Working paper

Product quality

A guide for small and medium-sized enterprises

UNITED NATIONS
INDUSTRIAL DEVELOPMENT ORGANIZATION

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UNITED NATIONS INDUSTRIAL DEVELOPMENT ORGANIZATION
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This publication is one of a series of guides resulting from the work of the United Nations Industrial Development Organization (UNIDO) under its project entitled "Market access and trade facilitation support for South Asian least developed countries, through strengthening institutional and national capacities related to standards, metrology, testing and quality" (US/RAS/03/043 and TF/RAS/03/001). It is based on the work of UNIDO consultant S. C. Arora.

PREFACE

In the globalized marketplace following the creation of the World Trade Organization, a key challenge facing developing countries is a lack of national capacity to overcome technical barriers to trade and to comply with the requirements of agreements on sanitary and phytosanitary conditions, which are now basic prerequisites for market access embedded in the global trading system. The World Trade Organization has adopted two important agreements in these areas: the Agreement on Technical Barriers to Trade and the Agreement on Sanitary and Phytosanitary Measures (both available at http://www.wto.org). With a view to meeting this challenge, developing countries need significant technical assistance to develop institutional infrastructure related to standards, metrology, testing and quality in order to be an able partner in the global trade regime.

With a view to developing national capacity among the South Asian least developed countries, the United Nations Industrial Development Organization (UNIDO) has implemented a project entitled "*Market access and trade facilitation support for South Asian least developed countries, through strengthening institutional and national capacities related to standards, metrology, testing and quality*". The project was financed by the Government of India and the Norwegian Agency for Development Cooperation.

To facilitate understanding of the complex subject of standards, metrology, testing and quality, a number of small guides, as listed below, have been developed as part of the project. These guides are available free of charge to small and medium-sized enterprises and other interested users.

Role of standards

Product quality

Role of measurement and calibration in the manufacture of products for the global market

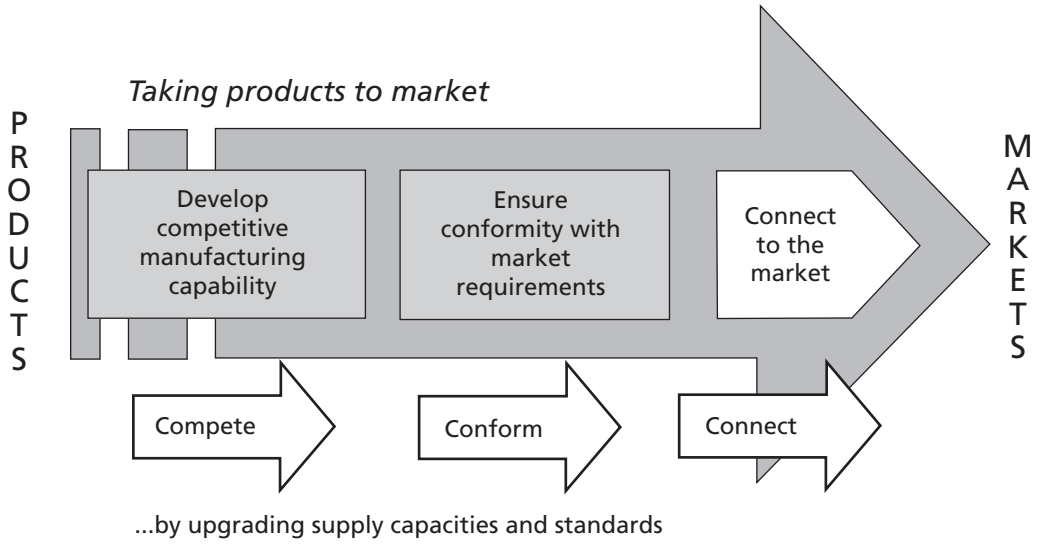
The purpose of the present guide is to assist small and medium-sized enterprises and other interested users to understand how to control product quality. Chapters 5-8 of the guide also cover various third-party schemes for product certification and pre-shipment inspection and also how the World Trade Organization Agreement on Technical Barriers to Trade can facilitate product conformity assessment procedures.

UNIDO 3Cs approach addressing developing country concerns

A strategic response:

UNIDO has developed a strategic approach to help developing countries to overcome trade participation constraints and to achieve a palpable increase in exports:

- COMPETE: removing supply-side constraints and developing competitive manufacturing capability
- CONFORM: developing and ensuring product conformity with technical and market requirements
- CONNECT: enhancing integration with and connectivity to markets



COMPETITIVENESS: activities under this heading are oriented towards the removal of supply-side constraints, the promotion of the manufacture of products with high export potential and the provision of assistance related to:

- **Developing productive capacities**
  - Developing a conducive policy environment for investment and private sector development
  - Identifying key export areas facing supply-side constraints and value chain analysis
  - Upgrading industrial structures and mechanisms for value addition
  - Advising on product design, technology, upgrading and quality control
  - Establishing technology support institutions to improve technology acquisition
  - Improving business efficiency and performance, especially quality management
  - Introducing energy-saving, cleaner technologies, minimizing waste and utilizing by-products

- **Enhancing capacity to meet international standards and client quality and safety requirements**
  - Introducing a legal framework for consumer protection
  - Ensuring access to requirements via WTO enquiry points
  - Advising on food safety requirements, HACCP, TBT/SPS requirements, ISO 9001/14001
  - Ensuring compliance with labelling and packaging requirements
  - Introducing SME subcontracting and partnership exchanges

CONFORMITY: activities under this heading are oriented towards promoting conformity with market requirements and securing a larger share in export markets, focusing on:

- **Upgrading conformity assessment infrastructure**
  - Establishing the requisite legal and regulatory framework for conformity
  - Establishing recognized standards, accreditation, certification and inspection schemes
  - Developing internationally recognized and harmonized conformity structures
  - Upgrading laboratories and supporting international accreditation
  - Establishing international calibration chains for measurement and precision manufacture

- **Creating an environment conducive to export promotion**
  - Creating an enabling environment for foreign direct investment
  - Establishing national investment promotion agencies
  - Developing export support policy and export promotion infrastructure
  - Introducing export support services and trade information services
  - Linking to global supply chains and export consortia and cluster development

CONNECTIVITY: activities under this heading are carried out in cooperation with other agencies and oriented towards supporting developing countries in their efforts to acquire the technological and institutional capacities they need to implement WTO agreements and participate fully in the new rules-based trading system. The focus is on:

- **Integrating with the international trade framework and rules**
  - Sensitizing developing countries to WTO rules and facilitating WTO accession
  - Enhancing negotiating capacities and promoting policies for the settlement of disputes
  - Adhering to notification requirements

- **Harmonizing customs procedures and transport mechanisms**
  - Improving port and harbour operations and handling procedures
  - Streamlining registration and documentation requirements
  - Improving pre-shipment inspection and facilitating customs clearance

CONTENTS

1 PRODUCT QUALITY

What is quality?

If a product fulfils the customer's expectations, the customer will be pleased and consider that the product is of acceptable or even high quality. If his or her expectations are not fulfilled, the customer will consider that the product is of low quality. This means that the quality of a product may be defined as "its ability to fulfil the customer's needs and expectations".

Quality needs to be defined firstly in terms of parameters or characteristics, which vary from product to product. For example, for a mechanical or electronic product these are performance, reliability, safety and appearance. For pharmaceutical products, parameters such as physical and chemical characteristics, medicinal effect, toxicity, taste and shelf life may be important. For a food product they will include taste, nutritional properties, texture, shelf life and so on.

Fixing product specifications

A specification is the minimum requirement according to which a producer or service provider makes and delivers the product and service to the customer. In setting specification limits, the following should be considered:

- The user's and/or customer's needs
- Requirements relating to product safety and health hazards provided for in the statutory and regulatory requirements
- Requirements provided for in national and/or international standards
- The competitor's product specifications, in order to gain marketing advantages

In designing the product, the capacity of processes and machines should be kept in mind. It is also necessary to maintain a balance between cost and value realization. The clearer the specification, the better the possibility of creating and delivering quality products.

Preparing product design

The specifications and drawings produced by the designer should show the quality standard demanded by the customer or marketplace in clear and precise terms. Every dimension should have realistic tolerances and other performance requirements

should have precise limits of acceptability so that the production team can manufacture the product strictly according to specification and drawings.

To achieve the above, those responsible for design, production and quality should be consulted from the sales negotiation stage onwards. The overall design of any product is made up of many individual characteristics. For example these may be:

- *Dimensions*, such as length, diameter, thickness or area;
- *Physical properties*, such as weight, volume or strength;
- *Electrical properties*, such as resistance, voltage or current;
- *Appearance*, such as finish, colour or texture;
- *Functional qualities*, such as output or kilometre per litre;
- *Effects on service*, such as taste, feel or noise level.

Manufacturing drawings and specifications are prepared by the designers and these should indicate to the production team precisely what quality is required and what raw materials should be used.

