



**TOGETHER**  
*for a sustainable future*

## OCCASION

This publication has been made available to the public on the occasion of the 50<sup>th</sup> anniversary of the United Nations Industrial Development Organisation.



**TOGETHER**  
*for a sustainable future*

## DISCLAIMER

This document has been produced without formal United Nations editing. The designations employed and the presentation of the material in this document do not imply the expression of any opinion whatsoever on the part of the Secretariat of the United Nations Industrial Development Organization (UNIDO) concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries, or its economic system or degree of development. Designations such as “developed”, “industrialized” and “developing” are intended for statistical convenience and do not necessarily express a judgment about the stage reached by a particular country or area in the development process. Mention of firm names or commercial products does not constitute an endorsement by UNIDO.

## FAIR USE POLICY

Any part of this publication may be quoted and referenced for educational and research purposes without additional permission from UNIDO. However, those who make use of quoting and referencing this publication are requested to follow the Fair Use Policy of giving due credit to UNIDO.

## CONTACT

Please contact [publications@unido.org](mailto:publications@unido.org) for further information concerning UNIDO publications.

For more information about UNIDO, please visit us at [www.unido.org](http://www.unido.org)

# **Experts Group Meeting on Quality, Standardization & Metrology For Developing Countries**

**April 18-22, 1995  
Beijing , China**

**Co- Sponsored by :**

**United Nations Industrial Development Organization  
China State Bureau Of Technical Supervision**

**Organized By:**

**National Institute of Metrology, Beijing China**

## PREFACE

Quality, Standardization and Metrology (QSM) are essential elements among the technological capability for activating industrialization process and strengthening trade competition of a country. In the 5th Review Meeting of the Asia/Pacific Metrology Programme, Seoul, 1992, it was proposed to organize a workshop on QSM for developing countries in the Asia/pacific region. Thanks to the cosponsorship of the United Nations Industrial Development Organization (UNIDO) and the China State Bureau of Technical Supervision (CSBTS), the organization of the National Institute of Metrology, China (NIM) and the support of the China International Center for Economic and Exchanges (CICETE), this Expert Group Meeting on QSM for Developing Countries will eventually be held on 18-22 April 1995.

This proceedings collect papers to be presented in the Meeting: 4 lectures from the UNIDO, OIML and ISO, 4 articles on the QSM work from the CSBTS, 3 papers from the NIM and the Beijing institute of Technology, China, as well as 5 implementation reports from 5 large enterprises in China. Reports on the QSM progress from the participating countries/ region will be distributed during the Meeting.

China is a member of the Metre Convention, ISO, IEC, OIML, ILAC, ect., and it has exerted great efforts on the development of QSM work. The CSBTS has embodied QSM tasks in the whole country under a unified umbrella and the NIM has established and maintained primary and national measurement standards for various quantities with an international traceability. Presently, China is giving impetus to the implementation of the ISO-9000 series, while nearly all of its enterprises are carrying out their quality management and quality assurance systems. Being a developing country itself, many of the experiences it acquired and problems it encountered may be interesting to other Asia/Pacific developing countries/region, while on return the Meeting would also create an opportunity for it to learn from international experts and fellow participating countries /region.

May the flower of QSM blossom in the Asia/Pacific region

Organization Committee of the QSM Expert Group Meeting  
April 1995, Beijing, China

## Contents

1. Quality, Standardization and Metrology <b>UNIDO</b> .....	1
2. The International Organization of Legal Metrology (OIML) <b>Bernard. Athané</b> .....	15
3. Relevance of International Standards for Business Activities and The ISO9000 Phenomenon <b>Christian J. Favre</b> .....	26
4. Role of International Standardization in Promoting Industry and Trade in Developing Countries <b>Anwar El-Tawil</b> .....	39
5. Retrospect on 1994 Quality Certification in China <b>Ding Qidong</b> .....	49
6. Quality System Registration in China <b>Guo Lisheng</b> .....	53
7. Metrology in China <b>Dai Runsheng, Dong Zheng, Wang Jilai</b> .....	59
8. Quality System Registration in China <b>Xiao Jianhua</b> .....	68
9. Impact of Emerging Technology on Metrology <b>Yang Xiaoren, Wang Lanxiang</b> .....	74
10. Uncertainty and Reliability Analysis <b>Liu Zhimin</b> .....	77
11. Study on Evaluation of Quality System <b>Lang Zhizheng</b> .....	101
12. ISO 9000 • Metrology • Quality <b>Chen Weidong</b> .....	107

<b>13. How Does Our Works Implement the Quality System Certification Yu Lizheng .....</b>	<b>117</b>
<b>14. Strengthening Data Mananement To Improve Metering Management Liu Wenmei .....</b>	<b>133</b>
<b>15. Internal Quality System Aucit for an Enterprise Liang Chengfa .....</b>	<b>139</b>
<b>16. Standards, Metrology and Quality Assurance of Mass Measuring Instruments in China and Shanghai YAMATO Scale Co., Ltd Pei Yuji, Yang Zengquan .....</b>	<b>143</b>

# **QUALITY, STANDARDIZATION AND METROLOGY**

## **United Nations Industrial Organization**

### **1. General Introduction to Quality, Standardization, and Metrology(QSM )**

The fundamental rules of competitive global manufacturing are changing with the emergence of a new approach to the organization of the firm . This approach has been most closely identified with key aspects of successful Asian manufacturers but is rapidly gaining adherents among manufacturers across the globe. Much of the analysis concerning this development centers on the leading role of quality and quality control. This is because leading manufacturers have been able to establish ever higher levels of product and service quality as sources of major competitive advantage.

Developing countries are rapidly recognizing that quality and its related disciplines figure prominently in strategic national objectives and can help to achieve social and economic progress.

Two other areas which are of prime importance for quality and improvement efforts are metrology and standards. For instance, industrial metrology serves to maintain a system of accurate measurements which are necessary to support the production of quality goods and services. This involves activities such as the careful calibration of machinery and laboratory instruments and greatly aids the quality improvement effort. Standards can play a very important role in the quality improvement effort. A standards is generally any set of requirements to be satisfied by a material, process, product, procedure, test method, and/or physical, functional, performance, or performance characteristic. Currently, the most important quality standard (and the fastest growing standard of all time) is the ISO9000 Series.

ISO9000 represents a series of international standards which prescribe acceptable methods to design, implement and assess a quality management and assurance system. This series has been directly linked to the Single Market of the European Union and firms that are certified as having met this standard are able to compete in this market. ISO9000 is an attempt to standardize a general approach to quality systems at the enterprise level. One factor explaining the rapid success of ISO9000 is that it brings a dergee of order to the market for

quality improvement services. Before ISO9000 there were many different types of "quality programmes" in use. ISO9000 offers a universal standard which reduces much confusion.

First, ISO9000 provides the enterprise with a ready set of definitions as to what constitutes quality. Second, clear guidelines are provided for setting up a quality system. Where the enterprise has had little or no experience with quality and improvement, ISO9000 can provide a solid foundation for subsequent improvement efforts. Moreover, enterprise managers do not have to be convinced of necessary changes in order to attain this certification. This represents a positive development - prior to ISO9000 many managers displayed cynicism regarding quality improvement programmes.

However, great care should be taken to avoid confusing ISO9000 standards with an actual system of continuous process and product improvement. ISO9000 only stipulates that an enterprise should have a documentable quality system - it does not tell management which system to use or how to go about the crucial business of continuous improvement of products and processes. UNIDO can promote the adoption of ISO9000 at the enterprise level which will help firms gain critical access to markets. But at the same time UNIDO should emphasize that ISO9000 alone does not ensure competitiveness. It is only a first step on the path to continuous process improvement.

Obviously the role of quality has become a critical variable influencing an enterprise's competitiveness. However, in the world's most competitive firm increased quality is merely one by-product of an approach that stresses the continuous improvement of all aspects of the production process. Increased product quality - along with a simultaneous stream of advances in productivity, flexibility, and cost performance - occur as a result of a dynamic form of continual improvement of the overall organization.

Continuous improvement is the crucial issue governing competitiveness - and can only take place within a managerial and organizational system which channels all the resources of the firm towards improving products and processes. It is the prime duty of top management to oversee the implementation of a system of total quality management and ensure that it is continually improved upon. This is an important point. Failure on the part of managers to recognize their responsibility for reshaping the organization has led to frequent disappointment with quality improvement programmes. Initially, efforts may yield impressive results - with significant increases in measured quality. However, without a managerial and organizational structure which encourages

continuous improvement the firm will find itself falling further behind its more dynamic competitors - despite relative increases in its own levels of quality. This is because the competition has in place a system which generates constant change and innovation in the course of production.

In other cases, an enterprise may vigorously pursue quality improvement only to find sales to be flat or even declining. Analysis often reveals that although product quality increased - it did not reflect characteristics that the customer valued. This is another instance of management's misunderstanding of quality improvement. All quality and improvement programmes must be aimed at increasing customer satisfaction. Comprehensive programmes of "total quality management" or "continuous improvement" should be designed to help managers achieve these capabilities.

## **2. A Proposed System for Quality and Improvement**

In the current global drive to improve quality and production efficiency successful firms have been rewarded with increased market shares. Emerging from this process are new forms of industrial partnership and horizontal integration - as well as new types of financial and accounting tools. While large enterprises have led the way in raising the global competitive standard, small and medium sized enterprises are increasingly seeking increased quality and performance. The rapid rise in applications for ISO9000 certification reflects the growing demand for services in support of better quality and improvement.

However, much confusion remains in the minds of enterprises managers concerning improvement programmes. An absence of clear quality improvement procedures often worsens the waste of effort and financial resources in many enterprises. Importantly, the lack of adequate performance measurements means that managers often overlook positive results from improvement efforts. While certain outcomes of improved quality may be difficult to measure (e.g. the impact of more satisfied customers), there are many techniques available which can be used to present demonstrable evidence of progress in quality and process improvement. Without such measurements many managers may eventually reject quality and improvement programmes.

The next section offers an integrated approach to quality and process improvement. This combines a system of quality improvement with a set of management tools designed to identify deviations from established goals, and to maximize the use of existing methods by providing a system to measure their effectiveness. New measures are needed to integrate the results of quality



improvement (crucial for customer satisfaction) with measures of efficiency and profitability ( a main concern of managers). Such a set of measures will allow managers to quicken the pace of modernization based on existing resources.

### **3. An Introduction to The System Approach**

The term system is frequently used. In principle, a system can be understood as a collection of interacting components. The components of a system include physical forms such as machinery, as well as functional relationships among various physical components of the system. A system can be a nuclear power plant, part of an engine, a process plant for production, a human being or the economic system of a country. In defining a system it is important to establish the boundary which separates the system from its environment. To speak of "controlling" a system means to adjust the outcomes of the system as closely as possible to the performance objectives. This can be done by "feeding back" information from the results of system activities and comparing this with stated goals or objectives. Corrective actions are then taken to reduce the gaps between objectives and actual results. Complex systems may require several different feedback actions in order to be controlled. The system approach provides a comprehensive overview of production performance. In this paper the system under study is the production plant defined as an "enterprise." This is represented in Figure 1.

This system is comprised of two major parts: an inner quality loop and an outer management loop. The inner quality loop, shown in gray highlights, involves the main activities that are responsible for compliance with specifications and the creation of consumer satisfaction. The management loop is responsible for the operational performance of the enterprise. Here objectives and strategies must be well defined and supported by accurate data. Without such information effective planning and strategy formulation will be difficult. The external environment is beyond the control of the production system.

The control of the production process can be achieved with the use of powerful analytical tools such as statistical process control (SPC). SPC comprises an indispensable set of tools used to control deviations from established specifications in the production process. However, within the management loop traditional accounting tools are often the only performance measurements used. Standard accounting practices can overlook the critical role played by product and processes improvements and may lead managers to undertake actions that can actually worsen quality within the enterprise. Along with the initial implementation of tools such as SPC the quality loop can be strengthened

through the introduction of inspections designed to detect deviations from specifications and to identify production non-conformities. As deviations are reduced (through the use of SPC ) so will the need for inspections. At this stage many types of improvements at the plant level can be undertaken by managers.

