

## A bird's eye view for small and medium-sized exporters

Abstracted from the complete guide on Export Quality Management



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On behalf of the German federal government, the Physikalisch-Technische Bundesanstalt (PTB) promotes the improvement of framework conditions for economic activity, thereby supporting the establishment of metrology.

This excerpt is based on the book “Export Quality Management: A Guide for Small and Medium-Sized Exporters”, published by the International Trade Centre (ITC) and Physikalisch-Technische Bundesanstalt (PTB) in 2011.

# Introduction

Standards and quality increasingly shape commercial prospects for developing and transition economies. Not only industrialized countries, but also developing and transition economies therefore need a national quality infrastructure (NQI). Economies all over the world have much to gain from such a quality infrastructure, the benefits of which include international partnership, demonstration of equivalence & compliance with national or international standards, access to information and technical expertise, transfer of knowledge, increased consumer protection, increased trade and development, and a higher standard of living.

For individual companies an NQI can offer the key to the global market place. However, it is not a door that will open automatically ... If you, as an individual company, want to enter the global market place ...

- you need to manufacture products according to the **standards, technical regulations** and **sanitary and phytosanitary** requirements of your export markets;
- you need to be able to use **testing laboratories** to determine compliance of your products; these laboratories should have access to **metrology and calibration services** to ensure that their test equipment are giving reliable results;
- you probably need your products/systems to be **certified by third parties** to give confidence to the buyers and regulatory organisations that the relevant requirements are being consistently met.
- You need to be sure that the certification organisations and laboratories that you use **have been accredited** to demonstrate their technical competences.

**Do you qualify for the global market place?**



Source: Physikalisch-Technische Bundesanstalt

# Part 1 – Understanding quality

## 1.1 What is quality?

Quality can be defined in many ways. For instance, ISO 9000 calls it:

“the degree to which a set of inherent characteristics fulfils requirements”.



Source: iStock

A more comprehensive definition is the following:  
“The quality of a product or service depends on an exchange between two persons, one supplying the product or service and the other receiving the product or service. The supplier and the customer can have different views on what quality is and this may lead to misunderstandings and disputes. In that sense, quality can be understood as “the conformance with customers, requirements or fitness for purpose”.

Two additional points should be made:

- it is the customer who defines whether a product is fit for use or not and
- customers’ requirements change over time as purchasing power increases or as more innovative products are made available on the market.

## 1.2 Why is quality important?

As a company in the international marketplace you want to be a winner, a preferred supplier!

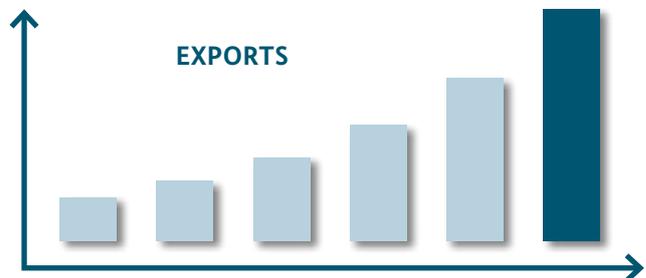
Winners will be those who manage to offer products or services that are better (in terms of quality), cheaper (in terms of costs) and supplied more efficiently (delivered in time or provided with a timely after-sales service) and in a sustainable way (creating shared value for all stakeholders involved).

Winners look beyond the costs of delivering quality products or services, to eye the opportunities of reaching the highest stage of performance. They reach levels of business performance excellence by applying quality management principles.

By aiming to produce or offer services “right the first time and every time”, winners will reduce waste and thus lower costs.

Winners will have more satisfied customers who will have fewer problems with the product or service. Customers will come back for more products and business will grow as the brand name gets established.

If a winner’s product or service is under warranty, costs will be minimized because they will have fewer calls for repairs during the after-sales service period.



Besides, a winner’s focus on sustainability, will drive innovation and increase efficiency.

All these will bring about a rise in productivity and a reduction in costs.

**Are you ready to become a winner?**

# Part 2 – Technical requirements – compliance is key



Source: fotolia

Becoming a preferred supplier means you will have to comply with prevailing technical requirements.

Technical requirements include:

- 1) standards
- 2) technical regulations
- 3) SPS requirements

The terminology is often a source of confusion. Common usage of these expressions in many countries does not necessarily correspond to the specific meanings given to them in the international context of agreements. This international context is important to comprehend before reading the details of the requirements.

## 2.1 International context

The Agreement on Technical Barriers to Trade, commonly referred to as the TBT Agreement, is an international treaty administered by the World Trade Organization. It was last renegotiated in 1995.