Preparation for manufacture

After the design, including the manufacturing drawings, has been reviewed and finalized, it is time to plan for manufacture. This will include the following steps:

(a) Deciding on the method of manufacture. Methods must be devised that permit the operators and processes to make the product in the quickest, easiest and most foolproof way, including preparation of manufacturing instructions, setting up procedures, listing various operations and so on;

(b) Providing the necessary machines, plant, tooling and other equipment. Everything that is required for manufacture must be selected, taking care that all the elements are capable of achieving the standard of quality demanded;

(c) Obtaining satisfactory raw materials. No one can make a good product from unsatisfactory raw materials, so every material must have a precise written buying specification so that the purchasing department can buy exactly what is required. Often purchasers are expected to buy from suppliers who have been assessed and approved by them and when supplies arrive the goods should be checked before acceptance into stores. Quality requirements and manufacturing processes should be discussed with the suppliers, as well as the inspection activities to be carried out by the purchaser on the goods on arrival;

(d) Obtaining and training suitable operators. Operators who are willing and able to do the work in a satisfactory manner must be chosen and given whatever training they need;

(e) Planning inspection and shop floor quality control. Plans for inspection activities should be prepared, proper workplaces provided for inspection staff, written inspection

procedures prepared, inspection equipment provided, checking and calibration of inspection equipment planned for, inspection personnel selected and trained and pre-pilot and pilot runs carried out. One should never attempt to solve a quality problem by carrying out more inspections.

Manufacture

Once the design and planning for manufacture have been completed, the manufacturing can begin. If the planning has been well done, there should not be too many problems. During manufacture the following are the most common factors that can affect quality:

(a) Set-up. Some processes, such as punching, cutting, printing and labelling, are so consistent that, if the initial set-up is correct, the whole lot will conform to the specifications. However, the initial set-up has to be checked by carrying out first-piece inspection;

(b) Machines and tools. From time to time changes can occur in machine or tool settings, which can then lead to defects. Processes of this type include machining, resistance welding and filling. Here it is necessary to carry out periodic checks by patrol inspection;

(c) Operator. There are some processes where the result depends on the skill and attention of the operator, such as welding, hand soldering and painting processes. For such processes it is necessary at the manufacture planning stage for the operator's working methods to be decided upon;

(d) Materials and components. It is important to ensure the quality of raw materials and components by undertaking regular checks on the suppliers' processes and also where necessary by carrying out incoming inspection.

Correction of quality deficiencies

In spite of all the efforts made, the required quality will sometimes not be attained and one may be faced with a pile of scrap and rework. This means that something has gone wrong during the quality planning and maybe also during the manufacturing process. The reason for the trouble must be located and permanently corrected so that it cannot happen again. The following are obvious possibilities:

- The shop-floor operators had no clear idea what standard of quality was required;
- The method was such that it was very difficult to get the job right, but very easy to get it wrong;
- The machine and equipment were incapable of achieving the tolerances required;
- The incoming materials and components were unsatisfactory;
- The operators were untrained and not up to the job;
- Shop-floor quality control was either not properly planned or not properly executed, or both.

Coordination

It is obvious from the above steps that everybody in the company, that is, the salesmen, designers, purchasing, stores and methods staff, plant engineers, jigs and tool personnel, production planning and production staff, operators, inspection and testing staff, packaging, dispatch and so on, are responsible for product quality. Indeed, quality is everybody's business. Unfortunately, if care is not taken, it ends up being nobody's business. It is therefore important to ensure that everyone is quality-conscious and that they all work together on matters related to quality

2 PRODUCT INSPECTION

Why inspection?

By "inspection" it is usually meant that, at certain stages in the course of production, a comparison is made between what has actually been produced and what should have been produced. The standard of reference may be a specification, drawing or a visual quality standard. The check made must be appropriate to the job and must be made with suitable measuring instruments. Inspectors should not waste time checking things that do not matter or fail to do a check that is important. Things that are unlikely to go wrong need little checking and those which are difficult to hold within limits will need a considerable amount of attention.

It is a misconception that the inspector alone is responsible for quality. Quality results from a combination of quality of the original designs, the methods, equipment and materials used and the skill and care of the operator. In spite of these, if the job is still wrong, no amount of inspection will put it right.

Different forms of inspection

According to production flow, the inspection may be divided into:

- Incoming inspection
- In-process inspection
- Final inspection

Incoming inspection

Incoming inspection concerns goods upon delivery from vendors and/or suppliers. It consists of inspection of raw materials, components, sub-assemblies and so on. The aim of incoming inspection is to prevent goods that do not fulfil the quality requirements from entering the production process. Incoming inspection is one of the following steps in the control of the quality of supplies:

- A buying specification is prepared, setting out exactly what quality of material has to be obtained;
- Possible suppliers are checked for their ability and willingness to provide this quality. This is called "vendor appraisal" or "supplier evaluation";
- If the results of the vendor appraisal are satisfactory, then the supplier is placed on an approved list and purchase orders are placed when goods are required;

- When goods are received, they are subjected to some form of goods inward inspection;
- The results of the inspection are used to give each supplier a numerical rating, showing how satisfactory or otherwise his suppliers are. This is called "vendor rating";
- The results at every stage are monitored and steps taken to improve or discontinue unsatisfactory suppliers.

In-process inspection

In-process inspection aims to prevent products of unacceptable quality from being manufactured. It provides data for making decisions on the product (accept or rework or reject), as well as on the process (run or stop). In-process inspection can take the form of:

- First-piece inspection
- Patrol inspection
- Operator inspection
- Last-piece inspection
- Stage inspection

Whenever a production run is started, it is prudent to check the first piece, the first assembly and so on before the main run commences. Many faults can be detected by checking the first piece off and this can prevent the whole batch from going wrong. For example:

- First-piece inspection can check whether the machine, jigs, fixtures, moulds, temperature and so on are correctly set up;
- First-piece inspection can discover whether the operator has fully understood his or her instructions;
- First-piece inspection can also identify any discrepancies between the drawing and the quality plan, which can be investigated to avoid any further damage.

While first-off inspection ensures that the job starts correctly, the purpose of patrol inspection is to help the operator to make the whole run correctly. From time to time, the patrol inspector visits the machine or operator and if the quality of the sample checked during the visit is wrong on any point, then this must be corrected as quickly as possible. If an operator goes wrong, he or she should be told quickly. The operator should be encouraged to regard the inspector as a friend assisting him in the task of keeping defective work to a minimum.

Operator inspection means that instead of the inspector, the operator carries out the inspection at a predetermined time during manufacturing.

Last-piece inspection is carried out on the last item manufactured in the lot. This allows action to be taken to rectify faults in the machine and/or tools before beginning

the next lot. If these faults are only detected when the next lot has started, there will be a risk of production delays.

Stage inspection involves inspection of products after every operation or group of operations. Stage inspection points are located on the shop floor itself, where components are tendered for inspection. Jobs found to be unacceptable are returned for rectification if they are rectifiable, otherwise they are scrapped.

Final inspection

Final inspection and/or testing is done after manufacture has been completed, with the object of making sure that the goods concerned are satisfactory for dispatch to the customer or maybe to another department for the next operation.

Based on the product specifications, inspection instructions are prepared that lay down the details of the tests to be carried out, the measuring instruments or test equipment to be used and the criteria for deciding acceptance of the product with respect to each characteristic. Inspection instructions should also include details of the sampling plan such as size of sample and the criteria of acceptance to be followed. Measuring instruments or test equipment used for inspection should be calibrated periodically to verify their accuracy.

It is necessary to exercise suitable control over the movement of the product through the inspection area in order to avoid a mix-up of accepted and rejected products. Ways to exercise such control include:

- Provision of clear labels (preferably of different colours) for products awaiting inspection, accepted products, rejected products, products on hold awaiting the results of tests and/or inspection and so on;
- Separation of accepted and rejected products;
- Review of rejected products for rectification or repair or for sale as seconds;
- The accepted product should only be released to the next process or to the customer by a person who is authorized to do so.

3 HUMAN FACTORS IN PRODUCT QUALITY

It is commonly believed that most quality problems are caused primarily by lack of interest or care on the part of the worker in the production department. However, it is usually not the worker who can be blamed for this, since the conditions necessary to carry out the work correctly often do not exist. For example, instructions may be inadequate, the incoming material may be defective, the machines may not be capable of producing goods of the required quality, proper conditions for conducting inspection of the product are not given to the workers and so on. Unfortunately the worker has no control over these factors, but they may lead to defective work.

In Japan, it is generally believed that 40 per cent of quality problems are caused by poor product design, 30 per cent of quality problems are caused by wrong or defective materials being purchased from suppliers and the remaining 30 per cent are due to errors made during the manufacturing process.

Both design and purchase problems can be solved only by intervention by the management and workers have no control over them. One could argue that the remaining quality problems in manufacturing are caused in equal proportion by managers (by not providing adequate training for workers) and by workers (e.g. by not paying adequate attention to machine settings).

Thus 85 per cent of problems come under management control, whereas 15 per cent are under worker control. Here too the worker can only be held responsible for the defects if:

- He or she knows what he or she is supposed to do;
- He or she knows the result of his or her own work;
- He or she has the means to influence the result.

There is another myth that product quality can be improved through propaganda and other motivational activities. This is based on the false assumption that human errors are primarily the result of lack of interest or care on the part of the people involved. Experience shows that considerably better results can be achieved if instead it is ensured that the proper conditions exist for doing good work or getting things right the first time, for example:

- The product specification must be clear and unambiguous;
- The technical conditions must be such as to enable the quality requirements to be met, for example, the materials must be appropriate for the work and the machines must be capable of producing the required quality. Everyone must know what to

do to prevent poor work. Everyone carrying out work should be able to judge whether the result of his or her work complies with the quality requirements;

- Everyone must know the consequences of poor work for the organization.

