What standards do I need for my product or service?

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There are standards for most products and services. Sometimes dozens of them. Examples of standards for products:

- Standards for connection to another product.
- Safety standards.
- Standard dimensions.
- Standards with test methods to be able to demonstrate the quality of the product.

Examples of standards for services:

- Standards that lay down what service the customer may expect.
- Requirements for staff training.
- Standard procedures.

Application of standards is sometimes compulsory or virtually compulsory because the law specifies this or because the customer requires it. But it may also be the company's own choice to use standards, for example to save costs or to serve the customer better. Standards can determine whether a product or services flops or is a mega-success (click **here** for examples). Standards can provide a steer for a company to capture new markets and achieve better operating results. Click **here** for benefits of standardization for producers and buyers. The importance of standards and standardization continues to increase. If you would like to know how this comes about, click **here**.

Searching for standards is difficult, as there are so many of them. The danger is that you can no longer see the wood for the trees. Set out below you will find a systematic approach for searching for standards for products and services. We assume that there is already an overall design of the product or service.

Tracking down standards with a search engine?

How do you search for standards? The quickest way to search for standards is: enter a few search terms (Dutch or English) plus the word 'standard' in a search engine and look at the result. In many cases you will then find something. That can give you an

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initial idea of what there is. But the question is whether in this way you will find what you really need:

- You find that a supplier says it uses a certain standard. Do other suppliers also use it? Are you best to use it yourself, or is there no reason to?
- There seems to be an official standard, designated with ‘NEN-EN, DIN-EN, BS-EN etc.' followed by a number. Is use of this standard compulsory? Or can you just as well use something else?
- You have found 10 standards. But there may perhaps be many more.

In short: you do find something, but perhaps not enough. If you think you are already there, you get yourself on the wrong track. It may therefore be sensible first to think carefully, and only then to use the Internet.

First think carefully

Searching for standards when you really hardly know what they are and what you can use them for, is not very clever. Click **here** for some brief background information. Only then can you really begin. You can go through the following steps here:

1. Search for directives and standards relating to CE marking.
   For more than half of all products requirements apply that relate to the so-called CE marking. This applies in particular for products whose use may involve hazards, for example due to mechanical movement or because electricity is used. Because this happens so often, we shall start with this. If you are looking for standards for services, you can immediately go on to step 2.

2. Search for other official standards.
   Via the website of the standardization institute you can use key words to find other standards of official standardization institutions.

3. Decide for which party or parties you can expect standards.
   Sometimes an organization may lay down its own standards. But then too it is sensible first to look at whether others have already devised something. Who might these others be? Where can these standards be found?

4. Determine possible standards for the product from a checklist.
   Think carefully about the product. You can do this using a checklist which we will give next. The result: a list of subjects for which standards are possible. You can then search more selectively.

5. Determine possible standards for the service from a checklist.
   The same as step 2, but now for services. Often a combination of product and service is involved.

6. Decide the significance in the market of the standards found and set priorities.

Once you have found such a list of standards, the question is whether it is advisable to use them. Perhaps their use is even compulsory. How do you find this out? How do you set priorities?

You do not always have to go through these steps in the order indicated. So first read through all the different steps so that you “know what is coming” and only then start with step 1.

Step 1: Search for directives and standards relating to CE marking.

More than half of all products must carry CE marking. In this way the manufacturer can show that these products meet the statutory requirements that are laid down in European directives. The requirements from these directives must be transposed into the national legislation. The manufacturer shows that it meets the requirements by marking its product with the letters CE (Conformité Européenne). European standards are prepared as a development of the requirements in the directives. Anyone who complies with the standards is also deemed to comply with the statutory requirements. Working according to standards is therefore the easiest way of meeting these requirements. Before you search for the directives and corresponding standards first read the brief explanation of CE marking or the detailed explanation of CE marking.

1.1 Which directive(s)?

First decide which directive(s) apply. There are now a considerable number of so-called New Approach Directives. Three of these relate to a very great number of products:

- Machinery Directive (mechanical safety);
- Low Voltage Directive (electrical safety);
- EMC Directive (to prevent interference between electrical/electronic equipment).

The other New Approach Directives relate to specific product groups, for example:

- equipment in explosive atmospheres;
- construction products;
- simple pressure vessels;
- explosives for civil use;
- medical devices;
- non-automatic weighing instruments;
- lifts;
- personal protective equipment;
- recreational craft;
- radio and telecommunications terminal equipment;
- toys.

Many products and product groups fall under the scope of more than one directive. For a list of the directives see the New Approach site: http://www.newapproach.org/. This gives information for each directive on what exactly it is about. It can at best be difficult to decide which directive applies. For a number of products you can do this using keywords.

1.2 Which standard(s)?

European standards are being developed for each New Approach directive. Sometimes they are there already, sometimes they are still under development or they are being revised again already. For each directive a list of standards can be found. These standards usually bear the designation EN. They have been taken over by the Netherlands and are then designated NEN-EN. In other countries they are designated DIN-EN (Germany), BS-EN (UK) etc. Usually they are in English (or German or French); some frequently used standards are perhaps translated into the mother tongue.

Once you have found these standards, then you will find that they often refer to other standards that relate to the same product.

Step 2: Search for other official standards.

Almost every European country has a national standardization institute. Most national standardization institutes have a catalogue of standards. The catalogue for each country can be found via this link, after which the country of choice can be selected.

The standards that the committees of institutes have produced specially for that country have a country-specific designation, followed by a number. NEN for the Netherlands, DIN for Germany, BS for the UK, etc. There are also normative publications with a slightly different status, designated NPR, and publications that are developed by a simpler procedure, designated as NTA.

Most standards that are important for national organizations are not produced at national level, but at world or European level. Official world standards come from:

- the International Organization for Standardization (ISO) – most standards are designated: ISO, followed by a standard number;
- the International Electrotechnical Commission (IEC) – designation: IEC + number;
- the International Telecommunication Union (ITU) – the standards are called ‘Recommendations’.

The official European standardization organizations are:

- Comité Européen de Normalisation (CEN);
- Comité Européen de Normalisation Electrotechnique (CENELEC);

- European Telecommunication Standards Institute (ETSI).

The commonest designation for European standards is EN, followed by a number.

All these standards are in principle voluntary standards: organizations are free to use them or not. For their development the following rules are used:

- (representatives of) all interested parties may take part;
- decisions are taken on the basis of arguments and 'consensus' (being in agreement on them so as no longer to be in disagreement);
- option for non-participants to comment on the draft standard; these comments are taken into account in a reasoned way.

This carefulness in the production contributes to the support for the standard. A standard of an official standardization institute in most cases therefore has a certain status in the market.

The official European standards can be found via the CEN catalogue using so-called ICS codes. ICS stands for International Classification for Standards. It is a code for classifying the standard. If a standard found has a particular ICS code, there is a good chance that other standards with the same ICS code will also be important. The International Organization for Standardization, ISO, that has developed the ICS code, offers a full list of all codes. By clicking through on these you get to sub-categories, and so on.

Step 3: Decide for which party or parties you can expect standards.

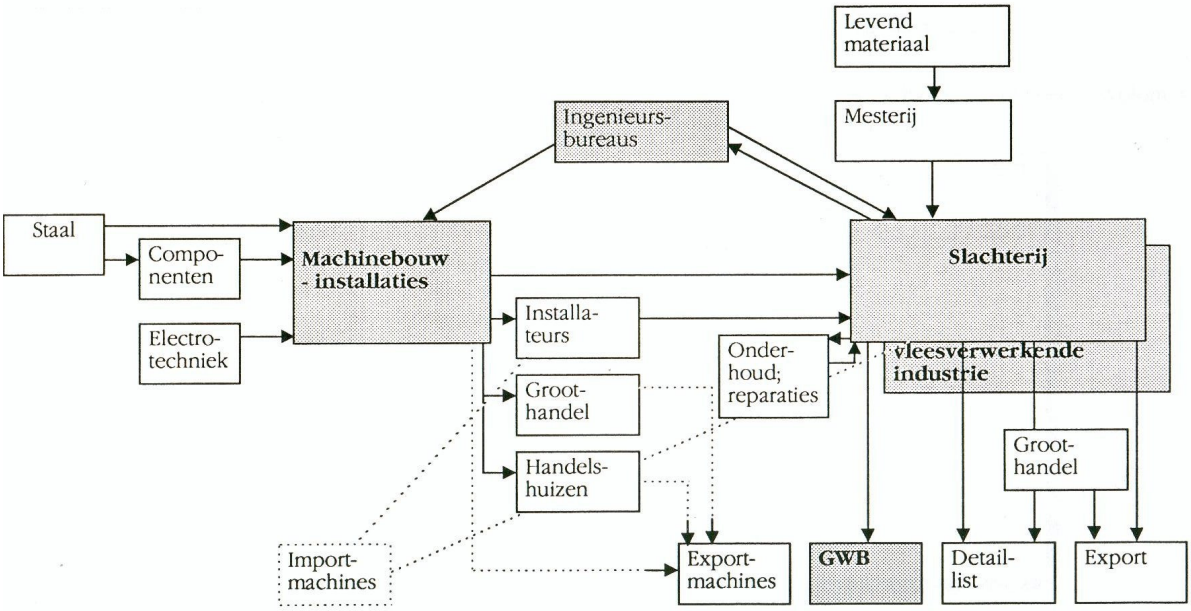
You have probably already discovered a whole series of standards for the product or service in the first two steps *(in the following we will only use the term 'product')*. These standards can be used by the manufacturer or supplier, but also by other market parties. These market parties however do not only use official standards, they may also lay down requirements themselves or use other organizations that do this. To search for standards systematically it is therefore necessary to assess which organizations these may be. We do this in 3.1. One particular party is the government, national or European. We have already met the European government under CE marking. In 3.2. and 3.3. we discuss other requirements of governments.