In a nutshell, the TBT Agreement exists to ensure that technical regulations, standards, testing, inspection and certification procedures do not create unnecessary obstacles to trade. The agreement empowers WTO Members to challenge all trade-restrictive measures that do not

serve legitimate purposes such as consumer or environmental protection.

The TBT agreement is closely linked to the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS), which was signed in the same year and has similar goals.

The TBT and SPS Agreements are complementary, or in other words, the TBT agreement deals with all technical barriers to trade other than SPS measures.

## 2.2 Standards, technical regulations and SPS measures further explained

### Standards – a voluntary choice, but increasingly important

A standard is “just” a document that describes the characteristics of a product or a service. These characteristics may cover a wide range of issues, such as: design, weight, size, performance, environmental requirements, interoperability, materials, production process or service delivery or for example protocols that allow computers or mobile phones to connect to each other.

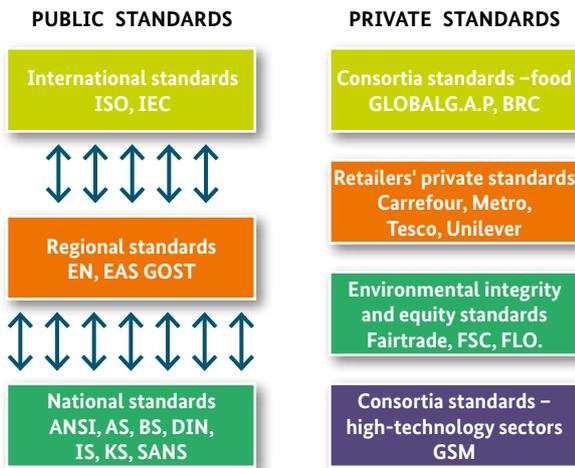
The standard may also include or even deal exclusively with terminology, symbols, packaging, marking or labeling requirements as they apply to a product, process or production method.

Standards are generally divided into public standards and private standards. The figure below shows examples of public and private standards at the various levels.

Public standards are developed and published by recognized organizations, usually standardization organizations. This takes place at three different levels: international, regional and national.

Private standards are developed outside the auspices of national, regional, and international standards organizations. The reasons for the development of these standards are many and varied. Four private standard groups can be identified, as shown in the figure above.

**Diversity of standards**



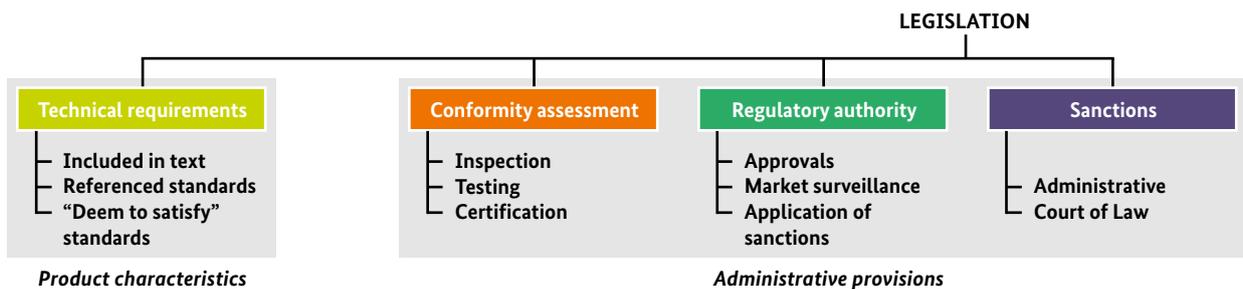
Source: Martin Kellermann, South Africa.

Although they are voluntary, private standards have gained in importance quickly in recent years, frequently also in relation to sustainability standards and social responsibility. “Voluntary” means that companies may decide for themselves which standards are relevant for them and whether the benefits of implementation outweigh its costs. However, remember that in several sectors (B2B) customers increasingly require compliance with standards, many of them private.

**Technical regulations – legislation, defined by the TBT agreement**

Technical regulations are not standards, but they are sometimes confused with each other because they seem alike. Technical regulations can be stand-alone documents, but they may also be based on standards or may reference them. Whereas standards are voluntary in principle and drawn up by all interested parties, technical regulations are the responsibility of public authorities and are mandatory, which means that everybody has to comply with them by law. The building blocks of a typical technical regulation are shown in the figure below.

**Building blocks of technical regulations**



Source: Martin Kellermann, South Africa.

