FFP1 FFP2 FFP3**	**4 12.5 50**	**4 10 20**
EN140	**Half Mask**	**P1 P2 P3 Gas**	**4 12 50 50**	**4 10 20 10**
EN136	**Full face mask All classes**	**P2 P3 Gas**	**17 1000 2000**	**10 40 20**
EN12942	**Power assisted Full face mask**	**TM1 TM2 TM3**	**20 200 2000**	**10 20 40**

Assigned Protection Factors (APF)

The APF is now recognised as the true value of a mask or respirator performance. This value has been reached by averaging techniques. The basis is the average protection factor the mask provides to 95% of competently fit tested equipment. This of course may not bear any relationship to a casual wearer, despite training and fit testing.

Fit testing

The shape and size of the human face varies with sex, race and other factors. It was accepted that masks should generally accommodate three sizes. The mask must be worn over a clean shaven face and the wearer must be trained in inspection, fit and application. The mask is fitted with a calibrated measuring instrument which accurately measures leakage and efficiency in a safe, artificially contaminated atmosphere. The test requires the wearer to undertake various tasks which include talking, turning the head and raising the arms etc.

From EN136 in **Table 3** it can be seen the nominal protection factor of 1000 was reduced to an actual protection or assigned protection factor of only 40.

Most importantly, it can be seen that the better the filter performance or ability to stop additional gas or chemical hazards, the lower the protection factor. This is because the increased resistance caused by the better filtration results in a higher risk of leakage at the mask edges or face seal.

Disputed protection levels

From the foregoing we can see that the original NPF was replaced by the APF because the measurement did not take into account facial muscle or jaw and chin movement or indeed general factors such as beard growth, or head turning. These two factors can be addressed to some degree by fit testing and acceptance of protection limitations. The explanation of the drop in the protection factor noted in EN136 Table 3 is, however, much more alarming. This shows that when better filtration is added, the protection factor actually drops - in this case from 40 to 20. This is because the better filtration causes a negative pressure to develop within the mask as periphery sealing edges are compromised from filter resistance.

The electrostatic filter works by electrostatic attraction of particulates instead of mechanically trapping them, this results in not only improved filtration from 99.97% of 0.3 micron particulates, specified for HEPA, to an incredible 99.999999% of all particulates, but a significant 80% reduction in breathing resistance. This breathing resistance reduction will immediately be seen as a major benefit in periphery sealing of the mask.

The problem with face fit and the generally acceptable ingress of contaminants past or through filters is of particular concern where pathogenic virus or bacteria are encountered. Government agencies from OSHA to HSE have published levels of acceptable exposure in terms of PPM over time periods for substances such as benzene and asbestos but none is available for biological agents generally. I suspect that where flu virus, for example, is encountered, only 100% protection would be suitable for workers engaged in essential services.

The possible failure of filtration levels coupled with known failure in mask and respirator sealing caused by head movement and breathing resistance requires a review of current RPE.

Innovation

A new approach to respiratory protection is the use of the hood. This seals around the neck and removes the leakage potential from the face and jaw movement. It also removes the need for fit testing and can be used by all including those with beards, long hair and spectacles. One such device www.safetyhood.com actually incorporates the electrostatic filter and single point neck seal. The obvious advantages are the combination of full head, ear and eye protection with respiratory and ingestion protection.

Conclusion

While the RPE available provides satisfactory protection for the majority of circumstances it can be seen that emerging threats such as viral infection, contagious disease, (bird flu) require greater protection and, more importantly, ease of use for the general public. The obvious problems associated with APF and competent use and fit of RPE means that the public could not expect to be protected to published standards unless they embarked on a lengthy training program and very expensive level A-B equipment or the adoption of new technology such as the safetyhood.