

Clear. Credible. Useful. What Are the Objectives of a National Standard?

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Abstract

Clear. Credible. Useful. What are the objectives of a National Standard?

The Australian standard documents on breathing protection were under revision for a number of years before the new 1715 and 1716 standards were released in 1991. The new Australian standard was greeted positively, and was generally seen as a clearer, more credible and, ultimately, more useful document than the previous version.

In this paper, we discuss some of the few remaining doubtful aspects of the documents that still remain, and how these discrepancies could be addressed in further reviews.

What Is "Protection Level"?

Actual protection levels cannot be measured by simply testing a protection device. The reason is that real protection can never be built into any safety product. The protection performance in a laboratory test is different from the protection level achieved in the workplace during a working day. The protection level of any safety device depends on a host of extraneous factors that have little or nothing to do with the features and performance of the device itself.

The current Australian Standard is in agreement with this reasoning, as expressed in the 1715-1991 standard (Section 7), which gives a long list of positive initiatives that are essential for any protective equipment to perform in the actual workplace.² These initiatives include such diverse actions as medical screening, regular inspections of safety equipment, filter replacement programs,

continuing safety auditing, no-beard policies, and comprehensive training of all users.

It is clear that all these steps are essential for the worker to achieve a high level of protection while using the protective device. It is also clear that the initiatives have nothing to do with the performance of the safety device itself. In fact, the positive initiatives suggested by the standard remain the same no matter which protective device, of whichever type and quality, is used.

Our first quandary, then, is this: If the protection level for a worker depends so much on extraneous activities that have nothing to do with the safety product, how is it possible to state, as the standard does, that the product provides a particular protection factor in the workplace?

The End User's View

Let us put ourselves in the shoes of a safety officer, employed to select and implement the necessary safety equipment in a factory.

In the field of breathing protection, Australian Standard classifies filters in three categories, and gives three different, fixed protection levels for respirators of various types.

How should this person interpret the standards marking on the product sheet? It may say that the filter is a class 2 filter, and the respirator has a protection factor of 10. But will the user achieve this protection? What if the user fails to maintain the respirator properly? Forgets how to fit it? Neglects regular filter replacement? What is the protection level then?

On the other hand, the safety officer knows that the protection factor of 10 is a "blanket" value, awarded to *all* respirators in the category. In fact, the respirator could give a much better protection factor. But there is no way of telling: one respirator could have achieved a protection factor of, say, 300 or even a thousand in tests. Yet, the two respirators are given the same protection factor, namely 10. How, then, is it possible for the safety officer to use the standard in the selection of masks?

When considering the above discussion, and putting the Australian Standard to *work—real work—what*, indeed, is the use of such a standard? What useful information does it actually provide to a purchaser, a safety officer, and end user.

Taking our hypothetical case further, all the way to the end user on the factory floor, *couldn't* the standard be downright *misleading—even dangerously so*? What if the user believes that the respirator provides a certain protection level, when it *doesn't*, because of poor maintenance or inappropriate fitting?

We are here addressing the very fundamentals of any standard. If the standard has to rely on the conscientiousness of people, and on *people's* behavior, how could it possibly fulfill the very function for which it was originally created: to give the public a reliable, accurate idea of the standard of the product?

It may seem that we are questioning the very concept of a standard, but this is not the case, because, as we shall see later, it is possible to design a functioning standardization system, using the system we already have, that will be useful to manufacturers, safety personnel and end users alike.

The Manufacturer's View

The Australian Standard is written for everybody involved with breathing protection, including not only users, but also inventors, designers and originators of the equipment.

As has been pointed out in a previous discussion paper,¹⁴ it is important to remember that the current Australian Standard is a minimum standard that assigns to each breathing device one of very few (only three) classifications. As long as a safety device exceeds the low threshold of a mask category, it is considered an approved product.

There are obvious disadvantages with such an approach.

Does the classification provide any help to the end user? *Hardly*. Does it give any idea of the relative performance between two different masks? Definitely not. Does it afford any useful information to the worker who will wear the respirator? *Unlikely*.