Managers and workers can join together in an effort to improve the products and the production and the production process. As defects, rework, and waste are all reduced motivation and profitability will improve. At this point the implementation of product certification can be used to highlight the technical characteristics of the product. Additionally, ISO9000 can provide incentives for the continuous improvement of quality and consumer satisfaction by requiring managers to document a system of good production practices.

In the next stage it is necessary to build up the outer feedback loop ( management loop) which includes different types of instruments used to measure the state of the system. As mentioned, standard accounting methods only provide a narrow picture of enterprise performance. To improve the performance evaluation of the enterprise new instruments have to be defined and implemented. Operational and financial metrics must be complemented by those which measure consumer satisfaction.

The results of this performance evaluation shall be compared with the objectives of the enterprise (standards, specifications, consumer requirements, management goals and plans, etc.) to further refine strategic decisions. The basic assumption of the system approach presented in Figure 1 is that when objective measurements of performance are tied to profitability and customer satisfaction entrepreneurs will need no further proof of the importance of continuous improvement.

Each box in Figure 1 indicates commonly used tools and methods in the operation of the enterprise. Naturally, the number and the complexity of the components within production systems vary widely. The systems in many small and medium enterprises can be controlled using a few relatively simple improvement tools and methods. Large enterprises require a substantial amount of effort and resources to achieve and maintain control. Further, they must optimize their production time constant to maintain competitive lead times.

Control strategies will only be effective if measurements provide enough information to support appropriate actions. This means that the instruments used to measure the performance of the enterprise have to be quick and reliable.

Two basic instruments have been developed by UNIDO for this purpose: a short-medium term measurement reflecting the difference between planned and actual performance and a medium-long term measurements to present the accumulated performance.

These two instruments are implemented through software toolkits. The first one - BEST (Business Environment Strategic Toolkit) - is a set of user friendly software modules designed to both teach entrepreneurs production planning and to support strategic decisions. The main modules are the Operation Management Assistance, the Strategic Management Assistance, the Investment Assistance and the Product Monitoring Assistance. BEST is not a traditional accounting system -but a comprehensive operational tool for managers. Operating indicators are used to monitor performance, productivity and utilization of facilities.

The second instrument - FIT (Financial Improvement Toolkit) - is a management support tool to aid in operational and strategic decision making. A group of important indicators are calculated and their evolution over time is displayed. These indicators are used to strategically position the business and to point to potential operational problem areas. This tool can analyze an entire enterprise, or specific strategic business units (SBU - consist of well defined products or services which are targeted at specific market segments) within an enterprise.

These software tools can provide entrepreneurs invaluable insight into their enterprise's operational performance. The results are presented in graphical form comparing monthly planned versus actual performance.

#### **4. UNIDO's Programmes in QSM**

UNIDO's activities in the field of QSM started in the 1970's with an emphasis on standardization and metrology. Over a period of two decades projects have been implemented in all continents for the establishment of standardization bodies and national metrology laboratories. From 1989 to 1993, over 75 projects representing more than US\$ 40 million were implemented. Minor assistance has also been offered to assess national institutions in product certification.

In 1987, the ISO(International Organization for Standardization) issued the ISO9000 series which has become the most rapidly growing standard of all time. The rate of growth in applications for ISO9000 certification ensure that much quality improvement activity will center around this important standard through the end of the century. As mentioned, ISO9000 is not the same as a system of continuous improvement - but can serve as an important catalyst for generating

sustained increases in enterprise performance. UNIDO is currently designing new types of assistance aimed at promoting the ISO9000 along with TQM and continuous improvement. In this context the above mentioned approach is being developed and implemented with great success in Argentina, Bolivia, Brazil, Chile, Colombia, Cuba, Ecuador, Mexico, Peru and Venezuela under a regional programme for the modernization of the capital goods sector. Other potential areas for development are assistance to national standardization bodies - or NGO's for acquiring assessment capability for ISO9000 certification.

The reoriented programme of UNIDO in QSM also deals with certain specialized "core" products. UNIDO services can be provided for different levels outlined below on request from member-states, and subject to availability of funds.

#### Policy level

- Assist Governments in the establishment of quality, standardization and metrology policies
- Assist Governments in the establishment of ISO9000 certification bodies

#### Institutional level

- Assist metrology bodies in up-grading the existent reference standards and procedures
- Assist national organizations in the establishment of sectoral laboratories
- Build capacity to assist enterprises in the application of the broad range of quality tools using a systems approach for quality improvement

#### Enterprise level

- Establishment of specialized laboratories
- Assistance to implement the system approach for quality improvement

In the future the commitment of enterprise managers will be necessary to guarantee the ongoing success of UNIDO programmes in QSM. In the early stages of improvement managers will be faced with the rigid requirements imposed by ISO9000. At this point it is equally critical that the manager be convinced of the need to measure enterprise performance and begin a programme of continuous improvement. Therefore, the system approach represents an effective way to combine both robust technical assistance in QSM and pragmatic improvement efforts.

## UNIDO's Core Products

The system approach described above offers an objective way to measure system performance and can serve as an overall methodology which can promote linkages across various QSM projects in UNIDO. The approach was first applied in 1993 in the regional programme of capital goods sector in Latin America and Caribbean countries and is presently being initiated in a national execution project in Tunisia. Below are presented some proposed core products which increase UNIDO's participation and impact in the rapidly growing area of QSM.

### a) Beyond ISO9000 or UNIDO ISO9000\*\* approach

ISO9000 has now become necessary to help firms enter foreign markets. However, it is not sufficient to guarantee their sustained success. An ISO9000 Certificate does not guarantee a product's quality nor the capabilities of managers. To achieve sustainable market performance the enterprise must go beyond ISO9000 and implement a comprehensive system that will generate continuous improvements in quality, cost and flexibility. Increased quality is one by-product of an approach that stresses continual improvement at all the steps of the production process. The crucial issue determining competitive success is the ability of managers to create a production system that channels all the resources of the enterprises towards improving products and processes.

Companies seeking for the ISO9000 certification must be concerned with strategies that should go beyond it and include:

- Programmes for implementation of Total Quality Management Systems and continuous improvement of the overall production process from product design to customer delivery
- Implementation of user friendly and precise instruments for measuring the technical as well as the managerial performance of the enterprise.

Experience gathered through the implementation of a series of projects for promoting quality improvement and ISO9000 certification has provided the basis for the above mentioned approach. This approach does not limit itself to ISO9000 certification - but aims at creating a sustainable basis for the continuous improvement of process and product quality. In addition, this strategy aims to disseminate methods and instruments to managers that can provide valuable insight into the competitive strengths and weaknesses of their enterprises. While the limitations of ISO9000 are recognized, the heavy demand for certification represent a good reason for UNIDO to intensify the assistance

for developing countries for quality improvement services. This recently developed approach is currently being successfully used in over 90 enterprises in Latin America and the Caribbean.

The UNIDO ISO9000\*\* is based on the system approach described above and includes, among others components for strengthening continuous improvement capabilities, implementation of Total Quality Management in enterprises, application of Statistical Process Control, preparation for ISO9000 certification, ISO9000 diagnostic at plant level, assessment methodologies for product certification, continuous operational performance evaluation, computerized production and business performance evaluation, strengthening strategic planning and decision making capabilities.

UNIDO ISO9000\*\* service could support activities at three major levels:

- Institution Building: Building capacity at the level of national organizations(industry associations, R&D institutions, consulting companies, etc.) to be used for assisting enterprises in implementing quality systems, and management and control based on ISO9000;
- Groups of enterprises: Cost effective implementation of the procedures required for certification in ISO9000;
- Individual enterprises: in implementing total quality management programmes and practices for continuous improvement, assessing conditions for ISO9000 certification and implementing corrective actions

b) Assessment and support for the establishment of ISO9000 certification bodies

ISO9000 certification increasingly represents a commonly accepted "seal of approval" for a firm to act as a sub-contractor or to export to large parts of the world. A recent ISO publication (ISO- 9000 News, January 1994) indicates that out of the 45,000 total certificates issued through 1993 only 0.7 percent were issued in developing countries - for a total of 315 certificates.

It is likely that this figure represents only those certificates issued by the most important assessment bodies from developed countries to enterprises in developing countries. A critical point is that national assessment bodies in developing countries do not have the credibility to be accepted around the world. Without mutual recognition of assessment bodies, standards such as ISO9000 are likely to represent significant non-tariff barriers to trade in coming years

With these important developments in mind a new UNIDO product is under development to assist Governments in the establishment of national assessment for ISO9000 certification of local enterprises.

The product will be implemented at selected groups of enterprises seeking ISO9000 certification in the country and will comprise support to local authorities in the selection of the national assessment body, application of ISO9000 procedures to the selected group of enterprises to be initiated by international experts who will then prepare the national teams, establishment of all required procedures and paper work at the selected institution and search for cooperation with assessment bodies from developed countries for the purpose of mutual recognition.

### c) Centres for Productivity and Quality

Another effective approach is to establish permanent centres dedicated to training managers, technicians and workers in the application of various improvement practices such as statistical process control. These could be based at a university, technical institute, or industry association facility. UNIDO is currently assisting in the creation of such centres in Brazil and Hungary. They can be staffed by full or part-time faculty with plant-level experience in applied methods of quality control and continuous improvement. Training sessions and seminars should also include quality and improvement of professionals from multinational firms as well as their national counterparts. Government support is required in the start-up phase. However, these centres are ultimately expected to be self-financing (usually within three years) through funds obtained from trade and industry associations and chambers of commerce, as well as fees paid by individual firms.

A permanent institution avoids some of the pitfalls commonly encountered with other methods for training and application. First, they will generally be cheaper than consultants and their training more appropriate than offered by universities. Second, consulting firms that tend to specialize in a limited range of improvement techniques while the appropriate mix depends on the products and processes of the firm and will change over time. A permanent centre is better able to meet these varied and changing needs. Third, assistance from consultants is almost always limited in duration, although the transition from a beginning practitioner to a continuous improvement firm takes many years. Fourth, a permanent centre is better prepared to advise on many of the strategic issues of continuous improvement which are of a long-term character and link suppliers with their customers. Finally, these centres can afford to take a very practical

approach to improvement problems while universities (and sometimes consultants) emphasize theoretical aspects rather than applications.

#### **d) Rehabilitation of metrology laboratories**

**Metrology is the science of measurement with the principal goal of creating and maintaining the uniformity of measurements in any required human activity. Metrology consists of three main parts, in particular: scientific, industrial and legal metrology.**

**Scientific metrology deals with the development and maintenance of national primary, reference and working standards and traceability of units of physical quantities from standards to working instruments.**

**Industrial metrology deals with calibration and testing services to industry.**

**Legal metrology deals with legal and regulatory control in relation to units of measurements, methods of measurements and measuring instruments.**

**To implement its goal in the creation and maintenance of national and reference standards, as well as in providing traceability to industry, a metrology system or metrology tree is a national infrastructure which has been created in developed countries and should be established in developing countries. It starts from the national standards maintained by the national laboratories, continues with the national network of calibration laboratories, goes to the reference standards of industrial companies and testing laboratories. In this tree, some elements are essential:**

- the national metrology standards which comply with the SI units (international system)
- the national laboratories which maintain the National standards and disseminate the units
- the calibration laboratories.

**The objective of the Rehabilitation of metrology laboratories is to improve or create credible capacity at regional, national and sectoral levels to enable the national system to provide traceability in measurements at any level with confidence to domestic and foreign customers.**

**The objective of the assistance will be achieved through evaluation of existing structures and available facilities by a UNIDO's staff member/international**



expert, identification of the major changes to be taken by the national institutions to overcome discrepancies, and implementation of the required actions to achieve the objectives of the assistance through utilization of national/international expertise and of additional/new equipment.

