

ISO 9001:2000
CEFIC Guidelines
for use by
the chemical industry

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Objectives

These Guidelines to ISO 9001:2000 are a revision of the CEFIC Guidelines published in 1994 to take into account both the changes contained in the new standard and the experience obtained by chemical companies in the use of the previous Guidelines.

They have been produced in order to:

- provide common application of this standard by the European chemical industry and certification bodies;
- help the chemical industry to implement or adapt current quality management systems to conform to the new standard;
- promote the establishment of quality management systems in the European chemical industry (and their certification) according to the revised standard and help further progress of quality management systems towards levels aspired to in excellence models.

Attention: These Guidelines do not replace ISO 9001:2000 and should only be used in conjunction with it. They are intended to facilitate application, and certification, if required.

Further generic guidance may be found in ISO 9004:2000. This standard, which is for guidance and not certification, is not considered in detail by these Guidelines.

Additionally, ISO 9000:2000 describes fundamentals of quality management systems and defines related terms.

Introduction

General

ISO 9001:2000 is based (as is ISO 9004:2000) on the following eight quality management principles:

- Customer focus
- Leadership
- Involvement of people
- Process approach
- System approach to management
- Continual improvement
- Factual approach to decision making
- Mutually beneficial supplier relationship

(For more details see ISO 9004:2000 clause 4.3; ISO 9000:2000 clause 0.2 or the Internet website <http://www.bsi.org.uk/iso-tc176-sc2>).

The fundamental difference between the ISO 9000:1994 series and the ISO 9000:2000 series is that ISO 9001:2000 replaces ISO 9001:1994, ISO 9002:1994 and ISO 9003:1994. The European version, EN ISO 9001:2000, contains an additional Foreword, covering regulatory requirements of the European Union.

The Scope has changed from addressing organisation's "capability to design and supply conforming product (where this) needs to be demonstrated" to "ability to consistently provide product that meets customer and applicable regulatory requirements, and aims to enhance customer satisfaction....".

The new standard emphasises the involvement of "Top Management", (e.g. the Board) in the quality management process. In this context customer satisfaction and continual improvement are of particular concern.

The new standard promotes the adoption of a process-approach. Processes convert inputs into outputs. They have first to be identified, then managed and linked to other processes. They form part of a system and can extend beyond the boundaries of the organisation. Once a process is identified and appropriately defined, the following

points should be checked:

- are responsibilities assigned (e.g. process owners nominated)?
- are the procedures implemented and maintained?
- is the process effective and providing the required results?

As a result of this process approach ISO 9001:2000 has been completely restructured in the number and sequence of clauses.

Annex B of the new standard shows the correspondence between ISO 9001:2000 and ISO 9001:1994.

To assist organisations which have already implemented a quality management system based on the ISO 9001:1994 standard and wish to amend their system to conform with the ISO 9001:2000 standard, or those seeking further explanation, ISO has published a number of supplementary introduction and support documents. These include Clause 1.2 Application, Terminology and Process Approach.

Process approach

In the new standard the process approach encompasses all organisational and operational activities. Whilst ISO 9001:2000 „only“ promotes the adoption of a process approach to quality management (clause 0.2 first paragraph), clause 4.1 actually requires that all the processes needed for the quality management system and their application throughout the organisation are identified and described.

The Chemical Industry is familiar with manufacturing processes, which are often interlinked. The extension of the process approach to other relevant organisational activities should, therefore, not cause undue difficulties and should improve the efficiency of the whole organisation. It may help to bring down functional hurdles, flatten the structure, further improvement and facilitate the integration of the different management systems.

„Management responsibility“ (clause 5) identifies the importance of top management commitment to establish, control and improve the quality management system and introduces its direct responsibility with regard to customer requirements.

„Resource management“ (clause 6) deals with the various resources needed to achieve customer satisfaction by meeting customer requirements and to establish, maintain and improve the processes of the quality management system. Emphasis is placed on human resources

and work environment.

„Product realisation“ (clause 7) includes all the various processes needed for product realisation, design and development and customer-related processes.

„Measurement, analysis, improvement (clause 8) is very comprehensive. Requirements are extended to include provision of data, analysis and performance indexes on all critical processes as well as on the continuous improvement of the quality management system and the products themselves.

Financial issues and business planning – valuable instruments for improving competitiveness – are not explicit requirements of ISO 9001:2000.

Their inclusion is, however, strongly recommended, as they will provide a more complete quality management system.

For the above reasons and with the intent of giving an indication on how to progress beyond compliance to ISO 9001:2000, (particularly with regard to clauses 5 & 6) these CEFIC Guidelines (Appendix 4) contain important links to

- the EFQM Business Excellence Model
- the Balanced Score Card Approach

Relationship with ISO 9004:2000

ISO 9001:2000 and ISO 9004:2000 are two stand alone documents which were designed to be a consistent pair of standards.

ISO 9001:2000 defines the requirements which have to be fulfilled in order to accomplish compliance with customer needs and continuous improvement of the quality management system. In addition, if considered necessary, this standard can be used to achieve third party certification.

ISO 9004:2000 develops the concept in a more extensive and intensive manner as a roadmap for organisations on their way to excellence.

The Bibliography, at the end of each standard, contains a listing of other related standards, notably ISO 19011 – Guidelines for Auditing Management Systems (replacing ISO 10011 standards); refer to Appendix 2.

Compatibility with other management systems

The standard has been made compatible with ISO 14001:1996 „Environmental management systems – Specification with guidance for use“ and should assist users in implementing (and certifying) both quality and environmental systems.

The common requirements in both standards (such as continuous improvement of the processes, training, auditing and documentation) will facilitate auditing, and integration if desired, by an organisation.



1. Scope

1.1 General

The emphasis of the scope has moved from prevention of nonconformities to effective application of the quality management system to consistently provide customers with products, which meet their needs and regulatory requirements. The requirement to continually improve the system has been added.

1.2 Application

Whereas in the ISO 9000:1994 series, separate standards established permissible exclusions, according to the organisation's function, (ISO 9002 and 9003), ISO 9001:2000 allows exclusions of requirements within the framework of clause 7, as long as these exclusions do not affect the ability to fulfil customer and applicable regulatory requirements.

These activities have to be specified and their exclusion has to be justified in the Quality Manual (clause 4.2.2)

2. Normative references

ISO 9000:2000

„Quality management systems – Fundamentals and vocabulary“.