But another important factor is the effect such a standard has on the manufacturer of safety goods. A standard which sets no scale, no relative values, provides no encouragement for manufacturers who want to improve their products. A standard with only one category gives no incentive to excel or to strive towards the next level of excellence. In fact, a minimum standard is a boon to the indiscriminate manufacturer, who simply has to produce equipment which passes standards requirements only with the lowest possible margin, and is then able to release the product on the market, using the prestigious standards approval as a sales tool. So again we ask: what is the purpose of the Australian Standard in the work place? What role does it fulfill in research and development? What encouragement does it give for Australian manufacturers to produce better goods?

Inconsistencies Between Standards

Whereas Standards Australia takes the "blanket" approach of a minimal standard for breathing protection, it takes a different tack altogether when it comes to hearing protection.

In the field of hearing safety, protective devices are given individual attenuation values, based on subjective tests. There is, so far, no way of conducting quantitative laboratory tests on hearing protectors: each qualitative test is conducted by a test panel (that is, people indicating to the supervisor when they think they can detect a sound through their ear muffs). Yet, the tests are considered reliable enough to give the products individual protection factors.

Moreover, the hearing protection standard requires a test panel of 16 persons in order to achieve statistical reliability, whereas the breathing protection standard considers just 10 test persons to be enough. We would suggest that the

breathing standard be revised to keep in line with the hearing standard.

Further breathing protection devices can be and are tested in quantitative tests, which do not depend on any person's subjective perception of leakage, filtration, and so on. Yet, Standards Australia does not apply individual values to respirators. What is the reason for this difference in approach?

Lastly, the two standards clash with each other in another major aspect. Whereas the hearing standard accepts the reliability of SLC_{go} as one method of classification, the breathing standard is less progressive. (The SLC₈₀ is an attenuation value of a pair of ear muffs, which can be expected to be achieved by at least 84 percent of the population, according to a statistical formula.) If the standard accepts such a system for hearing protection, it would be hard to justify non-acceptance of such a system for breathing protection.

A More Substantial Approach to Standard Approvals

The protection factor for a respirator can be expressed in a variety of ways. For instance, it can be protection factor for the mask itself, as measured in ideal laboratory conditions. Or it could be the protection factor achieved when the mask is fitted to a number of people that represent a cross-section of the population, or of the factory. An even more "realistic" protection factor could be assessed by constantly monitoring a worker in the workplace, performing normal duties.

What all these methods lack, however, is the significant incidence of much lower performance due to negligence, insufficient knowledge, lack of incentive, carelessness, and so on—factors which cannot be measured, because they are related to such indeterminate components as habits, behavior, motivation, conscientiousness, and care.

Therefore, any claim of measuring "actual protection factors" is suspect.

The Problem with Minimum Standards

Trying to overcome these inexactitudes, the Australian Standard takes the minimum standard approach, that is, it prefers to rely on minimum performance thresholds, saying that "This respirator is at least this good."

But this reasoning may contain a dangerous flaw. How good is the mask if it is not worn? What the Australian Standard fails to recognize is that a respirator is much like the seatbelt in a car. It is not the *seatbelt* that makes it safer to ride in the car: it is *wearing* the belt that does.

More Protection Factors

There have been frequent discussions of late about the *work protection factor* (workplace protection factor; program protection factor) as a valuable indicator in the efficiency of respirators. (The work protection factor is determined by measuring the in-facepiece concentration of contaminants during all work routines—including non-use.)