#### **Special considerations**

The core products described above are usually considered necessary to support countries in improving the quality of their goods and increasing the potential of enterprises to compete with foreign products. The costs of UNIDO assistance would vary from case to case, depending on the UNIDO's services considered necessary. Core products like "Beyond ISO9000" or assessment for certification may be estimated at the rate of US\$ 3,000 TO US\$ 5,000 per enterprise per year, over a period of time, for groups comprising 20 enterprises. As far as funding is concerned the core products are specially suited for self financing by the enterprises and cost shared by specialized funding agencies or donor countries.

For additional information please contact:

**UNIDO-United Nations Industrial Development Organization  
Institutional Support and Enterprise Development Branch  
P.O. Box 300  
A-1400 Vienna, Austria  
Fax: 43-1-23-9934**

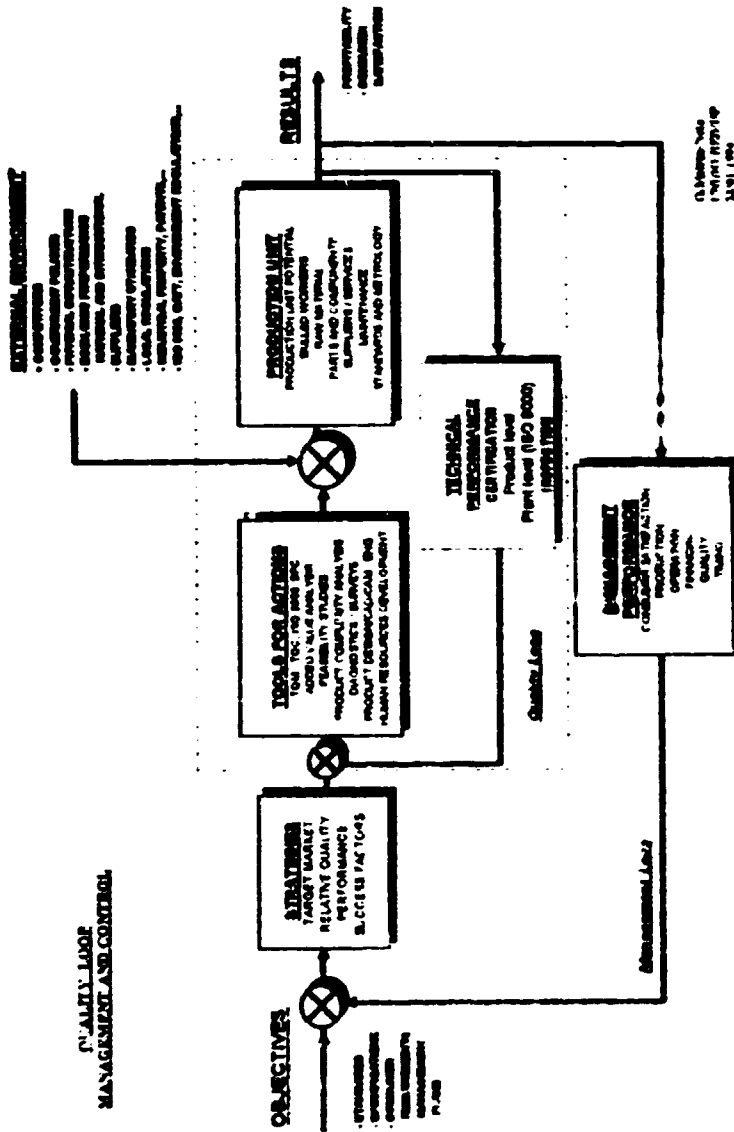


Figure 1 Graphic representation of the quality system approach

**EXTERNAL ENVIRONMENT**

- COMPETITORS
- GOVERNMENT POLICIES
- PHYSICAL INFRASTRUCTURE
- ECONOMIC PERFORMANCE
- NATIONAL AND INTERNATIONAL SUPPLIERS
- MANDATORY STANDARDS
- LOCAL REGULATIONS
- INDUSTRIAL PROPERTY, PATENTS, ...
- ISO 9000, GATT, ENVIRONMENT REGULATIONS, ...

**QUALITY LOOP  
MANAGEMENT AND CONTROL**

**OBJECTIVES**

- STANDARDS
- TARGETS
- REQUIREMENTS
- MANAGEMENT PLANS

**STRATEGIES**

- TARGET MARKET
- RELATIVE QUALITY
- PERFORMANCE
- SUCCESS FACTORS

**TOOLS FOR ACTIONS**

- TQM, TQC, ISO 9000, SPC
- ADDED VALUE ANALYSIS
- FEASIBILITY STUDIES
- PRODUCT COMPLEXITY ANALYSIS
- DIAGNOSTICS / SURVEYS
- PRODUCT DESIGN/CAD/CAM, BMS
- HUMAN RESOURCES DEVELOPMENT

**PRODUCTION UNIT**

- PRODUCTION UNIT POTENTIAL
- SKILLED WORKERS
- RAW MATERIAL
- PARTS AND COMPONENTS SUPPLIERS / SERVICES
- MAINTENANCE
- STANDARDS AND METROLOGY

**TECHNICAL PERFORMANCE CERTIFICATION**

- Product level
- Plant level (ISO 9000)
- INSPECTION

**MANAGEMENT PERFORMANCE**

- CONSUMER SATISFACTION
- PRODUCTION OPERATION
- FINANCIAL QUALITY
- TIMING

**RESULTS**

- PROFITABILITY
- CONSUMER SATISFACTION

*Quality Loop*

*Management Loop*

O. Nolasco-Nieto  
USIDO IIRI/ISF  
22/01/1994

# **THE INTERNATIONAL ORGANIZATION OF LEGAL METROLOGY (OIML)**

**B. Athané  
Director**

**International Bureau of Legal Metrology**

## **1. History**

The main dates of the OIML history are the following.

**1875:** Signature of the Convention du Mètre followed by the establishment of the Bureau International des Poids et Mesures

**1903-1920:** One of the goals of Convention du Mètre (to facilitate international trade through an harmonization of metrology practices) cannot be reached since BIPM restricts its activity to international measurement standards, whereas the solution of the problem would necessitate an harmonization of requirements to which measuring instruments are subjected. A proposal for establishing within BIPM a section dealing with practical and legal metrology is unsuccessful.

**1937:** First International Conference of Legal and Practical Metrology

**1939:** Second world war

**1950-1952:** Meetings of a provisional International Committee of Legal Metrology

**1955:** Signature of the Convention establishing an International Organization of Legal Metrology

**1956:** First International Conference of Legal Metrology

## **2. Legal Metrology And Its International Harmonization**

Legal metrology may be defined as the entirety of the legislative, administrative and technical procedures established by, or by reference to, public authorities and implemented on their behalf in order to specify and to ensure, in a regulatory or contractual manner, an appropriate quality and credibility of

measurements related to official controls, trade, health, safety, and environment. Legal metrology is applied in fields where conflicting interests may exist in measurement results, or where incorrect results may adversely affect individuals or the society.

Legal metrology may still differ from country to country by:

- the extent of its application. In certain countries, metrology regulations cover only a part of the applications in trade, health, safety, and environment whereas in certain other countries, a wider range of applications, such as standard instruments and instruments used in industrial processes, are covered by regulation.
- the nature of the national bodies responsible for legal metrology implementation. In certain countries, a national legal metrology service is responsible for only a limited part of the general application of legal metrology, for example: instruments used for retail trade, and there exist other national bodies responsible for implementing regulations that apply to measuring instruments in health, safety, and environment
- the nature of the requirements that may be, for example, either regulations or normative documents. The national bodies responsible for development of requirements may not be identical, may work in different ways, and may have different international liaisons
- the metrological content of the requirements. There are different degrees of implementation of OIML Recommendations in national regulations
- the application of the requirements. Identical requirements may be interpreted and implemented differently
- the degree of economic and technical development of countries, and the extent of resources made available for legal metrology.

This lack of harmony results in technical barriers to trade for measuring instruments in the first place, but also for all kinds of products and services the value of which is fixed on the basis of measurement, insofar as the measurements made by the exporting country and those made by the importing country are not coherent

The goal established by the GATT and other related regional agreements for a removal of trade barriers, particularly technical barriers to trade, makes it necessary to accelerate the harmonization of legal metrology requirements and of their implementation.

These is the main objective of OIML.

### **3. OIML Membership**

Because of its intergovernmental character, membership in OIML is restricted to nations that may join:

- as member states after having ratified the OIML Convention and accepted to actively support OIML, financially and technically
- as corresponding members for nations that are only interested in being kept informed of the result of OIML work

In addition to the this membership, OIML maintains liaisons with a number of international and regional bodies.

### **4. OIML Structures**

OIML includes the following main bodies:

#### **INTERNATIONAL CONFERENCE OF LEGAL METROLOGY**

54 member states  
40 corresponding members  
liaisons institutions  
meets every 4 years  
decides upon general policy, budget,  
formal sanction of International  
Recommendations

#### **INTERNATIONAL COMMITTEE OF LEGAL METROLOGY(CIML)**

54 CIML members (one for each Member  
state)  
meets every year  
monitors technical committees and BIML  
approves International Recommendations  
and Documents for immediate publication

**PRESIDENTIAL COUNCIL**

the President and the two Vice-Presidents of CIML plus CIML Members appointed by the President

**TECHNICAL COMMITTEES AND SUBCOMMITTEES**

responsible for developing draft Recommendations and Documents  
membership: experts from member states and liaison institutions  
TCs with a wide range of work include SCs for developing specific activities

**DEVELOPMENT COUNCIL**

makes proposals to CIML concerning specific activities aiming at assisting members in the development of their legal metrology resources (training, equipment, policy approach); coordination with other bodies (UNIDO, ISO, CIMET, APMP,...)  
For further information, see clause 11.

**INTERNATIONAL BUREAU OF LEGAL METROLOGY (BIML)**

permanent central secretariat of the Organization  
prepares meeting of Conference, CIML, Presidential Council, and Development Council; issues publications and bulletin; follow the work of TCs and SCs; ensures liaisons with international and regional bodies; organizes seminars; distributes publications; monitors certification activities; serves as central information center on OIML.

Staff: Director

Two Assistants Directors

One technical agent

One communications agent

One administrator

Two secretaries

Two documentation clerks

**OIML BUDGET**

1 500 000 US\$ per year (88% are contributions from member states and 12% from corresponding members, sale of

publications, interests on investments)  
60% of expenses are for staff costs  
(salaries, retirement, social security), 40%  
for operational costs

## **5. International Recommendations**

**OIML Recommendations** are model regulations specifying, for given categories of measuring instruments:

scope and application  
metrological performance requirements  
technical requirements (when applicable\*)  
testing procedures  
format for test report  
terminology

\* Note: technical requirements shall not impede progress

Recommendations are developed according to work methods very similar to those of other technical international bodies such as ISO/IEC.

Recommendations are developed in close cooperation with other international and regional bodies concerned: BIPM (units and primary measurement standards), ISO/IEC (technical standardization), specialized institutions (in chemistry, ionizing radiations,...), manufacturers associations, etc.

Recommendations, after their approval by CIML and publication, are formally sanctioned by the Conference and become then morally binding for member states; in addition, they are considered as "international standards" by the GATT Code of Standards.

## **6. Other Publications**

International Documents are developed by TCs/SCs following the same methods as for Recommendations, however, they are informative.

Other publications may be prepared by TCs/SCs or by BIML: vocabularies, guides, informative brochures, etc.

## **7. Communications**



OIML develops its communications tools with a view to reaching not only all those that have direct interest in legal metrology (legal metrology services, other metrology national bodies, calibration and testing laboratories, manufacturers and users of measuring instruments, consumers, etc), but also decision-makers whose actions may influence the developments of legal metrology at national, regional, and international levels.

The OIML Bulletin is a key component of the OIML communications policy.

## **8. General Policy and Strategy**

During the last three or four years, OIML has reflected upon its basic goals, and defined new strategies for a better adaptation of its activities to the present evolutions of our world. These thoughts are materialized in a three-part OIML policy paper. A general information brochure on OIML supplementing the OIML policy paper will be available soon.