3.1 Other parties with requirements

You can find other parties that may lay down requirements by systematically going through a number of sightlines.

1 Production chain

Requirements may be made of the product by the parties that play a part somewhere in the production chain. So try to assess this chain. This means the production chain from raw materials, via semi-finished products and parts to products, with then the users of these products and after this any reuse, recycling or processing into waste. Carriers and (the distributive) trade may also lay down requirements. Such a chain can at best be complicated, as shown by the following example.



Example of production chain for slaughterhouse machinery

Key to diagram:
Levend materiaal = Livestock
Mesterij = Fatstock farm
Ingenieursbureaus = Engineering firms
Staal = Steel
Componenten = Parts
Electrotechniek = Electrical engineering
Machinebouw – installaties = Mechanical engineering – installations
Installateurs = Installers
Groothandel = Wholesale trade
Handelzhuizen = Trading companies
Importmachines = Import machines
Slachterij = Slaughterhouse
Vleesverwerkende industrie = Meat processing industry
Onderhoud; reparaties = Maintenance; repairs
Groothandel = Wholesale trade
Exportmachines = Export machines
GWB = Chain store
Detaillist = Detailed list
Export = Export

2 Use

In the production chain we also meet the user: consumer or professional user. Sometimes other parties from the user side are also involved in the subject to which the standard applies.

3 Design

The companies in the production chain are often also those who are involved from the design side in the subject of the standard itself. But sometimes production and design are separated. In construction for example there is often a clear distinction between architect (design) and contractor (detailed design and production).

4 Technical interfaces

For each phase in the chain one has to check whether the product fits in, on, to or with something, such as margarine in a tub, a dashboard in a car or oil in a pipeline. There may be machinery or tools or people who 'do something' with the product. Standards for a product may also be relevant for parties involved with the technical interfaces of that product. Again a distinction must be made between production, use and design.

5 Inspection

Then there may be parties who must inspect the product, or the technical environment directly relating to the product.

- The producer himself.
- The buyer.
- Another party who has to do something with the product.
- A neutral inspection institution (for example a certification institution).

Some inspection institutions themselves develop the requirements on the basis of which they carry out inspections.

6 'Organizations of'

Based on the above sightlines, a large number of parties can be found. Some of these will be able to lay down requirements for the product. Often these parties are also associated in 'organizations of', such as:

- Trade unions
- Consumer organizations
- User organization
- Sector organization
- Consortia of companies
- Professional associations or other organizations of specialists in the special field

Such organizations in fact sometimes again lay down their own requirements.

The main parties that have developed requirement packages for the product are in many cases:

- The producer itself.
- The buyers.
- Official standardization institutions.
- Authorities.

Try to think which of the other parties mentioned will also lay down requirements for the product. All the parties mentioned, and there are very many of them for most products, may have developed requirement packages that are important for the product. In many cases they have a website and on this site you can see whether the organization is involved with standards. But that is not always clear; in particular companies that lay down requirements for themselves or their suppliers do not put that on their site.

3.2 European statutory product requirements

In addition to the New Approach directives already mentioned, for many products other European legislation is also important. We only mention the legislation most frequently involved:

Product liability legislation

Product liability is the liability of a producer for possible deficiencies in a product that it supplies. If something goes wrong during use by the consumer or another user or a product, then the European Product Liability Directive 85/374/EEC lays the onus of proof on the producer: it must be able to show that it has made, transported and stored its product such that it cannot be reproached for anything. If the producer can show that its product meets standards, it is in a stronger legal position, because courts will in many cases assume that the "accepted state of the art" is laid down in standards. If the producer also has a quality management system in accordance with standards (such as EN-ISO 9001), it is in an even stronger position. This liability legislation therefore makes it even more important to work in accordance with standards.

Public tendering

Is the product supplied to a (semi) government body? In some cases the government is obliged by European legislation to lay down requirements for this product that are preferably set out in European standards. The background to this European legislation is that national governments often tend to award large investment projects to national companies. To get a free European market here too, within the European Union in some sectors for investments above a certain amount, the tenders are public. Then companies from other countries can also compete for the contract. If the specifications refer to national standards, there is however a de facto a trade barrier. For this reason the European Union has decided that the specifications must refer to European standards, where there are any in the relevant area. Companies who want to compete for larger

government contracts cannot as a result get round European standards. There is also a knock-on effect from this to other projects outside the government sphere.

There are European directives for public tendering for government contracts in the areas of:

- Works.
- Supplies.
- Services.
- Utility sector.

Work equipment

European directives concerning CE marking lay down requirements for products, and relate to being able to market these products, for example machinery. A company that buys such a machine cannot just use this machine as a means of production. There is other European legislation again for this: the European Work Equipment Directive. This directive gives minimum regulations on health and safety during the use of work equipment by employees in the workplace.

For the Work Equipment Directive specific product standards were developed. Companies may use standards that were drawn up within the framework of product directives, such as the Machinery Directive, supplemented with other available world, European or national standards, as a pointer for meeting the Work Equipment Directive.

3.3 National statutory product requirements

Much European legislation has been transposed into the national legislation and regulations. Specific national product requirements have become increasingly fewer. The requirements that may be laid down in different European countries may differ. The European Commission endeavours to remove barriers to encourage free movement of goods between different countries. It is important to assess the country-specific requirements for a product.

Step 4: Determine possible standards for the product.

Using the following checklist, you can check which standards are possible for your product. The checklist is reasonably complete; some categories show a degree of overlap. We start with generally weighing up the choice between standard or custom work.

Standard or custom work?

Does every customer receive a different product or does everyone receive the same? If every customer receives the same, the product itself is standard. This often involves commercial decisions by the supplier. Customers have different wishes. That is an argument for variety. However: variety is often more expensive to produce. That again is an argument for uniformity. Often a solution between the two is best, where the customer does have options, but there is underlying uniformity, for example standard modules.

- What characteristics of the product may vary? (for example engine power, colour, dimensions)? Are there different options for each characteristic? If so, unlimited (for example any colour) or a limited number of options (for example green, blue, red)?
- Is the product composed of standard modules (that are perhaps in turn composed of sub-modules, etc.)? What alternatives per module?
    - For a mobile lifting crane, that is supplied in different sizes, the manufacturer can choose different wheel sizes (the bigger the crane, the bigger the wheels) or different numbers of wheels (the bigger the crane, the more wheels).
- Are standard parts used (for example standard screws)?

You can apply the following parts of the checklist both to the product as a whole and, where applicable, to its specific modules or parts. Don't go into everything mentioned, that is hopeless. Try to distinguish the main things from secondary things based on common sense.

Form

Can there be standards for the dimensions of the product?

- Sometimes it is useful to define a preferred range.
    - Shoes: sizes 38, 39, 40, 41, 42, etc.
    - Paper formats: cut an A4 sheet (216 x 297 mm) in two and you have two A5 sheets (148 x 216 mm) The Americans have different sizes, based on inches.
- Often one product has to fit in with another. Agreements on dimensions are then necessary:
    - Vacuum cleaner bag in vacuum cleaner.
    - Roll of film in camera.
    - Standard beer bottle in a standard crate that fits on a standard pallet that fits in a standard container.
- Geometric product specifications and fits: what tolerances in size, form etc. are permissible? If one thing has to fit on or in another, such as an axle into a wheel, then tolerances have to be defined: what deviation from the intended size or form is still permissible? The closer the margins that are defined, the more expensive the production …
- Standard measurement methods to measure dimensions.

Material

(required) properties, for example:

- Chemical composition.
- Minimum tensile strength.
- Maximum weight.
- Colourfastness.
- Leaching behaviour (no harmful substances given off into the environment).

Test methods to check such material properties.

Mechanical movement

If product components can move with respect to one another, different standards may be necessary:

- Standards for the interface between one thing and another, for example:
  - Gears (dimensions, properties, strength, calculation method, test method).
  - Lubricants (properties).
- Standards that make requirements of the movement, for example:
  - Maximum speed
  - Time within which the movement can be stopped.
- Safety requirements.

Electricity

Standardization in the area of electrical engineering came about earlier than in other areas, because the technology could not be properly developed without standards in particular for connectability and safety.

- Connectability, for example:
  - Plugs.
  - Wiring.
  - Voltage.
  - Amperage.
- Safety, for example:
  - Insulation.
  - Accessibility for people.
  - Connection conditions.
- Electromagnetic compatibility (EMC): the product must not interfere with other products (do not use a mobile phone in an aircraft) and may not itself be interfered with by other products.

