

Tomorrow's Standards—Where Are We Heading?

A case for objective, performance-based, internationally applicable standards in respiratory protection

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Looking back

In the past ten years, the international embracement of standards has almost reached fever pitch. The output worldwide of standards documents regarding respiratory protection equipment and use has grown from a trickle to a veritable avalanche.

The development has taken four forms:

- The strengthening and extension of existing standards, such as is the case in the United States.
- The development of new domestic standards in nations where previously no standard existed, such as in some Asian countries.
- The merging of disparate standards into a common standard among cooperating blocs, such as the European Union.
- The gradual conforming of domestic standards to other, more all-encompassing

standards, such as is the case with Australian Standard moving towards its European counterpart.

Add to this the proliferation of quality control schemes, and we soon realize what a predicament exporting respirator manufacturers find themselves in: and ever more rapidly burgeoning repository of guidelines and regulations, some globally applicable, some widely differing.

It must be said that, in the interest of occupational health and safety, and firm, fair, logically devised standard is preferable to no standard at all. But there are also problems associated with the development of standards worldwide during the past ten years.

The Present

In a world of growing globalization, the current situation raises a number of vexing questions, not only for users, purchasers and contractors, but also for manufacturers of respiratory protection and, in particular, those operating on a global scale, supplying goods to a number of countries with a wide array of differing standards.

Will we reach an impasse due to the proliferation of standards?

The advantage of standards is that manufacturers are provided with a benchmark against which to measure the performance and quality of their goods. The drawback is that the preponderance of disparate

standards might render the task of complying with the requirements impossible. There are simply too many standards for only one type of product. The result is a deadlock between standards compliance and manufacturing restrictions.

Is the testing method reliable?

Around the world, standards are commonly suffering from lack of definition. In other words, the testing procedures are often open to interpretation, and the assessment criteria might seem to be based on varying premises. This is one of the major problems in today's respiratory protection arena.

The problem is often caused by standards requirements and testing methods being written by persons from a single, local laboratory who are familiar with their own laboratory conditions and equipment, taking for granted certain local factors which might not be present—or even applicable—in other laboratories.

Indeed, testing methods are sometimes so vaguely formulated that the tests are in effect not reproducible—even from one day to the next, in the same laboratory. This usually has to do with such simple matters as working, layout, illustration, outlining and definition of test procedures.

An example of this is where one group of test personnel may have interpreted the instructions in a particular way. When the test is subsequently repeated by another group, the results are widely differing, due to another set of interpretations of the text.

If the test cannot be reproduced reliably in the same laboratory, how could it conceivably be repeated in another laboratory, perhaps in another country, using different equipment and calibration methods?

Clearly, this wide margin for error makes it nearly impossible for a manufacturer to determine the production specifications for the device.

Is the assessment objective?

Another quandary relates to the criteria by which the product is assessed. While many—if not all—standards are claimed to be performance based, some might carry elements of bias due to the way in which the assessment criteria were established. Most

standards are drawn by a committee comprising not only of independent experts, but also non-experts with varying interests in the outcome and formulation of the standard. Indeed, some committee members might have a direct self-interest, striving to adjust the standard to suit a particular product or group of products. Notwithstanding rigorous attempts to maintain objectivity in such committees, it is inevitable that some subjective bias filters through to the final document.

On a larger scale, a standard might contain elements of bias towards domestically produced goods. Such a standard is not a standard; it is a form of import restriction—and this is not the role of a standard.

In these circumstances, regardless of the nature of the bias, some manufacturers might find themselves in a difficult position, perhaps even experiencing distinct unfair disadvantages directly caused by failure of the standard to be truly and independently implemented.

Does the standard reflect real life conditions and human physiology?

It seems that discrepancies have crept into certain standards, leading to test criteria being used that have no real connection with actual work conditions and human respiratory physiology. In some cases, airflow rates and other factors appear to have been based simply on traditionalist thinking rather than in order to closely approximate real use of the equipment. It is difficult in these instances to explain or justify why a certain requirement has been set at a particular level.

A case in point is the European Standard for measuring the breathing resistance through air purifying filters, where filters with the highest protection factor are also allowed the highest breathing resistance. It seems paradoxical that those filters used in the most toxic atmospheres also impart the greatest physiological stress on the user, leading to deeper, faster breathing, and, consequently, a greater risk of inward leakage.

In this case, a carefully thought-through standard should set a "safe" maximum breathing resistance—and this ceiling level should apply to all filters, regardless of protection factor. Such a level would be easy to explain and justify, both in terms of physiological stress and risk of inward leakage.

A View to the Future

The problems inherent in today's respiratory protection standards should be—and can be—rectified. The main endeavors include:

To ensure maximum objectivity and rigor in standards testing. Final testing protocols must be formulated by experts in the field with proven competency in the formulation of **unequivocal**, definite, exact instruction designed to minimize the possibility of personal (mis-)interpretation of the set-up, calibration, execution, evaluation and reporting of the test. This should also include equally rigid specifications of test equipment and laboratory conditions. The standard should not be written by personnel from a single, local laboratory. One way to overcome this problem has been instigated in Europe, where members of various European testing laboratories meet regularly to discuss and compare their work. This is a good example of positive initiatives that could and should be adopted worldwide.

Wording should be kept at a minimum, in clear, succinct language. A good example of this is the ANSI Z88.8, where methodical cutting of wordage has been exercised.

To ensure performance-based formulation of standards. Every step should be taken to ascertain that products are examined and classified on their performance only, without regard to materials, design, construction or the identity of the manufacturer.

To strive towards globally compatible standards. Although a "world standard" might be a Utopian concept, if not a sheer impossibility, it is easily conceivable that individual national standards could be adjusted to a common global framework in which local differences are allowed up to a point to accommodate for climatic conditions and other factors which may warrant the addition of certain requirements and the omission of others. However, such a general framework would render respiratory protection a more "portable," globally understood concept.

This is where ISRP can play a major role. In effect, by endeavoring to initiate the changes and trends outlined above, ISRP can help to make national and international standards more authoritative, more reliable and, above all, more useful to anyone associated with respiratory protection, anywhere in the world.