Technical regulations are given a range of different names. In the European Union for example, they are called Directives, Regulations, Decisions. Technical regulations can apply to all industrial and agricultural products. An agricultural product may therefore be subject to both technical regulations and SPS measures.

Ensuring compliance with technical regulations can be challenging for several reasons:

- One product can be subject to more than one technical regulation,
- Each regulation can be administered by different regulatory agencies in a country.
- Some regulations can be old and therefore finding information about them can be difficult.
- Each regulation has its own testing, inspection, and certification requirements.

**SPS measures**

Sanitary and phytosanitary (SPS) measures are requirements imposed on goods by governments to control risks to human, animal or plant life and health. Most SPS measures are concerned with the maintenance of food safety, and the protection of animal and plant health against pests and diseases. Sanitary measures deal with the protection of the life or health of humans or animals; phytosanitary measures deal with the protection of the life or health of plants.

The measures include all relevant laws, decrees, regulations, requirements and procedures. These may stipulate end product criteria; processes and production methods; testing, inspection, certification and approval procedures; quarantine treatments and requirements for the transport of animals or plants, and for the materials necessary for their survival during transport. They may also impose obligations in regard to statistical methods, sampling procedures and methods of risk assessment. Finally, they may prescribe packaging and labelling requirements directly related to food safety.

# Part 3 – Management systems – towards excellence

Basically there are four categories of management systems that deal with quality in some way:

- Quality management systems (QMS)
- Environmental management systems
- Food safety management systems
- Other management systems



## 3.1 Quality management system: ISO 9001 is the profound basis

ISO 9001 is applicable to all sectors of industry, including manufacturing and service, and to organizations of all sizes. It is a management system standard to demonstrate an organization's ability to consistently provide goods that meet customer and regulatory requirements.

ISO 9001 specifies “what” is required to be done by an organization but does not indicate “how” it should be done, thus giving you great flexibility in running your business.

While the original idea was that ISO 9001 could be used by any sector of industry, some specific industry sectors, such as the automotive, telecommunications, aerospace, medical devices, oil and gas, and information technology sectors, felt the need for specific additional QMS requirements. This led to the development of sector-specific QMS standards, both by ISO and by industry groups. Some examples of such sector-specific Quality Management Systems are ISO/TS 16949:2009 (for the automotive industry) and AS 9100 (aerospace industry).

Although there are many benefits related to maintaining an ISO 9001 system and basically it is an investment in preventing failures, the biggest benefit is the huge savings you can make by considerably reducing the cost of failu-

res. For exporters from developing economies, adherence to the ISO standards can also enhance access to international markets.

## 3.2 Environmental management systems (EMS)

In the past decades environmental protection has become increasingly important. To enable organizations to manage environmental issues proactively, ISO has developed the “ISO 14001 Environmental management system – Requirements with guidance for use”. It is the world's most recognized framework for EMS. The overall aim of an EMS based upon ISO 14001 is to support environmental protection and the prevention of pollution in a balance with socio-economic needs. Companies have the possibility to integrate ISO 14001 EMS with ISO 9001 QMS as they are compatible with each other. ISO 14001 can be implemented by companies of all sizes.

For exporters, there are three important benefits of running an ISO 14001 system:

- Compliance with buyers' requirements
- boosting a company's image
- reduction of costs

## 3.3 Food safety management systems (FSMS)

An FSMS must ensure that food produced by an organization is safe for human consumption. An FSMS consists of several building blocks and has a few basic elements:

### ■ Good Practices

Companies need to implement prerequisite programmes for maintaining a hygienic environment in their unit. These programmes may include Good Hygienic Practice (GHP), Good Manufacturing Practice (GMP), Good Agricultural Practice (GAP) and/or Good Distribution Practice (GDP).

### ■ Hazard Analysis/HACCP

Hazard Analysis and Critical Control Points (HACCP) is defined as “a system, which identifies, evaluates and controls hazards which are significant for food safety”.

It is important for SMEs in the food processing business to use HACCP for two reasons. First, it brings internal benefits such as reduced risk of manufacturing and selling unsafe products, which will in turn generate greater consumer confidence in these products. Second, food regulatory authorities in many countries have adopted, are adopting or are likely to adopt HACCP in their food regulations. By implementing HACCP, companies will have greater chances of succeeding as an exporter to these countries.

■ **System management and interactive communication**

This includes requirements related to a food safety policy and related objectives, planning and documenting the food safety system, effective external and internal communication arrangements, the assignment of specific responsibilities to the food safety team leader, internal audits, management reviews, and continual improvement and updating of the FSMS.