Quality

Properties of the product in relation to the requirements and wishes of the customer. In the light of the standards the supplier can:

- describe this quality: 'My product meets standard X');
- demonstrate this quality, via a standard test method. This testing is carried out by or on behalf of:
  - itself ("1st party");
  - the customer ("2nd party");
  - an independent third party (for example a test laboratory or a certification institution).

Environment

Aspects of the product that may have an effect on the environment, for example:

- Energy consumption during production.
- Energy needed for use of the product.
- Raw materials consumption.
- Release of harmful substances or radiation.
- Noise production.
- Vibration caused by the product.
- Reusability ("design for re-use").

Standards may lay down a performance requirement or give a measurement method which can be used to test whether the requirements are met. There may be standards with sample solutions.

Safety

Toys may be dangerous for children, for example due to:

- sharp edges;
- parts that can come loose (eyes of a bear);
- release of toxic substances if the toy is put in the mouth;
- small parts, on which a child could choke.

Standards have been developed that lay down safety requirements for toys. That also applies for many other products. Standards aimed at preventing accidents concern among other things:

- Established safety level.
- Test methods to test for safety.
- Examples of solutions to ensure safety (for example railings along balcony).
- Preventive warnings (for example hazard marking on product, audible signal when a truck reverses).
- Signalling in case of hazard (for example in car: automatic warning that petrol has nearly run out).

- Protective devices in case of hazard (for example boiling dry protection in water boiler).
- Instructions for use.
- Instructions for commissioning.
- Instructions for maintenance / repair.

Should something still go wrong, standards can again be helpful:

- Standards that specify safety provisions (for example presence of fire extinguishing equipment).
- Standards that lay down requirements for safety provisions (for example requirements for fire extinguishing equipment).
- Instructions for use ("If the patient has taken too much of this medicine, make him drink plenty of water and consult your GP").

Hazardous situations may arise if a product is used in a different way to that intended. Sometimes such different use can be foreseen:

- opening a can of paint with a screwdriver;
- standing on the windowsill to clean the windows.

The manufacturer can warn against such use, but it is better to design the product so that it is protected from the outset from what the English call: 'foreseeable misuse'. The hygiene requirements for dog and cat food are so stringent that this food is suitable for human consumption!

Ergonomics

Requirements for the product in relation to the user, or for the interaction between user and product. Ergonomic standards relate among other things to:

- Design principles.
- Anthropometry: sizes and other characteristics of people, to be used to design products.
- Requirements for the use of products (for example required posture, lifting).
- Permissible exposure for example to noise, vibration, temperature or electromagnetic radiation.
- Requirements for product-human interface, for example keyboards, operating panels, displays, pictograms.

Human and animal health

Requirements for the product in relation to the health of the user and methods to measure this. This of course applies most directly for food products or animal feed:

- Standards with requirements for food safety.
- Standards with measurement methods to test the safety of food.

- Standards with requirements for the preparation, distribution and storage of food.
- Standards for use information (for example shelf life date).

Specifically for medical products there are requirements relating to the effect of the product on the person. In addition to quality requirements this relates to requirements for bio-compatibility: to prevent the product and the human body not tolerating one another well (for example skin irritation due to plaster).

Information

- Information for product identification, for example:
  - Numbers / codes.
  - Names / terms, definitions.
- Information on product characteristics, for example:
  - Classifications.
  - Terms, definitions.
- Information on how the product is made, for example:
  - Technical drawing.
  - Construction calculations.
- Information for the user
  - Required / intended use
  - Unadvisable use.
  - Instructions for use.
  - Shelf life
  - Possible 'side effects'.
  - Instructions for maintenance
- Relation between product and information: (instructions for:)
  - Affixing information to the product.
  - Bar codes etc.
  - Chips etc.
  - Bar codes

Information exchange

Standards for sending information from one computerized system to another relate among other things to:

- The physical connection (requirements for example for glass-fibre cable).
- Synchronizing the transmission of data.
- Addressing for and routing of data.
- Encryption and interpretation of data.
- Method of data entry.
- Method of representing data.
- Security of data.

Step 5: Determine possible standards for the service.

Services are associated with many products, for example:

- Installation (the supplier of the TV set comes to your home and sets the channels for the transmitters).
- Service (telephone help desk).
- Guarantee scheme.
- Complaints handling.
- Maintenance.

In many cases there are standards for this. Vice versa, products are also associated with many forms of service provision (for example a truck providing transport services, a medical device in care for the sick). So in providing service, standards are also often relevant for products. In the following we look at specific standards for services.

Standard or custom work?

Does every customer receive a different service, or does everyone receive the same? Services where the supplier does not or hardly sees its customer (“teleservices”) are often very standard, for example energy supply or a telephone subscription. Often there is direct customer contact for services and so by definition the service is not completely standard, not even at McDonald’s. Often a producer can anyway supply custom or near-custom work with underlying “uniformity”. Example: providing advice would seem to be completely custom work, but a professional consultancy firm has a database with standard solutions for problems that its consultants often come across. They also work in accordance with certain procedures.

- What is the service in this case? Can you think of this service as composed of standard modules (that are perhaps in turn composed of sub-modules, etc.)? Are there a number of alternatives for each module?

The service provision process and the result of service provision

Standards for service provision in the first place relate to the service provision process and to the result of the service provision. The two often overlap into one another in service provision. In a cabaret show the visitor enjoys the provision of the service during the process. Sometimes they can be clearly distinguished - the result of providing a transport service is that the goods are transported from A to B, have arrived at the right time and were not damaged on the way. To search for standards it is often enlightening to distinguish between ‘process’ and ‘result’.

Standards for the service provision process may among other things relate to:

- A specification of activities.
- Reliability.

- Privacy aspects.
- Safety aspects.
- Code of behaviour.
- Permit requirement.

Standards for results of the service provision relate among other things to:

- Result specification.
- Requirements of the result.
- Measurement method to check whether these requirements are met.

Staff within the service providing organization

A lot of service provision is carried out with direct interaction between supplier and customer. The person providing the service is therefore extremely important. Standards for people relate among other things to:

- Knowledge (for example: 'must be in possession of welding diploma')
- Skills.
- Attitude.
- Ethical code (for example confidentiality).

Customers

In some cases requirements are also laid down for customers:

- Admission requirement (for example no alcohol for children under 16, only rent car to someone who has driving licence and identity, health requirement for playing sport).
- Behaviour requirement (for example smoking ban).

Organization of the service provider

Anyone booking a holiday on the Internet will want to ensure that the travel organization is reliable, so that the trip does in fact take place and the promise of the apartment with its own sandy beach is fulfilled. That also applies for other forms of service provision: often requirements on the service providing organization are also important, such as:

- Quality management (for example a quality management system based on the international standard ISO 9001).
- Environmental management (for example based on the standard ISO 14001).
- Health and safety management (system for paying systematic attention to working conditions).
- Safety assurance (is the organization of Dance Valley geared to preventing accidents with visitors?).
- Liquidity and other financial aspects.
- Workforce, for example minimum staffing and level of training.

Physical objects that support the service provision

Examples:

- Technical requirements for trains providing public transport services.
- Requirements for tools for providing repair services.

Physical objects of customers

For some forms of service provision the service provider works with or on customers' objects and makes requirements of them. Examples:

- Requirements for objects to be repaired when providing repair services.
- Requirements for cargo to be transported by transport services, such as:
  - dimensions of containers or swap bodies;
  - requirements for impact- and water-resistance.

Work room

Requirements for the room in which the service is provided, for example:

- Requirements for daylight entry in an office.
- Requirements for the presence of safety provisions and good air extraction in a chemistry laboratory.

Measures to prevent anything going wrong

Examples:

- Safety procedures.
- Work instructions.

Measures for when something goes wrong

- Emergency measures, emergency plan.
- Complaints handling.
- Guarantee provisions.

Communication

There is always communication between customer and service-providing organization, often before, during and after providing the service. Sometimes there is communication within the service-providing organization (for example in providing a library service, where your library orders a book from another library). Standards can be important for all this communication:

Standards for sending information from one computerized system to another relate among other things to:

- The physical connection (requirements for example for glass-fibre cable).
- Synchronizing the transmission of data.
- Addressing for and routing of data.
- Encryption and interpretation of data.
- Method of data entry.
- Method of representing data.
- Security of data.

In addition there may be standards for example for:

- Standard forms.
- Bar codes.
- Pictograms.
- Protocols.
- Code of behaviour.
- Accessibility (for example times accessible by telephone, average waiting time).

Payment

- Method of payment.
- Deadlines.
- Payment terms.

Step 5: Decide the significance in the market of the standards found and set priorities.

We have seen above that the standards of official standardization institutions are voluntary standards: everyone is free to use them or not. In a number of situations the use of an official standard for a product is however more or less compulsory:

- Because of the connection to the technical environment (if the product must fit into the wall socket (officially: 'socket outlet') with a plug (officially: 'plug contact'),
- Because certain standards are so widely accepted in the market that a deviation would not be accepted in the market (for example QWERTY standard for keyboards).
- Because the buyer specifies certain standards (possibly contractually).
- Because the customer requires a certificate based on the meeting of certain standards.
- Because the law encourages or even specifies the use of the standard.