## **9. External Liaisons**

Many international and regional institutions have activities directly or indirectly connected with legal metrology. Below are mentioned certain of such institutions. Cooperation between OIML and international and regional bodies specialized in assistance for development will be considered under item 11.

BIPM has already been mentioned and, in the field of measurement techniques and instrumentation, IMEKO plays a significant international role.

IUPAC, IUPAP, IFCC, AIEA, WHO, etc have scientific or technical activities that include metrology, in fields of chemistry, physics, medicine, ionizing radiations, including activities close to legal metrology (specification of metrological performances, testing procedures, etc.)

ISO/IEC have a standardization activity that includes measuring instruments.

There is therefore a need for OIML to maintain close contact with all these bodies for avoiding duplication of work, and in particular the existence of international publications from OIML and from other bodies (especially ISO/IEC) that would contradict each other.

Cooperation agreements have been established between OIML and other international and regional bodies whenever necessary.

Apart from these bodies specialized in fields more or less connected with legal metrology, there are regional bodies with direct responsibilities in legal metrology. Examples are, at the European level, the Commission of the European Communities which, in its regulatory activity, includes legal metrology, and WELMEC, which constitutes a very efficient forum for discussing legal metrology matters of European interest and coordinating the national implementation of EC Directives ( and the accompanying European Standards) as well as of OIML Recommendations. At the Asia-Pacific level, the recently established A.P.L.M.F. will conduct similar activities.

Regional cooperation is necessary between countries which are linked by geographical and/or societal considerations.

However, this cooperation shall not develop to the prejudice of international cooperation.

Regional bodies do not consider to be bound by the international agreements that their members may have individually signed. Also, a country whose views have not been accepted at international level may try to make them prevailing at regional level. Regional cooperation shall therefore accept to respect, in its development, the consensus already reached at international level.

In turn, international cooperation must consider the specific needs of regions, do its best for satisfying these needs, and accept that certain activities develop first at regional level, whenever necessary, before being adapted to the worldwide community.

## **10. The OIML Certificate System**

The OIML Certificate System was established in 1991 with a view to facilitating the activity of national legal metrology services in OIML Member Nations and promoting measuring instruments that comply with OIML requirements. The system applies to those categories of measuring instruments covered by OIML Recommendations that contain at least the following elements: metrological requirements, test procedures, and a format for the test report.

A Manufacturer of a measuring instrument of a category covered by the system may apply to an issuing authority for an OIML certificate in a participating Member State. Tests are performed according to the Recommendation in

laboratories appointed by the issuing authority, these laboratories must comply with ISO/IEC Guides 25 and 38.

A certificate and an associated test report are issued if the instrument's pattern is found to fully comply with all requirements. Fees for testing and establishing the test report are perceived according to national practices.

Before being valid, the certificate must be registered by BIML which is responsible for sending copies to all OIML members and publishing appropriate information in the OIML Bulletin.

The certificate and associated test report may then be used by the manufacturer as evidence of the conformity of its instrument's pattern with OIML requirements.

Although this system is voluntary, OIML Member Nations are encouraged to take full advantage of it to avoid unnecessary duplication in national pattern evaluation. The system applies to patterns of instruments, not to the individual instruments manufactured according to the patterns. Possible future developments could include formal mutual recognition of certificates among OIML Member Nations as well as the application of certificates of conformity to individual instruments.

At present, the OIML Certificate System applies to nonautomatic weighing instruments, load cells, barometers, high precision line measures of length, and certain chromatographs used for measuring pollution. However, up to now, only nonautomatic weighing instruments and load cells have been the subject of OIML certificates.

The number of issued certificates is promisingly increasing: 1 in 1992, 25 in 1993, and about 50 in 1994.

The OIML certification will soon apply to pressure balances, then to gasoline pumps, automatic discontinuous totalizing weighing instruments, gas meters, direct mass measuring systems for quantities of liquids, spectrometers for metal pollutants in water, sound calibrators, and clinical electrical thermometers, as soon as the relevant publications are issued.

Periodically, BIML conducts inquiry to know the degree of acceptance of OIML certificates by the metrology services of our members. We will also soon conduct an inquiry among manufacturers of measuring instruments that have

applied for certificate, in order to know whether they have been able to draw advantages from their certificates.

## **11. OIML Activities in The Field of Development**

Metrology is an essential element of our every-day life and permits a sound development of many human activities in fields such as science, technology, industry, energy production and distribution, medicine, environmental control, and trade. Therefore, it is a vital factor of economic development.

In developing countries, the establishment of appropriate metrology infrastructures should accompany the general economic and technological development, so that tools may be available for a sound founding of all activities that need metrological support.

A crucial factor of development is external trade. Developing countries must be able to assess the value of the products they export and import, from the double point of view of quantity and of quality. This applies, for example, to the mass or volume of ores or of crude oil that a country produces and exports, including the physical characteristics of such products. For developing countries the economy of which is based on agriculture, the same concern exists with the quantity and quality (e.g. sugar or fat contents) of the production. Metrological tools must exist and their proper usage must be monitored by the national authorities responsible for the economic development.

For countries that have already developed manufacturing, chemical, or textile industry, quality control systems must exist and should be recognized by other countries. This will not be possible without a proper national metrology infrastructure, which is not necessarily as developed as in industrialized countries, but which nevertheless must be coherent with those of other countries.

Because of a general lack of human, material, and financial resources, developing countries may find it appropriate to adopt an integrated approach of metrology and of other related activities such as standardization and quality control. This offers the possibility of saving money by a better usage of available resources. However, such an integrated approach should not be detrimental to metrology, which must keep its place as an independent discipline, and must not be considered as a sub-product of standardization. It must be kept in mind that a bad metrology will automatically conclude in bad standardization and bad quality control.

**Now, what may the place of legal metrology in a developing country?**

**I have already mentioned the necessity of developing metrological tools for ensuring a fair external trade, and this is a typical legal metrology responsibility.**

**Concerning trade at the level of individual persons, fairness could be considered of low importance compared with other factors of development, at least at the very first stages of development; this is perhaps true from a purely economic point of view but must be attenuated by considering other factors, such as psychological factors. A simple but efficient system, using both very simple metrology resources and police action on the market place, may introduce a reasonably good consumer protection and simultaneously will permit consumers to realize that their interests are protected.**

**With the economic progress, legal metrology must develop and increase its efficiency. When consumers are correctly protected against unfair trade, there remain more money available for other purchases, and it must be kept in mind that development of internal trade is a key factor of general economic development.**

**The other aspects of legal metrology must not be overlooked, especially in the field of medicine and safety.**

**In fact, legal metrology is a part of the metrology infrastructure that covers matter such as industrial development and quality control. Its progress must be parallel with the progress of other national factors.**

**OIML has a special activity for addressing problems of development. The OIML Development Council comprises a number of representatives from both developing and developed OIML Members States and observers from international and regional bodies.**

**The Council specifies actions that are conducted after having been endorsed by CIML. Such actions may cover, e.g. preparation of brochures, organization of seminars, inquiries, establishment of liaisons between developing and developed countries, etc.**

**A special budget voted by the OIML Conference permits the financing of the participation of legal metrology officials from OIML developing Member States in certain OIML activities.**

However, OIML shall not take the place of UNO agencies and other international or regional bodies that are specialized in assisting developing countries. For example, OIML does not organizes expert missions in the field of legal metrology; this is the responsibility of, for example, UNIDO; but whenever UNIDO is searching an expert in the field of metrology, OIML may advise UNIDO concerning availability of appropriate metrology experts in OIML Member States.

Therefore, OIML maintains close links with UNESCO, UNIDO, International Trade Center, and regional bodies such as Commonwealth Science Council and Asia-Pacific Metrology Programme

# **RELEVANCE OF INTERNATIONAL STANDARDS FOR BUSINESS ACTIVITIES AND THE ISO9000 PHENOMENON**

**Dr. Christian J. Favre  
Deputy Secretary-General of ISO**

## **Trends and Development in International Standardization**

### **1.1 Setting the Scene of International Standardization**

There is much evidence that sophisticated standards were already intensively used by ancient civilisations, as can easily be noted from looking at very ancient buildings, pottery or coins of this country.

National standardization has its roots in ancient history, but international standardization is a relatively new phenomenon which began approximately 100 years ago. The International Organization for Standardization is comparatively a newcomer. ISO began operating less than half a century ago, in 1947. Given the accelerating pace of change in the world, ISO's 47 years of activity can be considered a relatively long period of time as many new things have emerged during this period.

In 1947, ISO began with just 27 member countries, the majority of them European. among them were countries like United Kingdom, France and Germany, whose national standards then enjoyed a strong measure of international acceptance because of factors such as their presence around the world, early industrialization and the high reputation of their engineering products.

Despite the position of strength of countries like these, their national standards were obviously not applied everywhere. The attractiveness of International Standards was clear to them. International standardization of such basic requirements for doing business as common engineering terminology and dimensions, meant that suppliers and potential customers would be speaking the same *technological* language anywhere in the world.

Such countries were also involved in international standardization from the start, because of a healthy measure of enlightened self-interest, which is the principal motivation for participating in ISO's work. They were out to influence the International Standards being developed in the direction of the standards used by their own industries. This would reduce the need to modify products for different export markets. Today, this is still one of the major reasons why any country has an interest in participating in the development of International Standards.

But these industrial heavyweight countries, to which Japan, the former USSR and the USA should be added, do not have ISO all to themselves. Some of the most active members come from smaller scale economies having a major interest in adopting International Standards rather than the national standards of an industrialized heavyweight country, thus avoiding permanent dependence on another country's standards. Indeed, a country that uses the standards of another country cannot influence the development and content of the standards they use.

For countries with smaller economies, commitment to international standardization has had, still has and will continue to have two advantages:

- first, by direct use of International Standards, their industries are increasingly free to compete on many more markets worldwide,
- second, their industries have an equal footing in the development of those International Standards (remember that standards are developed by consensus, so developing economies can also make their voices heard.)

Considerations such as these were true when ISO was founded and they are still true today. They also explain the recent reorganization of the ISO governance structure to increase participation of countries with smaller economies in the decision-making process of ISO and to make it closer to the businesslike organization which the ISO stakeholders in industry and government expect us to be.

ISO started out with 27 member countries, mainly European. Today, ISO is a truly worldwide federation of standards bodies from 100 countries. It is significant that in recent years, the new republics emerging from the break-up of the former USSR have been keen to stake their claim to a place in the market by joining ISO.

The numbers have also been swelled by the developing countries of Asia, Africa and South America. International Standards allow such countries to make meaningful comparisons between goods offered by vendors from different



countries. International standards also provide a repository of technical knowledge to aid in technology transfer and the development of local industry. In addition, International Standards specify technical criteria that will be used by potential export customers to evaluate goods from the developing countries and so help the latter in making the right choices in utilizing their scarce resources.

## **1.2 What Is ISO, How Does It Work?**

As mentioned, ISO is an international organization whose members are the national standards bodies of some 100 countries (one member from each country, the member body for China is the China State Bureau of Technical Supervision[CSBTS]). ISO is closely associated with the International Electrotechnical Commission (IEC) China's participation in IEC is also supervised by CSBTS. ISO and IEC operate as a single system and service to facilitate the development of global consensus agreements on International Standards. ISO and IEC are non-governmental organizations, and their standards are voluntary in nature, which means that they have to be good enough for industry and service organizations to find them advantageous and to apply them. ISO and IEC are not part of the United Nations, but have many technical liaisons with the UN specialized agencies. The ISO/IEC international standardization process operates approximately 1000 specialized technical committees and subcommittees of national delegations from member countries and 3000 working groups of technical experts. The work of these committees results in the publication of approximately 1000 new and revised International Standards every year.

The standards range from basic engineering such as fasteners and bearings, from raw materials of all types to intermediate and finished industrial products, and to broad areas of activity such as information, transport, agriculture, health and environment. Each technical body has its own programme of work for different standardization projects(test methods, terminology, specifications, performance requirements, etc).