■ **Statutory and regulatory requirements**

It is possible for food processors to demonstrate to some extent compliance with statutory and regulatory requirements for food safety. This can be done by consideration/identification of the relevant statutory and regulatory requirements in the following steps:

- Selection and establishment of the prerequisite programmes,
- Defining specifications of raw materials, ingredients and product contact material,
- Defining the characteristics of the end product,
- Determination of acceptable levels of food safety hazards in your end product. Also refer to the legal requirements when the critical limits of critical control points are set.

#### 4.4 Other management systems

There are two other groups of management systems that can be relevant for exporters from developing economies. The first group deals with working conditions and has become increasingly important in the past years. Some examples in this group are OHSAS 18001 and SA 8000 standards on social accountability. The other group deals with IT services and security. Examples in this group are ISO/IEC 27000 standards on information security management systems and the ISO/IEC 20000 international IT service management standard.



Source: Physikalisch-Technische Bundesanstalt

# Part 4 – Quality infrastructure – your partners towards compliance

## 4.1 What is a quality infrastructure?

The quality infrastructure (QI) can be understood as the totality of the institutional framework (public or private) required to establish and implement standardization, metrology (scientific, industrial and legal) and the accreditation and conformity assessment services (inspection, testing, and product and system certification) necessary to provide acceptable evidence that products and services meet defined requirements, whether these are imposed by the authorities (in technical regulations and sanitary and phytosanitary measures) or the marketplace (i.e. contractually or inferred).

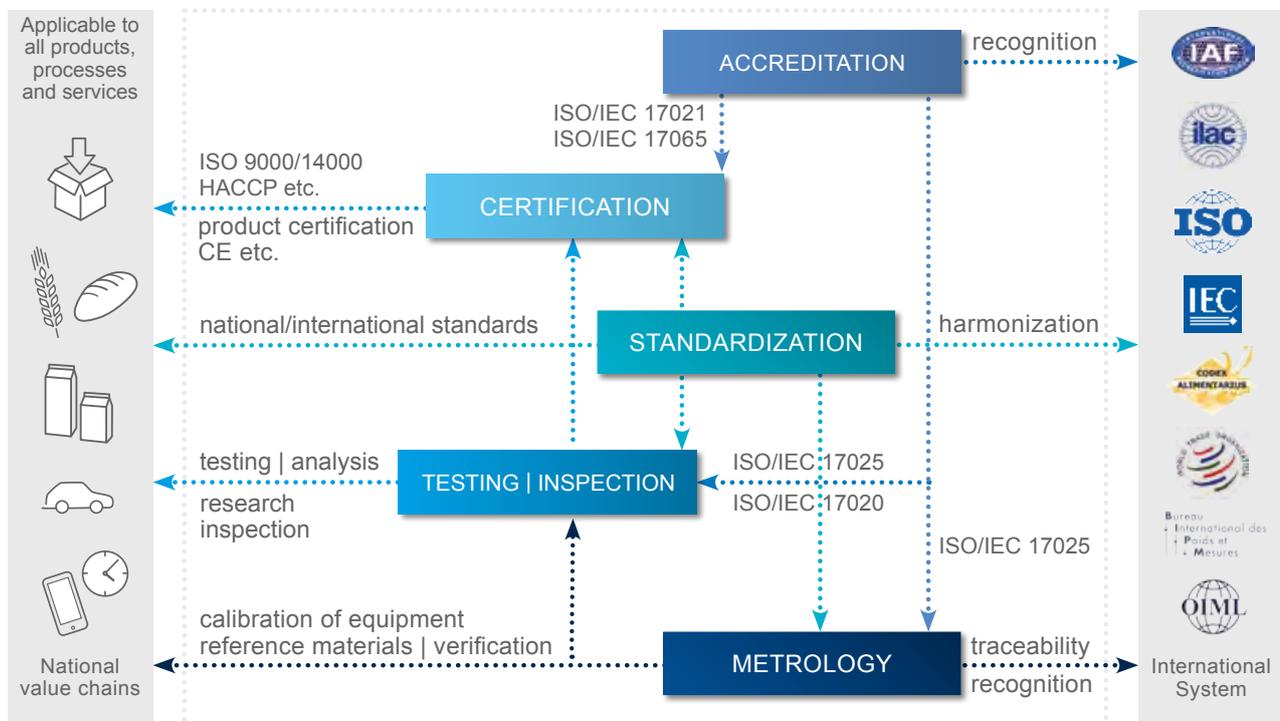
A simplified model identifies five main components of a (National) QI:

- standardization
- testing
- metrology
- certification and
- accreditation.