This standard supersedes ISO 8402:1994 , ISO 9000-1:1994 and ISO 9000-3:1997. The clauses of ISO 9001-1 that constitute the road map to the ISO 9000 family of standards (the actual „guidelines for selection and use“) have been published separately by ISO as a brochure¹.

In ISO 9000:2000, the eight quality management principles, referred to in clause 0.2, the fundamentals of quality management systems and all terms and definitions applicable to the ISO 9000:2000 series are included and described in detail.

¹ "Selection and Use of ISO 9000 - Third Edition"

3. Terms and definitions

Compared to ISO 9001:1994 the most significant changes are the substitution of the term „supplier“ by „organisation“ and of „subcontractor“ by „supplier“.

The relevant terms and definitions with regard to the ISO 9000:2000 series are contained in ISO 9000:2000 „Quality management systems – Fundamentals and vocabulary“

Appendix 1 contains additional information on terms and highlights differences between the 1994 and 2000 versions.

Additional terms and definitions, which are important to the chemical industry, can be found in Appendix 5 of these CEFIC guidelines.

4. Quality management system

4.1 General requirements

A key objective of an organisation's quality management system is to ensure that only products and/or services that meet customer's requirements are delivered to them. An effectively operating quality management system is a powerful instrument enhancing the organisation's competitive performance (e.g. cost reduction). Prior to the introduction of a quality management system it is essential for the organisation to make an inventory of all relevant processes which determine the quality of the products and/or services generated by the organisation. To this end it is necessary to identify, measure, describe, monitor and control all of the identified processes.

The generic ISO 9000 term, „process“, as applied to the chemical industry, relates in the first place to chemical processes in which raw materials are converted into intermediates or end products by means of chemical reactions. The conversion can take place in continuous or batch processes, following strict set-up requirements (parameters, such as, temperature, pressure, concentration, solvents, etc.) to achieve end products. A reliable quality management system will control all variations of raw materials, the process parameters, in-process control and analysis of intermediates and end products.

In manufacturing where multiple-staged processes are involved it will be necessary to establish a hierarchy of the processing stages and key parameters, which mostly determine the end product's quality. Where applicable, the interaction of the various processes will need to be taken into account.

It is clear that chemical companies perform many other activities besides manufacturing. Activities that support product realisation may include development, marketing, purchasing, warehousing, distributing and servicing its products, in addition to the management and administration of the company. All of these activities are processes (in the sense of the ISO 9001 standard) which are necessary for the implementation of the quality management system. They therefore have to be established, documented, implemented, maintained, monitored and continually improved.

The standard makes no distinction whether the processes are performed within the organisation or outsourced. Relevant outsourced processes must be monitored and controlled within the quality management system.

4.2. Documentation requirements

4.2.1 General

Documentation requirements are less explicit and prescriptive than in ISO 9001:1994.

A documentation system remains, however, a fundamental component of any quality management system. The main objective of such documentation is to identify and describe what should be done, how it should be done and record what has been achieved to supply product, which meets customer requirements. The documentation is a useful tool to keep all processes in a state of control and is a primary means of demonstrating conformance with the standard.

One of the basic documents in any quality management system is the quality manual and is a requirement in clause 4.2.2 of the standard (see below).

Additional documents in the form of organisation descriptions, operational procedures and records will be necessary. Their number and degree of detail will depend on the size and complexity of the organisation and its processes. Regulatory requirements also need to be taken into account.

4.2.2 Quality manual

The basic document of any quality management system is the quality manual which, according to clause 4.2.2 of the standard, is compulsory but may be part of a company's overall documentation. Concerning its content, there are only a few restrictive rules and it is at the company's discretion to decide the level of detail. The main elements to be incorporated into the quality manual include the scope, the quality policy and a description of the main processes and their interactions. The main quality management system responsibilities should also be included.

The manual should be of value not only to the organisation and its employees but also beneficial to customers and other interested parties.

Where exclusions, as described in clause 1.2 of the standard, are made, these must be detailed and also be justified in the Quality Manual. Such exclusions are limited to the requirements listed in clause 7 of the standard.

Manufacturing process development is very frequently an on-going activity in the chemical industry, even if there is no official R&D department. These development activities must now be included in the scope of the quality management system and this inclusion may require some additional effort by those organisations previously certified to the ISO 9002 standard.

The requirement concerning process sequence and interaction here is new and reflects the process-orientation of the new standard. This will require some attention as it refers to business processes, not merely chemical manufacturing processes.

4.2.3 Control of Documents

4.2.4 Control of Quality Records

These two clauses are self-explanatory.

5. Management responsibility

5.1 Management commitment

Emphasis is placed here on the role of top management providing evidence of its definition of and its commitment to the development of the quality management system. Top management must demonstrably communicate the importance of meeting customer requirements. In addition and of particular relevance to the chemical industry is the reference in the standard to meeting regulatory and legal requirements. The latter includes environmental, health and safety aspects. Top management is increasingly required to ensure appropriate risk management.

5.2 Customer focus

Top management should clearly allocate responsibilities associated with the requirements and satisfaction of customers. Customer requirements are to be understood so that, when fulfilled, they will lead to customer satisfaction.

This will require close communication with customers, particularly regarding needs, which are not always explicitly stated, e.g. in purchasing documents. It can include technical performance items as well as service issues, such as delivery and customer support details. For the chemical industry, where appropriate, particular attention must be paid to regulatory and legal obligations, as well as product-related requirements.

5.3 Quality policy

Top management must make sure that a commitment to complying with requirements and also a commitment to continually improve the effectiveness of the quality system are explicitly included in the quality policy. Although not required by the standard, it is recommended that thought be given to criteria affecting the efficiency of the system. The policy is to be actively used as a basis for the quality objectives, which receive new emphasis in Section 5.4.1 of the standard. The quality policy is thus more closely coupled with company operational planning. A bland “statement on the wall” which has no subsequent relevance to

the way the company actually works is clearly not acceptable. The quality policy must, therefore, also be reviewed for continuing suitability in view of the inevitable changes that occur in and around the organisation. In the new standard responsibility for these activities is clearly allocated to top management.

5.4 Planning

5.4.1 Quality objectives

A new requirement is that top management should ensure that quality objectives are known and widely used within the organisation. This will create a working environment that enables employees to identify with and become fully involved in reaching the agreed objectives. Emphasis should be placed on the measurable nature of the quality objectives set and their alignment with the quality policy, as well as continual improvement. The “SMART” criteria; S=Specific M=Measurable A=Achievable R=Relevant T=Time-framed, should be applied when establishing quality objectives.