However, it has become clear that such surveys cannot be relied upon to estimate the efficiency of a mask; rather, the only use of work

protection factor studies is to estimate the efficiency of the **respirator policy** in the particular workplace.³

There are a number of reasons for this. To begin with, the work protection factor leaves itself open as to how it should be measured and, indeed, interpreted. Several surveys have been undertaken with obvious shortcomings in the way the tests were carried out, such as incorrect testing techniques, failure to record the presence of facial hair, incorrect storage and maintenance of respirators, and many other variables.^{3,4,5} Work protection factor studies have even been conducted in areas where the concentration of contaminants was so low that respiratory protection was not required at all. Predictably, the respirator was a (not surprisingly very high) protection factor.⁵

The fact that the work protection factor does not take into account such important aspects as under training, storage, maintenance and proper

use of the mask means that there are numerable unknown variables which will no doubt have a great impact on the outcome of the test.³

In short, the work protection factor can be used as an indicator of how the **respiratory program** is working in the particular situation, but can rarely, if at all, be relied upon to give any information on the performance or efficiency of a facepiece, since a great deal of the contaminant sampling often occurs during non-use of the mask.⁴

What the Australian Standard needs is a system whereby it is possible to place a guide value on a respirator that is universally applicable. A system in which the testing procedure is not too costly, and not too time-consuming. Also, a system which takes into account not only test results and performance curves, but also all the variables and imponderable factors.

What follows is a suggestion as to how such a system could be created.

The Attainable Protection Factor₉₇

By creating what we call an Attainable Protection Factor (**APF₉₇**), we can achieve all the objectives outlined above.

This new, simple concept could best be described thus:

Instead of using a low threshold value and saying,

"This respirator should give you this level of protection,"

we use the actual performance in peak conditions saying,

"This respirator could give you this much protection."

How Does It Work?

As we have pointed out before (and as the current Australian Standard explicitly acknowledges), the true protection level of any safety device depends on two premises:

- The performance of the device (easy to measure)
- The correct use of the device (impossible to measure)

The first premise is entirely within the control of Standards Australia, or any individual with access to the necessary measuring equipment. This is why it is advantageous to take a "top-down" approach, letting us start with a real, ideal value which denotes the highest level of protection the

respirator can be expected to give, provided it is used and maintained correctly. This includes 100% wear time in all hazardous atmospheres. This value, the Attainable Protection Factor, or **APF₉₇**, is a protection factor which can be expected to be achieved by 97% of any group of people. The **APF₉₇** will be different for all respirators, depending on the test results in each case.

How do we deal with the second premise? By looking at how the **APF₉₇** can be achieved in the workplace.

Section 7 of the Australian Standard 1715-1991 sets out no less than eleven major points (and a host of sub-points) which are deemed essential to any successful respiratory protection program,

spanning from respirator selection and issue, through training and information, to regular medical checks and continuing safety auditing and monitoring of the implementation of the safety program. The list falls short of individual mask fit testing on a regular basis but, presumably, if all these measures are taken, management can be reasonably assured of its employees' health. The

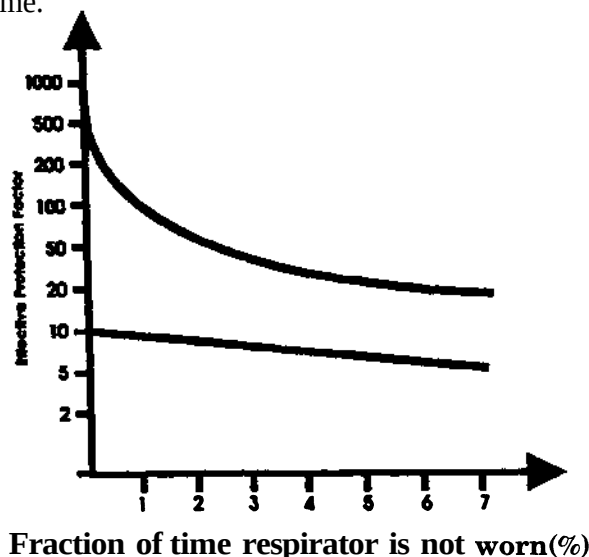
list is a comprehensive one, and is an excellent starting point for anyone wanting to achieve the APF₉₇ of any respiratory device.

If all the actions in the list are taken, we can be fairly confident that the workers in any given workplace will be at or very close to the APF₉₇ of the respirator.

Motivation Is Vital

There is one crucial element that is missing from our program: *motivation*.

Motivation to wear the protection is extremely important, because it has great influence on wear time.



