

THE BASIC PRINCIPLES UNDERLYING THE STANDARDIZATION OF RESPIRATORS

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INTRODUCTION

In some countries, respirator standards were rashly written and quickly accepted; in some others, they were object of very long discussions and in a few other countries, even now no final agreement could be reached. Most of the difficulties in the way of writing rapidly, clear respirator standards, originate in the fact that respirator standards, and among them, dust respirator standards, are rather different in their basic principles from most other standards. These differences reside a) in the standard character (sections 1 and 2); b) in safety, cost and benefit considerations (sections 3 and 4) and c) in the pluridimensionality of the standard and of the means to be used for the test (section 5).

Compliance standards and fitness standards

The overwhelming majority of ASTM, BS, DIN, AFNOR . . . and therefore, also of ISO and CEN standards are compliance standards. Each of them is a rule or a set of rules, defining how close an attribute of a product shall be to some agreed value. There are tens of thousands of such standards. They concern dimensions of various objects; tensile strength, color, specific weights, and so on.

This plethora of compliance standards contracts with the relative scarceness of fitness standards. The latter shall answer to a question of the type:

- Which car(s) are above/below standard?
- What camera to chose?

And, last but not least, our instance:

- Which respirators will guarantee the safety of a given category of users?

The main characteristics of fitness standards are:

1. While all compliance standards are one-dimensional, fitness standards are multi-dimensional.

Compliance standards establish the good/not good dichotomy, independently for each attribute. A sample of concrete may pass the crushing strength test and fail the expansion test, or the hardening time test . . . Any one of these tests measures just one dimension: length, time, strength, etc.

Fitness standards take simultaneously into account a combination of several attributes. Therefore, they are multi-dimensional. Take the example of the car: its power, its dimensions, its suspension, its stearability, its gas economy . . . and many other individually (= one-dimensionally) measurable attributes contribute and add up to its acceptability. Somtimes, there is a way to combine the figure representing the different attributes into one index, but most of the time the quality indices are arbitrary and contain hidden, biased assumptions. Therefore, practical tests, which are integral (rallies, endurance contests . . .) are often preferred. They establish an order of fitness.

2. In opposition to compliance standards which can be formulated in an user-independent way, fitness standards are strongly user dependent. The "good car" has different definitions for cross-country or crowded city or other uses. So the uranium miner's professional respirators, respectively the standards approving them, could be different from those meant for people doing some polishing at home.

It will easily be recognized, that by the above two criteria, respirator standards must be fitness standards. Many of the difficulties and delays in respirator standardization originated from not recognizing this fact and the wish to write these fitness standards in the same way as compliance standards are.

Safety standards

In our trade, the word "safety" is being used in two quite distinct senses. By not distinguishing between them, one heaps hardship upon difficulty.

One of the senses is "safekeeping" = protection, that is, our action or wish to preserve human health and wellbeing.

The other is in "safety margin", which in a sort of bet on the (low) probability of the occurrence of some ill effect. Most standards are devoid of internal safety margin. If it is required that concrete should have a crushing resistance of 1 ton/cm², that is all that is said in the standard. It is up to the architect to include the required (perhaps required by another standard) safety margin. Not so for respirators. By specifying a figure for the penetration of some test aerosol, a safety factor has been built in. Unfortunately, most of the time the numerical value of this safety limit is unknown even by those who wrote the standard. This intuitive inbedding of a safety margin occurs mostly through the admissible limit. It is assumed that the wearer of the respirators, working in a given ambiance, should neither inhale during the time so and so more than the "admissible dose", nor that he should be exposed to a concentration above the maximum admissible.

The idea of the MAC is so fundamental, so disputable, so immense and so fuzzy, that its thorough discussion within the limits of this paper is a sheer impossibility. Nevertheless, it will be unavoidable not to include (in the next section) a short digression about this subject. For the time being I want only to stress that by the use of a MAC, a safety factor has been imposed onto the user. The architect using the concrete had the choice to use a safety factor of 5, 10 or more depending what he builds. His compromise involved an overt optimization process in the cost-benefit field. In safety standards, this optimization process is not only built in covertly, but remains quantitatively unknown even by those who drafted the standard. Therefore, gross overestimations "to be on the safe side" are often the rule, mostly way off from the economic optimum, for which a lot more knowledge would be desirable.

Built-in safety margins are common feature of standards or standard-like rules which are meant to preserve life or health (= safety standards). You do not chose freely your maximum speed in a highway bend: it has been computed for you, including a safety margin, and all you can do is to comply. The thickness of the safety windshield, or that of a worker's hardhat, have been decided in the same way.

Admissible limits

One can expose one thousand beams or ten thousand strands of wire to tensile tests, then do statistical computations and obtain a resistance value associated with a probability level. This latter is then equivalent to a safety factor. Just this kind of neat experiment is morally and materially excluded in fields involving human safety. In our field, we have the incomplete statistics of past accidents and the analogy of animal experiments.