5.4.2 Quality management system planning

Planning should ensure that the integrity of the quality management system is maintained when making the changes necessary to keep it effective and efficient.

Inputs for quality planning could include

- strategies and organisational objectives
- needs and expectations of the customers and other interested parties (including e.g. regulatory authorities),
- performance levels of the products, services and processes,
- risk assessment and analysis, etc.

Outputs from the quality planning could include

- skill and knowledge requirements,
- allocation of task responsibilities,
- resources, including financial and infrastructure
- metrics to monitor performance
- contingency plans, etc.

5.5 Responsibility, authority and communication

5.5.1 Responsibility and authority

ISO 9001:2000 requires that responsibilities, authorities and their interrelation be not only defined but also communicated.

5.5.2 Management representative

The responsibility of the management representative for promoting awareness of customer requirements is now explicitly stated. In the past this was often already the case, with the management representative providing general quality management training and ensuring effective use of customer complaint information. The obvious intention in the standard is to increase the level of customer focus throughout the organisation.

5.5.3 Internal communication

Examples of such communication could be:

- team briefings,
- notice-boards,
- news sheets and company magazines,
- intranet websites,
- special quality events.

Internal communication could be improved by inclusion of quality matters on the agenda of all appropriate meetings.

5.6 Management review

5.6.1 General

The new standard identifies an enhanced role for the management review, with management using it to actively take steps to ensure continuing effectiveness and improvement of the quality management system.

5.6.2 Review input and 5.6.3 Review output

The standard is much more explicit than its predecessor regarding specified inputs and outputs for the management review.

6. Resource management

6.1 Provision of resources

To manufacture products and/or deliver services, an organisation needs to provide all kinds of resources, including: people, raw materials, facilities, financial means, etc. It is the responsibility of the organisation's management to identify and to provide the needed resources to achieve the objectives stated in the company's policy directed towards meeting customer's requirements and thus satisfaction.

6.2 Human resources

ISO 9001:2000 only includes those aspects of people involvement relating directly to product quality. Clearly, far more contribution is needed from people in order to run an effective and efficient organisation. The following only considers those aspects mentioned in the standard.

When recruiting new employees, particular attention should be given to their qualification and skills resulting from their competence, experience and training. Employees must be made aware of the impact of their activities on quality and other organisational objectives. This is of particular importance when selecting operators for work with dangerous, toxic or inflammable substances.

Adequate job descriptions including competence requirements for all staff should be developed.

To maintain and upgrade the skills and to enhance the knowledge the continuous training of personnel is of utmost importance. Specific training to perform assigned tasks, as well as general training in order to improve quality awareness, is essential.

The training activities apply to all staff, including top management.

Training activities should be planned, monitored, recorded, periodically evaluated and adapted to the organisation's changing requirements.

6.3 Infrastructure

To achieve and maintain conformity of its products to customer requirements, the organisation must have the appropriate facilities, processes and equipment.

Where cross contamination can occur, measures are to be taken to avoid incidents. The same applies to piping systems used for multiple purposes and equipment susceptible to explosions. People operating at such facilities need to be aware of potential implications and must know how to behave and react.

The installed facilities and the equipment, as well as the qualifications of the personnel, must meet all legislative requirements laid down by the regulatory authorities (safety issues, occupational health problems, environmental aspects, etc.).

6.4 Work environment

The work environment must be conducive to maintaining conformity of the product to specification. For example, clothing which eliminates product contamination, filtration and dehumidification equipment to maintain appropriate atmospheric conditions should be considered. Product contamination can occur from a variety of causes, including improper tools, poor work instructions or inadequate cleaning practices. These risks must be identified and minimised or eliminated.

Additionally, conditions in work areas (temperature, noise, humidity, smell, exposure to chemicals) should be such that the performance and health and safety of the personnel will not be detrimentally affected.

Full account should be taken of regulatory requirements.

7. Product realisation

This clause describes value adding activities in the loop from customer requirements to customer satisfaction (as illustrated in Figure 1 of the standard) and includes:

- determination and review of customer requirements
- design and development of plants, processes, products and services
- purchasing
- production
- preservation of products
- service provision

Note that exclusions to the standard may be made only from requirements in this clause!

7.1 Planning of product realisation

Planning includes the establishment of

- specifications
- supply chain processes
- resources (e.g. raw materials, personnel, facilities)
- monitoring activities (e.g. for process parameters, product characteristics)
- data recording and documentation for proof of product conformity

One of the results of quality planning is a Quality Plan or Plans. ISO 9000:2000 defines a Quality Plan as a “document specifying which procedures and associated resources shall be applied by whom and when to a *specific* (our emphasis) project, product, process or contract”; refer also to ISO 10005 for further details.

7.2 Customer-related processes

This clause makes it clear that the product requirements, specified by the customer, can be complemented by requirements determined by the organisation itself. Furthermore, they must include statutory and regulatory requirements.

These requirements, in written or verbal form, must be reviewed to ensure that they can be met before making an offer or concluding a contract. Fulfilment of the requirements must be confirmed to the customer.

Effective communication with the customer is required regarding the following:

- product information e.g. hazard warnings and handling and disposal instructions
- enquiries, contracts and agreements, including subsequent amendments
- customer feedback, including complaints

7.3 Design and development

These activities must be planned and targets must be defined.

The progress of development should be monitored and assessed on the basis of milestones.

Throughout the design and development process, responsibilities and authorities must be clearly defined. This is especially important for the transition period as a newly developed process or product becomes the standard routine.

There has been a tendency to understand design and development as referring purely to material products, i.e. the activities of a classical R&D department. It should be noted that changes to product realisation processes might also constitute design changes under this clause of the standard if they impact product quality.

The development result must be assessed, verified and validated, i.e. checked against the specification and the customer's requirements. Any changes necessary must be documented and the new results, where appropriate, must be verified and validated.

7.4 Purchasing

Purchased items, which could impact final product quality must be purchased to defined requirements. Before use, the purchased items must be checked to ensure that they meet these requirements. For legal reasons it is strongly advised to at least include an identity check.