As shown by the graph above, 100% wear time is of the utmost importance. Failure to wear a respirator even as little as 1% of the time (or about 5 minutes in an 8-hour day) makes a very big difference to the protection provided by the mask. Not surprisingly, the higher the protection factor of the mask (and of the protection required), the more dramatic the effect of failure to wear the respirator for very brief periods.⁶

The diagram shows that the time effect is much more dramatic for masks with a high protection factor. The uppermost curve describes the performance of a mask with a protection factor of 1000. The bottom curve shows that the period of

non-wear has less effect on a mask with a low protection factor (PF 10 in this illustration).

Couldn't it be argued, then, that it is better to award a low protection factor to all masks, to be on the safe side?

But look at the graph in a different perspective. It clearly shows that the respirator will give the wearer a very high protection factor, as long as it is worn all the time.

Isn't it dangerous to talk about high protection factors that depend so much on crucial 100% wear?

No, it isn't. To a properly motivated worker, entering a hazardous environment without breathing protection would be as unthinkable as a scuba-diver entering the water without his diving set.

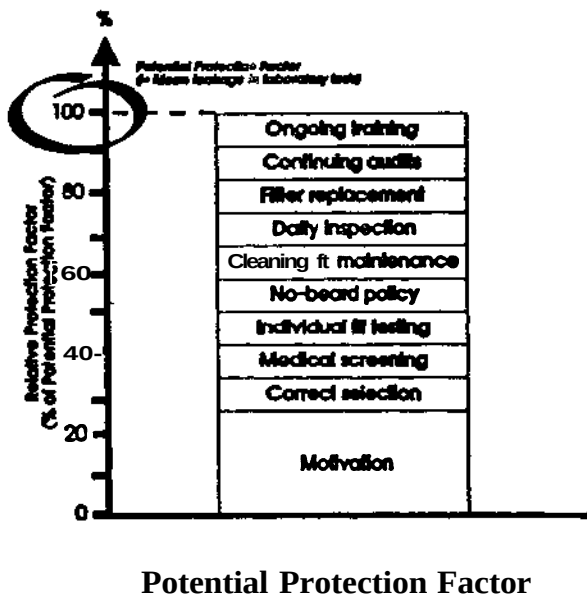
If divers can have such motivation, there is no reason why workers couldn't achieve it.

Motivation stems from a variety of basic feelings towards wearing the respirator, such as attitude towards breathing protection, ease of use and maintenance of the equipment, and comfort. Color and overall looks also come into this category.

No matter how well users are educated in use and maintenance, a breathing protection program fails completely if the equipment is not worn 100% of the time when it is needed. This can only be achieved through acceptance of the equipment, understanding of the reasons for wearing breathing protection, and acknowledgment of the benefits of breathing safety: in other words, the motivation to wear it.

A Simple Illustration

By combining the performance of the respirator in ideal conditions with the correct use and 100% wear time, we now have all the ingredients required to achieve the **APF₉₇**.



(Please note that the graph is an illustration only—it is, of course, impossible to place a percentage value on the various actions taken.)

We begin with the ideal conditions: in other words, the **APF₉₇**. This can be achieved if ALL steps, as suggested by the Australian Standard, are taken. 100% wear time is, of course, a consequence of all steps being adhered to.

By failing to implement one or several of the steps (or choosing not to), a user is likely to receive a lower protection factor. On the other hand, taking positive measures in any of the areas will increase the protection factor.

In this regard, no-beard policies cannot be emphasized enough^{7,8} and the importance of proper maintenance, cleaning and storage is also great.^{9,10}

In this way, Australian Standards has set the **APF₉₇** for the respirator, and it is up to the end user to achieve the level of protection he needs.

Advantages of the New Concept

The **APF₉₇** has a number of significant advantages over other methods of standardization and evaluation of breathing protection equipment:

Advantages to Standards Australia

- The testing method would not have to be changed. (Standards Australia's existing quantitative tests would be used).
- It is easy to calculate.
- It is easy to justify.
- It eliminates the uncertainty factor of non-wear or wrong wear.
- It doesn't bundle together widely differing devices in the same category.
- It takes the onus of establishing the actual protection factor of the product in the workplace away from Standards Australia and on to the end user; yet allows Stan-

dards to award the product a clear, credible, useful performance value.