In an attempt to reduce the analogy and the hearsay effects which affect so heavily the MACs, a few years ago I proposed the use of the available data for the construction of a three-dimensional concentration-time-frequency of effect diagram (Benarie, 1974). Seven relatively simple geometrical and topological rules (of the kind: some given category of curves does not have intersection points. . ." etc.) establish the three-dimensional web of curves, which thus become anchored by relatively few experimental points. The intersection rules for the curves extend the possibility of data interpretation; fewer experiments yield better defined limits. Any plane section at constant frequency level defines an unequivocal choice, linking the probability of occurrence of some given effect to one pair of concentration/time value.

Unfortunately, there are very few substances for which even the thus reduced amount of adequate data is available, and even less for which the above mentioned three-dimensional diagram has in fact been constructed (in fact, only SO_2).

The UK dust regulations for coal mines, which post date the above mentioned paper, are based on such recognition of risk levels. They establish a maximum dust concentration which ensures a particular probability of avoiding a specified level of disablement at the end of a working life.

Risk-benefit analysis

Informal comparisons of risk and benefits occur in setting most safety standards. The question of acceptability of risks is currently fashionable. There is a bid to state an unambiguous level beyond which a risk is deemed unacceptable, substantiated by a number of papers and reports which contain dazzling flowsheets which at nearer scrutiny reveal themselves as tautological and/or impossible to fill in with real data. Their underlying decision structure includes (or at least, should include) at least three basic considerations:

- a. The necessity of making tradeoffs;
- b. Tradeoffs must be made between noncommensurate entities;
- c. A large uncertainty about impacts of alternative decisions. The magnitude of uncertainty about both risks and benefits is often much greater than the magnitude of their most likely values.

A widely accepted approach is the collective determination of the market value of the risk. This is expressed e.g. by Calabresis (1970, p. 208) as a collective judgement, a guess as to what value a true market would give to

various injuries. Such as a method would use what indications could be gotten from the figures derived from bargaining situations (in-court, out-of-court, etc.). It would then proceed to use them, together with what monetizable elements that could be isolated, to derive money values for various injuries. The aim would be to approximate the market; in theory it would arrive at the amount that the actual injured party, had he been properly and fully aware of the risk people in his category bore, would have been received in exchange of bearing the risk. The value of the actual injury would technically be this figure multiplied by the odds against the injury occurring.

When we deal with health risks we are dealing with costs, for that is what injuries to health involve. We are, to be sure, also dealing with emotional and moral attitudes, but we are always dealing with these in relation to costs. If we were not, we would wish to avoid risks "at all costs" and e.g. never construct level crossings. It follows that in examining any approach to risks we must always keep in mind the cost of establishing and effectuating the approach, as well as the benefits the approach is expected to bring about. These costs and benefits, moreover, must be compared with the costs and benefits of alternative approaches. We must, in short, always ask whether the game is worth the candle not in terms of the cost of the candle but in terms of other games we might be playing.

Because highway data are readily available, risk-benefit studies are most numerous for vehicular accidents and choices of safety features for automobiles. It is too easy to be misled and attempt to use similar methodology for respirators. The analysis of the following three items will point out the difference.

1. Usually the tradeoffs are bi-lateral between economic benefits and disability or loss of life. Respirator tradeoffs are triangular (see 4.1).
2. The tradeoff between present inconvenience and risk of disability in a distant future (see 4.2).
3. The distinction between voluntary and involuntary risks (see 4.3).

Some of these conditions arise in other fields of safety also, but the specific combination of the three is a characteristic of respirator standards. The fact of recognizing and expressing them clearly is not yet a cost-benefit analysis, nevertheless represents a significant step towards this goal.

1. The special instance of a triangular tradeoff

The added "third angle" of the tradeoff is the inconvenience of wear.

1. A very efficient, tightly fitting respirator with low respiratory resistance is usually heavy, hard to wear and more often than not, quite expensive.
2. Respirators which are very easy to wear, often do not fit well and are not very efficient.

3. At least with fibrous filters (unassisted respiration), pressure drop and efficiency are opposite properties. One can obtain high efficiency and low pressure drop by increasing the filter area -- and thereby the weight. Here the loop closes and we re-start at 1.

The dangerous, alas too often occurring breakout of this loop arises with the theoretically perfect respirators which are so cumbersome that out of the sight of white collars the respirator is not worn. Publicity about risks and benefits is a poor indicator of individual values. Further discussion of this topic, see below.

2. Long term effects

Most safety devices are meant as protection in the present tense. A hardhat avoids injury by a falling object here and now. Was the hardhat not worn and a wrench fell two yards away, so that was perhaps a good warning for the future and nothing else. That wrench has no more consequences. The instance of dust respirators is basically different.

While many toxic gases are irritant, or they present such manifest and immediate danger, that the tradeoff to wear/not-to-wear a respirator is self-evident. Not so for dust respirators, where the discomfort is present and ill effects will perhaps follow after 5 or 20 years. Probability of injury within 20 years might make a person to think that he will not be affected. If you consider this affirmation as far-fetched, think only about smokers. Probabilities of favourable issues are in general overestimated -- if not, nobody would visit Las Vegas, or bet on races, or buy a lottery ticket. Probabilities of unpleasant issues are either underestimated, or "they concern only others, not me". The two effects, underestimation and unconcern are often simultaneous and mutually reinforcing.