These are closely related and depend on each other (see figure below).

The institutions in the quality infrastructure provide services to support SMEs with conformity assessment.

### National quality Infrastructure



Source: Physikalisch-Technische Bundesanstalt (PTB)

Note: CE and GS refer to the European Union's CE mark and to the German Geprüfte Sicherheit or tested safety certification® mark respectively.

## 4.2 Conformity assessment services: How does it work?

Conformity assessment services can be provided by either the manufacturer (first party), the purchaser (second party), or by a third-party conformity assessment organisation. The third-party option, which means the provision of the services by an organization that is independent of both the supplier and the purchaser, is in most cases the best option for exporters from developing economies.

There are five important categories of conformity assessment services:

- Testing
- Inspection
- Metrology
- Certification
- Accreditation

### Testing

Testing is defined as a “technical operation that consists of determination of one or more characteristics of an object of conformity according to a procedure”. Testing can be done in-house or by external laboratories.

### Inspection

In technical terms, activities commonly referred to as inspection range from what might otherwise be labelled “testing” through to “certification”.

Inspection includes many elements of other forms of conformity assessment but is distinguished by the degree of subjectivity and judgement. “Is this article fit for purpose? Is it safe?” are questions that may require both objective data (test results) and the judgement of a knowledgeable and experienced inspector. Such questions may also form part of the decision-making process on whether or not to issue a certificate of compliance for batches of product or for individual products or installations.

In the context of international trade, inspection is used to control and monitor not only the quality and technical aspects of the import and export products, but also quantity, packaging, handling and logistics. While inspection of non-perishable goods will normally be a purely visual examination, perishable materials are subject to much more rigorous inspection.

### Metrology

Metrology is to ensure correct, comparable and reliable measuring results. In international trade, measurements

are necessary if you have to meet specifications required by regulations, standards, your customer, or if you sell your product, for example, by mass (kg) or length (m). Measurements and tests must therefore be correct within specified limits, comparable and reliable to ensure confidence in certificates. In general, the accuracy of measuring instruments is achieved through regular calibrations. Such calibration services can be offered by accredited calibration laboratories in the country.

### Certification

Certification is a statement by a third party that (services or) products, either a batch or the continuous production thereof, have been inspected and tested by it and that the products collectively comply with specified requirements, usually enclosed in a standard. Other important types of certification involve process certification (e.g. “good agricultural practices” or GAP) and management system certification.

Nowadays, there are several multinational inspection and certification organizations providing inspection, testing and certification services on a worldwide basis. Your choice for a particular certification organization in a particular foreign market may depend on the following:

- If the product or service you wish to export falls within the scope of a technical regulation or SPS measure in the target country, then you should obtain information about the preferred or even designated certification organisations from the relevant authorities in the target country. Your national enquiry points for TBT and SPS should be able to help you to find this information.
- The preference or advice of your client.

### Accreditation

Put simply, accreditation is a statement by an authoritative organisation that another organisation is technically competent to perform certain specified activities. In the context of conformity assessment, accreditation is applied to laboratories, inspection bodies and certification bodies.

Accreditation bodies have been working towards the universal acceptance of test reports and certificates from accredited organizations for years. This has resulted in global networks overseen by the International Accreditation Forum (management systems) and the International Laboratory Accreditation Cooperation (laboratories). Through these networks, it is possible to find accredited organisations all over the world.



# Part 5 – Get ready and plan your next step

## **Do you want to become a winner?**

### **Do you want to expand your sales to foreign markets?**

Don't underestimate the importance of quality! Quality is a prerequisite for your successful market access and for improving your international competitiveness. Make sure that:

- You dispose of up-to-date information about the applicable technical requirements, both voluntary and mandatory, in your target markets.
- You adapt your products and processes to meet export market requirements and demonstrate compliance with them.

- You select (accredited) conformity assessment service providers for this purpose. If your country is lacking the necessary quality infrastructure, you may need to use foreign certification organisations.

So, don't waste time and contact your business support organisation. They may be able to help you to obtain information on relevant technical requirements and to draw up a roadmap towards compliance.



**The chameleon is ready for change. Are you?**

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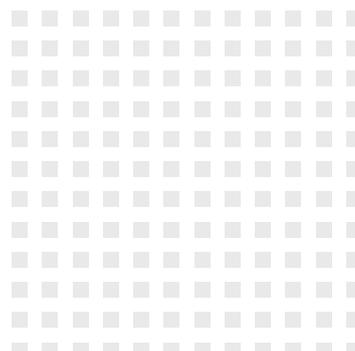
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