

Practical Implementation of the Personnel Protective Equipment Directive*

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As we move towards 1992, the potential of a larger market with fewer trade barriers is the goal, and many European Directives are being produced to facilitate this. Ultimately there are many benefits that manufacturers and users alike will gain from this open market though there are still concerns being voiced about the practical steps needed to make this change happen.

In the area of personnel protective equipment (PPE), the Directive 89/686 should be adopted in member states by 1 July 1992. The proposals in this Directive will assist the free flow of hard hats, hearing protection, and all other forms of PPE within Europe.

The Directive should mean that manufacturers will be able to design one product for all of Europe and, once approval has been gained, to sell the product in any member state; there will be no need to resubmit the product to other government bodies. This should reduce costs for the manufacturers and increase the choice of products for purchasers. At present, when a new form of respiratory protective device (RPD) is launched by a manufacturer throughout Europe, it has to be tested in six **different** countries and approved by nine different national government organizations. In many cases the standards to which the product is tested can be dramatically different and in every case the marking of the product is required to be changed. As a result, what started out on the drawing board as one product becomes between 9 and 12 products in the factory unless multilingual marking is possible.

The adoption of Directive 89/686 will do much to solve these problems. It will require that manufacturers demonstrate that their products meet the Basic Safety requirements laid out in the Directive, and once this has been done it will require that the product and its packaging is identified with a "CE Mark."

The Directive places much emphasis on harmonized European Standards but recognizes that the production of these standards can lag behind product development. As a result, there are two basic routes for gaining a CE Mark: either by demonstrating that the product meets the harmonised European Standard, where one exists, or by producing a technical file demonstrating that the product has met the basic safety requirements.

Once a manufacturer has chosen whether to use the technical file route or the harmonised standard route, one of three procedures will be adopted. Which route will depend on the complexity of the device and the degree of risk against which it is to be used. For devices of simple design, such as sunglasses, the manufacturer will assemble the necessary information and **affix** the CE Mark without any input from or reference to an outside body. For devices of complex design, such as RPD to be used to protect against serious and irreversible harm to health, an independent body will test the product either to the harmonised standard or technical file to ascertain that the product meets those requirements. After this the product will be re-tested by the same independent body at least once a year, or the manufacturer will have to have an **EN29003** system operating at the manufacturing site which will be assessed by an independent body.

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Precise lists of products in these two categories are given in Article 8 of the Directive. All products outside these categories will require an independent assessment to a harmonized standard or technical file but without requiring ongoing testing or quality requirements.

This three-tier system causes my first concern. The CE Mark will be what users look for after 1992 to ensure the product has met the basic safety requirements and will be regarded by them as some form of quality mark. This is not what it was intended for, but I have no doubt this is the purpose for which it will be used. Unfortunately there is no obvious way the end user can tell whether the product has been subjected to a one-off test by an independent body or whether there are ongoing checks on the performance of the product. To prevent this confusion, national bodies could continue to promote schemes similar to the kitemark but these are nationally based and could eventually become a barrier to trade in themselves. What is needed is some form of European quality mark that can be linked to similar principles as the kitemark but which is internationally recognised.

My second concern relates to the timescales being set for the implementation of the Directive and the limited facilities we have in Europe to test to harmonised European Standards. In some cases even the harmonised standards needed are not yet in place. Although an additional six months are

allowed after the implementation date, during which time national standards may be used, the result may be that standards are rushed into existence without sufficient detailed discussion on content. Most worrying is the lack of test facilities in Europe. Other than manufacturers' in-house facilities, there are only 15 independent institutes capable of RPD testing to European Respirator Standards.

Some of these test houses may not be completely functional by 1 July 1992. It is likely that between 3500–4000 types of respiratory protective devices will need to be tested to ENs by 1 July 1992. The process has not yet started, as the national legislation is not in place to appoint approval bodies, and the current UK approval body—the Health and Safety Executive—has stated that it will be withdrawing from approving respirators for industry after July 1992.

Several years may be needed to re-test all RPD products, and when this is extended to all forms of PPE the problem will be enormous. Six to nine months is insufficient time to carry out all necessary testing to meet the Directive, and some contingency measures must be found.

The ultimate goals of the Directive are welcomed, and the system being proposed is a good one, but the timescales do not recognize the reality the situation.