

European Technical Directives in the Engineering Education

Prof. Dr. Atanas I. Lazarov
Faculty of Automation
Technical University of Sofia, Kliment Ohridski 8,
1000 Sofia, Bulgaria

Abstract

Now a days it is compulsorily the engineering students to be aware of the European Technical Directives (ETD). Such a knowledge is important for the stage of the design, verification and production, for the further career of the students as well. In fact all Directives of the New Approach and Global Approach set up the engineering legislation in EU, so that the product to be placed on the European market.

Key words

New Approach, technical Directive, harmonized standard, essential requirements, conformity assessment, CE marking, notified body.

1. Introduction

Every student in Engineering has to be aware of the European technical legislation and particularly of the European Technical Directives, because every manufactured product in order to be placed on the European market has to comply with the essential requirements of the appropriate Directive(s) and with the technical specifications of the harmonized standards. For the first time such a course has been submitted as elective course at the Department and sixteen students made their choice for the course.

2. Structure of the course

There are three basic parts of the course [1].

First of all the basis of the New Approach. Then the New Approach technical Directives with the applicable harmonized standards. Also it is so natural the students have an information for the history of EU. In order the history to be clearer it was described as an algorithm, step by step including its creation and enlargement as well. This year Europe celebrated on 25th March a half of century from the Treaty of Rome (Robert Shuman Declaration), when the European Economic Community (EEC) and Euratom have been founded. EEC was a custom union based on the "four freedoms":

- (1) freedom of movement of goods
- (2) freedom of movement of services
- (3) freedom of movement of capital
- (4) freedom of movement of people.

The main part of the course is about the New Approach laid down in a Council Resolution of 7 May 1985. Differences between national laws, standards, and conformity assessment procedures made trade between the countries difficult, contentious, and expensive. In order to eliminate these barriers, a new legislative technique and strategy was instituted in order to serve the single market. The New Approach was designed to envelop, or "harmonize," the health, safety, and environmental requirements into one European-wide legislative package. The new approach involves the development of legislation specifying only the essential requirements that are general and mandatory. The detailed technical specifications that may be used to demonstrate conformity with the essential requirements are elaborated in voluntary harmonized standards, published in the Official Journal of the European Communities (OJEU).

3. Technical Directives

Directives indicate a product has met certain health and safety requirements. A company affixes the CE mark [2] to its product once it has met the requirements of the applicable New Approach Directive(s).

Not all products fall under the New Approach Directives.

There are essentially three levels of regulatory control [3].

Old Approach - The Old Approach Directives apply to the foodstuff, motor vehicle, chemical, cosmetic, and pharmaceutical sectors. These regulations have technical specifications.

New Approach – The New Approach Directives make references to harmonized standards and apply to broad product sectors. The directives usually set down general health and safety requirements, and the specifications for meeting these general requirements are found in the standards applicable to the manufacturer's product. Conformity assessment procedures are also contained in these Directives.

The General Product Safety Directive (GPSD) covers all products not specifically covered by the CE mark directives but which do require some level of safety regulation. These products may also be regulated at the national level by member states.

There are New Approach Directives (21 in number) for electronic and electrical products, machinery, medical devices, radio and telecommunications terminal equipment, recreational craft, pressure equipment, equipment for use in potentially explosive atmospheres, personal protective equipment, toys, simple pressure vessels, and others.

Very important for the students is first of all to know the scope of the appropriate Directive and then the essential requirements. To know the responsibilities of all members of supply chain, namely :

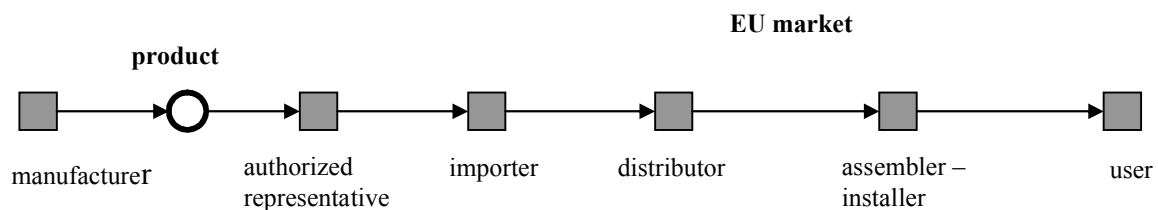


Figure 1: Supply chain

As a general rule, the manufacturer must take all measures necessary to ensure that the manufacturing process assures compliance of the products, to affix the CE marking to the product, to establish a technical documentation and to draw up the EC declaration of conformity.

4. Conformity assessment

Conformity assessment in Europe is the process by which compliance with essential requirements is determined. Conformity assessment is defined by the International Organization for Standardization as any activity concerned with determining directly or indirectly that relevant requirements are fulfilled.

Typical examples of conformity assessment activities are sampling, testing and inspection, evaluation, verification and assurance of conformity, certification, registration, accreditation, and approval as well as their combinations.

Conformity assessment is based on:

- manufacturers' internal design and production control activities;
- third party type examination combined with manufacturers' internal production control activities;
- third party type or design examination combined with third party approval of product or production quality assurance systems, or third party product verification ;
- third party unit verification of design and production; or
- third party approval of full quality assurance systems.

The module Decision on Conformity Assessment.

The conformity assessment can be subdivided into modules which relate to the design phase of products and to their production phase.