The primary function of ISO is to provide a mechanism through which people work together when they need international agreements. Structures and rules of operation are contained in a basic organizational document: the ISO/IEC Directives for the technical work of the organization. The technical structure in ISO is built around the 800 specialized ISO technical committees and subcommittees which are managed by a chairman, with a secretariat assigned to one of the ISO members(approximately 30 countries hold secretariats at the present time). The secretariat of each committee is in direct contact with the

**administrative structure based at the ISO Central Secretariat in Geneva(Switzerland)**

**This astonishing decentralized mechanism has been able to produce 9200 ISO technical agreements such as the ISO metric screw, the ISO paper size(A4), the ISO series on freight containers(more than 95% of maritime freight containers used in worldwide transport conform to ISO standards), the ISO film speed code, the Open System Interconnection (OSI) series of standards in the field of information technology and the famous ISO9000 series on Quality Management**

**In addition, ISO is in liaison with some 450 international and regional organizations having an interest in standardization (and has especially close ties with the International Telecommunications Union [ITU]).**

### **1.3 Development Prospects For International Standardization**

**International standardization at the world level is already well established for many technologies and it will continue to become increasingly dominant for all sectors of industrial activity in the longer term future.**

**The primary reasons are that global standardization will be:**

- **the inevitable consequence of worldwide progress in trade liberalization (according to GATT statistics, international trade is growing at double the rate of growth of production);**
- **a practical necessity for future development of viable worldwide communications systems;**
- **a necessary (if not sufficient) condition to achieve environmentally sustainable industrial development on a worldwide scale;**
- **an important stability influence for economies undergoing transitions or partial adjustment to market-oriented economies;**
- **a continuing process of technological interchange fostering technology transfer.**

**These propositions are not just the hopes of the ISO Secretary-General, they are being verified on a daily basis and supported by the industries of the world. Indeed, the costs of international standardization work are borne primarily by the industries of the world, because they pay nearly all the costs of their participating experts which run easily into the hundreds of millions of US dollars every year.**

This money is spent because the use of International Standards is seen to be even more beneficial than the costs, otherwise no one would be interested. These benefits are generally for market success and produces better economic returns for individual businesses, countries and regions. Standardization is understood to provide essential lubrication for trade and commerce; its main contributions are improvements in :

- avoidance of technical barriers to trade;
- quality and reliability of goods and services at reasonable price and steady supply;
- user satisfaction and safety;
- compatibility and interoperability of interacting goods and services;
- simplification for user convenience;
- environmental protection;
- production efficiency.

The growth in interest in international standardization is illustrated by the growth in production of International Standards over the past few years. From 1984 to 1994 the yearly output of technical pages of ISO standards has grown by approximately 150%, i.e.15% per year. During that same period the number of ISO standards has increased from about 5000 to 9200. Much of this increase in output is the result of increased work in newer technologies, and particularly in the information technology area. At present, ISO's work in Information Technology(IT) accounts for about 30% of the total. This work is undertaken jointly with the IEC in a committee that is very well known in the industry, i.e. ISO/IEC JTC 1.

The series of ISO standards 9000, 9001, 9002, 9003 and 9004, published in 1987, became a phenomenal success on which I will now focus my attention.

## **2. The ISO9000 Phenomenon**

### **2.1 The Beginning**

From the beginning, in 1979, when the member of ISO and IEC for the United Kingdom, the British Standards Institution(BSI), submitted its proposal that ISO prepare International Standards relating to quality assurance techniques and practices, it was recognized that these standards may be significantly different from what might be called *normal* standards such as those for test methods, terminology, units of measurement, product specifications, etc. It was definitely something special. The idea that certain generic characteristics of management practice could be usefully standardized, giving mutual benefit to producers and

users alike, that they would be developed into what is known by now as the ISO-9000 series was not accepted without challenge. Opinions differed widely and, to some extent, still do.

The BSI proposal to establish an ISO technical committee to prepare International Standards relating to quality assurance was accepted in 1979. The technical committee was given the chronological number ISO/TC 176, the title *Quality Assurance, a scope*, and Canada undertook the secretariat.

Twenty member countries decided to become active participants in the work of this new committee when it was set up and another 14 countries opted to follow the work as observers. Today, the number of countries actively participating in ISO/TC 176 is 51 P-members and 16 O-members.

The new ISO/TC 176, which had to develop generic quality management standards for worldwide application, could count on a substantial base of national experience in the UK and Canada. In the UK, the BS 5750 standards were well on their way to broad acceptance and in Canada a series of national standards known as CAS Z299 were also widely used. Naturally, there were some differences in the approaches taken in the UK and Canada, and also a recognition on both sides of the Atlantic that both sets of standards could be improved. Other countries with well-developed quality management practices such as Japan with its TQC concepts were also starting to take a keen interest, so the programme of ISO/TC 176 quickly became a substantial work effort. It was clear from the beginning that the International Standards produced by TC 176 would need to have national equivalents, not only in the UK and Canada but also in many other countries. In this sense one could say that BS 5750 and CSA Z299 were the mother and father of the ISO9000 standards, but only if it is understood that the offspring has now become the parent nourished by the 51 participating members of ISO/TC 176.

To complete this short historical review. I should state that the first editions of the ISO9000 standards (9000 to 9004) were completed in 1986 and published in the early part of 1987. Up to this point, one could have said that the existence of the ISO9000 standards was not a very unusual kind of international standardization event. A new committee had been formed, it had taken about seven years to produce its first major set of standards, and we would wait and see how well these standards came to be accepted.

## **2.2 The Phenomenon**

We did not have to wait very long, because it soon became apparent that the ISO 9000 standards would enjoy the most widespread recognition in industry, the most rapid adoption by the International Standards community, and the greatest sales of any ISO standard in existence.

Opinions differed widely in 1987, and differ even to some extent today, as to how far the concept could be carried. Nevertheless, we cannot ignore what has happened since the ISO9000 standards became available. Let us look at some of the highlights.

- The ISO9000 standards have been directly adopted, without change, as national standards in at least 70 countries. This includes all of the EU and EFTA countries, Japan and the USA.
- Third party assessment and registration services exist for recognizing conformance to ISO9000 standards in at least 50 countries. The number of companies on the waiting list to be registered is so long in some countries that the delay for assessment service is running into months.
- The ISO9000 standards have been cited as a basic building block for the development and operation of the European Organization for Testing and Certification (EOTC). In certain fields, such as medical devices, EU legislation may refer to ISO9000 registration by suppliers for specific fields. Whether it is true or not, many companies have come to the conclusion that registration to ISO9000 is an advantage for doing business in the newly forming integrated market of Europe.
- Many nationally and internationally recognized product certification systems (for example the BSI Kitemark in the UK, and the JIS mark in Japan) have incorporated the ISO9000 standards as a first-phase requirement for approval to use their mark in specific product certification schemes.
- Very many large industrial companies, particularly those with operations in many countries, have initiated vigorous company programmes to implement the ISO9000 standards at their operation sites. The list we know about includes major multi-national companies
- Numerous large governmental purchasers, including the Ministries of Defence in the UK and Singapore, and the Department of the Navy in the USA, have made ISO9000 registration(or its equivalent) a requirement for their large contract suppliers.
- This list could go on, but I think it unnecessary to illustrate further that the ISO9000 standards have had a major worldwide impact. The interesting questions are Why?, Why now? and What come next? Let us begin with the :

## **2.3 Why Now?**

The general trend described in the introduction of the ISO 9000 series gives us a hint. It states:

"There is a worldwide trend towards more stringent customer expectations with regard to quality. Accompanying this trend has been a growing realization that continual improvements in quality are often necessary to achieve and sustain good economic performance"

The ISO 9000 standards, like all other standards, are simply tools to be used to achieve an objective, or a set of objectives. In this case, the broad objective is total quality improvement; it is being actively pursued at all levels in today's society. Businesses in every sector of private enterprise have shifted their emphasis to the quality side of the quality/price equation because they believe that doing so is absolutely necessary to remain competitive in today's global markets. Many political leaders and their governments have initiated and implemented National Quality Policies intended to stimulate the competitiveness and economic vitality of their nation's productive capacity. Even in non-competitive sectors such as government administrations, the push for quality and client satisfaction is at an all-time high.

Let us come now to the next W question:

## **2.4 Why?**

This audience does not need much explanation in answering the Why questions. Nevertheless, a few graphics will make sure the point is understood.

First, remember that quality means satisfaction of the customer and success of the supplier.

We know very well that dissatisfied customers means trouble for the company. A study conducted in the United Kingdom determined that one dissatisfied customer tells 9 other people about his dissatisfaction. (Graphics 1&2) The same British study shows that 13% of dissatisfied customers tell 20 other people about their dissatisfaction. It must be understood that ISO 9001, 2 or 3 should not be used as a checklist to obtain a certificate but rather to achieve quality.

**(Graphic 3)**

On top of that it costs five times as much to create new customers than to retain an established customer...better make sure the quality of delivered products or services matches the expectations of the customer.

## **2.5 The ISO9000 Series**

The documents prepared by ISO/TC 176 mirror the current state of the art on which Total Quality Management can be built. As pointed out in the introductory remarks of the ISO9000 standard, it is not a set of generally-binding specifications, it is not a description of some set of natural laws. It is the best possible summary of empirically determined knowledge of many users in large and medium size companies.

The standard ISO9000 provides the introduction to the whole concept.

The standard ISO9004 gives a comprehensive description of all known quality system elements, their purpose, and presents the organizational structure in detail. This standard is definitely the document to be read and reread by those wanting to introduce a total quality programme within their company.

The standards ISO9001, 9002 and 9003 have been prepared with the view to serving as models for contractual agreements between customers and manufacturers or suppliers in general. They can be expanded or restricted by supplementary agreements as needed in the specific cases.

Those having developed a quality system in accordance with ISO9004 will, in principle, find no difficulty in using 9001, 2 and 3 in their contractual relationship.

It is however obvious that the ISO9000 series of standards relies heavily on the practical use of other International Standards, some prepared by ISO/TC 176 as far as terminology is concerned (ISO8402) and guidelines for auditing quality systems (ISO 10011 series) and others like some of those prepared by IEC/TC 56 Dependability concerning reliability and maintainability or ISO/TC 69 Application of statistical methods.

## **2.6 1994: First Revision of The ISO9000 Series of Standards**

A first revision of the ISO9000 series of standards (9000, 9001, 9002, 9003, and 9004) was published on 1 July 1994.

The revised standards are the result of more than four years of international consensusbuilding, in which all countries participating in ISO/TC 176 Quality management and quality assurance have had multiple opportunities to propose changes, to comment and to vote on them.

### **3. Toward an ISO14000 Phenomenon**

During the last five years, it has become clear that industry in general is requesting the standardization system at international, regional and national level to develop the tools needed in order to effectively meet the challenge of developing its production of goods and services, without putting an excessive load on the environment. The role of ISO in this respect was formally welcomed and recognized at the Earth summit in Rio de Janeiro, the United Nations Conference for Environment and Development (UNCED) in 1992.

The recommendations of the ISO/IEC Strategy Group for Environment (SAGE) to develop, as fast as possible, a set of standards recommending the best possible practices for organizing Environmental management were welcomed by UNCED and ISO. According to ISO practice, explained at the beginning of this address, ISO established early in 1993 an ISO technical committee ISO/TC 207 Environmental management which is preparing a series of standards registered under the ISO serial number 14000 and which look like receiving in the future similar attention to that the ISO 9000 series attracted in recent years.

The main fields of work of ISO/TC 207 are:

- Environmental management systems(projects 14000, 14001, 14002);
- Environmental auditing and related environmental investigations (projects 14011, 14012...);
- Environmental labelling,
- Environmental performance evaluation;
- Life cycle assessment;
- Terms and definitions.

Experience gained in developing Quality management standards is being used to develop Environmental management standards which must be compatible and harmonized with the ISO9000 series to allow the conduct of a unique audit covering both Quality and Environmental management.

### **4. Assessment of Supplier's Quality System**



The success of the ISO9000 series, originally developed for use mainly as a tool for buyers (second party) recognition of conformity to an ISO9000 quality system, led thousands of companies worldwide to go a step further and request auditing and registration (or certification) by an external quality system registrar as conforming to ISO9001, 2 or 3 standards (third party certification).