For an organization to reach an adequate standard of quality, the people at all levels must cooperate actively. This means continuous staff development. The Japanese "revolution in quality" is largely the result of comprehensive education and training aimed at all functions and levels, from the top management to the worker level.

4 SIMPLE TOOLS FOR QUALITY CONTROL

Seven quality control tools

The seven quality control tools were developed by Kaoru Ishikawa,[1] known as the "father of quality control circles". It has been the Japanese experience that 95 per cent of problems in the workshop can be solved by using the following seven simple quality control tools and by the effective working of quality circles:

- Process flow charts
- Check sheets
- Graphs
- Pareto analysis
- Cause and effect diagrams
- Scatter diagrams
- Control charts

Process flow charts

Process flow charts record a series of events and activities, stages and decisions in a form that can be easily understood and communicated to all. Figure I gives an example of a flow chart. Flow charts can also be used as a problem-solving tool. For this, first a flow chart is drawn up by a team of persons in order to reflect the way the process *actually* works. Then the members of the group are asked to draw up a flow chart on how the process *should* work ideally. The difference between the two represents the problems to be solved. It thus helps first to understand the process and then to make improvements.

Check sheets

Check sheets, or tally charts, are a simple device on which data is collected by putting a mark against predetermined items of measurement. The purpose for which the data is collected should always be clear. For example, check sheets can be used to track events by factors such as timeliness (in time, one day late, two days late, etc.), reasons for failure during inspection (defects like blow holes, cracks, etc.) or number of customer complaints per day. An example check sheet for the final inspection of bracket casting in a foundry shop is shown in figure II.

[1]Kaoru Ishikawa (1915-1989), a Japanese university professor, was one of the great Japanese management thinkers. The "fishbone" or "cause and effect" diagram is his best known contribution to quality and is popularly known as the Ishikawa diagram. It is one of the problem-solving tools in this area. Ishikawa also showed the importance of seven quality tools and explored the subject of quality circles (see www.mftrou.com).

Figure I. Flow chart for obtaining spare parts for maintenance activity

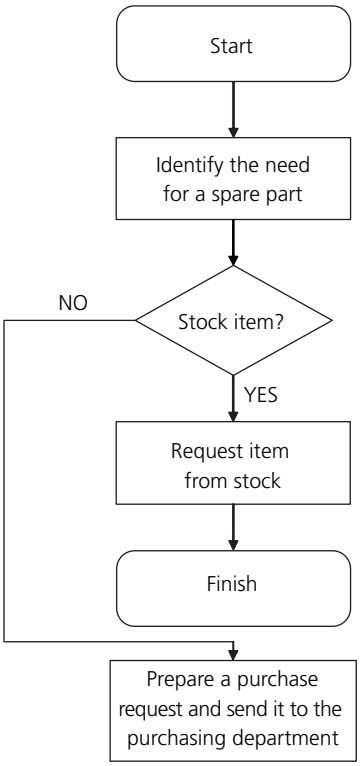


Figure II. Check sheet for final inspection of bracket casting

Check sheet

Product: Bracket casting
Date: 24 November 2004
Stage: Final inspection
Shop: Foundry
Total number inspected: 800
Inspector: _____

Defect type	*Check*	*Subtotal*
Cracks	𝍸|	7
Blow holes	𝍸||𝍸||—	18
Out of shape	𝍸||𝍸—	12
Others	𝍸||𝍸	14
	Total	**51**

Graphs

There are numerous types of graphs, ranging from simple plotting points to a graphic presentation of complex and interrelated data. Graphs are a good way to organize, summarize and display data for subsequent analysis. The most common examples of graphs are histograms (figure III) line graphs, pie charts (figures IV and V).

Figure III. Histogram of weights of bars

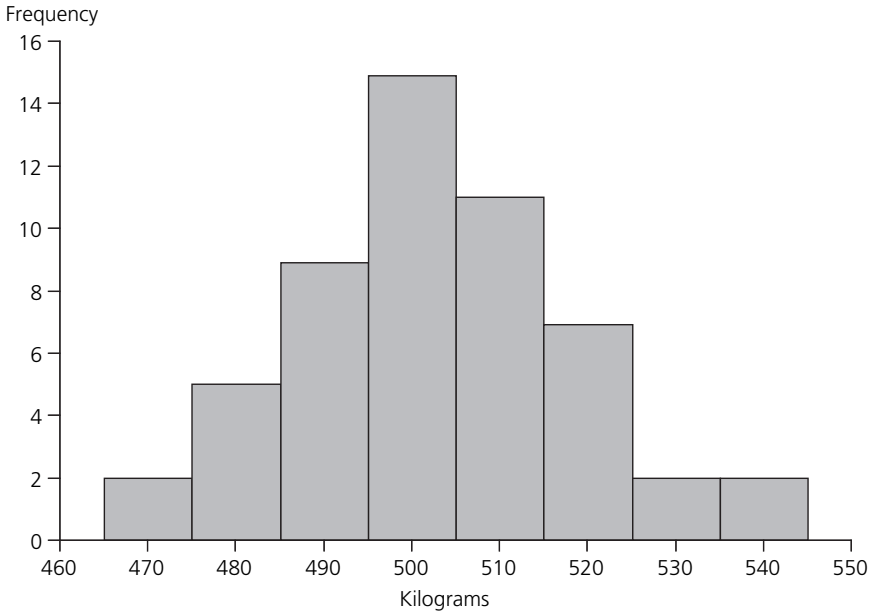


Figure IV. Radar chart of monthly temperatures in three cities

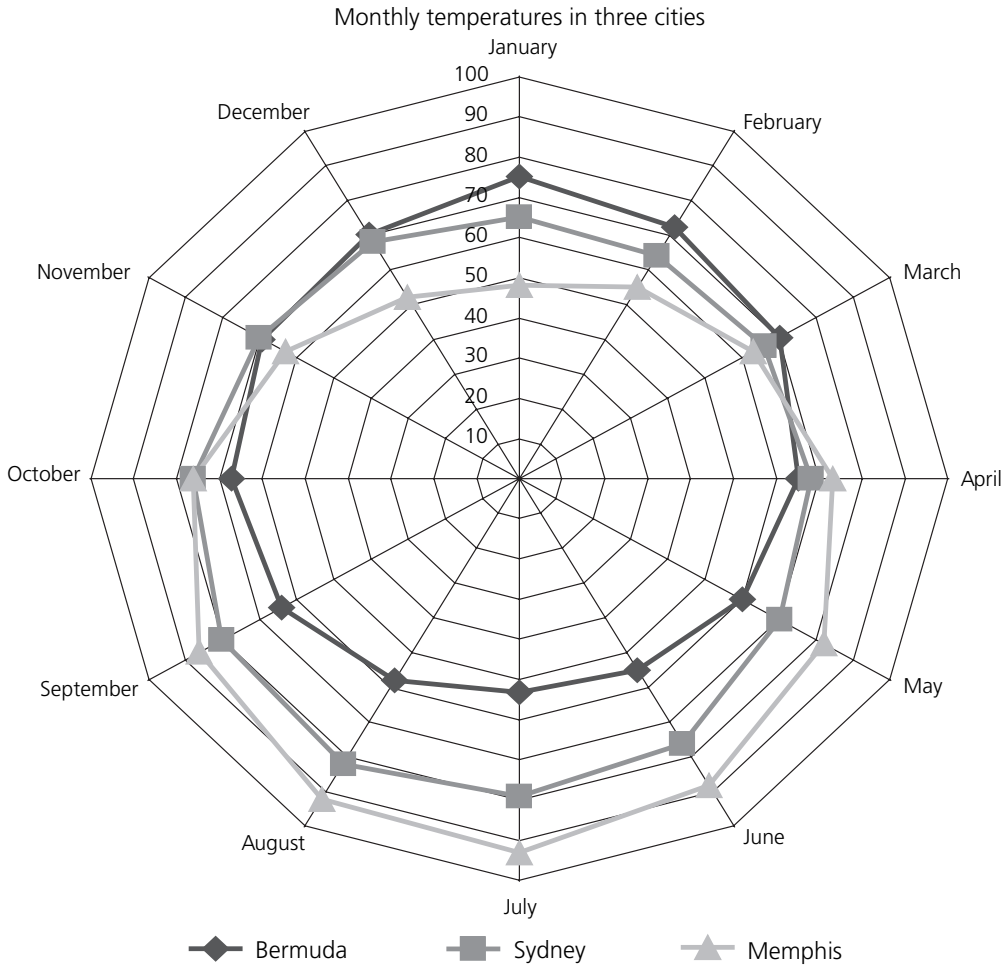
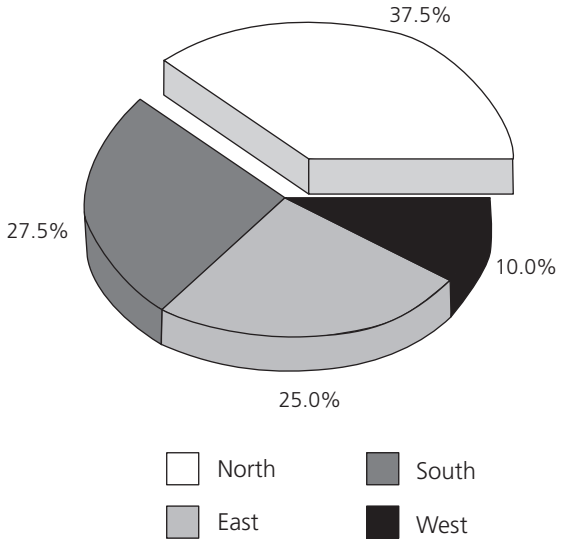