Suppliers should be selected on the basis of their ability to supply the items and their performance. Particular attention should be paid to:

- changes to the supplier's processes or products, which could impact the organisation's final product, e.g. changes in method might impact product purity or performance
- purchasing documentation, which may include data relating to the suppliers quality management system e.g. Good Manufacturing Practices (GMP), Hazard Analysis Critical Control Point (HACCP). Purchasing data would also be expected to include Certificates of Conformity, test results, etc.
- verifying that the product is as ordered, so as to prevent cross-contamination or process disruption

7.5 Production and service provision

Production and service provision must be systematically planned and controlled to predetermined conditions e.g. specifications, formulation, process parameters, contents and scope of service, operating procedures, apparatus and test equipment.

If the product cannot be tested against the specification (i.e. cannot be "verified") during production, it is necessary that the output of the process is tested for its fitness for use in the customer's application, (i.e. the process must be "validated").

In-process testing in the chemical industry usually takes one of two forms. For batch processing, samples may be taken from each batch and analysis conducted to ensure that the batch is within specification. For continuous or semi-continuous processes, the process parameters are monitored. If the process parameters are monitored and recorded as correct, then the product specification has been met.

Process validation often can only take place on the basis of customer feedback. Either the customer or the end user determines whether or not the product meets their needs during actual use.

In the chemical industry traceability may be difficult to achieve because of the nature of the processing, e.g. bulk silos and storage tanks, continuous processing. Identification and traceability are imperative if stipulated by contract or by regulatory requirements.

Care must be exercised with customer property, such as containers, drums, etc. In the special case of toll manufacturing specified control conditions must be observed and deviations notified to the customer.

Product conformity must be continuously maintained throughout the entire supply chain by appropriate measures for identification, handling, packaging, storage and protection.

7.6 Control of monitoring and measuring devices (test device)

Devices used to monitor product and process characteristics must be confirmed suitable for the intended purpose, controlled, calibrated and regularly maintained. This includes equipment used for in-process instrumental control and/or measurement of process parameters, as well as laboratory instruments, e.g. viscometers, hydrometers and reagents (standard analytical solutions, buffer solutions, etc.).

For more details and guidance, refer to ISO 10012-1 and ISO 10012-2.

8. Measurement, analysis and improvement

The requirements of the standard refer to all business processes impacting conformity to customer product requirements.

To exercise control over a chemical process, which produces product meeting the specifications, and be in a situation where improvements can be achieved, the critical process and product parameters must be measured and the relationship between the parameters and the process performance should also be known.

This chapter of these Guidelines and the clause of the standard deal with the measurement of data, the analysis of these data and gives some examples on how this knowledge can be used for improvement.

8.1 General

Products and processes must be monitored and measured against policies, objectives and requirements for the product. The results are used to demonstrate conformity of the product and quality management system and improve the effectiveness of the system.

8.2 Monitoring and measurement

8.2.1 Customer satisfaction

The standard requires that customer satisfaction shall be monitored as one of the measures of performance of the quality management system. The methodology used for determining the degree of customer satisfaction should be focused on the product and its specific applications.

Criteria for evaluation may include

- Has the product technically and commercially given satisfaction to the customer?
- Has the product been delivered on time?
- Was the relevant documentation adequate and delivered punctually e.g. SDS, certificates
- Has the packaging been satisfactory?
- Has the post-sales service been up to customer's expectations?
- Have complaints been handled to the satisfaction of the customer?

Answers to these questions should preferably be collected in direct communication with customers.

Generally speaking, the monitoring and measuring of customer satisfaction are useful for improving both product quality and quality management system effectiveness.

8.2.2 Internal audit

Internal audits, when planned and conducted at regular intervals, are a powerful tool for management and are essential for formal verification that the quality management system has been effectively implemented and maintained and conforms to the requirements of the standard.

In order to benefit from the audits and to be able to use the audit findings as a tool for continual improvement, it is important that they are conducted by auditors who have adequate knowledge of the standard and the processes (in the department or the section, which is audited). Note that the revised standard may require retraining of the auditors.

The actual composition of the audit teams may be left to the judgement of the lead auditor and may include a wide range of disciplines, including external experts.

The number of persons in an audit team should be carefully judged and should not be larger than necessary; often one person, who is sufficiently qualified, may be enough.

Normally auditors will use records as evidence of conformance with the standard. If verbal instructions or notices on a blackboard are acceptable for certain operations, then this approach should be documented, e.g. in a procedure. The frequency of the internal audits should be based on the importance to the activities and also on the results of earlier audits.

The audit shall result in a written report stating the audit findings, including recommendations for any corrective actions.

For further details, refer to ISO 19011:2001, Guidelines on quality and environmental management systems auditing.

8.2.3 Monitoring and measuring of processes.

The standard requires that the product realisation processes necessary to meet customer requirements shall be monitored using methods,

which confirm the continuing ability of the processes (manufacturing as well as business processes) to satisfy their intended purpose.

This means that e.g.:

- the control of the production processes employed (continuous or batchwise) is based on measurement of process variables or product characteristics, allowing feedback to the process parameters to keep the measured variable within the permitted, stated, tolerance.
- the inevitable variation of the process and product characteristics is monitored and analysed to demonstrate that the process continuously operates within the accepted deviation. Statistical analysis of the measurements can be effectively used to demonstrate that the process is under control.

Examples of production processes, which shall be controlled, include

- Releasing raw materials for use in production.
The extent to which raw materials are tested depends on the criticality of the material in the process. One extreme situation may be a simple control of the shipping papers plus an identity check while the other extreme may be that the raw material is not allowed into the storage before a complete analysis according to a specific procedure has been carried out. It is strongly recommended that the procedure to release raw materials be documented.
- In-process inspection and testing.
The inspection may consist of automatic analysis or measurement of process parameters or samples taken at specific locations and intervals and subjected to analysis. The result of the analysis provides the feedback to the process, manual or automatic, on actions to be taken. The procedures and the actions to be taken when the result is deviating from the wanted value have to be described.

Examples of other business processes, which are not specific to the chemical industry, but need to be monitored and measured, include:

- Research and development.
Even if no active research is being done, monitoring of the normal, continual development of the production process should be done.

- Procurement and marketing.
The reaction time of the people of the organisation is one method by which performance can be measured
- Budgeting

8.2.4 Monitoring and measurement of product

The product, which is the final result of the production process, should be analysed (measured and monitored) in order to verify that the requirements are met and the results shall be documented.