The certificate of conformity to ISO9001, 2 or 3 is allocated by a certification/registration body at the national level. In many countries certification registration bodies are accredited by a governmental organization or by a nationally recognized association.

The big question for an exporter having received an ISO900X certificate in his country of origin is: Will this certificate be recognized by my customers in other countries, which is not always the case if the certification body is not well known in the country of the buyer.

To overcome this problem, ISO and IEC were requested to develop a proposal for an international system to encourage worldwide recognition of the ISO9000 certificate: an ISO/IEC Quality System Assessment Recognition (QSAR).

A proposal was submitted to the ISO Council which decided, in January 1995, to take steps to establish such a system with the cooperation of IEC, which, according to the proposal of the QSAR ad hoc preparatory group, should have the following characteristics:

- The system of international recognition should focus on the assessment of Quality systems, but keeping in mind that it could one day be extended to certification in general, including possibly laboratory certification, product certification and eventually environmental assessment;
- QSAR should develop a system for recognition of specific competence and to ensure impartiality of certification bodies;
- QSAR must be a simple efficient system with a minimum of bureaucracy and documentation;
- QSAR must be open to all quality system assessment bodies (from all trading regions);
- QSAR has to foresee some means to help developing country assessment bodies improve their capabilities. (Some sort of monitoring system was suggested).

The following primary performance objective of the international system has been agreed:

**When a supplier is registered by a qualified (QSAR) certification/registration body in the ISO/IEC QSAR system, that registration should be recognized as valid by his customers, regardless of the location of the registration body, the supplier or the customer.**

**From the ISO/IEC perspective, QSAR must be a semi-autonomous subsidiary of ISO and IEC due to two fundamental considerations:**

- members of the QSAR system will be authorized to use an ISO/IEC QSAR logo specially designed and registered for the ISO/IEC QSAR purpose;
- QSAR system will be based exclusively on ISO/IEC documents coming either from ISO or IEC technical committees or the ISO Committee on conformity assessment. (Copyright and text exploitation policies have to be respected).

**Full autonomy of QSAR will be assured concerning:**

- Autonomy of the peer review decision process
- Financial autonomy vis-a-vis other ISO and IEC programmes.

**It should be noted that the actual establishment of the above international recognition system depends on the will of ISO and IEC members who stand to benefit largely from such a system.**

## **5. Conclusion**

**Yes, a certificate of conformity to an ISO9000 standard may well be on the way to becoming a market requirement for doing business, especially on export markets when the exporting company is a long way from its market. But an ISO-9000 certificate on the office wall of the managing director is like the glow on the skin of a healthy person. To enjoy the external signs of good health, our body's internal system needs to have been getting wholesome food, fresh air and exercise for some time.**

**An ISO9000 certificate is an external assurance that the company's internal quality system is functioning well. It is suggested that obtaining a certificate is secondary to achieving the internal benefits, for the organization, that result from implementing an effective quality management system.**

**ISO9000 is a distillation of the best management practices, as proven in use by some of the most successful companies around the world, and the revision**

**process ensures that the latest finding and improvements are integrated into the document.**

# **ROLE OF INTERNATIONAL STANDARDIZATION IN PROMOTING INDUSTRY AND TRADE IN DEVELOPING COUNTRIES**

**Dr. Anwar El-Tawil  
Director  
ISO Programme for Developing Countries**

## **1. Concept And Evolution of Standardization**

Standardization is the activity of establishing ... provisions for common and repeated use, aimed at the achievement of the optimum degree of order...

The standardization activity usually culminates in the publication of standards. Standards are documents established by consensus and approved by a recognized body that provide, for common and repeated use, rules, guidelines or characteristics for activities or their results aimed at the achievement of the optimum degree of order...

The early beginnings of standardization can be traced to the ancient civilizations, where measurement standards were established by the highest authority in the land and disseminated by a system of periodic calibrations. Artefacts of standards of mass and length and their accessories have been found in the civilizations of Egypt, the Indus Valley, Mesopotamia and China. The early systems of units of measurement developed in close relationship with numbers and arithmetic. In most of these civilizations, dimensional standardization was applied to building construction and to related design such as carriage wheel base and the width of roads and city gates.

Standards for weights and measures, vital for trade, continued to be of importance through all historical periods. However, the advent of the industrial revolution raised standards to a new, higher level.

Mass production became possible through standardization. In addition to standardized dimensions interchangeability also requires accurate measurements based on a recognized system of units. The metric system of units which was first developed in France in 1793 became the first system to be standardized internationally when the Metre Convention was signed by 18 states in 1875.

By the turn of the century, standardization was already recognized in industrialized countries as powerful tool to increase productivity through interchangeability and reduction of variety.

During World War I, the drive to increase productivity and conserve materials and production equipment which were then in short supply brought about further application of standardization principles. The War Industries Board in the US enforced a programme of variety reduction and standardization that achieved spectacular results.

It is not, therefore, surprising that the war years saw increased attention being given to standardization and that the decade following World War I saw the founding of national standards bodies in most industrialized countries of the time.

The first formal standards body was the Engineering Standards Committee established in the UK in 1901. It was followed by Germany in 1917 and the USA in 1918. By 1928 national standards bodies were established in 16 industrialized countries.

Developing countries started to establish their national standards bodies just before, during and after World War II. Argentina (1935), Brazil (1940), Mexico (1943) and Chile (1944) were the first to establish their national standards bodies. They were followed after the War by China, India and the Philippines (in 1947) then by North Korea (in 1949). Other developing countries following and the list is still growing

## **2. Benefits of Sandardization**

The advantages that can be achieved through the establishment and application of standards are numerous and have been widely discussed and publicized. They can be summarized as follows.

- 1) Well-prepared standards represent optimum economic solutions to repetitive technical problems in the design, manufacture, packaging, transportation and delivery of goods.
- 2) Standards protect health, safety, property and the environment against hazards due to the production, use and disposal of products. They provide rules for the prevention and fighting of fire and explosion and for controlling chemical, radiation and other hazards

- 3) **The application of standards can ensure interchangeability, interoperability and compatibility of products and services within one industry and between industries.**
- 4) **Standards can reduce variety to its optimum level, thus leading to overall savings in design, production, handling, storing, ordering and use of goods and services.**
- 5) **Standards can provide a solid basis for the assessment of quality of products and services. Their application facilitates the contracting and ordering of goods and services and the assessment of their quality, and reduce disputes over specifications and quality.**
- 6) **Standards on quality management and quality assurance (ISO 9000 standards and their national equivalents) provide a universal guide on how best to establish and assess quality management system. Their widespread application enables suppliers to improve the quality of products and services, and buyers to have confidence in their ability to supply goods of consistent quality.**
- 7) **Standards facilitate communication in most fields of human activity.**

**In a free market economy, the use of the large majority of standards at industrial and national levels is voluntary, though application of some standards may be made compulsory by reference in legislation or administrative rules. In spite of the voluntary character of those standards, they are generally observed by the majority of companies thanks to the method of their preparation, which is based on the widest possible participation of all interests concerned to achieve true consensus. Manufacturers in a competitive market apply standards in the economic advantages they perceive in their application and because they are demanded by their customers. Companies that do not apply generally standards risk becoming isolated and losing their share of the market.**

**One feature of voluntary standardization in developed countries is that more and more product standards specify performance criteria and methods of measuring performance and avoid mentioning types of materials and manufacturing methods, in order not to impede innovation.**

**Although use of the majority of standards in free market economy is voluntary and the customer is free to choose which goods to buy based on his assessment**

of quality, price and availability, there are cases where the application of standards is made compulsory by the government through its regulatory bodies to protect individual consumers who have no means of assessing certain hazards related to the use of products or to protect the environment and other national and global resources. Examples of such compulsory standards can be found in the areas of foods and drugs, fire prevention and fighting, building materials and construction, toys, safety of machinery, electric appliances, gas appliances, protection of the environment and others.

Although regulatory bodies can use other texts as a basis for regulation, they prefer in an increasing number of cases to use standards for this purpose. On one hand, this reinforces the voluntary use of standards and gives them additional weight. On the other hand, it increases the responsibility of standardizers and ensures active participation of industries in the standardization process.

### **3. Role of International Standardization In Promoting Industry And Trade In Developing Countries**

It is clear that developing countries, that have adopted open trade policies and wish to orient their industries towards export, should align their standards with International Standards which represent the state of the art in different fields of the technology and were established by consensus between nations.

Active participation by developing countries in international standardization work would ensure numerous benefits for them. The most significant of these benefits are grouped under the following four headings.

#### **3.1 Receiving Technical Information Through International And Foreign Standards**

Standards express the state of the art as achieved through technological innovation and research and proven and accepted in practice. Developing countries can use up-to-date information on International Standards and foreign national standards (especially those of advanced industrial countries) for the following purposes:

– As a basis for establishing national standards for products and services. In this way the time and money needed to carry out research for the elaboration of national standards can be reduced considerably and the national standards community will be assured of adopting standards up to the highest technological

level known at the time. It will also be assured that the solutions it is adopting have received international recognition and that local industries can build their future development on a solid basis that ensures compatibility with other countries and remains valid for a relatively long time.

– As a basis for decisions by manufacturers and exporters concerning the quality level of their products, their safety and freedom of health and environmental hazards and their appropriate packaging and labelling. In this way exporters and manufacturers producing for export will have a better chance of reaching export markets and a lesser risk of seeing their goods rejected on the basis of non-conformity to standards and regulations of export countries and/or inappropriate quality level, packaging or labelling.

– As a basis for regulation to protect the consumer and the environment from hazards related to products. Such regulation is usually based on national standards which should be properly linked to international standards. However, in some cases it may be based directly on International or foreign national standards as an interim measure (namely, when national standards do not exist yet).

– As a basis for decisions to establish new industries and/or to buy new equipment for manufacturing, testing or packaging. In all these cases industrial developers should use standards information put at their disposal by the national standards information service to weigh carefully the pros and cons of buying a given type of equipment with a view to avoiding outdated and/or hazardous technology, ensuring compatibility at the national/international levels, and ensuring quality levels acceptable locally and internationally.

### **3.2 Possibility of Influencing International Standardization**

Standards are increasingly becoming the basis for trade exchange and for legislation for the protection of consumers and the environment. Although International Standards have a fully voluntary nature, they are increasingly adopted as national standards and as such are often taken by national legislators and regulating agencies as a basis for regulation intended to protect the consumer and the environment. It should not be forgotten that the GATT agreement on Technical Barriers to Trade ( GATT Standards Code) stipulates (in Article 2, clause 2.2) that " Where technical regulations or standards are required and relevant International Standards exist or their completion is imminent, Parties shall use them or the relevant part of them as a basis for the technical regulation or standard".



**A difficult situation may arise for developing countries, if International Standards are adopted that cannot be applied by their industries for any reason. Possible reasons for non-applicability may be: absence of the required materials, production or test equipment or simply adoption of solutions completely at odds with the existing practices in the country. In this case, a developing country may find itself shut out of its traditional markets due to standards.**

**Consequently, developing countries should follow attentively the preparation of new International Standards and, where necessary, intervene through the proper ISO channels to avoid that future International Standards create barriers to the exports of developing countries in the given field. There will be cases where proposed stipulations in International Standards are dictated by real technical and economic progress. In those cases developing countries will have to accept them. But, at least, they will be prepared in good time to undertake the necessary changes in their own industries to conform with the new Standards. In other cases, proposed stipulations may not be dictated by technical progress but simply reflect existing practices in certain countries. In those cases developing countries should actively voice their point of view and explain and defend their own practices in meetings of ISO technical committees until a solution acceptable to all parties is achieved through consensus.**

**In this way developing countries have the possibility through participation in international standardization work to safeguard their vital economic interests.**

### **3.3 Enhancing Export Capability And Global Competitiveness**

**In addition to applying appropriate standards and choosing designs and quality levels acceptable to target markets, developing industries should employ quality management techniques and testing and certification infrastructures that would assure the quality of their products and secure customer confidence in that quality.**

**Proper application of internationally accepted quality management techniques as expressed in the ISO 9000 series and other International Standards prepared by ISO/TC 176 Quality management and quality assurance could go a long way to assuring the quality of products of developing industries. Moreover, establishing testing and certification infrastructures modelled according to the relevant ISO Guide would facilitate the acceptance of products in export markets. If these infrastructures receive recognition at the international level (through bilateral agreements or a future international system of recognition of national**

certification schemes), this would greatly boost the export capability of those developing countries that have achieved such recognition. Consequently, the information contained in ISO Guides and other documents prepared by ISO General Assembly Committee on Conformity Assessment (CASCO) and in standards and drafts prepared by ISO/TC 176, can play a crucial role in enhancing the export capability and market competitiveness of developing industries.