Figure V. Pie chart of customer complaints, by zone



Pareto analysis

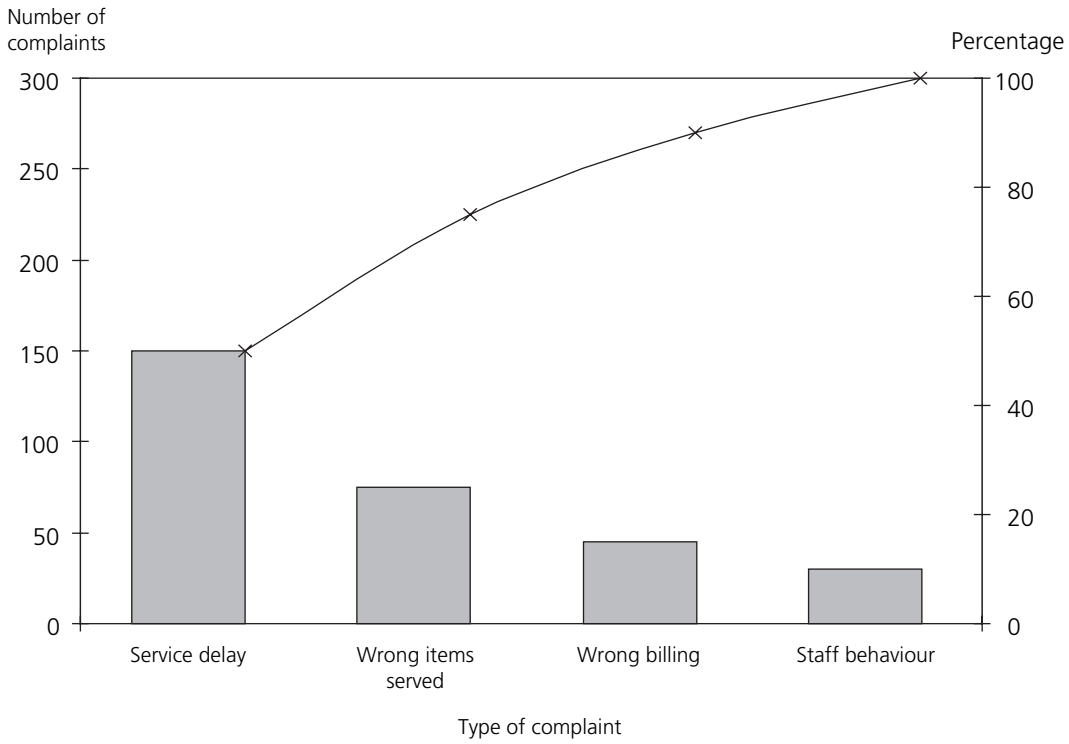
Pareto analysis is based on a bar graph and a line chart. The bar graph lists in descending order the problems affecting a process. The line chart accumulates the percentage of the total number of occurrences for each problem area. The other name of this tool is the 80-20 rule, indicating that 80 per cent of the problems stem from 20 per cent of the causes. It helps to identify the most important area to work to solve the problem. Joseph M. Juran, an expert on quality control,[2] has said that one should concentrate on the "vital few" rather than the "trivial many" in tackling quality problems.

Let us take an example of a restaurant that is trying to analyse and prioritize the complaints received from its customers. The complaint data is shown in the table below. The Pareto diagram of this data is shown in figure VI.

Type of complaints	*Number*	*Percentage*	*Cumulative percentage*
Service delay	150	50	50
Wrong items served	75	25	75
Wrong billing	45	15	90
Staff behaviour	30	10	100
Total	**300**	**100**	

[2]Joseph M. Juran, a living quality guru, was also called the "father" of quality. In 1937, Mr. Juran conceptualized the Pareto principle, which millions of managers rely on to help separate the "vital few" from the "useful (trivial) many" in their activities (see www.juran.com)

Figure VI. Pareto analysis of complaints received in a restaurant



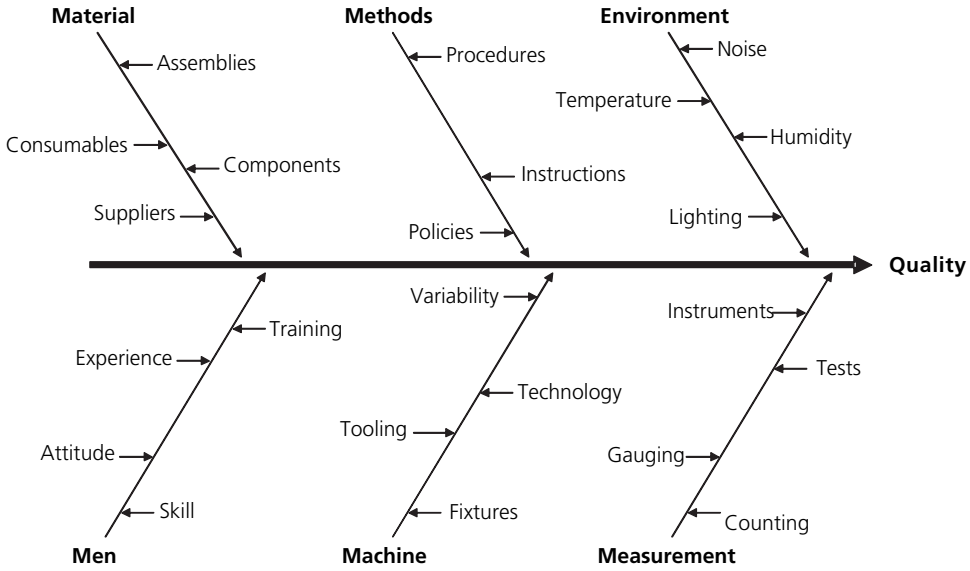
The above analysis shows that 75 per cent of customer complaints are related to service delays and wrong items being served. Based on this finding, the restaurant can use cause and effect diagrams to determine the root cause of these two major problems (see the next tool).

Cause and effect diagrams

Cause and effect diagrams represent the relationship between a problem and its potential causes. They are also known as fishbone, or Ishikawa, diagrams. These diagrams deal only with factors, not quantities.

To prepare a fishbone diagram, all the causes relating to a problem (effect) are collated through brainstorming among the people concerned. The problem is indicated on the horizontal arrow (see figure VII). All the causes listed from the brainstorming are classified by theme. Each theme represents a diagonal attached to the spine of the diagram. Individual causes are listed along the diagonal. Figure VII shows a cause and effect diagram of factors affecting quality.

Figure VII. Factors affecting quality



Scatter diagrams

Scatter diagrams are used to study the possible relationship between one variable and another. This can be used to test the possible cause and effect relationship. It does not prove that one variable causes the other, but it does make it clear whether a relationship exists between them and determines the strength of the relationship.

Usually the horizontal axis in the diagram is the one over which there is control. Each data point as observed is plotted. The more closely the dots group along an axis, the stronger the correlation. The more scattered they are, the weaker the correlation. Figure VIII shows an example scatter diagram showing a positive relationship and figure IX shows a negative relationship.

Figure VIII. Scatter diagram: positive relationship

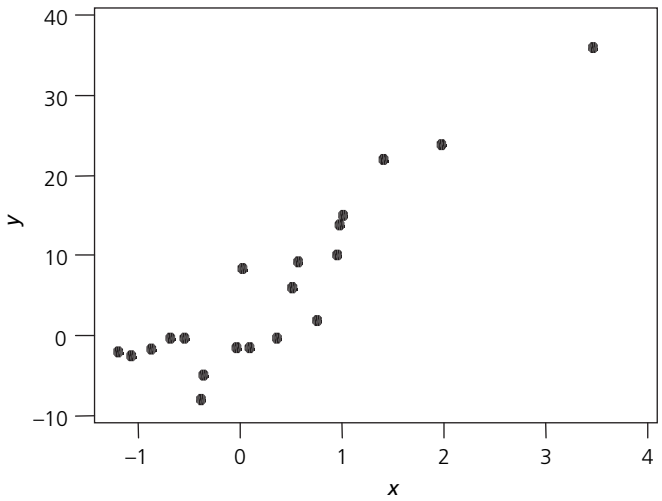
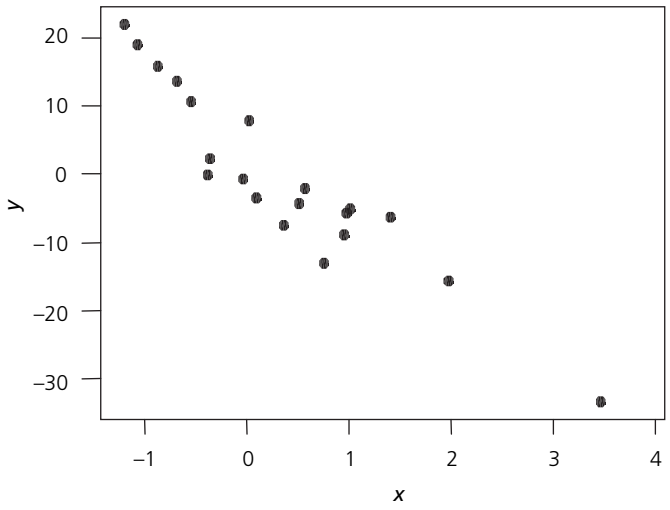