There are also official standards that are not very much applied, for example because there is a competing industry standard. In short, even if you have now found a large number of standards, you have not finished yet: You will have to check which standards

are now used most in practice, and preferably also why. On this basis you can then decide yourself which you want to use.

This information cannot generally all be found on the Internet. You will have to ask experts. These experts will usually work for the organizations that you have already identified.

- In many cases the sector organization has a good idea and if it does not, it can indicate what other organization(s) can tell you what standards are important.
- Companies, particularly the larger ones, also often know this, but they will often not want to divulge this know-how.
- The same applies for inspection and certification institutions.
- A National standardization institute in many cases has an idea of what official standards there are, but is less able to give information on other requirements.

Do not bother such experts with the question “What standards are there for product X”? It takes a lot of time to answer such a question. The better you have prepared yourself, the sooner they will be inclined to be kind enough to spend some of their valuable time answering your question. You can present to them what you have meanwhile found and ask them:

- whether you have forgotten something;
- or whether what you have found is in practice really important.

In many cases you will have found a labyrinth of standards. The danger is that you can no longer see the wood for the trees. It seems to be hopeless. What standards can you now best use?

It is difficult to give a general answer to this question. Often however two categories of standards are most important:

- standards that are necessary to be able to meet the customer’s requirements;
- standards that relate to the legislation.

If an organization does not use these standards, the question is whether it can or may supply.

A third category has to do with weighing up the choice between standard or custom work: doing things in a standard way to produce as cheaply as possibly, but still with a certain degree of custom work, as customers’ requirements differ. Standards relating to this are as a rule of great commercial importance.

In fact the priorities in the field of standards relate to the strategy of the organization. Click **here** for a somewhat abstract business story about how the standardization strategy can be based on the corporate strategy.

(1) Examples of standardization

McDonald's

The Big Mac is the same all over the world. But standardization at McDonald's goes much further. Even the procedure within the restaurants is the same all over the world. There is even a "Hamburger University" where the senior management of the company can learn the ropes of "these are our ways". This is a form of standardization within the company, also called corporate standardization. Both the production method and the presentation to the customer are standardized.

Credit card and bank card

In almost every country of the world you can pay with the same card. Shops, hotels and restaurants accept it. You can go to financial institutions with it, to the counter or cash machine. Clearly a great number of parties have accepted this means of payment: banks, businesses, individuals. McDonald's can set its standards itself, but for agreements on bank cards and credit cards consultation is needed between a large number of parties.

Light bulb fitting

The lamp fits, all over the world, thanks to standardization. Before the Second World War Philips produced around 3000 different light bulb fittings. Now there are only 400. But the number of different light bulbs is now much greater. Type restriction in

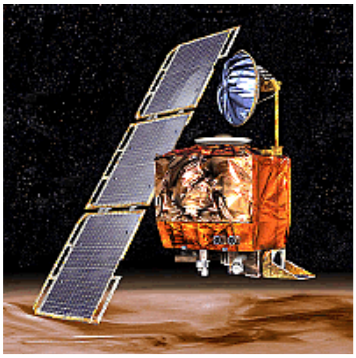
connection requirements *and* more variety, among other things in colour and energy range.

Camera film

The film roll fits into every camera. All over the world photos can be printed. The film sensitivity is 100, 200 or 400 ISO (named after the international standardization institute ISO: International Organization for Standardization). Modern cameras detect the film sensitivity of DX films automatically, so that the user no longer has to set the film sensitivity himself. Standardization then for a standard "interface" between film and camera, with standard properties for standard treatment in a development laboratory, and with optimum user convenience. As a result the product is acceptable and affordable for very large user groups and the manufacturers can sell their cameras, films and development fluids worldwide. Supplier-independent, user-independent and not bound to national borders. Typical standardization.

Crash on Mars due to conflicting standard systems

Our ancestors talked about Rhenish rods and yards. The length of the yard varied depending on the arm length from the fist. Now the standard metre is in Paris, variables and units have been laid down in international standards and national institutes such as the Netherlands Measurement Institute monitor the use of the right units: not a pound, but half a kilo. Often these units are also laid down by law. Measuring instruments such as scales can now be calibrated.

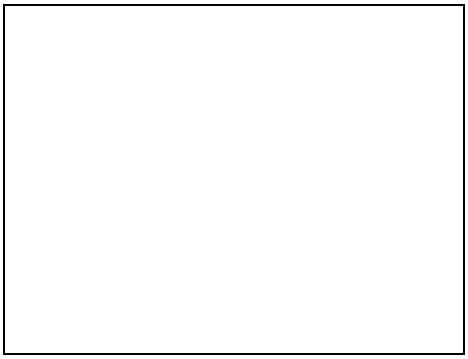


The internationally agreed variables and units are not always used in the United States and Great Britain. That can have fatal consequences. In 1999 the American spacecraft Mars Climate Orbiter burned up in the atmosphere of Mars. The damage: $ 125 000 000. The cause: using the internationally standardized metric system and different American units alongside one another. The Orbiter software systems used the metric unit Newton (1 N = 1 kg.m/s2) for the variable force. The team on earth however used the ‘pound-force’ that corresponds to 4.448 Newton. The engineers in the space organization NASA failed to convert the data measured by the Orbiter into the other system. As a result they were working with wrong data on the precise location of the spacecraft with respect to the surface of Mars and then gave the wrong instructions for adjusting its course. The Orbiter came too low and the craft very probably burned up in the atmosphere of Mars. This was a ‘human error’ of an overworked team, but if the metric system had been used consistently, the problem would not have occurred.

Motor fuel

The petrol of Shell, BP, Esso etc. shows no or very little difference as regards composition. This petrol can also be used for any make and type of car. The same petrol is not only available in the Netherlands but also abroad, so there generally is no problem about filling up abroad. The independence of the supplier, customer and place greatly increases the ease of use for the buyer. The suppliers will have to compete with one another on things other than the product specifications, the constancy of the product specifications is their common interest.

Paper formats



The A series of paper formats is generally known. The ratio of length to width is $\sqrt{2} : 1$).The area of A0 is m^2. A1 is created by dividing A0 into two equal parts, A2 is half of A1, etc. This standardization was developed in Germany, in around 1920. The main purpose was the economic use of paper: sheets of paper are cut from big rolls of paper, and standardization reduces the cutting losses. A second advantage lay – and still lies – in the convenience for the user: the sizes of the storage media, such as folders, ring binders and filing cabinets can be matched to the standard paper formats.
After seventy years the same paper formats still prove their worth: for copying, faxing, digitalizing, printing etc. Thanks to standard paper formats these new technologies have been accepted more quickly, because no "conversion problems" had to be overcome.

Screw thread

Even older than the standardization of paper formats is that of screw thread: nuts and bolts that match one another. From the infinitely large number of options a limited number of alternatives has been determined. The user can choose from this "preferred range". Because the designation is also standardized, screws, bolts, nuts etc. of the required size can be ordered everywhere, without being dependent on one supplier.

Condoms

Condoms have to protect against pregnancy, sexually transmissible diseases and HIV. So they have to be reliable, but without unnecessarily detracting from the experience of intimacy. A number of standards have therefore been developed for them. Standards for male condoms include requirements among other things for dimensions and model, colourfastness, packaging and labelling. Also test methods to determine the length, width, bursting volume, strength and elongation at break and holes in condoms have been laid down in standards.

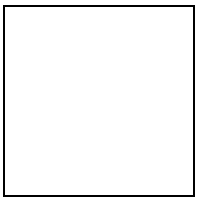
Bar code

We all know it from the supermarket: the bar code. A number is represented by a pattern of lines. The code indicates the country of origin, the manufacturer and the product number assigned to the product by the manufacturer. A scanner can read the code. Scanning the bar code at the till makes it possible to issue itemized till receipts. But this can also be used to keep stock records. That makes it possible to automatically place additional orders for products. These and other types of bar codes make it possible to link products and product flows with data on these products and on transport of the products. By standardizing the bar codes, their use becomes universal: irrespective of sector, product type and application. In addition affordable scanners can be developed that can read the standard codes. Without standardization bar codes could only be used in isolated environments.

Electric voltage

The Dutch 220 Volts is gradually being changed to the 230 Volts agreed at European level. Uniformity in electric voltage makes it easier for manufacturers: they do not have to make different versions of their products for each country. Users also benefit from this, by – slightly – lower prices and because they can also use their shaver etc. abroad (apart from problems with plugs). It will be clear that once a voltage has been chosen it is difficult to change: the change may have consequences for both the electricity grid and for the equipment connected to it.

GSM



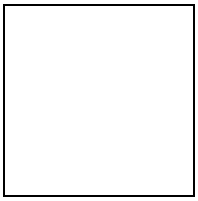
Without standards your mobile phone would not work. Your mobile phone transmits a signal that is received elsewhere and ultimately reaches the person you are calling. Without clearly agreed specifications on the transmission signals this is impossible. These agreements are set down in the standards of ETSI: European Telecommunication

Standards Institute. In this case the product itself has been given the name of the collection of standards: GSM – Global System for Mobile Communications.