Advantages to End User

- It gives management control over how high a protection factor they need and want to achieve.
- It gives a clear indication of how high a protection level can be achieved.
- It tells the end user what actions need to be taken in order to achieve a certain level of protection.
- It makes it easy for end users to compare respiratory devices and select the best model for their particular requirements.

Advantages to the Manufacturer

- It mirrors the real performance level of the product.

- It gives an incentive to design and manufacture better equipment, by “rewarding”

better products with higher protection factors.

Summary

The suggestions presented in this discussion paper need not in any way throw the current standard into disarray. In fact, very few changes would need to be made to the standards document, and existing testing methods are not affected.

In short, our suggestions are as follows:

1. Retain minimum protection factors as outlined in the standard, but view them only as threshold values—in other words, *entry points* for respirators to be approved by Standards Australia.
2. Implement an APF₉₇ system, which utilizes the real quantitative test results and gives each respirator an individual attainable protection factor, provided all steps in section 7 (1715-1991) are taken.

This new system would then, replace parts of section 6 of the 1715 standard to espouse a philosophy that matches other standards, such as the SLC₈₀ system in the standard on hearing protection.

3. Complete section 7 of the 1715 document by adding the crucially important element of *motivation* and 100% use of breathing protection.
4. Improve the statistical reliability of test results by extending test panels to at least 16 test persons. (This would also concur with the standard on hearing protection). For even greater statistical reliability, the test group could be required to perform added and more varied tasks during the test.

Conclusion

By inverting the current minimum-based standards system to a potential maximum-based one, the Australian Standard could come a long way to reaching its objectives among anyone and everyone involved with breathing protection, whether manufacturing it, purchasing it, or using it.

The concept of an Attainable Protection Factor is a starting point for further development, and we welcome suggestions for additions or improvements to the new system. Once complete and in force, such a standards system would add significant weight to the Australian Standard:

It would add:

- **Clarity**, because it would clearly indicate the optimal performance of each protective device.
- **Credibility**, because it would be based on absolute test results, coupled with real considerations about the workplace and its people.
- **Usefulness**, because it would provide a valuable selection tool to manufacturers, purchasers and users alike.

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APPENDIX:

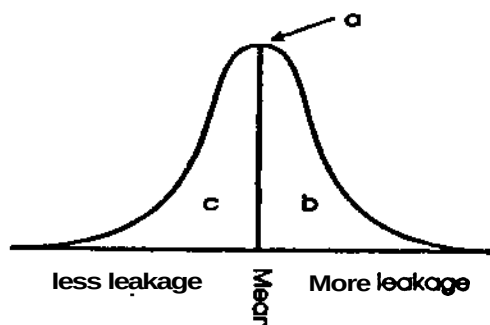
Attainable Protection Factor₉₇—Explanation

Description

The attainable Protection Factor₉₇ (APF₉₇) is a protection factor for breathing protection equipment. It signifies the protection factor which can be expected to be achieved by 97 percent of any group of people when the respirator is fitted correctly, and is in good working order.

Background

The APF₉₇ has a counterpart in the SLC₈₀ value, which is used to classify hearing protectors. The SLC₈₀ is a system which is recognized in Australia, and which has been found to be an acceptable indicator of the protection performance of a safety device.



Definition

The APF_{97} is calculated through a statistical formula, based on a number of quantitative tests. If we use a normal distribution curve, as illustrated above, the mean of the total inwards leakage is found at the center line of the curve (a). Values to the right of the center line (b) signify the number of people whose respirators resulted in *more* leakage than the average; and values to the left of the center line (c) signify the number of people whose respirators achieved *less* leakage than the average. Each of these groups (b and c) constitutes 50% of the number of test persons.

Naturally, in the field of personal protection, it is not enough to know that 50% of all people can achieve a certain protection factor: we need a much higher proportion.