Figure IX. Scatter diagram: negative relationship



Control charts

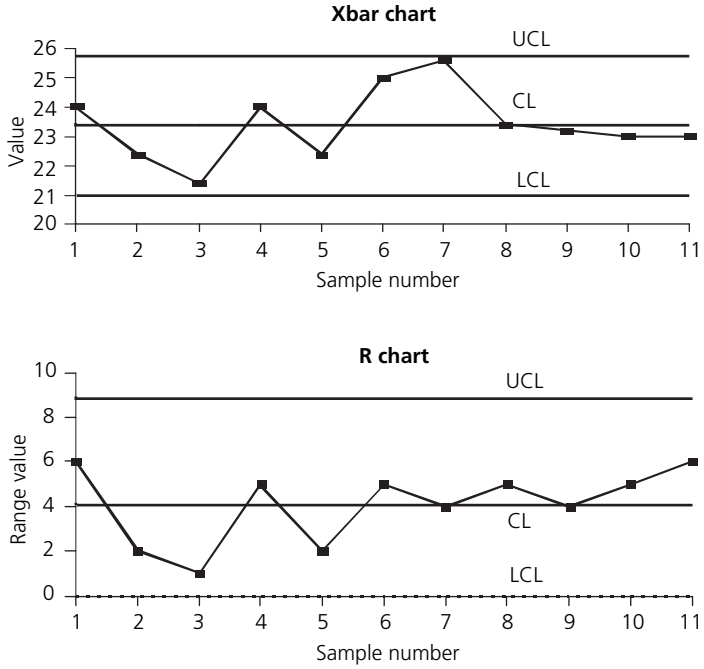
Control charts are pictures of variations found in a process. The data of measurement or observations is plotted on graphs against time. These charts consist of two lines, called upper control limit (UCL) and lower control limit (LCL). These are not the same as specification tolerances, rather they are the values within which a process is expected to operate and if the results of measurements exceed these limits then the cause must be investigated and action taken on the process immediately.

In order to reduce variations in the process, fundamental changes may need to be made in methods, machines and/or materials. Control charts help to monitor and control quality by acting as a set of process "traffic lights" and are valuable in all types of activity.

Control charts can be plotted for variable or continuous data (such as weight of a bag, temperature of cold storage, time of baking, dimension of a rod or speed of a conveyor). Control charts for variables consist of mean and range charts (see figure X).

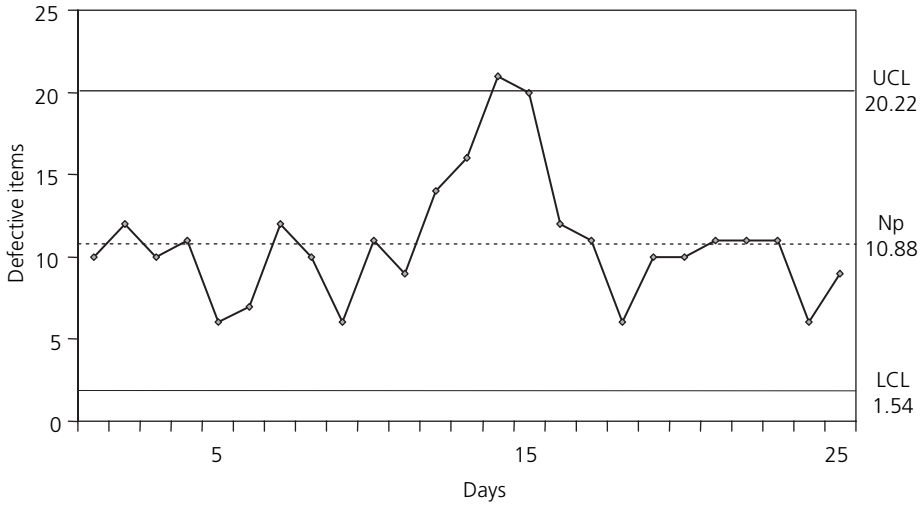
Control charts can also be plotted for attribute or discrete data such as the number of defects found in a lot, the number of cracks in a piece, the number of missing stitches in a garment, percentage delays in shipments or percentage delays in responding to customer complaints. As regards attribute data, the two most popular charts are control charts for the number of defective items in a lot, known as an "np-chart" (figure XI) and the proportion of defective items, known as a "p-chart" (figure XII).

Figure X. Mean (Xbar) and range (R) charts



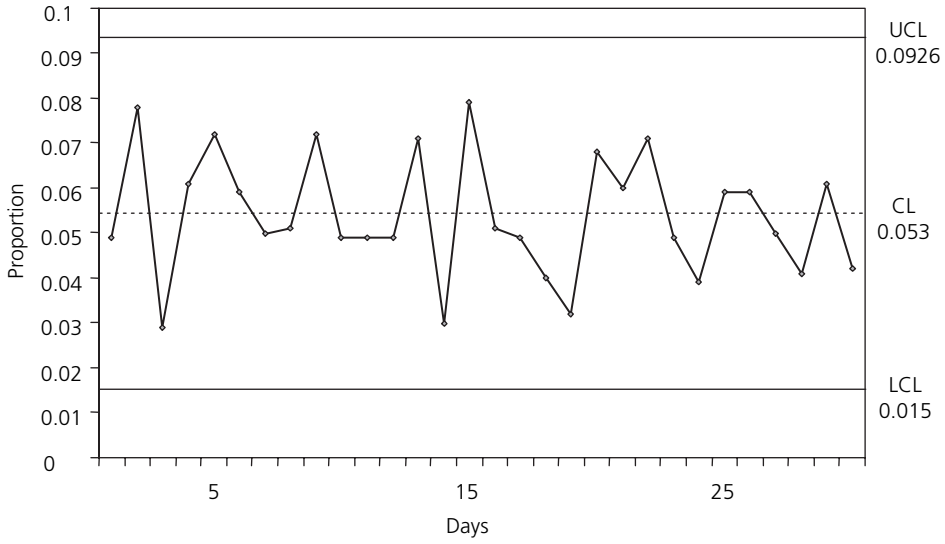
UCL = upper control limit
CL = control limit
LCL = lower control limit

Figure XI. Number of defective items (np-chart)



UCL = upper control limit
Np = number of defective items
LCL = lower control limit

Figure XII. Proportion of defective items (p-chart)



UCL = upper control limit
CL = control limit
LCL = lower control limit

Other good practices

While the above seven quality control tools can help operators and supervisors to monitor their processes and find the causes of variations, there are other simple practices that have been very successfully practiced in Japanese industry. They are:

- Japanese 5S
- Quality circle
- Kaizen

Japanese 5S

Japanese factories are reputed for their cleanliness and orderliness. They follow the well-known "5S" practice, which refers to the following five Japanese words:

- Seiri (Structurize: organize well)
- Seiton (Systemize: neatness in all areas)
- Seiso (Sanitize: cleanliness)
- Seiketsu (Standardize)
- Shitsuke (Self-discipline: do 5S daily)

Seiri (Organization)

This means separating things that are necessary for the job from those which are not, or keeping the number (inventory) of necessary ones as low as possible and at a convenient location. In other words, unnecessary items in the workplace should be sorted out and discarded.

Seiton (Neatness)

The necessary items should be arranged in good order so that they can be easily picked out for use. In other words, a place for everything and everything in its place.

Seiso (Cleanliness)

The workplace should be completely cleaned so that there is no dust on the floor or on any machines or equipment. Cleaning should be done by everyone in the organization, from the managing director to the worker level.

Seiketsu (Standardization)

The above standards of neatness and cleanliness should be maintained on a regular basis as a system. In other words, company standards or work instructions should be set for such practices to be followed by all.

Shitsuke (Discipline)

A workplace with good habits should be created. Training should be given to everyone who needs it and everyone should put their training into practice.

Quality circles

A quality circle is a small group of staff working together to contribute to the improvement of the enterprise, to respect humanity and build a cheerful work group through the development of the staff's infinite potential. A quality circle team usually comes from the same work area. Quality circle teams meet voluntarily on a regular basis to identify, investigate, analyse and solve their work-related problems. It has been the experience of Japanese industries that 95 per cent of problems at the workplace can be solved by using the above seven quality circle tools and by the effective work of quality circles.

Kaizen

Kaizen is a Japanese word, which means "continuing improvement". A company will fail if the people working in it have attitudes such as "we have done enough", "let's stop here", "we will hold our performance at this level" and so on. The fact is that every company works under two external pressures, one from its customers and the marketplace, who are demanding better and better products and services, and secondly

from improvements made by competitors. It is therefore necessary to build awareness of *kaizen* as a continuous process throughout the organization. *Kaizen* recognizes the following principles:

- Maintaining standards is the responsibility of the workers, while the management's role is to raise standards;
- Small and gradual improvements in work standards should be made;
- Problem-solving tools (the seven quality circle tools) should be used;
- Not a day should go by without some kind of improvement being made somewhere in the company.

The introduction and direction of *kaizen* should be top-down, but the suggestion has also been made that it should be bottom-up, as specific suggestions for improvement usually come from the people who are closest to the problem. The *kaizen* strategy therefore calls for both a top-down and a bottom-up approach.