Environmental measurement methods

The government lays down statutory requirements for the maximum permissible concentration of pollutants in water, soil or air. To be able to measure these concentrations determination methods are needed. If the polluter and the inspection body use different methods, no-yes situations can arise: is there too much contamination or not? To prevent this determination methods are standardized.

Management systems



Who does not know them, the ISO 9000 standards for quality management? They came about from the need to lay down requirements for a supplier, so that one could be sure that the latter can fulfil the agreements on supplies. Because there is a need for generally accepted criteria for this, these requirements are laid down in international standards.
Meanwhile there are also international standards for environmental management and various countries, including the Netherlands, have started on standardization in the field of management of working conditions.

(2) Examples of standardization

A standard offers a solution to a problem that occurs or could occur repeatedly. Something that is used once does not have to be standardised. It is after all not used by others. It is however feasible that one-off products are composed of standard parts, and/or made with standardized methods:

- A dressmaker who makes tailored suits takes the measurements in a standard way and puts standard buttons on them in a standard way.
- A ship is usually made to customer specifications, but using standardised design and production methods. A shipbuilder produces near-custom work for each buyer, by putting together the ships from standard modules, where it gives a few alternatives for each module, for example a number of types of wheelhouses, a number of rudders, etc.

By using standard methods and standard elements far-reaching adaptation to a great variety of customer wishes is possible, without the products becoming too expensive.

Benefits for producers

The main examples of standardization for producers are:

- Better management
  By using standard methods and standard parts, the management can be set up more efficiently

- Greater market acceptance
  Standardization brings continuity in what the company does and in the level at which it does this. As a result the customer knows what he is facing. That creates confidence.
  In this respect, this also involves the "cooperation" of the products that the company supplies with the environment in which these products are used. One can think for example of the roll of film in a camera, or a mobile telephone that is not interfered with, itself causes no interference and cannot be listened in to.

Benefits for buyers

The main examples of standardization for buyers are:

- Greater security
  The buyer has more security, due to continuity in the range from the supplier.

- Lower price

Uniform mass production is of course cheaper than custom work for each customer. But the market wants variety. In many cases standardization can ensure "underlying uniformity": if a car were not standardized down to under the bonnet, the manufacturer could not offer a variety of different types for a price that – in view of the high technical level of the product – is low. Examples are differences for example in engine power, number of doors, or colour of the upholstery. Standardization also leads to savings in other ways, for example due to better connectability, lower stock costs and lower material losses.

- Safety
  Many product standards contain safety requirements and/or test methods to check whether a product is safe.

(3) Increasing importance of standardization

In *Standaard of Maatwerk – Bedrijfskeuzes tussen uniformiteit en verscheidenheid (Standard or Custom Work – Business choices between uniformity and variety)* (C.A.J. Simons and H.J. de Vries, Academic Service, Schoonhoven / NEN, Delft, 2002) the authors give the following reasons why the importance of standardization is increasing:

Technical developments

A company is increasingly less of an island. More and more often the company is linked in a technical sense with its environment: other companies, authorities, etc. The product of one company must fit in with that of another. The service that one supplies must meet the requirements that the other lays down for example for quality, time and safety. It must be possible for the electronic signal that one transmits to be received and interpreted by the other. Standards are necessary for the (often technical) interfaces.

Outsourcing

Many companies concentrate on core activities and outsource other activities. This makes it necessary to specify what is supplied. The same suppliers often also supply to others. It would be useful for them if the specifications for their different customers at least partly corresponded. This not only involves specifications of the products or services to be supplied, but also for example the administrative handling (for example development and product documentation, stock statements, customer data) and the computer systems that support these. All this harmonization with one another is standardization, although it is often not called this.

Chain management

There is not only harmonization between one company and its suppliers, but through the whole production chain, from ‘top to bottom’ and from ‘start to finish’. This harmonization concerns the raw materials, semi-finished products and services, as well as quality and environmental aspects, logistics, transport, packaging, information and money transfers.

Quality management

Thousands of companies work with a quality management system according to the ISO 9001 standard. They therefore make it possible for their organization to be managed and controlled. This can form the basis for quality improvements. The quality management system can be checked against ISO 9001, by or on behalf of the organization itself, by or on behalf of a buyer, or by a neutral third party organization: a certification institution. If an organization complies with ISO 9001, it may be assumed that it is able to fulfil agreements on product or services to be supplied.

A quality management system provides a structure for the work in the company. This can most efficiently be done if there is also a system in the product range, if the means of production are set up in a structured way and if the information systems fit together logically, in short: if standardization of products, means of production and information systems has been carried out. Standardization provides structure for products, means of production and information systems; quality management provides structure in the way these are worked with. In the light of standards the quality of the products or services to be supplied can also be specified and measured.

Internationalization

Trade is becoming increasingly cross-border. This has given rise to a need for internationally recognized standards, so that trade can run smoothly. As a result the importance of world and European standardization continues to increase.

E-business

The Internet makes it possible to search for suppliers worldwide. But who can say whether these suppliers and their products and services are reliable? If the supplier himself has an approved quality management system, based on ISO 9001, that creates a certain degree of confidence, namely that it must be able to supply products/services that also meet the standards mentioned by name and number.

Certification

The more anonymous markets have become and the increasing quality awareness have resulted in a great increase in certification: of management systems, products, services, processes and persons. Standardization goes before all certification: after all objective testing criteria are needed. In this way the advent of certification is strengthening the importance of standardization.

Government procurement and public tendering

Government procurement has long formed an area where national companies have received preferential treatment. To get a free European market here too, within the European Union in some sectors (among other things the construction of infrastructure, energy supply, information technology) governments are obliged for investments above a certain amount, to make the tendering public. Then companies from other countries can also compete for the contract. If the specifications refer to national standards, there is however a de facto trade barrier. For this reason the specifications must refer to European standards, where there are any in the relevant field.

Product liability

When using a product on one occasion something goes wrong, resulting in an accident or damage. Who is liable in this case, the consumer or the producer? European legislation in the field of product liability lays the onus of proof on the producer: it must

be able to show that it has made, transported and stored its product so well that it cannot be reproached for anything. If the producer can show that its product meets standards, it is in a stronger legal position, because courts will in many cases assume that the "accepted state of the art" is laid down in standards. If the producer also has a quality management system in accordance with the ISO 9001 standard, it is in an even stronger position. This liability legislation has therefore made it even more important to work in accordance with standards. Apart from that: in our legal system the furnishing of proof is free, in case of disputes the court also permits other information in addition to standards.

Environment, safety

The increased attention paid to environment and safety is leading to standards for safety or environmental aspects of products and services, for related information (for example environmental labelling) and to standards in the light of which the capacity of an organization to work in an environmentally friendly or safe way is demonstrated (for example ISO 14001 for environmental management or VCA, the Veiligheids-checklist Aannemers (Safety Checklist for Contractors)).

CE marking

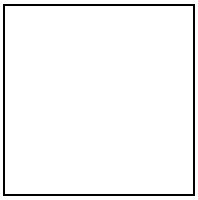
CE marking is now compulsory for more than half of all products that are marketed in Western Europe. With the CE marking the manufacturer indicates that it meets certain statutory requirements laid down by the European Union. In many cases these requirements are further specified in European standards, or these standards give test methods to check whether the product meets the requirements. The easiest way to meet the statutory requirements relating to CE marking is by using (European) standards. There are now thousands of these. So CE marking has led to strong growth in the use of standards.

Legislation

CE marking, European directives for government procurement and product liability involve legislation that encourages the use of standards. There are even more examples of these, such as the Dutch building regulations. The "Buildings Decree" that forms the basis for granting permits to build, refers to Dutch standards which indicate among other things how one can measure whether the statutory requirements are met. In Dutch Practice Guidelines (NPRs) in addition examples of constructions are described: building constructions that meet the statutory requirements.

(4) CE marking – brief explanation

Almost all toys found in the shops bear the letters CE. This stands for Conformité Europeenne, and means that the manufacturer declares that its product meets requirements laid down in the European directives relevant for that product.



CE symbol.

Behind this simple symbol hides a world of (European) legislation, standardization and certification, with fundamental consequences for the producers. And it is not only for toys, for over half of all types of products marketed in Europe the CE marking is or is becoming compulsory. This applies among other things for almost all electrical and electronic products and for most products where mechanical movement is involved.

If requirements differ for each country, that is an obstacle to free trade. The European Commission wants to prevent that. It is therefore setting out the essential requirements relating to safety, health, environment and EMC in European Directives. European Directives are laws at European level that as regards effect must be transposed into the national legislation. They therefore give direction for national legislation in all the EU states.

These essential conditions are formulated in overall terms. They may be further elaborated in European standards which, like all European standards, are published as a national standard in all the states of the European Union (and the European Free Trade Association). Many of these standards contain test criteria in the light of which it is possible to establish whether the product meets the requirements laid down in the Directive. The standards reflect the state of the art and are prepared via the private circuit of the standardization institutions. So legislation and standardization are complementary. Legislation and technology are separated. New technical developments may make a revision of the standards desirable, while the legislation can remain the same.