The situation is further complicated by the fact that the reverse is often true. Uncertainties or ignorance of consequences can significantly affect an individual's value system. Fear of unknown risks often instills greater conservatism in action than is warranted by the objective situation. A minute but well publicized probability of death from exposure to a hazardous material might make an unknowing person think that he will be affected.

3. The distinction between voluntary and involuntary risks

Starr (1969) has pointed out that we accept voluntarily a number of risks such as driving, flying and smoking, which expose us to a risk of death of 10^{-5} per person per year (pppy) or more sometimes a lot more. We also accept, with little or no complaint, a number of involuntary risks as floods, earthquakes, bites of venomous creatures, influenza, etc., which expose us to a risk of death of about 10^{-7} pppy. (The figures are approximate and may have been calculated using different assumptions. Furthermore, some of the comparatively small number of workers in this field copy from each other, so any error, once introduced, is repeated in various papers and acquires an aura of authenticity. There is as yet no consensus on the subject although there is much debate: Kletz 1976; 1977; Farmer 1976; Lowrance 1976; Oi 1977; Collinson 1979).

The wearer of a respirator will consider the respiratory hazard as involuntary if it is occupational and as a voluntary one if he is pursuing his hobby. In this latter instance, he is likely to accept a hundredfold larger risk. Indeed, professional safety engineers select high performance respirators, while hobbists (provided they realize the need of a protection) are often happy with the lightweight gauze-type mouthpieces which do not provide much protection.

4. What candle, what game?

This is the crucial question of risk assessment. For respirators, the answer is in the triangular choice, respectively in the "breaking of the loop" analyzed in 1. It would be an error to evaluate the benefits of the respirator against the risks and injuries avoided by wearing it. The main respirator tradeoff is: To wear or not to wear the respirator (or to reject it clandestinely, if one is provided).

Therefore the respirator – and herewith we set physically easily accessible values on which to build a standard – must guarantee in the first line:

- Adequate respiratory comfort, i.e., physiologically reasonable pressure drop at inhalation and expiration;
- Tolerable facial pressure;
- Acceptable weight and balance;
- Visual comfort and safe field of vision.

The conditions where respirators are used must be without exception standby, emergency, temporary or last resort situations, until working conditions (ventilation) are improved to make the respirator unrequired. But even if reliance on the respirator is a last resort, it must still be acceptable.

The game being defined this way, we can add one more rule which follows from 2 and 3:

Individuals do not know best for themselves.

Although safety engineers are aware in most cases about the grain size distribution and the toxicity of the dust against which they exhort respirators, we must consider this an optimal limiting situation. Within the frame of the tradeoff of acceptability, we must require in the standard the maximum realizable efficiency against very finely divided aerosols.

Under the terms of this postulate, we reject the principle either of multiple test aerosols or dust respirator categories for different situations, as many users are unable to define to which category they belong. The respirator defined by our standard must be safe in an uranium mine; it will be perhaps overdimensioned for a woodworking shop – but we cannot recognize different set of safety rules for first class and economy fare passengers on a plane.

Test aerosols

There is one more hurdle, one more difficulty specific for dust respirator standards: their efficiency must be tested with dust.

Standards are rules for measurements. Linear dimension, intensity of light, color, percentage . . . all have units or unit definitions which do not change. But you cannot preserve a reference dust concentration in a cellar at Sevres, as it is done with the International Meter stick.

This alone would be a minor difficulty, as e.g., "ampere" is neither being conserved physically; it exists as a definition only. Yes, but defined entity has unequivocally the dimension of an intensity. What is the dimensionality of suspended dust?

First, there is the mass concentration. Then, there is the size distribution, which in its most basic form can be approximated by a two-parameter function. Then we need one more function with up to three parameters to characterize the form of the grains. We must add another function for the distribution and perhaps more to characterize the physico-chemical state of the particle surfaces. Thus the minimum number of dimensions needed for the standardization of a test dust is about ten.

One of the most essential properties of an aerosol is its metastability. It is a dynamic system which changes by coagulation and settling with a time-constant shorter than one second.

It is almost hopeless to standardize an eleven-dimensional (ten, plus time) entity. Therefore national standards preferred the detailed description of a procedure and of an apparatus for test dust generation. With a lot of optimism, we accept that each nationally standardized procedure yields the same test dust in each of its individual realizations. In fact, one of the main objectives in writing these standards was to define reliable and reproducible aerosol generators. Unfortunately, the high dimensionality of the metrics leaves an almost infinite number of combinations and allows such a wide choice, that each nationally standardized generator is basically different from all others. Due to the same reason, it is impossible to translate the efficiency rating of any one national standard into terms of another.

Here we close one more loop – the argument introduced in point 1, that fitness standards are multidimensional. A single attribute of the respirator fitness standard, the efficiency, has been split into eleven or more dimensions.

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