5 PRODUCT CERTIFICATION

Introduction

If a product bears a recognized mark such as a national or regional (e.g. "conformité européenne" (CE)) certification mark or international mark (e.g. an International Electrotechnical Commission (IEC) mark), this gives an assurance to the buyer that the product meets the specifications to which the mark corresponds. In other words, the product may be considered a "quality/safe product" by the buyer.

"Product certification" is defined as "a procedure by which a third party gives written assurance that a product, process or service conforms to specified requirements". The product certification authorities usually permit the use of a mark on the product to demonstrate that the product meets a defined set of requirements, such as safety, fitness for use and/or specific interchangeability characteristics that are usually specified in a standard. The mark is normally found on the product or its packaging; it also carries a reference to the number of the relevant product standard against which the product is certified. Ideally, a product certification mark should demonstrate to the consumer that a product meets the generally accepted standard for that product.

Aim and benefits of product certification

- Product certification helps the consumer to choose products that meet the requirements of the specified standard, are suitable for the purpose and are safe from hazards to life and property;
- Product certification gives an organized purchaser such as a government greater confidence in the integrity of the product, saves unnecessary product inspection and provides a convenient basis for concluding contracts;
- For the manufacturer, product certification streamlines the production process and introduces a quality assurance system for ensuring conformity of the product to the standard;
- Product certification enhances the marketability of products and provides an opportunity for competing with similar products and building a better image of the product both in the domestic and the international market;
- Product certification helps reduce technical barriers to trade, as the World Trade Organization's Agreement on Technical Barriers to Trade recognizes certification as an instrument to prevent technical barriers and as an important factor in the furtherance of international trade.

For certain products, it becomes a prerequisite for putting certain products on the market, for example:

- Certain products that appear on the list of European Union product regulations are required to bear a CE mark;
- Certain electric and/or electronic products cannot be marketed in Canada unless they bear the Canadian Standards Association mark;
- In India, food colouring, cement, infant foods and so on are required to bear the certification mark of the Bureau of Indian Standards before they can be offered for sale.

A product bearing a mark carries a third-party guarantee that:

- The product has been produced according to an applicable standard;
- The production process has been supervised and controlled;
- The product has been tested in an independent laboratory;
- If the customer finds that a marked product does not meet the declared standard, he or she can approach the certification body for redress of the complaint.

Product certification carried out by third-party certification bodies (i.e. independently of the consumer, seller or buyer) is most acceptable to purchasers, importers and regulatory authorities. Many national standards bodies in developing countries provide third-party product certification services. In some countries, certification is carried out by trade or industry associations, governmental institutions or private certifications bodies, for example, the certification mark of KEMA, a producer of electrical items in the Netherlands, the certificate of lubricants given by the Lubricant Manufacturers Association in the United States of America and the certification of raw agricultural produce (AGMARK) of the Directorate of Marketing and Inspection of the Ministry of Agriculture of India.

Procedure for certification

The following are generally the steps followed by national standards bodies with a view to granting licences to use their standard mark:

- An application is submitted to the national standards body on the prescribed application form.
- After scrutiny of the application, the national standards body arranges an inspection of the applicant's premises to establish the production capability and quality control system.
- During the inspection the national standards body also takes a sample for independent testing.

- The national standards body grants the licence if:

  The test report from an independent laboratory meets with the requirements laid down in the applicable standard;

  The applicant agrees to follow a scheme of testing and inspection as a minimum quality control during production;

  The applicant agrees to follow the conditions of granting of licence, including payment of the licence fee.

During the operation of the licence to use the mark of the national standards body on the product, the following surveillance is maintained by that body over the licensee:

- The licensee must continue to follow the scheme of testing and inspection and to maintain records of testing and inspection, which are checked through periodic surprise inspections by the inspecting officers of the national standards body;
- During the inspections product samples are tested in the laboratory of the licensee and test results are compared with the testing data of the licensee;
- Samples taken during inspections, from the open market or from bulk users, are tested in an independent laboratory. (Normally four such samples are tested in a year;)
- If the inspection reports and the test reports are satisfactory, then renewal of the licence is granted and the above checks continue every year.

All certification systems are subject to certain practical limitations. One of the most common limitations is that total item-by-item compliance with the specifications is not attainable. However, a properly devised certification system can provide the optimum assurance that goods have been produced under the best practicable conditions of manufacture, in compliance with the commercial, legal and social situation prevailing at the time, and it thus can minimize the chance or risk of the buyer obtaining substandard products.

References

Agreement on Technical Barriers to Trade of the World Trade Organization (United Nations, *Treaty Series*, vol. 1868, No. 31874. (See also www.wto.org, click on “TRADE TOPICS”, “Goods”, then “Technical barriers to trade”.)

6 CONFORMITÉ EUROPÉENNE

Conformité européenne marking and international product certification

What is “conformité européenne”(CE) marking?

“CE” is the abbreviation for “conformité européenne”, French for “European conformity”. CE marking is not a quality mark. Firstly, it refers to the safety rather than to the quality of a product. Secondly, CE marking is mandatory for the product it applies to, whereas most quality marking is voluntary.

CE marking is a kind of trade passport for any country in the European marketplace. It allows the manufacturer to circulate products freely throughout the countries of the European Economic Area. There is only one set of requirements and procedures to comply with in designing and manufacturing a product for the entire area: the various conflicting national regulations have been eliminated. As a result, the product no longer needs to be adapted to the specific requirements of the different member States of the area. In addition, it may be considered a benefit that, by implementing the requirements, the product will be safer for the user and this may also reduce damage and liability claims. Manufacturers located outside the European Union are also required to obtain CE marking on the products covered under the product regulations of the Union for exports to the European Economic Area.

Products requiring CE marking

CE marking is required only for the following types of product:

- Toys
- Machinery
- Electrical equipment
- Electronic equipment
- Personal protective equipment
- Pressure equipment
- Medical devices
- Active implantable medical devices
- In vitro diagnostic devices
- Radio and telecommunication terminal equipment
- Simple pressure vessels

- Gas appliances
- Lifts
- Recreational craft
- Equipment and protective systems for use in explosive atmospheres
- Non-automatic weighing instruments
- Cableways
- Construction products
- Explosives for civil use
- New hot-water boilers

Directives relating to the above products can be found on the website of the European Union (www.europa.eu.int). Each directive includes the conformity assessment procedure to be followed. For the following products there are no European Union directives, so CE marking is not required:

- Chemicals
- Pharmaceuticals
- Cosmetics
- Foodstuffs

Procedure for CE marking

A manufacturer must follow a conformity assessment procedure in order to place CE-marked products on the market. The company may select from among the modules listed below, depending on the modules that are permitted or required by a particular European Union directive and the product's perceived risk level. Some products may require a combination of these modules.

- Internal control of production (module A)
- European Union-type examination (module B)
- Conformity to type (module C)
- Production quality assurance (module D)
- Product quality assurance (module E)
- Product verification (module F)
- Unit verification (module G)
- Full quality assurance (module H)

For example, for toys, the manufacturer can choose between module A (if he produces to the European standards) and modules B and C (if he does not produce to the European standard). In the former case, he submits a supplier's declaration of conformity, but in the latter case, he needs a notified body (see below) for module B.

Notified bodies are designated by European Union member States to carry out conformity assessment tasks according to the directives. A list of them is published in the *Official Journal of the European Union*. The notified body could be a third-party organization, such as an International Standards Organization (ISO) 9000 certification body or testing body, or a product certification body accredited by the national accreditation bodies of member States of the European Union.

More details of CE marking can be obtained from the website www.CEMarking.Net.

International product certification

While national product certification is popular and widely accepted by buyers as a symbol of conformity of a product with quality and/or safety requirements, a product bearing a national mark of a country when exported may not generate the same confidence in the customer in the importing country. Further, in some countries certain products can be sold only when they bear the national product certification mark. This may be due to regulatory requirements or the customer's preference to buy products with national product marks. In such cases exporters will have to obtain the national product certification mark of the importing country by complying with the requirements of the product certification scheme of that country. For example, certain electrical appliances cannot be sold in India (being a regulatory requirement) without a product certification mark of the Bureau of Indian Standards. Accordingly, for example, a manufacturer from China who wishes to export electrical appliances to India will have to obtain a licence to use the Bureau's mark on those of his products for which it operates a special product certification scheme. This process is at times expensive and time-consuming and becomes a barrier to trade. It would have been ideal if international product certification schemes had been available to overcome this barrier.

International Electrotechnical Commission

To a limited extent, the International Electrotechnical Commission (IEC) is operating international product certification schemes for certain electrical and electronic products. The Commission is the leading global organization that prepares and publishes international standards for all electrical, electronic and related technologies. Like ISO standards, the Commission's standards serve as the basis for the development of national standards either by adopting IEC standards or preparing national standards based on IEC standards. (See the website of the Commission: www.iec.org).

The IEC international conformity assessment schemes, based upon its international standards, are truly global in concept and practice. They are designed to help reduce

the trade barriers caused by different certification criteria in use in various countries. When used these schemes can avoid the delays and costs associated with multiple testing and certification. The IEC schemes described below are available to manufacturers/exporters the world over.