This "new approach" distinguishes from the "old approach" in which in European legislation very detailed technical requirements were laid down. Because of the difficult creation process for these, the requirements were sometimes already out of date by the time they came into effect. The "new approach" is much more flexible.

By affixing the CE marking, the manufacturer shows that it is meeting the essential conditions applicable for its product from all the directives applicable for its product. The

CE marking says no more than this, it does not for example give any indication of the quality level of the product.

The CE marking can be regarded as a "border document", just like a passport: without CE marking the product cannot cross the border. Apart from that: even companies that do not export must affix the CE marking. This CE marking is like a signature at the bottom of a letter: the manufacturer has signed that its product meets the applicable requirements.

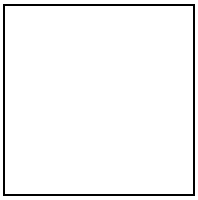
As has been said, the essential requirements are laid down in European directives. A manufacturer may affix the CE symbol if it can demonstrate that its products meet these requirements. That is therefore a question of translating the requirements in the directive for the manufacturer's own products. Most manufacturers prefer to carry out this translation in the light of European standards that, by publication in the Official Journal of the European Union, are linked to the directive. They may however carry out this translation without using these standards. The meeting of the requirements is then however more difficult to demonstrate.

Would you like a more detailed explanation of CE marking? Click here.

(5) CE marking – Detailed explanation

(This text is taken from *Standaard of Maatwerk – Bedrijfskeuzes tussen uniformiteit en verscheidenheid* (Standard or Custom Work – Business choices between uniformity and variety) (C.A.J. Simons and H.J. de Vries, Academic Service, Schoonhoven / NEN, Delft, 2002, 245 pages)

Toys found in the shops in Western or Central Europe must bear the letters CE. This stands for 'Conformité Europeenne'. It means that the manufacturer who markets the product within the borders of the European Economic Area (European Union plus Iceland, Liechtenstein and Norway) (the manufacturer or the importer – for the sake of convenience in the following the manufacturer is talked about) declares that its product meets requirements in the area of health, safety, environment and consumer protection, laid down in the European directives relevant for that product.



CE symbol.

Behind this simple symbol hides a world of (European) legislation, standardization and certification, with fundamental consequences for the producers. And it is not only for toys, for over half of all types of products marketed in Europe CE marking has now become compulsory. This concerns in particular products with a high safety risk: almost all electrical and electronic products, most products where mechanical movement is involved, and products that are partly or completely pressurized, such as pressure vessels.

The European Commission then wishes to protect citizens with such requirements *and* it wishes to prevent requirements differing for each country and so forming a barrier to free trade. The essential product requirements are therefore laid down in European Directives, which are laws at European level that as regards effect must be transposed into the national legislation. The directives therefore give direction for national legislation in all the EU states.

This combination of legislation and standards is called the 'new approach'. In the 'old approach' there was no added role of standards, but detailed technical requirements were laid down in European legislation. Because of the difficult development process for this legislation, the requirements were sometimes already out of date by the time they came into effect. In addition this approach hindered new technical developments. The 'new approach' is much more flexible: standards can be adapted to new technical developments, while the statutory requirements remain unchanged.

The manufacturer affixes the CE marking to the product itself (for example to the type plate, on a label or a sticker) or, if permitted, to the packaging (for example contact lenses). It may do this if it can demonstrate that its product meets the requirements for its product of applicable New Approach directives. It therefore has to translate the requirements in the directive for its own products. Most manufacturers prefer to carry out this translation in the light of European standards that, by publication in the Official Journal of the European Union, are linked to the directive. They may however also carry out this translation without using these standards. The meeting of the requirements is then however more difficult to demonstrate. For this reason this option is hardly used in practice.

Because the essential requirements are formulated in overall terms, different interpretations are possible, which could lead to trade barriers. This is however prevented with the European standards.

The standards are drawn up by committees of the European standardization institutions CEN and CENELEC. A practical problem is that some directives are already in force, without all the relevant standards already being finished. The possible difference in interpretation of the essential requirements may then cause new technical trade barriers.

With the CE marking, the manufacturer only declares that it is meeting the essential conditions applicable for its product from all the directives applicable. The CE marking says no more than this, it does not for example give any indication of the quality level of the product, hence we do not talk of the ‘CE quality mark’. Also in the field of safety they are only minimum requirements – some producers lay down higher requirements for their products. Buyers of products can of course also lay down higher requirements for the products of their suppliers.

The CE marking can be regarded as a "border document", just like a passport: without CE marking the product cannot cross the border. Apart from that: even companies that do not export must affix the CE marking: without CE marking the product may not be marketed.

For consumers the CE symbol has hardly any value. It does not guarantee that these products are safe or environmentally friendly. It only says that according to the manufacturer they meet the requirements in applicable European Directives. By affixing the CE marking the manufacturer has ‘signed’ for it, as with a signature at the bottom of a letter:

Because the control mechanisms are not sufficient, sometimes products are marketed that bear the CE marking, but which do not meet the statutory requirements. It is in that respect just like for the enforcement of the maximum speed limit on the road: too little control leads to massive breaking of the rules. That also happens with European safety legislation. Usually the CE marking is affixed, but that does not yet mean that all manufacturers therefore actually meet the requirements. In particular imported goods from for example South America or South-East Asia often do not meet the requirements. This is not only a problem for users, who may obtain unsafe products, but also for bona

fide producers – they sometimes have to incur additional costs to have their products meet all the requirements and are faced with unfair competition. The government is also proving disappointing in carrying out enough supervision. In the area of toys alone each year tens of thousands of different new products appear on the European market. The work has barely started in checking them all. But the government could carry out more frequent random checks. The fact is that violation of the requirements is usually only discovered when something goes wrong. The CE marking hence offers false security.

Requirements for being able to affix CE marking

What must the manufacturer do to be able to affix the CE marking? This differs for each product, and depends on what European directives apply for that product. Figure 3.5 shows the different possibilities.

The “lightest alternative”, ‘module A’, is the so-called ‘manufacturer’s own declaration’. With this, the manufacturer himself declares that its product meets the essential requirements mentioned in the directives applicable. The following is therefore expected of the manufacturer:

- to ensure that its product meets the requirements;
- in the design phase of the product: produce a file with technical information on the product, and keep this file available for the national authorities for up to 10 years after the last product is manufactured;
- draw up a declaration in which the manufacturer declares that its product meets the applicable essential requirements;
- affix the CE marking.

	Module A. Internal production control	Module B. Type examination				Module G. Uniformity inspection	Module H. Full quality assurance
Design phase	The manufacturer: - holds technical documentation available for the national authorities **Aa** Action of notified body	The manufacturer submits to the notified body: - technical documentation - (proto) type The notified body - assesses conformity with the essential requirements - carries out tests if necessary - issues declaration of EC type examination				The manufacturer - submits technical documentation to the notified body	(EN 29001) The manufacturer - uses an approved quality management system (QMS) for the design The notified body - exercises supervision of the QMS - checks conformity of the design* - issues certificate of EC design *
		Module C. Conformity with the type	**Module D. Production quality assurance** (EN 29002)	**Module E. Product quality assurance** (EN 29003)	**Module F. Product inspection**		
Production phase	**A.** The manufacturer - prepares statement of conformity - affixes CE marking	The manufacturer - prepares statement of conformity - affixes CE marking	The manufacturer - uses an approved quality management system (QMS) for production and inspection - prepares statement of conformity - affixes CE marking	The manufacturer - uses an approved quality system for control and inspection - prepares statement of conformity with the approved type or the essential requirements - affixes CE marking	The manufacturer - declares conformity with the approved type or the essential requirements - affixes CE marking.	The manufacturer - submits the product - prepares statement of conformity - affixes CE marking	The manufacturer - uses an approved QMS for the production and inspection - prepares statement of conformity - affixes CE marking
	As The notified body: - carries out tests on specific aspects of the product* - takes samples at random times*	The notified body: - carries out tests on specific aspects of the product* - takes samples at random times*	The notified body: - approves the QMS - exercises supervision of the QMS	The notified body: - approves the QMS - exercises supervision of the QMS	The notified body: - checks conformity - issues certificate of conformity	The notified body: - checks conformity with the essential requirements - issues certificate of conformity	The notified body: - exercises supervision of the QMS

* The special directives may contain additional provisions.

Modules with requirements for being able to affix CE marking.

In a number of cases specified in the directives a 'notified body' must inspect the product again, after which an EC 'type examination' certificate can be issued. According to the EMC Directive (EMC 89/336/EC), a directive under which almost all electrical appliances fall, instead of a 'notified body' a 'competent body' may also be called in if the manufacturer does not want to use European standards (for this directive it can always use standards, because generally applicable EMC standards have been developed). Also if the manufacturer *does* use the European standards it can if wished have inspections carried out by a 'competent body'. The Pressure Equipment Directive (97/23/EC), in addition to the 'notified bodies', also has 'recognized third-party organizations'; these are also 'notified bodies' that have an inspection function in the phase during which the equipment is used. To illustrate the complexity of some directives: The directive for 'transportable pressure equipment' (99/36/EC) talks, not only of 'notified bodies', but also of 'approved bodies' that must carry out inspections on among other things shut-off valves.