Similar to the procedure for the production processes, the characteristics of the product must be measured either by the process characteristics or by direct measurements on the product itself. Depending on the production process, the characteristics of the product may be monitored at appropriate stages in the process.

Procedures shall be established such that no product (or intermediate product) is released (for further use or delivery to customer) before all required inspections have been performed. The procedure must reflect the basics of the production process (single units, product from a batch process, product from a continuous process being delivered either to an intermediate check storage or directly from process to the final storage or production processes which share intermediate products and where the intermediate stock is not physically segregated).

8.3 Control of nonconforming product

The monitoring of processes and product as described in sections 8.2.3 and 8.2.4 have as their main objective to assure that the processes, raw materials and intermediate and final products are conforming to specifications.

When it is discovered that any raw material, intermediate or final product is not conforming to specifications, then the standard requires that these materials are segregated, physically or electronically, from the materials conforming to the specifications to prevent inadvertent use or delivery. Documented procedures must be established and maintained to provide evidence of the history of the nonconforming materials, (marking of containers, keep in separate storage areas, etc.), as well as of the responsibility for disposition of the nonconforming material (see 7-5-3).

Consideration should always be given, during the planning of new processes or modifications of existing plant, to the addition of recycle lines for reprocessing and to include off-specification storage capacity.

As an integral part of these procedures for nonconforming material, the sources of the nonconformities should be identified and remedial actions proposed and taken to prevent recurrence (see 8.5.2)

If reprocessing or blending of non-conforming product into conforming product is not possible, suitable methods for disposing of it shall be decided and documented (e.g. sale as off-spec, dispose of as scrap etc.)

Special circumstances may exist which make it impossible to take the correct actions (extreme temperatures, pressures or corrosive nature of product) to immediately segregate the nonconforming product. Actions to be taken in such situations must be documented.

8.4 Analysis of data.

The data which are collected to verify that the requirements of the product and the production (and other business) processes are met, shall be analysed to determine the suitability and effectiveness of the quality management system and to provide a basis for the identification of improvements. Appropriate statistical techniques should be used.

The following areas could be analysed to provide information on the suitability and effectiveness:

- Customer satisfaction or dissatisfaction (see 8.2.1)
- Customer satisfaction with the
 - marketing and after-sale service
 - technical information on the use of product and access to specialist advice
 - logistics and packaging
 - ease of handling
 - safety and environmental information
- Conformance to customer requirements (see 7.2.1, 7.2.2 and 7.2.3)
Customer requirements as provided in the enquiry, order or other communication should be analysed and compared with the actual product specification in order to confirm conformance.

The analysis may show a development of customer requirements, which should influence the controlled change of product specifications, (e.g. reduction in level of impurities)..

- Characteristics of processes, products and their continual development
Trends in the process variables and product characteristics should be monitored to facilitate early intervention, i. e. before nonconformance is a fact. The trend analysis will also facilitate the change of process or product specification to meet changing customer requirements
- Suppliers (see 7.4.1)
The data collected on suppliers should be systematically analysed and used to identify improvements. Factors such as variation in waste generation as a result of using different raw materials, the ability of the supplier to reprocess product, timely delivery and other aspects which influence the development and improvement (in own production) of the final product or the processes should be included in the evaluation.

Statistical techniques can be applied to any area where data are available (e.g. packaging, distribution, etc.) Care should, however, be exercised and specialist advice should be sought when applying statistical methods to data.

8.5 Improvement

The intention of the standard is that continual improvement shall be planned and implemented on all levels:

- the quality management system shall be improved. This will have a positive effect on the entire organisation.
- the improved quality management system will influence the production processes through better control and better knowledge of the effect of variations.
- the improved production processes combined with the improved quality management system will supply products that will better meet customer requirements. The organisation will also be in a position to respond to changing requirements and supply improved products.
- ultimately improved customer satisfaction and a more cost-effective operation should result.

The difference between the three following actions, which are used frequently, should be noted:

- **Correction** Solving the immediate problem (as discussed in 8.3)
- **Corrective action** Finding and eliminating a root cause so that a problem does not reoccur (8.5.2)
- **Preventive action** Identifying and eliminating potential causes before a problem occurs (8.5.3)

See ISO 9000:2000 for full definitions.

8.5.1 Continual improvement

Continual improvement should be planned using appropriate tools and techniques. Rather than wait for problems to reveal opportunities, the organisation, through knowledge of the interactions in, e.g. the production processes, should continually look for improvements - and implement them.

8.5.2 Corrective action

Nonconformities can occur in any organisation and with any product. One of the requirements of the standard is that there shall be a specific procedure for the actions taken when a nonconformity is reported. The documented procedure should describe requirements for identifying the nonconformity, the cause of the nonconformity, the action taken to eliminate the causes and a review of the corrective actions taken to evaluate if the results are acceptable

In the chemical industry methods for eliminating product non-conformities may be to

- change the specification (taking account of customer product requirements), if the cause of the nonconformity is in the composition of raw materials which cannot be modified or controlled
- remove non-critical components from specification of internal or final products.
- change the process
- modify materials of construction
- re-train personnel

Only components critical to the final product need be considered in the above.

8.5.3 Preventive action

In addition to the corrective action procedure as described in 8.5.2, a documented procedure aimed at identifying and eliminating potential causes of nonconformities must be implemented. The procedure should include how to record the measures and the results and how the review (evaluation) of the actions should be done.

The analysis described in sections 8.2.3, 8.2.4 and 8.4 will provide valuable and extensive information on the processes and will be an excellent starting point for the search for possible causes of nonconformities.

Modifications to plant and equipment and the introduction of changed process conditions may, if preventive actions are not taken, lead to nonconformities. The preventive action procedure should include the requirements for the evaluation of any plant or process modification e.g. change of materials of construction, modifying separation equipment, changing raw materials, etc. It should also be extended to include evaluation of the marketing, research and development, ordering and other business processes.

A risk analysis is a typical example of a preventive action.

Preventive actions, which have significant financial impact or could influence customer satisfaction, would be typical outputs from the management review process.

Appendix 1

Summary of differences between key terms used in the “1994” and “2000” versions of the ISO Quality Management Standards.

1994

2000

SUPPLIER - ORGANISATION – CUSTOMER

The 1994 version of the standard used the term “supplier” to mean the unit that provides a product or service to a customer and the term “subcontractor” to mean any provider of product or service to a supplier.

The new standard replaces the previous term “supplier” with the term “organization”. The term “supplier” is now used instead of the previous term “subcontractor”.