Scheme for conformity testing and certification of electrical equipment

The IEC Scheme for conformity testing and certification of electrical equipment, commonly known as the CB Scheme, is the first truly international system for acceptance of test reports dealing with the safety of electrical and electronic products intended for use in homes, offices, workshops, healthcare facilities and similar locations (at present 16 product areas are covered). It is a multilateral agreement among participating countries (at present 43 member countries) and national certification bodies, at present 57 in number). By obtaining CB test reports from CB testing laboratories (at present 145 in number), a manufacturer can obtain national certification in other member countries of the CB Scheme. The CB test certificate is a formal CB Scheme document issued by an authorized national certification body to inform other national certification bodies that a sample of the product tested was found to be in compliance with the applicable requirements. In all, 27,683 such test certificates were issued in the year 2002 and out of the total certificate issued till the end of 2002 over 100,000 such certificates are still valid for use. The Scheme is based on the use of the IEC standards related to the product under certification. If a member's national standards are not yet harmonized to IEC standards, then national differences are permitted and declared in the *CB Bulletin* published by the IEC. A periodically updated list of all national certification bodies and the scope of their recognition is published in *CB Bulletin* (available from IEC website www.iec.ch/webstore/).

CB-Full Certification Scheme

The CB-Full Certification Scheme (CB-FCS) is an extension of the CB Scheme. It is a full certification system, which, in addition to product type testing, requires an initial assessment of the manufacturer's quality assurance system and follow-up surveillance, which may include quality system audits and testing of factory samples and samples drawn from the market as required. The Scheme provides for national certification bodies to reach mutual agreements on the conduct of the necessary ongoing factory and market surveillance.

CB-FCS currently has 16 participants (Canada, Finland, France, Germany (2), Italy, Japan (2), the Netherlands, Norway, Singapore, Slovenia, Sweden, Switzerland, the United Kingdom and the United States) have signed on to its multilateral agreement and certificates of conformity are currently available in a limited range of information technology products, but will rapidly be extended to a wider product range.

Quality Assessment System for Electronic Components

The IEC Quality Assessment System for Electronic Components (IECQ-CECC) is a comprehensive, worldwide approval and certification programme that assesses electronic components according to quality requirements. The supplier's declaration of conformity under third-party supervision is an essential element of the system. The IEC

mark can be used for components certified under this scheme, which can provide assurance that electronic components and related materials and processes meet the conformity requirements of buyer/seller specifications. Details of the scheme can be obtained at www.iecq-cecc.org.

Scheme for Certification to Standards Relating to Electrical Equipment for Use in Explosive Atmospheres

The IEC Scheme for Certification to Standards Relating to Electrical Equipment for Use in Explosive Atmospheres (IECEx Scheme) provides the means for manufacturers of electrical equipment intended for use in explosive atmospheres (Ex equipment) to obtain certificates of conformity that will be accepted at the national level in all participating countries. The certificate issued by an Ex certification body will attest that the equipment design conforms to the relevant IEC standard(s) and that the product is manufactured under a quality plan assessed by an Ex certification body. Manufacturers that hold certificates of conformity may affix IECEx marks of conformity to the equipment. Details of the Scheme can be obtained at www.iecex.com,

Another example of an internationally accepted product safety mark is the UL mark awarded by Underwriters Laboratories Inc. (UL), an independent, not-for-profit, safety testing and certification organization in the United States. At present there are 886 UL standards and 127 UL inspection centres located in 65 countries. Some 66,000 manufacturers worldwide produce UL-certified products. The UL mark on a product is a voluntary mark that has become a recognized symbol of product safety against fire and electrical and other hazards. The details of the UL scheme can be obtained at www.ul.com.

7 PRE-SHIPMENT INSPECTION

Introduction

International trade covering exports and imports depends largely on the good faith of the trading partners. As in all human affairs, however, failures do occur and complaints do sometimes arise about short weight, short measure or unsatisfactory packaging or for some other reason. Although the International Chamber of Commerce has set up machinery for arbitration and conciliation of trade disputes in international trade, any redress obtained by these means takes time and involves some expense—the greatest drawback, however, is that trade nevertheless suffers, because doubts about the good faith of the trading partners are generated that may persist even after the complaint has been redressed.

Both the trading partners and the Governments of the States involved in export and import are equally concerned to prevent substandard goods from entering foreign markets. An accepted method to do this is by imposing some kind of pre-export inspection, mandatory or otherwise, that will not only ensure an independent third-party guarantee of quality of products exported, but will also preclude the export of low-quality products. Export inspection is an essential prerequisite in seeking and expanding export markets and has received wide acceptance in developing countries.

Classification of export inspection

Export inspection can be divided into three categories:

- Export inspection carried out under the domestic legislation of the exporting country;
- Export inspection carried out in connection with systems and legislation concerning the quality and safety of products in the country of destination;
- Specific demands for inspection in the exporting country made by the buyers.

Export inspection under the domestic legislation of the exporting country

Many developing countries in Asia, including China, India, the Philippines, the Republic of Korea, Sri Lanka and Thailand have introduced compulsory pre-shipment inspection on certain products and commodities by national legislation. The standards used as the basis for such inspections are adopted taking into consideration the trends

in demand in the countries of destination and as well as domestic industrial standards. However, there is always a minimum standard below which exports are not permitted. The inspection is performed by official designated inspection agencies, mostly governmental but sometimes private. In some countries, for example, the Philippines, Sri Lanka and Thailand, national standards bodies also perform pre-shipment inspection activities. The methods used in checking the compliance of products with the prescribed specifications include testing of samples from each consignment, periodic audit of in-process quality control during manufacture and national product certification marking or any other method approved by the regulatory authorities.

Export inspection under the legislation of the country of destination

In order to protect the safety and health of their consumers, many countries have prescribed technical legislation covering product specifications. Compliance with these technical regulations is compulsory both for products manufactured within the country and those imported. For many such products, compliance with technical regulations is checked by the designated agencies of the country of exportation. For example, the American Association of Motor Vehicle Administrators has an authorized agency in Japan (the Industrial Manufacturers Inspection Institute) to carry out safety tests on automobiles for import to the United States. Another example is the agreement between Australia and Thailand, which provides that the parties (the Australian Transport Safety Bureau and the Thai Industrial Standards Institute) will mutually accept test reports for road vehicles, equipment and parts issued and/or certified by each other as a demonstration of compliance with listed regulations. Many more regulatory authorities are placing reliance on the inspection, testing and/or verification carried out by the authorities in the country of exportation, which facilitates early clearance of consignments at the point of destination. For example, in India the following certifications carried out by export inspection agencies established by the Government are being accepted by the authorities of importing countries:

- Certificates of authenticity for basmati rice for export to member States of the European Union;
- Certification by export inspection agencies of black pepper for export to the United States;
- Assessment and approval by export inspection agencies of fish-processing units for export to the European Union, with the names of approved units sent to the European Commission for formal notification, after which only those processing units can export to members of the Union;
- Health certificates from export inspection agencies for export of seafood consignments to Australia, with such consignments undergoing only random verification sampling not exceeding 5 per cent of the consignments.

Again, 85 commodities, including milk products, fruit and vegetable products, household electrical appliances and switches, steel and steel products, electrical cables and

cement, which are covered under the import inspection scheme of Sri Lanka, are not further subjected to testing by Sri Lankan authorities on import into that country when accompanied by an inspection certificate from export inspection agencies.

The above arrangements are also in conformity with the World Trade Organization Agreement on Technical Barriers to Trade, which provides in its article 6.1: "Members shall ensure, whenever possible, that results of conformity assessment procedures in other Members are accepted, even when those procedures differ from their own, provided they are satisfied that those procedures offer an assurance of conformity with applicable technical regulations or standards equivalent to their own procedures."

Specific demands for inspection made by the buyers

In the case of specific demands made by the buyers, inspections are carried out by the agents or inspection agencies nominated by the buyers as agreed to in the relevant contract. The standards for inspection are also mutually agreed upon and would also include quantity, price verification and so on. These inspections are popular for bulk commodities such as mineral and ores and food grains.

With increasing trade liberalization hundreds of third-party national and multinational inspection bodies have been set up. These agencies are being nominated by buyers to examine a huge range of products, materials, installations, plants, processes, work procedures and services. The overall aim is to reduce risk to buyers, owners, users or consumers of the items being purchased. The European Organisation for Conformity Assessment provides information about well known inspection bodies on its website (www.ticqa.eotc.be). The addresses of such bodies and their areas and network of operation within and outside Europe are available on the website.

Benefits of export inspection

Some important benefits of export inspection include:

- It ensures that only goods that meet standards fixed for export are accepted for shipment. This goes a long way towards preventing damage to the reputation of the exporting country on the international market;
- Manufacturers will exert the efforts necessary in advance to ensure compliance with prescribed standards;
- The feedback of results from inspection bodies to manufacturers provides opportunities to improve the quality of products;
- The presence of an export inspection system provides an assurance to buyers and consumers that goods imported from the countries concerned will be safe and fit for the purpose.

For small and medium-sized enterprises that wish to export and/or import, it is necessary to obtain information relating to existing regulations, if any, concerning

compulsory pre-shipment inspection of exports or, on arrival, of imported goods. Information concerning products and commodities that are subject to such inspection, the standards applicable for such products, the inspection agencies authorized to conduct inspections and administrative procedures involved should be obtained before finalizing export contracts so as to avoid delays or rejections at the time of shipment or arrival of goods.

8 CONFORMITY ASSESSMENT

What is conformity assessment?

