2.2.2 GUIDE TO THE IMPLEMENTATION OF DIRECTIVES BASED ON THE NEW APPROACH AND THE GLOBAL APPROACH

The CE marking on a product indicates that it complies with all relevant directives. The so-called "new approach" directives that have adopted the CE mark are the more technical directives that have separated out the "essential requirements" specified in the directives themselves from the detailed technical standards that are used to demonstrate compliance.

The Guide is a lengthy (112 page) document that discusses all aspects of the New Approach and Global Approach directives and CE marking. It is written from an EU point of view, so much of the emphasis is on the requirements of member states rather than users of equipment or those involved in the supply chain. However, it is an invaluable resource in helping to understand the principle of CE marking, as it comes directly from the European Commission and provides an overview of all aspects.

The Blue Guide is at present being reviewed, but it remains a useful document in the understanding of the operation and function of new approach directives.

The Guide includes the following sections:

1. Introduction
2. Scope of the New Approach directives
3. Responsibilities (including manufacturer, authorised representative, importer, distributor, assembler/installer and user/employer)
4. Compliance with directives
5. Conformity assessment procedure
6. Notified bodies
7. CE marking
8. Market surveillance
9. External aspects

The following quotes are taken from the Guide:

Introduction

A new regulatory technique and strategy was laid down by the Council Resolution of 1985 on the New Approach to technical harmonisation and standardisation, which established the following principles.

~ Legislative harmonisation is limited to essential requirements that products placed on the Community market must meet, if they are to benefit from free movement within the Community.

~ The technical specifications of products meeting the essential requirements set out in the directives are laid down in harmonised standards.

~ Application of harmonised or other standards remains voluntary, and the manufacturer may always apply other technical specifications to meet the requirements.

~ Products manufactured in compliance with harmonised standards benefit from a presumption of conformity with the corresponding essential requirements.

New Approach directives are based on the following principles.

~ Harmonisation is limited to essential requirements.

~ Only products fulfilling the essential requirements may be placed on the market and put into service.

~ Harmonised standards, the reference numbers of which have been published in the Official Journal and which have been transposed into national standards, are presumed to conform to the corresponding essential requirements.

~ Application of harmonised standards or other technical specifications remains voluntary, and manufacturers are free to choose any technical solution that provides compliance with the essential requirements.

~ Manufacturers may choose between different conformity assessment procedures provided for in the applicable directive.

New Approach directives are addressed to the Member States, which have an obligation to transpose them into their national legislation as appropriate.

Scope

2.3. Placing on the market and putting into service

~ Placing on the market is the initial action of making a product available for the first time on the Community market, with a view to distribution or use in the Community. Making available can be either for payment or free of charge.

~ Putting into service takes place at the moment of first use within the Community by the end user. However, the need to ensure, in the framework of market surveillance, that products are in compliance with the provisions of the directives when being put into service is limited.

~ A product must comply with the applicable New Approach directives when it is placed on the Community market for the first time and put into service.

~ Member States are obliged:

** not to prohibit, restrict or impede the placing on the market and putting into service of products that comply with the applicable New Approach directives; and*

** to take any measures necessary to ensure that products are placed on the market and put into service only if they do not endanger the safety and health of persons, or other interests covered by the applicable directives, when correctly constructed, installed, maintained, and used in accordance with their purpose.*

Responsibilities

3.1. Manufacturer

~ A manufacturer, in the meaning of New Approach, is the person who is responsible for designing and manufacturing a product with a view to placing it on the Community market on his own behalf.

~ The manufacturer has an obligation to ensure that a product intended to be placed on the Community market is designed and manufactured, and its conformity assessed, to the essential requirements in accordance with the provisions of the applicable New Approach directives.

~ The manufacturer may use finished products, ready-made parts or components, or may subcontract these tasks. However, he must always retain the overall control and have the necessary competence to take the responsibility for the product.

3.2. Authorised representative

~ The manufacturer may appoint any natural or legal person to act on his behalf as an authorised representative.

~ For the purposes of New Approach directives the authorised representative must be established inside the Community.

~ The authorised representative is explicitly designated by the manufacturer, and he may be addressed by the authorities of the Member States instead of the manufacturer with regard to the latter's obligations under the New Approach directive in question.

~ The manufacturer remains generally responsible for actions carried out by an authorised representative on his behalf.

3.3. Importer/person responsible for placing on the market

~ An importer (a person responsible for placing on the market)– in the meaning of New Approach directives – is any natural or legal person established in the Community who places a product from a third country on the Community market.

~ The importer must ensure that he is able to provide the market surveillance authority with the necessary information regarding the product, where the manufacturer is not established in the Community, and has no authorised representative in the Community.

~ The natural or legal person who imports a product into the Community may, in some situations, be considered as the person who must assume the responsibilities placed on the manufacturer according to the applicable New Approach directives.

3.4 Distributor

~ Provisions regarding distribution are in general not included in New Approach directives.