CUSTOMER SATISFACTION

In the 1994 version of the standard customer satisfaction was not specifically indicated as a requirement.

In the new standard, customer satisfaction becomes an important requirement as an indicator of the degree to which the quality management system has fulfilled customer requirements.

MANAGEMENT

In the 1994 standard the term “management” was referring to the organisation’s management with executive responsibility which defines and documents its policy for quality, objectives and commitment to quality.

The new standard introduces the term “top management” with the intent of indicating the highest level of the person or group of people who direct and control the organisation and commit it to the development and improvement of the quality management system.

MANAGEMENT REVIEW

The management was accomplishing at planned intervals, review activities to ensure the quality system suitability and effectiveness in respect to the supplier’s stated quality policy and objectives.

The new standard has very specific requirements for the inputs and outputs of the management review. This has been deliberately done to increase the involvement of management (see 5.6)

PROCESS

Although the concept of process – as a set of activities which convert inputs to outputs – was already present in the 1994 version of the standard, the process approach was substantially focused on production process, its monitoring and control and maintenance of equipment.

The new standard is entirely “process oriented”. The process approach goes beyond the manufacturing process area to encompass all organisational and operational activities, e.g.: R&D, purchasing, marketing, measurement and monitoring of production and processes, customer satisfaction, logistics, human resources management, safety, managerial processes and continual improvement.

Note: The approach advocated is to be used when developing, implementing and improving the effectiveness of a quality management system to enhance customer satisfaction by meeting customer requirements.

QUALITY MANAGEMENT SYSTEM

Formerly “Quality System” in the 1994 standard, it was covering all the organisational structure, procedures, processes and resources necessary to assure that product conforms to quality specified requirements.

The new standard introduces the term “Quality Management System” instead of the generic term “Quality System”. In addition, it encourages the adoption of a management by processes. The quality management system becomes part of the overall management system of the organisation.

IMPROVEMENT

Quality improvement is an objective of the organisation aimed at increasing the effectiveness and the efficiency of activities and processes.

The new standard introduces the requirement of continual and progressive improvement of the quality management system.

The continual improvement shall be planned and implemented on all levels of the organisation aimed at seeking and pursuing every improvement opportunity.

QUALITY MANUAL

The quality manual shall cover the requirements of the standard, including or making reference to quality policy, documented procedures and activities, structure of documentation used in the quality system.

In addition, the new standard requires that the quality manual shall include:

- The scope of the quality management system with details and justification of any exclusions;
- The processes identified and their interactions
- The documented procedures or references to these

QUALITY PLANNING

The organisation was defining objectives and requirements for quality as well as the activities appropriate in meeting agreed quality specifications.

In the new standard more emphasis is placed on the identification and allocation of resources such as human resources, facilities and work environment, needed to achieve quality objectives.

Quality planning shall include the continual improvement of the quality management system.

Note: ISO 9000:2000 clause 3.7.5 defines quality plans as documents specifying which procedures and associated resources shall be applied by whom and when to a specific project, product, process or contract. Such quality plans are not mandatory but may be used as an additional tool.

Appendix 2

Reference List

In addition to ISO 9001, on which these guidelines are based, the International Organisation for Standardisation (ISO) and the National Standards Bodies produce a number of other complementary standards, guidance and other documents. Many of these are referenced in the Bibliography included with the core quality management system standards; ISO 9000, ISO 9001 and ISO 9004.

Although most documents are published by ISO and available through National Standards Bodies, a number are only available by consulting the various originating organisations. Fast access to most information is available through the respective organisations' Internet web sites. The following are the addresses for the most relevant international standards bodies:

International Organisation for Standardisation: <http://www.iso.ch>. This site contains general (factual) information about management systems standards and provides a number of documents for free downloading. In addition, a useful link to other standards bodies is provided at <http://www.iso.ch/infoe/stbodies.html>

The ISO Technical Committee 176 charged with developing quality management standards is located at <http://www.tc176.org>. This site provides news on latest standards developments and other ancillary information.

The British Standards Institution currently holds the Secretariat of the main Sub-committee within ISO/TC 176. Their site at <http://www.bsi.org.uk/iso-tc176-sc2> contains useful information and guidance, as well as some documents available for downloading.

Other key sources of information include certification bodies, whose sites often contain useful general or specific guidance information, as well as procedures to be followed to obtain certification to ISO 9001. Other organisations concerned with quality, such as the European Foundation for Quality Management (EFQM, <http://www.efqm.org>) and the European Organisation for Quality (EOQ, <http://www.eoq.org>) can provide further information, some of which may be suited to companies more advanced in quality management practices.

Appendix 3

Sector Initiatives

Initiatives by individual industry or business sectors can take several forms:

- As standards, incorporating requirements additional to the generic quality management system specification contained in ISO 9001
- As certification schemes, which may incorporate additional product, system or certification requirements and may include industry ‘best practices’
- As formal guidance, in the form of “standards” issued by the International Organisation for Standardisation (ISO) or an individual National Standards Body
- As industry guidelines, such as this document, aimed at clarifying the application of the generic ISO 9001 for a particular industry.

At the time of writing these guidelines, many additional sector initiatives were being developed, thus making a listing of such initiatives inappropriate. Advice on current availability may be sought from your National Standards Body, Accreditation Bodies or reputable certification bodies. Note, however, that in the case of the latter, there could be self-interest in providing the answer.

Chemical companies should determine to which documents and certification schemes to subscribe based on the requirements of their stakeholders, primarily their customers and legislators.

CEFIC, on behalf of the chemical industry has taken the position that, in general, certification to the generic requirements of ISO 9001 should adequately demonstrate the adequacy of a company’s quality management system. The requirement to identify and meet both customer and regulatory requirements being part of the ISO 9001 specification. However, it is recognised that in contractual situations specific customer requirements may be identified. In such cases, use of sector standards, guides or certification may be appropriate.

When adopting sector specific requirements or certification schemes, the advantages of meeting the additional or specific requirements should be

carefully weighed against the costs of obtaining conformance. In the case of a small company with a single large customer, for example, it might be more cost effective for the customer to audit the supplier than for the supplier to pay ongoing fees to a certification body.