The term "conformity assessment" covers all activities performed either at the supplier's end or at the buyer's end or by regulators to check whether the product meets the requirements of the interested parties. "Conformity assessment procedures" are defined in the World Trade Organization Agreement on Technical Barriers to Trade as "any procedure used, directly and indirectly, to determine that relevant requirements in technical regulations or standards are fulfilled". These include, inter alia:

- Procedures for sampling, testing and inspection
- Evaluation, verification and assurance of conformity
- Registration, accreditation and approval, as well as their combinations

It is important for buyers, sellers and other interested parties to understand and agree on the conformity assessment procedures in order to avoid delays and repeat inspection and/or testing of products.

Conformity assessment activities

Conformity assessment generally consists of the following activities:

- Inspection
- Testing and calibration
- Product certification
- System certification
- Accreditation

While each of the above activities is a distinct operation, they are closely interrelated. The reliability of the results of any of the activities depends on many factors, such as the competence of the assessment body, methods followed and the appropriateness of the standard against which the product is evaluated.

Inspection

Inspection is generally used for visual examination of products, services and installations. Simple instruments, tools and gauges are used during inspection, for example, of bulk commodities like iron ores, food grains, rice or spices, which normally undergo

inspection, and acceptance of these commodities is based on both the inspection report and other evidence of conformity such as laboratory test reports on the product samples drawn during inspection.

With the growth of world trade and increasing trade liberalization, as well as the rapid development of new manufacturing and distribution technologies, hundreds of third-party national and multinational inspection bodies have been set up. These organizations are nominated by buyers to examine a huge range of products, materials, installations, plants, processes, work procedures and services, in the private as well as the public sector, and they provide reports on parameters such as quality, fitness for use and continuing safety in operation. The overall aim of such inspections is to reduce the risks to the buyer, owner, user or consumer of the item being purchased.

Many countries also use regulatory inspectorates to authorize their exports and/or imports. On the export side, this might apply in particular to products where there are sensitive export markets that a Government may wish to protect by ensuring that no substandard product is actually shipped. For example, many countries have introduced compulsory pre-shipment inspection of foodstuffs for export to Japan, the United States and the member States of the European Union.

In the private sector, too, inspection is an important part of any overall conformity assessment or quality assurance process. Inspection before release of the product to the customer is an integral part of the quality assurance of almost all manufacturers. Goods for export are also almost always subject to some form of inspection either by the manufacturer or a nominated commercial inspection body prior to shipping.

Testing

Gradually, manufactured goods are becoming technically sophisticated and the demands of the market are becoming more stringent. Testing is thus becoming an increasingly important part of trade protocols. Further, the move to freer trade will require greater recognition of testing carried out in the country of origin, but this can only happen if importers can have confidence in the competence of the laboratories conducting the tests.

Where the test results for a product are required to be submitted to a regulatory authority for approval before sale in a particular market, it is necessary for the authorities to recognize the laboratory that has performed the tests. In many cases, this may be a laboratory operated by the authority itself or a laboratory nominated by the authority. Increasingly, regulatory authorities are nominating only testing laboratories that are accredited by national accreditation bodies. Accreditation of laboratories is carried out by authorized national bodies in different countries following examination of the laboratory's competence with respect to the requirements of international standard ISO/IEC 17025.[3]

[3]ISO/IEC 17025 is an international standard published jointly by ISO and the International Electrotechnical Commission (IEC). It gives general requirements for the competence of testing and calibration laboratories.

More details about accreditation of testing laboratories are included in the United Nations Industrial Development Organization (UNIDO) guide entitled *Role of Measurement and Calibration in the Manufacture of Products for the Global Market* (see the preface to this guide).

Calibration

In order to establish the authenticity of the test results obtained either from the manufacturer's own laboratory, from another private or public sector or other institutional laboratory, it is necessary, inter alia, for the instrument and/or equipment used by the laboratory in performing measurements and/or tests to be accurate and calibrated. The primary reason for calibration is to ensure the accuracy of measurements.

It is possible for instruments to be damaged during handling and it is also possible for the readings given by the instrument to drift with usage of the instrument or with age. If measurements are carried out by a faulty instrument, then the conformity of the product to the specifications also becomes questionable. The instruments should therefore be calibrated at the time of purchase and thereafter at regular intervals, depending upon their use. Some instruments need to be calibrated before every use.

More details about calibration are included in the UNIDO guide entitled *Role of Measurement and Calibration in the Manufacture of Products for the Global Market* (see the preface to this guide).

Product certification

"Certification" is defined by international standard ISO/IEC 17000 (Conformity assessment; Vocabulary and general principles) as "third-party attestation related to products, processes, systems or persons". Product certification involves the issuance of a mark by a third party to demonstrate that a specific product meets a defined set of requirements, such as safety, fitness for use and/or interchangeability characteristics for that product, usually specified in a standard.

Product certification carried out by third-party certification bodies, that is, independently of the consumer, seller or buyer, is most acceptable to purchasers, importers and regulatory authorities. Many national standards bodies provide third-party product certification services, which include placing their certification mark on the product, along with the reference number of the standards used as the criterion for testing the product. In some countries, product certification is also carried out by trade or industry associations, government institutions or private certification bodies.

More details about product certification are included in chapter V of this guide.

System certification

Inspection of a product, whoever carries it out, is not a very reliable way of ensuring that the product will perform as desired and/or give satisfaction. It is a well-known

fact that required levels of quality can only be built into a product through the management of processes. A properly established quality management system in conformity with international standard ISO 9001, which defines the requirements for a quality management system, will help an organization to reduce costs, to improve the conformity of the product to the buyer's requirements and to create an image as a reliable supplier.

At the national and international levels, certification and/or registration of an ISO 9001 quality management system of an organization has received wide acceptance, as it demonstrates the existence of good manufacturing and business practices followed by suppliers. Certification here refers to the issuing of written assurances by an independent and accredited certification body that has audited the system of an organization and verified that it conforms to the requirements specified in the international standard (ISO 9001). This form of certification is different from product certification: under this system the product cannot be marked with a system certification mark. System certification marks typically appear on letterheads, promotional brochure and product information documents and/or brochures of certified suppliers. These marks are often accompanied by the mark of an accreditation body that has recognized the competence of a certification body to undertake management system certification.

More details about system certification are provided in the UNIDO guide on *Implementing ISO 9001:2000 on requirements for a quality management system* (see the preface to this guide).

Accreditation

The word "accreditation" originates from the Latin word *credere* meaning "to believe" or "to be confident in". Accreditation therefore means "to give confidence", and is an internationally accepted system that recognizes that a conformity assessment body (laboratory, inspection body, product certification body or system certification body) is able to provide its services in a professional, reliable and efficient manner.

Accreditation of conformity assessment bodies is granted by national accreditation bodies, which are either governmental bodies or sponsored by the Government or societies with their own governing boards with membership of Governments, certification bodies, experts, institutions, industry associations and so on.

Accreditation bodies use criteria given in ISO and IEC guides to evaluate the competence of a conformity assessment body for the granting of accreditation. An accredited certificate provides greater confidence to the user of the services of a conformity assessment body. There are presently 43 accreditation bodies in the world, for example, the United Kingdom Accreditation Service, the Dutch Accreditation Council, the Registrar Accreditation Board of the United States and the National Accreditation Board for Certification Bodies of the Quality Council of India.

World Trade Organization Agreement on Technical Barriers to Trade

The conformity assessment activities described above can become a technical barrier to trade if they are carried out by each trading partner in its own way without accepting the other's inspection, testing, product certification or system certification. For example:

- The test report of the product furnished by the supplier is not accepted by the customer as a result of certain procedural matters;
- Suppliers are required to have their product tested only in testing laboratories approved by the buyer or by the regulating authority of the importing country;
- The product certification mark awarded under the national product certification mark scheme of a country is not accepted as a means of product conformity in the importing country.

The World Trade Organization, whose members are the Governments of member States, was established in 1995 with the overriding objective of helping trade to flow smoothly, freely, fairly and predictably. The Agreement on Technical Barriers to Trade is one of the Organization's agreements, which obliges members to ensure that technical regulations, voluntary standards and conformity assessment procedures do not create unnecessary obstacles to trade. The following are the important features of the Agreement concerning conformity assessment:

- When a proposed technical regulation or conformity assessment procedure is not in accordance with the relevant international standard, guide or recommendation and it may have a significant impact on the trade of other members, this may be notified. Enterprises that may be affected can submit comments through their Governments;
- Conformity assessment procedures have to be the same for both domestic and imported products. For example, the certification mark for a product group available to domestic producers should also be available to foreign manufacturers under the same conditions. This enables foreign producers to compete on an equal footing, especially if that certification mark is well recognized by consumers;
- Member States are encouraged, at the request of other members, to negotiate agreements for the mutual recognition of results of each other's conformity assessment procedures. If mutual recognition agreements are reached, retesting or re-certification of the product in the importing country can be avoided. This is applied within the European Union.

The overall objective of the Agreement is to minimize obstacles in the trade between countries such as differing procedures of inspection, testing, calibration and product certification system certification. It is advisable to obtain information relating to these matters from trading partners or from the World Trade Organization enquiry points (see the list on its website at www.wto.org) in the country of exportation and/or importation before entering into export/import contracts so as to avoid unnecessary delays or cost overruns during execution of contracts.

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