~ A distributor is to be considered as any natural or legal person in the supply chain who takes subsequent commercial actions after the product has been placed on the Community market.

~ The distributor shall act with due care in order not to place clearly non-compliant products on the Community market. He shall also be capable of demonstrating this to the national surveillance authority.

3.5. Assembler and installer

~ The installer and assembler of a product, which is already placed on the market, should take necessary measures to ensure that it still complies with the essential requirements at the moment of first use within the Community. This applies to products where the directive in question covers putting into service, and w here such manipulations may have an impact on the compliance of the product.

3.6 User (employer)

~ New Approach directives do not lay down obligations for users, apart from those related to putting into service.

~ Community legislation concerning the health and safety of the workplace has an impact on the maintenance and use of products covered by New Approach directives that are used at the workplace.

Compliance with directive

4.1. Essential requirements

~ Essential requirements lay down the necessary elements for protecting the public interest.

~ Essential requirements are mandatory. Only products complying with essential requirements may be placed on the market and put into service.

~ Essential requirements must be applied as a function of the hazards inherent to a given product.

4.3. Presumption of conformity

~ Conformity with a national standard that transposes a harmonised standard, whose reference has been published, confers a presumption of conformity with the essential requirements of the applicable New Approach directive that is covered by such a standard.

~ References (such as titles, identification numbers) of harmonised standards are published in the Official Journal for the directive in question.

Editor's note: The website link given in the guide is no longer current but the documents referred to can be found at the following address:
http://ec.europa.eu/enterprise/sectors_en.htm

The NAWI and MID directives can be found through the "Metrology, pre-packaging" tab.

~ Member States must publish the reference of the national standard that transposes a harmonised standard. It is useful to indicate in the publication the link with the legislation in question.

~ The application of harmonised standards, which give a presumption of conformity, remains voluntary in the field of New Approach directives. Thus, the product may be manufactured directly on the basis of the essential requirements (83).

Conformity assessment procedure

5.1. The modules

~ Conformity assessment is subdivided into modules, which comprise a limited number of different procedures applicable to the widest range of products.

~ The modules relate to the design phase of products, their production phase or both. The eight basic modules and their eight possible variants can be combined with each other in a variety of ways in order to establish complete conformity assessment procedures.

~ As a general rule, a product is subject to conformity assessment according to a module during the design as well as the production phase.

~ Each New Approach directive describes the range and contents of possible conformity assessment procedures, which are considered to give the necessary level of protection. The directives also set out the criteria governing the conditions under which the manufacturer can make a choice, if more than one option is provided for.

5.4. EC declaration of conformity

~ The manufacturer or the authorised representative established within the Community must draw up an EC declaration of conformity as part of the conformity assessment procedure provided for in the New Approach directives.

~ The EC declaration of conformity should contain all relevant information to identify the directives, according to which it is issued, as well as the manufacturer, the authorised representative, the notified body if applicable, the product, and where appropriate a reference to harmonised standards or other normative documents.

CE marking

7.1 Principles of CE marking

The CE marking symbolises the conformity of the product with the applicable Community requirements imposed on the manufacturer.

The CE marking affixed to products is a declaration by the person responsible that:

~ the product conforms to all applicable Community provisions, and

~ the appropriate conformity assessment procedures have been completed.

7.2 Products to be CE marked

~ The CE marking is mandatory and must be affixed before any product subject to it is placed on the market and put into service, save where specific directives require otherwise.

~ Where products are subject to several directives, which all provide for the affixing of the CE marking, the marking indicates that the products are presumed to conform to the provisions of all these directives.

~ A product may not be CE marked, unless it is covered by a directive providing for its affixing.

Market surveillance

8.1. Principles of market surveillance

Market surveillance is an essential tool for the enforcement of New Approach directives.

~ The purpose of market surveillance is to ensure that the provisions of applicable directives are complied with across the Community. Citizens are entitled to an equivalent level of protection throughout the single market, regardless of the origin of the product. Further, market surveillance is important for the interest of economic operators, because it helps to eliminate unfair competition.

Member States must nominate or establish authorities to be responsible for market surveillance. These authorities need to have the necessary resources and powers for their surveillance activities, ensure technical competence and professional integrity of their personnel, and act in an independent and non-discriminatory way respecting the principle of proportionality.

Notified bodies should, basically, be excluded from the responsibility of market surveillance activities. This is to avoid conflicts of interest.

New Approach directives provide for two different tools that enable surveillance authorities to receive information on the product: the EC declaration of conformity and the technical documentation. These must be made available by the manufacturer, the authorised representative established within the Community, or under certain circumstances by the importer or person responsible for placing on the market. Other natural or legal persons, such as notified bodies, distributors, retailers, suppliers or subcontractors, cannot be obliged to make these available. However, they can assist the surveillance authority in obtaining them. Further, the surveillance authority may request the notified body to provide information on the conduct of conformity assessment for the product in question. …The EC declaration of conformity must be made available for the market surveillance authority immediately upon request. Therefore, it should be kept inside the Community.