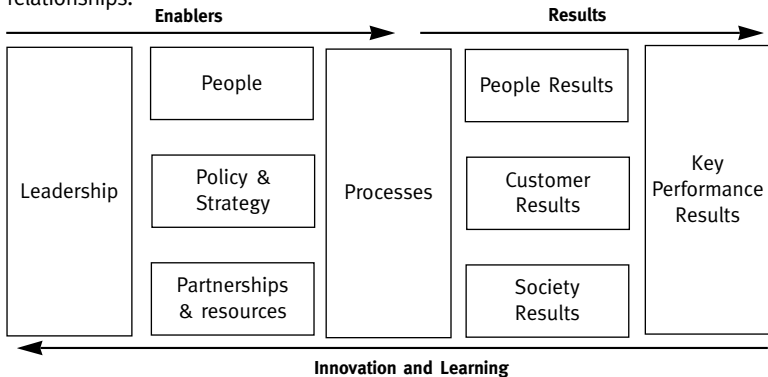
Appendix 4

Beyond ISO 9001 - Advanced Quality Management Systems

Quality management systems based on the ISO 9001/9002 standards are now widespread and well established within the European chemical industry. Many companies are looking for ways to expand the scope of their systems beyond compliance with the minimum requirements as laid down in these standards. In particular the need has been recognised to better align the quality management system with overall business operations. Such integration of the quality management system will prevent its isolation and will release its full contribution to the health and competitiveness of the company. This is to some extent addressed in ISO 9004:2000, „Guidelines for performance measurements“, which is of broader scope than ISO 9001:2000. Whilst not being intended for certification purposes, ISO 9004:2000 does include a set of questions and a rudimentary rating scheme, which enables self-assessment in its use as a roadmap to organisational excellence. Two more advanced approaches, which are particularly recommended as being suitable for the further development towards an advanced quality management system, are the EFQM Business Excellence Model and Balanced Scorecards. The following provides a brief introductory description of these.

The EFQM Business Excellence Model²

At the heart of this simple but comprehensive model is a framework of nine “criteria” which are considered to provide the basis of a successful business. These criteria are arranged in the manner shown to clarify their inter-relationships.



² European Foundation for Quality Management (<http://www.efqm.org>) Avenue des Pléiades 15, B-1200 Brussels © EFQM 1999, The EFQM Excellence Model is a Registered Trademark

The EFQM Business Excellence Model differs fundamentally from the ISO standards by not being a prescriptive list of requirements regarding e.g. documentation, contract review etc. etc. In the Model each of the criteria is developed by a series of challenging questions designed to provoke constructive thought and establish the current organisational excellence profile. This recognises that many different approaches may be taken to achieving sustainable organisational excellence. It represents a total quality, stakeholder view with due account being taken of customers, employees, shareholders, society and suppliers. The scope of the EFQM Model is thus deliberately significantly broader than that covered by the ISO 9001 standard, although this gap has been reduced considerably with the revised ISO 9001:2000 issue, and even more so for the ISO 9004:2000 standard.

An additional strength of the EFQM Model is its quantitative nature, with a detailed scoring system to assess the status with regard to the basic criteria. Whilst the European Quality Award is based on this EFQM Model, the latter is very suitable for self-assessment purposes. Indeed the most frequent application of the EFQM Model is for such internal self-assessments.

Several different approaches have been developed for the self-assessment exercise. All provide the company with a detailed analysis of the strengths and weaknesses throughout the entire organisation. These, in turn, can be used as inputs for targeting improvements, progress towards which can then be quantitatively monitored by a subsequent, repeat self-assessments. As such application of the EFQM Model for Business Excellence is not a continuous, ongoing exercise. Self-assessments are typically performed at 1-3 year intervals, providing snap-shots of the development of the overall organisational quality.

Balanced Scorecards³

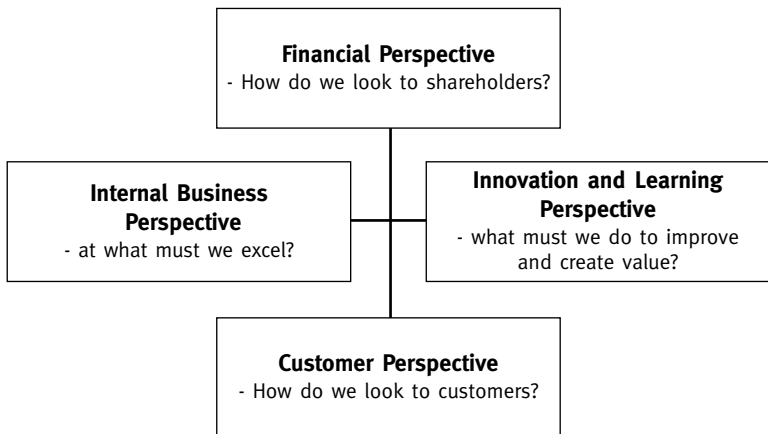
The balanced scorecard approach is based on performance indicator metrics. The use of “Key Performance Indicators” is not new. Such KPI metrics are usually, however, of limited scope, mainly comprising manufacturing and sales volumes plus classical financial result ratios such as Return on Investment (ROI) etc.

³ “The Balanced Scorecard – Measures That Drive Performance”, R.S. Kaplan and D.P. Norton, Harvard Business Review, Jan.- Feb. 1992, 71-79.
“The Strategy-Focused Organisation – How Balanced Scorecard companies thrive in the new business environment”, Harvard Business School Publishing, 2001

In contrast, the metrics for balanced scorecards are more comprehensive. They are derived from a broader base, the so-called perspectives:

- Financial perspective
- Customer perspective
- Innovation and learning perspective
- Internal business perspective

The Balanced Scorecard Approach



This is the “balance” in the title, ensuring that the various and different factors impacting company performance are given due consideration and weighting.

The organisation thus develops a set of goals, which are of direct relevance to the overall strategy for each of these perspectives. Subsequently, and most importantly, a monitoring and feedback “scorecard” system is implemented to enable management to monitor the state of progress towards these goals. The metrics chosen are company-specific, reflecting the specific operating environment and the strategic plan. The scorecards are cascaded down through the organisation, from divisional to departmental and ultimately to the individual levels. To maintain transparency, consistency and manageability, the particular metrics should be chosen carefully. The temptation to define too many parameters in the early stages is to be resisted, as also should subsequent frequent changes. Properly designed, the balanced scorecards will perform like the instruments in

an aeroplane cockpit, providing Top Management with important information about a complex system “at a glance”.