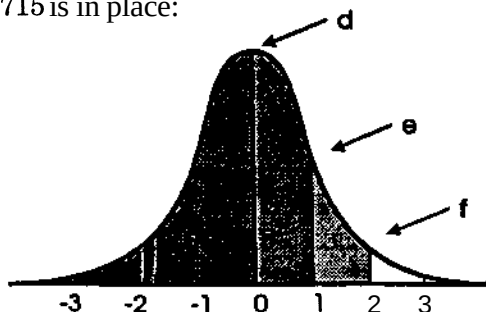
This can be established by using a formula which adds *standard deviations* to the mean. The standard deviation for any product can be easily determined.

If *ONE* standard deviation is added to the mean, the result is that 84.12 percent of any group of people can be expected to achieve *at least* the desired protection level.

The fit factor will cover even greater numbers of people if more standard deviations are added to the calculation. The APF_{97} suggests that we add *TWO* standard deviations to the mean. Now, we have a fit factor which should be achieved by 97.72 percent of any group of people.

By adding more standard deviations to the calculation, even higher confidence levels can be attained, provided a protection program in accordance with AS 1715 is in place:

Add	%
0.S.D.	50
1 S.D.	84.13
2 S.D.	97.72
3 S.D.	99.87
4 S.D.	99.997



Example

This graph (a normal distribution curve) shows the test results of a respirator whose average leakage among the test persons was 0.1045 percent (d). Half of the group achieved better protection factors (and they are therefore not of any interest). The other half showed more leakage than the average.

Our aim is to award a protection factor to this particular respirator that could reasonably be expected to be achieved by a very high proportion of people.

(Naturally, it is assumed that the respirator is fitted in the correct way, and that it is maintained and stored in the correct manner.)

- If we award the *mean* protection factor (d), we can be statistically confident that 50% of any group of people can achieve 0.11045% leakage or less ($FF > 957$).
- If we add *ONE* standard deviation (e), we can be statistically confident that 84.13% of any group of people can achieve 0.2865% leakage or less ($FF > 349$).
- By adding *TWO* standard deviations (f), we can be statistically confident that 97.72% of any group of people can achieve 0.4685% leakage or less ($APF_{97} > 213$).

Total Inward Leakage (%)—Sodium Chloride Aerosol Method

Subject	Mask No.	Walk only	Head left/right	Head up/down	Talk	Walk only	
		A	B	C	D	E	
A.J.	1	0.01	0.01	0.01	0.03	0.01	
A.N.K.	2	0.003	0.003	0.002	0.003	0.003	
F.H.	4	0.001	0.001	0.001	0.008	0.001	
H.L.H.	3	0.12	0.09	0.13	0.33	0.10	
J.B.	5	0.03	0.04	0.04	0.09	0.04	
J.C.	6	0.003	0.003	0.002	0.005	0.001	
J.V.	7	0.002	0.002	0.002	0.03	0.004	
D.G.	8	0.003	0.002	0.002	0.005	0.002	
P.M.	9	0.13	0.11	0.12	0.18	0.10	
S.G.	10	0.11	0.22	1.4	0.43	0.30	
A.B.	4	0.11	0.51	0.21	0.39	0.16	
A.N.K.	1	0.06	0.07	0.07	0.09	0.05	
H.K.	2	0.04	0.04	0.05	0.11	0.04	
H.L.	3	0.05	0.04	0.04	0.11	0.10	
L.G.K.	5	0.18	0.18	0.17	0.31	0.16	
M.P.	6	0.17	0.11	0.11	0.24	0.12	
Min		0.001	0.001	0.001	0.003	0.001	
Max		0.18	0.51	1.4	0.43	0.30	
Mean		0.0639	0.0894	0.1474	0.1476	0.0744	0.1045
S.D.		0.0634	0.1304	0.3405	0.1474	0.0828	0.1820

Formula used for Standard Deviation (S.D.): $\sqrt{\frac{a^2 + b^2 + c^2 + d^2 + e^2}{5}}$