In this concern, developing countries can also participate in the process of elaboration of international rules and systems for certification of products and for the recognition of quality management systems. Their objective would be to make these schemes correspond better to their particular needs and conditions.

### **3.4 Exchange of Experience on The Application, Information And Promotion Aspects of Standardization**

Several aspects related to the application, information and promotion of standards are in continuous evolution. An example is ISO/IEC Guide 2 - General terms and their definitions concerning standardization and related activities which has been published in its sixth edition by 1991. Other examples are the rules for exchange of information on standards and related documents prepared by the General Assembly Committee on Information (INFCO) and embodied in ISONET, the International Classification of Standards, methods of standards data interchange and the compatibility of computerized information systems.

Participation of developing countries in international standardization work would provide them with very useful information in the experience of other countries and the solutions accepted internationally in these and other fields such as application of standards, training and teaching of standardization, company standardization, experience in the application and promotion of quality management standards (ISO 9000). Developing countries should also participate actively in ISO meetings devoted to application, information and promotion aspects in order to voice their views and ensure that the internationally adopted solutions fulfil their needs.

The means at the disposal of ISO members from developing countries for this exchange of experience include ISO Development Manuals, ISO 9000 Forum, workshops and meetings organized by DEVCO jointly with Policy Development Committee or separately by such as CASCO, COPOLCO, and the committees on general standardization principles REMCO, STACO.

#### **4. How International Standards Are Established**

ISO (and IEC) technical work is carried out by the technical committees and subcommittees. The secretariats of these committees are held by ISO member bodies who also nominate the chairmen of the committees. Technical committees are established by ISO Council on approval of a proposal for a new field of technical activity. Such a proposal can be made by an ISO member body, an ISO technical committee or one of ISO governing bodies. The approval of a proposal for establishing a new TC requires:

- a) a two-thirds majority of national bodies voting
- b) that at least five national bodies declare their intention to participate actively in the work.

The secretariat of a new technical committee is usually allocated to the member body that made the proposal for its establishment provided that it has the necessary resources. All national bodies have the right to participate in the work of technical committees and sub-committees. The nature of this participation can be as a:

- P-member that participates actively in the work and has an obligation to vote on draft International Standards and to participate in meetings whenever possible;
- O-member that follows the work as an observer and receives the documents and has the right to submit comments and to attend meetings.

The primary duty of technical committees and sub-committees is the development and systematic review of International Standards. Any work intended to lead to the issue of a new, amended or revised International Standard is known as a project.

A project is developed in the following stages:

**a) Proposal stage:** A new work item can be proposed by an ISO member body, the secretariat of the committee, another committee, a liaison organization or an ISO governing body. The proposal is circulated for a three-month ballot to P-members of the committee. Approval requires a simple majority of P-members voting and a commitment by at least five member bodies to participate actively in the work.

**b) Preparatory stage:** Successive working drafts are prepared till they reach the status of a committee draft.

**c) Committee stage:** The first committee draft is circulated to all members of the committee for comments and possibly for a vote. A compilation of comments may then be circulated to the members for their views. The committee draft is processed by correspondence and in committee meetings until consensus within the committee is reached and the secretariat of the committee prepares and submits the approved committee draft to ISO Central Secretariat for circulation as a draft International Standard.

**d) Approval stage:** Central Secretariat edits the text according to ISO rules then circulates it to all national bodies for a six month vote. The draft is approved if it obtains a two-thirds majority of the votes cast by P-members of the committees provided that not more than one-quarter of the votes cast are negative.

**e) Publication stage:** ISO Central Secretariat is responsible for carrying out all the necessary work for publishing the standard. The secretariat of the committee is responsible for checking the proofs before printing. - The published International Standard is distributed to all ISO member bodies.

## **5. Participation of Developing Countries In International Standardization**

Although 64% of ISO members are from developing countries, only 2% of ISO/TC/SC secretariats are held by developing countries. Very few developing countries send delegates to participate in meetings of ISO technical bodies or even comment by correspondence on ISO documents and drafts. This situation must be radically changed if developing countries are to benefit from international standardization.

ISO is a vast organization. It is, therefore, impossible for any country to participate actively in all ISO technical bodies (182 active TCs, 630 SCs and 1918 WG) or in the development of all projects (7000 WI of which 1750 are CDs and 2350 have reached the stage of DIS). Developing countries, in particular, should carefully choose those priority areas in international standardization in which they wish to participate actively and those in which they would like to follow-up the progress of international standardization work. This choice should be based on the national interests. For example, the existence of

important industries and export trade. It is also desirable that, in the case of areas for active participation, the necessary technical expertise should be available in the country.

The process of choosing priority areas for the participation of a developing country in international standardization work should take place in consultation with the interested industries and institutions in the country. In this way the degree of national interest as well as possible support can be determined correctly.

If sufficient interest in international standardization work in a certain area has been identified, a mechanism should be set up to establish a coordinated national standpoint regarding international proposals and drafts. The most appropriate form for this mechanism is a national committee in the given field. The national committee should represent the main interests at the national level and it should be consulted on all basic questions and proposals. The ISO coordinator in the national standards body can organize a smaller group of competent experts within the national committee to help study lengthy documents and report on them to the committee, prepare draft comments and replies, help with editorial review and provide technical support generally. In this way the national committee will be sufficiently dynamic and responsive to international partners, while taking account of all interests at the national level.

When it is decided to send a delegation to a meeting of an ISO technical body, the chosen delegate(s) should have adequate technical competence and language ability. The delegate(s) should receive adequate instruction from the national committee on the national standpoint and how far he/they can deviate from the standpoint in order to contribute to an international consensus.

If the field concerned is a priority area in which national standards already exist or are needed urgently, the national committee will be in a good position to review the national standard(s) in order to bring it into harmony with the international standard or to prepare a new national standard along the same lines.

However, if the field concerned has only second priority, and there is no urgent need for a national standard, then the national committee will have an observe status with the objective of following the progress of international standardization. At the appropriate time this observer national committee may propose the adoption of one or more International Standards as national standards.

# **RETROSPECT ON 1994 QUALITY CERTIFICATION IN CHINA**

**Ding Qidong**

**Director, Dept. of Conformity Assessment, CSBTS**

1993 is the year when China's quality certification system was established and operated, and 1994 is the year when great progress was achieved. Looking back on China's history of quality certification, some important progresses are shown as follows:

## **1. Accreditation Bodies Have Been Basically Established**

To establish accreditation bodies is not only the key part in China's Quality Certification Scheme, but also the concrete embodiment of unified management in the work of quality certification by the China State Bureau of Technical Supervision (CSBTS). Identifying the qualification of related personnel and administering the registration system according to international regulations are the prerequisites for construction of socialistic market economy system. Our country demanded that certification bodies should be qualified according to laws, operative systems should be established in accordance with market regulations, and they should accept the administration and supervision from related governmental departments. To accredit certification bodies, the CSBTS had approved to set up the China National Accreditation Committee for Quality System Registration Bodies (CNACR), the China National Registration , the China National Registration Board for Auditors (CRBA) and the China National Accreditation Committee for Laboratories (CNACL). The China National Accreditation Committee for Product Certification Bodies is now under preparation and will be established in early 1995. So we can say that the quality certification scheme has been basically established on schedule.

## **2. Certification Administrative Documents and Procedure Documents of the Certification Work have been Gradually Normalized**

The characteristics of certification work require its administration and operation to be normalized, and that should be embodied in their documents. The accreditation activities of our country will not reach the international level unless we have implemented the normalization of these documents. On the level of certification bodies, each of them is required to perfect its quality manuals and procedure documents and use them as the premise for accreditation. The

accreditation bodies will also issue some general instructive documents for directing the certification bodies's work and the Regulation on the Implementation Procedure of Quality System Certification has been issued. For example, beside normalizing the charter and procedures of itself, the CNACR has developed quality manuals, thirteen procedure documents and one work instruction according to its demand of development and the international practice. However, our preparation of administrative documents and operation procedure documents is just in the primary stage and there is still a gap between written documents and practices. We should do our best to make it better and better.

### **3. Certification Work Has Got Significant Effect**

In 1994, quality system certification bodies have operated in line with international regulations and procedures, CNACR has accredited 12 system certification bodies and 3 independent auditing bodies, to which the CSBTS has granted certificates. CNACR's accreditation and CSBTS's granting of certificates have caused great response at home and abroad. In the late 1994, the secretariat of CNACR has begun to handle applications from other 6 bodies.

In 1994, with the approval of CSBTS, 4 product quality certification bodies were established. They are China Certification Committee for Tyre, China Certification Committee for Drug, China Certification Committee for Environmental Labelling Products and China Certification Center for Medical Appliance. Up to now, there are 14 Product Certification Committees in China. The work on making the product certification body an independent body is now under way. For example, the newly established Certification Center for Medical Appliance is such a body.

Before the establishment of CNACL, CSBTS had assessed laboratories for certification use. 50 laboratories applied for accreditation and 40 had been accredited.

In 1994, 111 enterprises were certified in accordance GB/T 19000-ISO9000 standards, which their level of management has been improved and their competitiveness has been strengthened. In 1994, 7987 categories of product from 3288 enterprises have been certified. Especially, after the supervisory administration on 8 categories of electrical products has been implemented, 845 application forms from 45 enterprises in USA, Japan, Germany, France, South Korea, South Africa, Taiwan and Hongkong have been sent to China Certification Committee for Electrical Equipments, and 56 Certificates have been

issued to those enterprises outside China. It symbolizes that the product certification in China is now facing to the outside world.

#### **4. Training and Registration of Certification Personnel**

The level of certification personnel is the key factor to assure the quality of certification work and the international recognition. In 1994, the training work was conducted on the normal way. Reference books on training courses have been published, qualification of trainers and trainees should be ascertained and trainees should pass the unified examination. Up to now, 46 training courses have been held and 1076 trainees have passed the training examination. In 1994, 851 trainees passed the National Unified examination for Auditors and 793 of them were approved to be registered.

#### **5. China ISO9000 Forum Was Established and Put in Operation**

With the development of the quality certification, the professional personnel is not enough and qualified persons from enterprises are needed to take part in. Consequently, the China ISO9000 Forum has been established to provide a forum to the enterprise and professional personnel for exchanging ideas. This Forum serves also as a bridge between ISO9000 activities at home and abroad. The first activity of the Forum, the 94 Beijing Forum, is very successful.

Besides, a periodical, the China Quality Assurance was started to be published from 1994 which is another forum to accelerate the pace of the quality certification. The "China Quality Assurance" is also an authorized instructive periodical for the certification work.

#### **6. International Activities And International Cooperations In Quality Certification**

In 1994, we took part in a lot of international activities: the conference of ISO conformity Assessment Committee, the International Accreditation Forum, the activity of international mutual recognition system (QSAR), the International Laboratory Accreditation conference and other related activities of the Asia and Pacific region. In respect of mutual recognitions, the CSBTS has signed agreements with Israel Standardization Association, Finnish National Technical Inspection Center and Korea Department of Industry Advancement. Besides, CSBTS has signed MOU with the Department of Trade and Industry of UK in the field of certification, and keep close contacts with accrediting, training and consulting bodies in Australia, Hong Kong, Japan and UK.