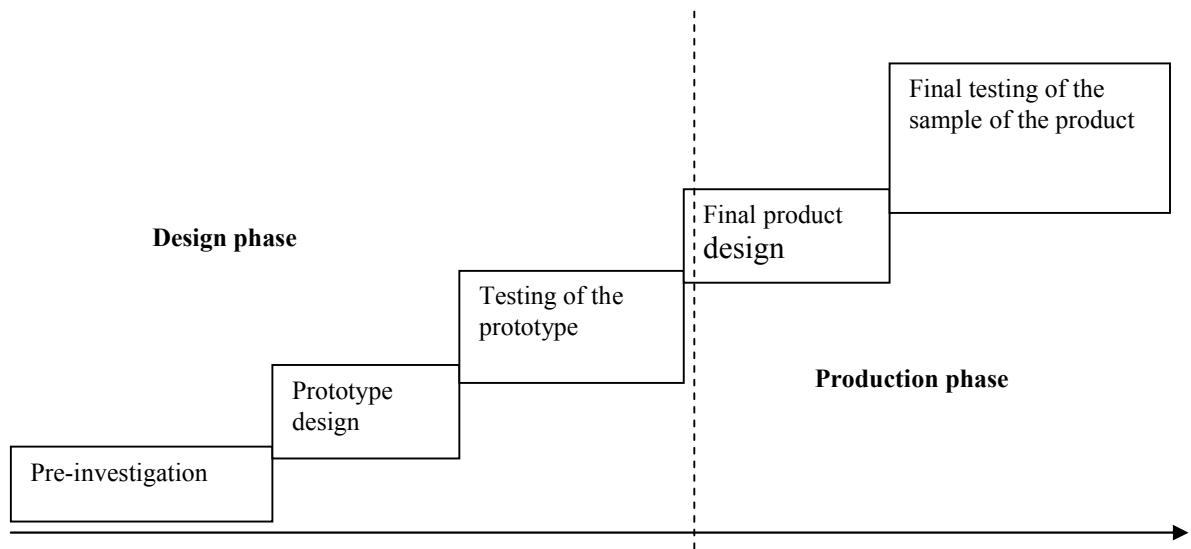


Figure 2: Production phases

Basic modules [4]:

- A. Internal control of the production
- B. EC type-examination
- C. Conformity type
- D. Production quality assurance
- E. Product quality assurance
- F. Product verification
- G. Unit verification
- H. Full quality assurance

The manufacturer is given the possibility of using an approved quality system for the purpose of demonstrating compliance with the applicable essential requirements.

5. Some practical methodical aspects

According to the syllabus, the course was divided into two general parts :

- I. Basis of the New Approach (Lecturers).
- II. Technical Directives (Labs).

For every lecture sheets with a short description of the lecture were given to the students. The same text was downloaded in PCs in order to be used and filled out by the students. The full text was presented using the multimedia system.

For every Lab c.d. was prepared for the students with the appropriate Directive and with a list of the harmonised standards.

6. List of Directives and Resolutions used in the course

1. Council Resolution on New Approach to technical harmonization and standards – 85/C136/01
2. Global Approach Directive – 90/683/EEC
3. CE Marking Directive – 93/68/EEC
4. Modules for conformity assessment Directive – 93/465/EEC
5. Module Decision 90/683/EEC
6. General Product Safety Directive (GPSD) - 2001/95/EC
7. Product Liability Directive (PLD) - 85/374/EEC
8. Low Voltage Directive (LVD) – 73/23/EEC
9. Medical Devices Directive – 93/42/EEC
10. Machinery Directive – 98/37/EC

11. Measuring Instruments Directive – 2004/22/EC
12. EMC Directive – 2004/108/EC
13. Automotive Directive – 95/54/EC
14. Directive on Radio Equipment and Telecommunication Terminal Equipment (R&TTE) – 99/5/EEC
15. EEC Regulation № 339/93 for products imported from third countries.
16. Safety of toys Directive – 88/378/EEC
17. Directive on Minimum safety and health requirements for the use of work equipment by workers at work - 89/655/EEC
18. Telecommunication Terminal Equipment Directive – 91/263/EEC
19. Satellite Equipment Directive – 93/97/EEC
20. Radio Communication Transmitters Directive – 91/263/EEC or 93/97/EEC
21. Directive on Non-automatic Weighting Instruments – 90/384/EEC
22. Directive on Agricultural and Forestry Tractors – 75/332/EEC
23. Motor Vehicles Directive – 72/245/EEC
24. Directive on Active Implantable Medical Devices – 90/385/EEC
25. Diagnostic Medical Devices Directive – 98/79/EEC
26. Council Regulation № 3922/91 - Aircraft and flight equipment
27. Marine Equipment Directive 96/98/EC
28. Directive on the minimum safety and health requirements for work with display screen equipment – 90/270/EEC
29. Directive on safety and health of workers at work – 83/465/EEC.

7. Conclusions

Here the most important subjects of the ETD course are given so that the content of such a course to be clear. The ETD course is delivered for five years at the Technical University of Sofia, English Language Faculty of Engineering (ELDE). The course is prepared to be delivered as a distance learning course as well.

8. References

1. Lazarov A., European Technical Directives, Technical University of Sofia, 2007.
2. Council Directive 93/68/EEC of 22 July 1993 for CE marking.
3. Guide to the implementation of directives based on the New Approach and the Global Approach, Luxembourg, European Communities, 2000.
4. Council Directive 2001/95/EC of 3 December 2001 on general product safety.