The EFQM Model and balanced scorecard approaches are not mutually exclusive and, moreover, they do not necessarily compete with each other. It is increasingly being realised that, properly deployed, these two advanced tools can be mutually supportive.

The combination of

- a *periodic but comprehensive and detailed* EFQM Model self-assessment, and
- the *on-going, specific and company-wide* application of balanced scorecards

is the optimal guidance system for charting the course to success through the choppy waters of stakeholder value.

Those companies that now have mature “ISO-based” quality management systems could well find it of interest to take a closer look at the EFQM Model and balanced scorecard approaches to provide a practicable route to the harmonisation/integration of the quality management and environmental, health and safety management systems. This holistic approach is what is meant by the modern “triple bottom line” of a truly sustainable business which balances economic growth with environmental integrity and social responsibility, - which is of particular relevance to the chemical industry.

More recently, Kaplan and Norton have been advocating that companies use the Balanced Scorecard to become ‘strategy-focused’. Their research has show that companies may effectively use the scorecard to translate the strategy into operational terms and align the organisation to the strategy. The Scorecard thus becomes another possible model for the management system.

Appendix 5

Definitions (of particular interest to the chemical industry)

In addition to the definitions in ISO 9000:2000 “Quality Management Systems – Fundamentals and Vocabulary”, the following definitions are useful in relation to the chemical industry. Individual usage of the terms may differ by country and company but the definitions listed are those used throughout these Guidelines.

Agent

A company or person appointed by an organisation to sell product on a commission basis. An agent does not have ownership of the product.

Batch

In a batch process, this is the quantity of finished chemical produced at one time. In a continuous or semi-continuous process, it is not possible to define a batch in the above sense, and consequently is usual to talk in terms of a lot.

Calibration

All the operations establishing, in specified conditions, the relation between the values given by an instrument and the corresponding known measured reference if available. In practice, the result of a calibration allows for establishing the value of deviations of an instrument indication against the national or international references. It also allows, by using systematic corrections, for the reduction of the measurement uncertainty.

Certificate of analysis

A document giving the results of testing of a representative sample drawn from the material to be delivered. In this case it incorporates test results, as agreed between customer and organisation.

Certificate of conformity

A document of conformity to a specification. The provision of a certificate of conformity is not a requirement of the standard although customers may request organisations

to provide this document. See the guidance notes to sections 7.2 and 7.4.

A certificate of conformity does not imply that the actual material delivered has been tested, but that all the material from which the delivery have been made up, has, at some stage, been inspected and tested according to the requirements of the established quality management system, and found to conform to specification.

Certified reference material

A reference material of which one or several property values are certified by a technically valid procedure and having a certificate, or other documentation associated with it, provided by a certification body. This material is used for calibrating instruments.

Consignment stock

A quantity of product owned by the organisation but kept in the customer's store for his specific use and transferred to his ownership when used.

Consignment stock may be either packed or bulk product.

Contract

Any type of agreement either written or in any form or type of medium between the organisation and the customer (see 7.2).

Distributor

A company which is formally appointed by a organisation to buy, stock and resell all or part of the organisation's product range, e.g. within defined geographical areas, use sectors, and load size limitation for delivery.

The distributor may be a manufacturer, may supply in part, purchase for resale (PFR) and may also have his own direct sales organisation with whom a close liaison will exist. A distributor takes ownership of the product in contrast to an agent who does not.

Integration of Management Systems

The 2000 revision of ISO 9001 standard has made it more coherent and compatible with other management system standards, in particular with the ISO 14001:1996 "Environmental Management Systems".

This allows an organisation to integrate, if desired, its own quality management with related environmental management systems requirements using common elements. This can facilitate planning, allocation of resources, definition of complementary objectives and assessment of the overall effectiveness against ISO 9001 and ISO 14001, as well as reduce the number of controlled documents.

Lot

The quantity of chemical, from which a representative sample is available, for example, a quantity of chemical drummed off or packed out from bulk tank or silo storage.

Outsourcing

The transfer of an activity, service or product manufacture to a third party.

Primary standard

A standard representing the highest metrological quality in a specified field (e.g. a national or international standard).

Purchase for resale

A situation where finished product has been purchased by the organisation with a view to reselling under the organisation's own label. Purchase for resale product is often abbreviated to the phrase "PFR product". Examples of circumstances for PFR product are:

- where there is no manufacturing capacity
- where the organisation is covering shortfalls in capacity, peak demands, plant shutdowns, emergencies, etc.

In PFR the organisation is acting as a trader.

Reference material

A material or a chemical of which one or several property values are sufficiently well defined to allow for its use to verify an instrument, to assess a measurement method or to attribute values to materials (e.g. products of which values are determined by round robin tests).

Reference standard

A standard, generally of the highest metrological quality available in a particular place, against which the measurements performed

in this particular place, are compared.

The company reference standard is aimed at the calibration of its own working standards. The reference standard should be directly or indirectly connected to a primary standard.

Representative sample

Sample taken according to a well-defined procedure in order to obtain information on the batch or the lot. Where applicable, this should assure the homogeneity of the whole or part of the lot as agreed with the customer.

Swap Deal

An agreement between two organisations A and B, whereby A provides product to B's customer and B supplies an equivalent quantity of the same product to A's customer in a different location. These agreements are typically undertaken to minimise or eliminate the costs of transportation.

Technical service

A routine day to day support for the performance of a product supplied to a customer, e.g.:

- processing conditions for the polymer material;
- dyeing processes for textiles;
- application of coatings and films;
- field of application for stabilising systems;
- long term behaviour of articles made from chemical products.

Toll manufacturer

A supplier who undertakes the whole or a prescribed part of the organisation's manufacturing process.

Trader

An organisation which purchases product from a variety of sources and sells under its own name usually without acknowledgement of the source.

Where the organisation provides product to a trader, that trader should be regarded as a customer within the chemical industry.

Working standard

A standard which, usually calibrated by comparison with a reference standard, is employed for the calibration or

CEFIC, the European Chemical Industry Council, is the Brussels-based organisation representing national chemical federations and chemical companies of Europe.

CEFIC represents, directly or indirectly, more than 40 000 large, medium and small chemical companies in Europe, which employ about 2 million people and account for more than 30% of world chemicals production.

© CEFIC March 2001
Dépôt légal D/2001/3158/2



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verification of measurement equipment or measurements already established.

Note: only reference and working standards should be found in laboratories and metrological departments in the chemical industry.