Many producers obtain parts from suppliers. They must ensure that all the components purchased also meet the requirements.

Module A is only used for products for which European standards linked to the directive exist. If there is no European standard, a ‘notified body’ (some directives speak of ‘Competent Body’), namely an inspection laboratory, determine whether the product meets the essential requirements. This is then module B.

The ‘most stringent’ alternative for obtaining the CE marking is module H. This applies for products such as pacemakers, where it is particularly vital that the product does indeed meet all the requirements. Stringent requirements already apply here in the stage of product development, for if the draft does not take sufficiently into account the requirements from the relevant European directives, that may cause problems in the ultimate products. Manufacturers of such products are expected:

- to have a quality management system in accordance with the EN-ISO 9001 standard, approved by a certification institution that is also a ‘notified body’;
- to have the product design approved by a notified body: a certificate shows that the product design meets the essential requirements;
- to issue a declaration in which the manufacturer declares that its product meets the essential requirements (a model for this can be found in the European standard NEN-EN 45014 ‘General criteria for suppliers' declarations of conformity’);.
- to affix the CE marking.

There are also all sorts of alternatives in between. The module diagram sets them out. In this diagram a clear distinction is made between two phases: the design phase and the production phase. In both cases requirements are laid down. Module A is the easiest alternative, module H the most stringent. From left to right in the diagram the control continually increases. Producers will in general prefer to use the easiest alternative, module A. In fact this alternative does not involve any more than is already expected of the manufacturer from the point of view of product liability legislation. The only difference is that the manufacturer must declare in writing that the requirements are met (the manufacturer’s own declaration) and must affix the letters CE to the product.

If external parties (‘notified bodies’) have to examine the products and/or management, the manufacturer has less in its own hands. But this does not release the manufacturer from its own ultimately responsibility and liability. Demonstrating that the essential requirements have been met then requires additional attention. In addition apart from its own time, it also costs money that must be paid to certification and inspection institutions.

The modules may also be used in combination with one another: module C is always used in combination with module B, modules D, E and F are often used in combination with module B. Modules H, D and E refer to standards EN 29001, EN 29002 or 29003. This means the standards NEN-EN-ISO 9001:1994, NEN-EN-ISO 9002:1994 and NEN-EN-ISO 9003:1994 These standards have now been replaced by one new standard: NEN-EN-ISO 9001:2000. This contains additional requirements with respect to the standards from 1994. Manufacturers may therefore exclude some requirements from NEN-EN-ISO 9001:2000, without the presumption of conformity with the statutory requirements disappearing as a result.

The road to CE marking

To be able to affix the CE marking the manufacturer must do the following:

Search for requirements

There are now a large number of New Approach directives. Three of these relate to a very great number of products:

- Machinery Directive (mechanical safety);
- Low Voltage Directive (electrical safety);
- EMC Directive (to prevent electrical/electronic equipment interfering with one another).

The other New Approach directives relate to specific product groups, for example:

- equipment in an explosive environment;
- building products;
- simple pressure vessels;
- explosives for civil use;
- medical devices;
- non-automatic weighing instruments;
- lifts;
- personal protective equipment;
- recreational craft;
- radio and telecommunications terminal equipment;
- toys safety.

Many products and product groups fall under the scope of more than one directive. In addition there is other product legislation in addition to the New Approach directives: The general Product Liability Directive and more specific legislation, such as the Environmental Management Act, the Public Contracts Directive and the Work Equipment Directive. The manufacturer must find out which statutory requirements its product must meet. In addition it will want to keep track of which statutory requirements will be expected in the future so that it can adapt its product design to this in time, or may even affect the creation of the legislation. See here for a list of the directives.

Determine who is responsible

For products produced within the EEA the manufacturer is responsible for the conformity with the essential requirements and for affixing the CE marking. If the products come from outside the EEA, the importer or manufacturer's or importer's 'authorized agent established in the Community' is responsible. The business concern that assembles, modifies or extends products as a result of which the safety level is changed or sells a

product under its own name (private label) is regarded as the producer. A trading enterprise that is not regarded as the producer however is still obliged to check that agreements on CE marking are set down in purchase agreements, or a user guide and an EC declaration of conformity is present and that the CE marking is affixed.

Risk analysis

A risk analysis for a product (group) is recommended, even if the applicable directives do not make this compulsory. To be able to affix CE marking, the manufacturer must be able to show that it has wanted to make its product meet the essential requirements. This includes for example (safety) risks among other things for use, assembly, maintenance, service, transport and demolition/recycling. A risk analysis shows what the risks present are and how these can be reduced.

Risk reduction

The manufacturer must in the first place ensure that its product meets the essential requirements. It checks its product against the requirements and, if necessary, adapts the product design to it. Risk reduction can also be carried out by:

- protection from the hazard (for example protective cover);
- use of personal protective equipment (for example safety goggles);
- safety instructions (pictogram on the product, manual, course).

Applying/not applying standards

If the European standards relating to the European directive(s) are available, then obviously these should be used – there is then after all a 'presumption of conformity' with the essential requirements. If the company does not use the standards, it is more difficult to demonstrate conformity with the requirements. But this manufacturer is free in this – it will have to make a well-considered choice as to whether or not to apply the standards. See here for a list of standards for each directive.

User guide

In many cases the directives may make the use of a user guide compulsory. The user guide includes among other things:

- a description of the intended conditions of use;
- instructions for specialist staff that install, commission or maintain the product;
- if necessary, a tutorial;
- instructions for use for the user of the product;
- a warning of any hazard from (incorrect) use of the product.

For consumer products instructions for use are sufficient. The guide must be translated into the language of the country where the product is used.

Technical construction file

A technical construction file includes among other things:

- the technical specifications for the product (designs, drawings);
- list of the requirements from the directive(s) and other technical specifications taken into account in the design;
- description of the action taken to meet the requirements;
- inspection reports and certificates.

It can serve as evidence for the manufacturer should problems occur. It does not have to have it all present, but must be able to put it together and submit it within a reasonably short time if requested. The Machinery Directive obliges the manufacturer to keep the relevant documentation available for inspection purposes for up to 10 years after the last product has been produced. For products that fall under other directives a construction file is not always compulsory, but is sensible.

Inspections

For products with a low risk, internal production control is enough to demonstrate that the product meets the requirements of the directive(s). The directives also include the inspection procedures that the manufacturer must follow as a minimum. Products with greater risks, or which have not been produced according to the standards relating to the directive(s) must be inspected by an external inspection institution. This must be an authorized body: ‘notified body’ or ‘competent body’. The manufacturer must then find an inspection institution, have its products inspected and keep the certificate (the ‘declaration of conformity’). Even if inspection or testing is not compulsory, it can if required call in an ‘authorized body’ to have its product inspected. An authorized body may only issue advisory and inspection reports.

Purchase agreements

A manufacturer, who assembles products and buys parts for this, is well advised to reach agreements with its suppliers on CE marking and to set down these agreements in a purchase agreement. The agreements not only relate to meeting technical requirements, but also for example to calling in an inspection body or compiling the parts of the technical construction file. The person who markets the product also bears the ultimate responsibility.

EC Declaration of Conformity

The manufacturer or its representative in Europe draws up a ‘declaration of conformity’ for each product or product series for which CE marking is compulsory. This states that the product conforms with the requirements from the directive(s), that are then mentioned by name. The declaration is drawn up in the language of the user guide and sent with the product. A copy goes into the technical construction file. Sample declarations can be found in the annexes to the directives.

Organizational measures

The manufacturer must embed the package of measures in its organization. Responsibilities, powers and tasks must be clear and agreements made with for example suppliers and inspection institutions. It is obvious – but usually not compulsory – to use a quality management system for this. If the manufacturer already has an ISO 9001 quality management system, then ISO 9001 obliges it to integrate the CE measures in that management system.

(6) Corporate strategy and standardization

This contribution is taken from *Standaard of Maatwerk – Bedrijfskeuzes tussen uniformiteit en verscheidenheid* (Standard or Custom Work – Business choices between uniformity and variety) (C.A.J. Simons and H.J. de Vries, Academic Service, Schoonhoven / NEN, Delft, 2002),

An entrepreneur operates on the interface of his own organization and his environment. He has vision, sets objectives and devises plans in order, from the possibilities of his own organization, to mean something for his environment, by supplying products and/or services that are in line with manifest (or perhaps still only latent) needs. His products and services depend on his own production facilities and what others offer in the way of products and services. Depending on the extent to which the customers want to pay for his products and services, his organization will grow, be maintained, shrink or cease to exist. In the Anglo-Saxon tradition, that is gaining influence in the Netherlands, the generation of as much money as possible for the shareholders is the main objective here, in the Rhineland model business continuity is the most important. Internally the entrepreneur is primarily involved in dealing with the people together with whom he forms the organization. The art is to work well together, focusing on the objectives of the enterprise.

Harmonization of people – group – company – environment

Management is the art of formulating and transferring objectives and then optimising the harmonization of people – group – company – environment. This harmonization can be broken down into:

- **Social harmonization**

  This relates to harmonization between:

  - the enterprise and its environment (customers, suppliers, capital providers, government, media and so on);
  - the organization as a whole and individual or groups (for example project teams, departments, business units) within them;
  - between one group and another;
  - between one individual person and another.

- **Harmonization in a technical sense**

  In traditional work harmonization problems were solved on the spot - the carpenter makes the timber for the frame to fit on the site where the house is built. In ‘industrial building’ the frame is made in advance, in the factory, using drawings with tolerances indicated on them. It is transported to the site and used or set up there. In industrial production what one person supplies to the other meets clearly pre-determined requirements. One can think here of dimensions, modular coordination, tolerances,

fits and so on, but also for example product information, environmental agreements, transport, logistics or quality of services. The harmonization problems are solved beforehand using a model: thinking and doing are separated. Good "technical" agreements are required for this.

- **Harmonization over time**

  The different successive operations in production must fit in well with one another. The "output" of one forms the "input" for the next in the chain. Fine execution techniques are important here, but so are site installation, network planning and the proper establishment and transfer of work results. This concerns the time aspect in the short term. In the longer term the entrepreneur must among other things take into account staff turnover, a changed market situation, changes in the legislation and regulations and, last but not least, technical development. The art of enterprise is also, when necessary, moving with the times.

These three, social, technical and time, are related to one another. If for example a technical harmonization problem is not solved (for example: a door does not fit) then that is still solved (shave off door), which takes time, as a result of which the agreed delivery time may possibly not be met, which can lead to stress or rows. As a rule of thumb 80 % of the problems during execution are attributable to unsolved problems earlier on.

Doing business is only possible on the basis of what customers ask for. They have their own requirements and wishes. The entrepreneur translates these into objectives for his enterprise. This leads to contracts with buyers. The compliance of the contract must be audited: has what was promised and agreed actually also been done? From the audit report errors made may come to light that can lead to corrective action. The corrections in the business can in turn lead to doing business more successfully, which completes the circle. From the way business is done (approaching customers, negotiating, brochures, catalogues, demos, and so on) among other things via the specification of requirements and setting down of the agreement in a contract, to the corrective action in the company it is all standardization (record what you did, what the result was, what went wrong, what you are now going to do). Standardization after all means that activities/processes can be repeated in a structured way. This then means that the company does not waste time working out what has already been found to work well before and that it also learns from its mistakes (see also the figure with the two loops in paragraph 5.4.).

Market development makes harmonization even more complex. The markets are becoming geographically bigger. The development time for new products must be constantly reduced. The economic life for products is falling. The influence of customers and legislation and regulations is increasing, among other things in the area of environment and safety. This also leads to joint ventures: horizontal (in the sector) and vertical (in the production chain): co-design, co-maker, co-shipper. Within the company and over the corporate borders logistics and quality management are given more attention. The product package is often composed of modules with standard interfaces between them. The customer-order disconnection point can as a result be increasingly

closer to the start of the production process: among other things in the automotive industry in spite of mass production is still carried out to order. The customer can want and get a red car, with yellow upholstery, sunroof, built in satnav and telephone. Due to the possibilities of telecommunications the information exchange between companies is more efficient, but also more anonymous. Because transport costs are falling, commercial relations (customers and suppliers) are spread out all over the world. As relations become more anonymous there is more need for certification: of products, but also of (supplier) companies. That should give "justified confidence" that the products or companies meet pre-determined requirements.

Solving harmonization problems with standardization

Harmonization problems are typically the sort of problems that can be solved with standardization.

> Standardization is the development and recording of a limited number of solutions for harmonization problems which occur now or possibly later, focussed on benefits for the participant(s), weighing up their interests, and with the aim and expectation that a considerable proportion of the intended users will repeatedly or constantly apply these solutions, for a certain period.

In short, wherever in the central management question of solving harmonization problems (social, technical and in time) the same harmonization occurs repeatedly, standardization is desirable. In other cases custom work is better. The consideration is each time to choose between standard or custom work. We now discuss this consideration for the three different aspects of harmonization.

Standard versus custom work in social harmonization

Harmonization between organizations or groups is in fact harmonization between people, as organizations consist of people. In the book *Brave New World* Aldous Huxley describes how people are standardized. But that is fiction. They can however learn certain rules of behaviour, carry out standard actions and communicate in a standard way. The need for this increases as the solution becomes less ‘informal’, that is within bigger organizations and for more anonymous relations with the business environment. Formalization limits the individual freedom and that runs up against the human freedom ideal. In weighing up the choice between control (by formalization) and freedom the execution of the corporate objectives must be the guide, but in such as way that individual freedom is retained. For more about finding the balance between freedom and control we refer to the book *Kwaliteitszorg zonder onbehagen*, (Quality control without discomfort), a case study on the standard ISO 9001.

Within one’s own organization this involves primarily defining processes and linking people with these processes, by establishing responsibilities, powers and tasks. The behaviour of all these separate people can hence mesh with the objectives that the organization has set itself. In addition to this formal aspect, that is also a question of (corporate) culture in which the individual leanings of one person fit in better than those

of another. As cultural diversity increases in society, standards (of behaviour) also become more necessary within the enterprise. Corporate standards for inter-personal cooperation can best be produced with a combination of bottom-up and top-down. Then there is on the one hand support from the staff and on the other hand a link with the corporate objectives and coherence in action.

Harmonization with the outside world in the first place concerns customers. The 2000 version of ISO 9001 can help to assess the requirements and wishes of these customers properly, to use them as an input for the company's own processes and, after delivery of products and services, to check whether they were in fact to their satisfaction. If this standard does in fact provide am umbrella for harmonization with customers, other standards help in particular in the area of communication. Also in an informal culture it is in any case useful to lay down some basic agreements. The greater the distance from the customer, literally and figuratively, the more reason to use (corporate) standards.

What applies for the relationship with customers applies 'in mirror image' for the relationship with suppliers. A good standard is not a dictate from one side, but the result of consultation about how the parties want to deal with one another.

Also harmonization with other external parties, such as authorities and capital providers can take the form of standardization. Above all the relationship with official bodies, such as social security institutions, is largely standard, but the enterprise itself has little influence on this. In the way in which it accounts for itself (financially, but for example also in the environmental field) this freedom is much greater, but the clarity and comparability of different reports with one another is served with standardization.

Standard versus custom work in harmonization in a technical sense

Both within the enterprise and in the production chain harmonization in a technical sense is involved and where 'repetition' is involved standardization is desirable, though not essential. This involves:

- the choice of the *portfolio of products and services*, in relation to the choice of the sales markets. The more uniformity is offered, the lower the costs, but with more variety more different customers or customer groups can be served.
- the *specifications of these products and services*, in relation to one's own production facilities and to the requirements and wishes of the customers.
- *harmonization in the production chain,* both within one's own enterprise and in relation to suppliers, carriers and buyers. This concerns the standardization of parts of products, the harmonization of means of production, such as machinery, the information flow through the chain, process control, quality, safety and environmental aspects and logistics.

Standard versus custom work in harmonization over time

In harmonization over time in the first place one can think of agreements on delivery times, so that the next party in the chain can carry on with the output from the previous

process. This harmonization is not in itself standardization, because the time agreement is a one-off one. Often however the same process is carried out repeatedly, which then involves standardization.

The key to the consideration of choosing standard or custom work in case of harmonization over time is however: how quickly does the organization make changes in the existing procedure? If everything is different each time, then there is no standardization. Then there is only improvisation and the organization will probably quickly fail. If there is more structure, then the change question first concerns the portfolio of products and services. How quickly does this change? Then this concerns the markets, production facilities, and so on. In many cases it will be desirable to innovate in a certain area and at the same time to keep other things constant.

A particular effect, in relation to harmonization over time, is that of adopting standards. Once a particular standard becomes available and is used by some people, others also tend to start using it. Then they can decide together on the choice that has been made. We will not move away from the QWERTY keyboard, even though better ones have now been devised.

Standard versus custom work and corporate strategy

The corporate strategy indicates where the company now is, where it wants to get to and how it will get there. The strategy therefore indicates in outline what can remain constant over time and what must change. This concerns the products and services in relation to markets and possibly the relationship with market parties other than customers, and concerns the company's own organization. This also concerns the products/services and production facilities in a 'technical' sense. Each time the question is:

- Where do our know-how, skill and other possibilities lie?
- What portfolio of products and services do we want to supply to what customers?
- What do we want to do as standard, where do we choose custom work?
- Where do we want to keep things stable, where do we want to innovate?
- In case of standard / stable – do we ourselves determine our (corporate) standards or do we use external standards?
- Do we regard external standards as a given or do we want to exert an influence on their creation?

The last two questions have to do with external standardization, for example by participation in committees. There is generally little sense in re-inventing the wheel – usually it is wiser to profit from external standards. Anyone who leaves making these standards to the competition however by definition does not lead the way. It may be a good strategy – to follow, without the costs and risks of leading the way. It may however also be a dangerous strategy. In any case it would have to be a conscious choice of whether or not to participate in external standardization. Such a choice is only possible if the most important areas of standardization for the company have been assessed and then a choice is made, by linking this assessment with the corporate strategy.