In conclusion, when we see the progress in our quality certification, we should also be aware that it is just begun in China. There are still a lot of problems and difficulties to be solved in combination with the China's socialistic market economy construction and there are still some differences between our current operation and the international practice. In addition, some enterprises and personnel in the field of quality may have some misunderstanding on the certification work due to insufficient popularization. However, with the further reform on China's economic construction as well as our further efforts, we should perfect our quality certification system, raise the quality of concerning personnel, normalize the activities of certification, make our quality certification work in line with the international practice and strengthen further international cooperations.

# **QUALITY SYSTEM REGISTRATION IN CHINA**

**Guo Lisheng**  
**China State Bureau of Technical Supervision**

- 1. Legal Bases**
- 2. Organization Structure**
- 3. Basic Procedures for National Accreditation**
- 4. National Accreditation Mark**
- 5. Basic Procedures for Quality System Registration**
- 6. List of Quality System Registration Bodies**
- 7. Principles Quality System Registration for China**

## **1. Legal Bases**

- Clause 1 of Article 9 of the “ Law of P.R. C. on Product Quality”
- Regulations of CSBTS:
  - “ Regulations of Accreditation of Quality System Registration Bodies”
  - “Regulations on Implementation of Quality System Registration”

These Regulations are in conformity with EN 45012 and ISO/CASCO N227-93

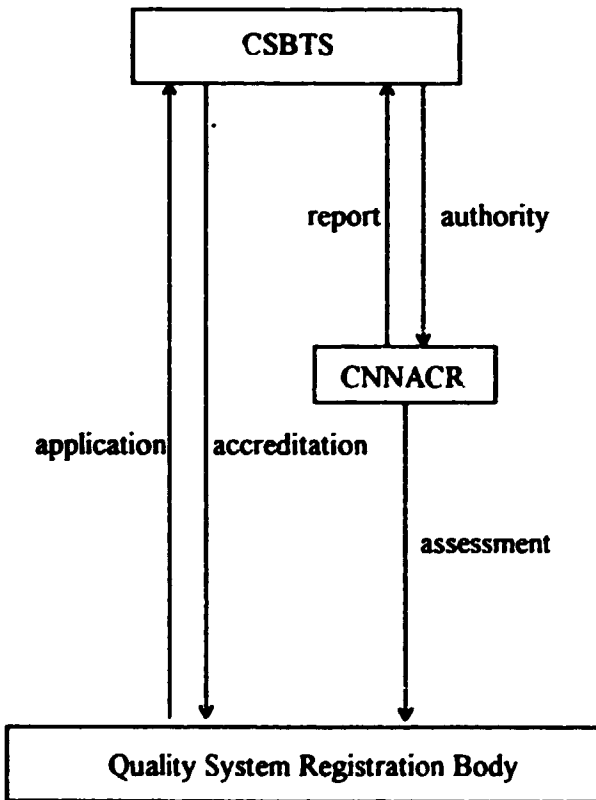
## **Article 9 of the Law of the People's Republic of China on Product Quality**

The state shall practise a certification system of enterprise's quality system according to international generic quality system standards. An enterprise may on voluntary basis apply to a quality system certification body accredited by the department in charge of supervision and control over product quality under the State Council or a department authorized by the department in charge of supervision and control over product quality under the State Council for quality

system certification. The certification body shall issue a certificate of conformity of quality system to the enterprise whose quality system has been certified to conform with the specified requirements.

## 2. Organization Structure

Organization structure of national accreditation body



**CNACR: China National Accreditation Committee for Quality System Registration Bodies**

Composed of :

- (1) China State Commission of Economy & Trade
- (2) CSBTS

- (3) Ministry of Machinery Building Industry**
- (4) Ministry of Chemical Industry**
- (5) Ministry of Domestic Trade**
- (6) State Scientific Working Commission for National Defence**
- (7) Ministry of Metallurgical Industry**
- (8) Ministry of Electronics Industry**
- (9) Ministry of Construction**
- (10) State Bureau of Nuclear Safety**
- (11) State Bureau of Building Materials**
- (12) China National Federation of Light Industry**
- (13) China National Federation of Textiles Industry**
- (14) China Association for Quality Control**
- (15) China Association for Standardization**

**Secretariat of CNACR: located in CSBTS**

### **3. Basic Procedures for National Accreditation**

- Application & its Acceptance**

**Application of QSRB → CNACR Secretariat which decides the acceptance of the paper**

- Assessment**

**Competence of QSRB and its auditing procedures carried out by Assessment Group organized by the Secretariat → Auditing Report**

• Assessment of Accreditation

Whole membership examination of CNACR on Assessment Report → Voting → Conclusion

• Approval of Accreditation

Conclusion → To CSBTS for Approval → Issuing Certificate

Surveillance following accreditation at least once a year organized by the Secretariat → Reporting to CNACR

#### 4. National Accreditation Mark

Authorized to QSRB holding Accreditation Certificate, used within certified business scope.



## **5. Basic Procedures for Quality System Registration**

- Application & its acceptance

Enterprise Application Form → QSRB → decides to accept or not

- Auditing

Auditing Group sent by QSRB → Report

- Approval

Special Committee of QSRB Examination & Voting → Result → QSRB Chief to sign the Certificate of Quality System Registration

- Surveillance

At least once a year by the QSRB.

## **6. List of Quality System Certification Bodies Accredited by CNACR**

1. Shanghai Audit Centre of Quality System (No. SC01)
  2. China Classification Society Quality Assurance Ltd. (No. SC02)
  3. Beijing Quality Assurance Centre of China Quality Control Association (No. SC03)
  4. Guangdong Audit And Certification Centre of Quality System (No. SC04)
  5. China Xinshidai Quality System Certification Body (No. SC05)
  6. Great Wall Centre of Quality Assurance (No. SC06)
- (Bodies being accredited by CNACR)
7. Northeast Audit Centre of Quality System
  8. QCCECC CEPREI Quality System Certification Body

**9. Zhejiang Audit Centre of Quality System**

**10. Chinese Certification Centre for Quality System of Electronics**

**11. China Certification Committee for Quality Mark**

**12. China Commission for Conformity Certification of Electrical Equipment**

### **7. Principles on Quality System Registration for China**

• China adheres to the principle of positively promote the international cooperation on the basis of equal rights and mutual benefits, particularly the cooperation in Asian and Pacific region. In this regards, China gives full attention to the interests of the developing countries.

• China has joined the International Accreditation Forum (IAF) and we agree that on the basis of peer assessment, the national accreditation systems on Quality System Registration bodies may realize mutual or multilateral recognition os as to promote the internationalization of the Quality System Registration.

• China supports ISO and IEC in the establishment of a Quality System Assessment Recognition System and appreciate the International Recognition System put forward by ISO/IEC QSAR based on the national/ regional accreditation system.

• China opposes the action of taking the Quality System Registration as a means of restriction of international trade to form a new type of technical barrier to trade.

## **METROLOGY IN CHINA**

**Dai Runsheng, Dong Zheng, Wang Jilai  
China State Bureau of Technical Supervision**

**Metrology, particularly legal metrology has a long history in China and was recorded more than 3000 years ago. The first Emperor of China, Qin Shi Huang issued a rule to unify the Weights and Measures, and developed some measurement standards for unifying the weight and volume units in the whole country. These early measures that guaranteed the uniformity of measurement were of great significance in the history of metrology all over the world. The System of Weights and Measures has been paid a great attention in Chinese history, despite a few differences between the Measures and Weights systems in different dynasties existed since then.**

**After the founding of the People's Republic of China, modern metrology has been set up and developed formally and systematically. In order to meet the requirements of the rapid economic expansion and defence construction, Chinese government has paid much attention and taken a set of measures to promote and develop metrology.**

**Firstly, the organizations in charge of metrology were reformed. These include:**

- 1. the State Bureau of Metrology was set up in April, 1954. It was responsible for promoting the Metric System; establishing and developing primary measurement standards; controlling verification of instruments; supervising the manufacturing, repairing, importing, exporting and sale of instruments and issuing metrology regulations in the whole country.**
- 2. the Metrology Division of Tool Research Institute, which was under the leadership of the First Mechanical Ministry at that time, was incorporated into the State Bureau of Metrology. Thus, the State Bureau had more than 800 staff and established 11 laboratories for 6 divisions.**
- 3. The National Institute of Metrology (NIM) was set up in January, 1955 and was responsible for establishing primary measurement standards and disseminating the quantity value of units. Now, NIM has become a center for developing metrological science and technology.**



Secondly, metrology regulations were issued . Several regulations have been adopted. They were :

1. "Decree about Unification of Unit System of Measurement" issued by the State Council in June 1959. It stipulated that metric system should be the essential metrology system in China and should be used in all fields in the whole country.

2. "Act on Metrology Control of the People's Republic of China" promulgated by the State Council in May 1977. It improved the unification of unit system of measurement, set up the policy in order to strengthen metrology management and supervision and prompted the development of metrology in China.

3. "Decree on Adoption of Unified Legal Unit of Measurement in China" promulgated in February, 1984. It determined the name and symbol of legal measurement units of the country which was based on "SI" and was realized completely the transformation before 1990.

4. "Law on Metrology of the People's Republic of China" promulgated in September, 1985. It was a milestone for metrology in China . Because of the promulgation of the Law on Metrology and its supplementary regulations, there existed a complete set of Metrology Law and Regulations in China. It has changed the model of metrology management and supervision, and will surely promote the economic construction and improve the protection of the interest of the people.

Now , we will introduce briefly the " Metrology in China" from three aspects :

## **1. A Series of Laws and Regulations Have been Promulgated Which Include Two Aspects:**

### **1.1 Law and Measures on Administrative Control of Metrology**

It includes the Law on Metrology approved by the China People's Congress, Rules for the Implementation of the Law on Metrology promulgated by the State Council, and several Measures promulgated by the State Council and the CSBTS (State Bureau of Technical Supervision of China). Figure 1 shows their relationships.

The main aims of the Law on Metrology of the People's Republic of China are: to strengthen the management and supervision of metrology; to guarantee the

uniformity of measurement units in the whole country and accuracy and reliability of the results of measurement; to contribute to the development of production, trade, science and technology; to meet the needs of social modernization and construction and to safeguard the interests of the state and the people.

The Metrology Law stipulates that the "SI" system and some other supplementary units chosen by the State are adopted as the national legal measurement unit. It is forbidden to use the nonlegal measurement units in China. It describes how to manage the primary standards, reference standards and the manufacture, repair and use of measuring instruments. It also lay down how to carry out metrology supervision on the economical activities.

The Metrology Law stipulates that the Metrology Administrative Department should execute compulsory verification of those measuring instruments used for settling trade accounts, safety protection, medical treatment as well as health and environmental monitoring. The list of these instruments has been published by the State Council.

The managing procedures on the manufacturing and using of measuring instruments includes pattern approval for new type of instrument, initial and subsequent verification, and supervision on instruments being used. They are similar to those implemented in most other countries.

## **1.2 Technical Regulations and Norms**

There are three kinds of technical regulations and norms

### **1.2.1 Verification Scheme**

It includes a diagram and the statement concerned. It describes the name of instrument, capacity of measurement, method used in verification , etc. for primary standards to working instruments. It is just like the Hierarchy Scheme for measuring instrument described in No.5 ID of OIML . There are 89 verification schemes at present.

### **1.2.2 Verification Regulation**

The content of verification regulation in China includes the metrology requirements, items to be verified method used in verification, verification interval, processing method for measurement results, etc. There are 880

verification regulations. Efforts are being paid to reform our regulations so that they can be more compatible with the IR of OIML.

### **1.2.3 Technical Norms**

Technical norm is the procedures to implement the metrology administrative management and supervision. There are 189 technical norms now

## **2. Metrological Traceability Has Become Suitable to the Needs of Economical Development in China in Principle**

The traceability is basically carried out in four levels in China. Namely, the State is responsible to develop or set up primary standard and disseminate its value to reference standards set up by provincial metrology institute. The provincial institutes is responsible to verify the reference standards kept by factories or county institutes. Most of working instruments are verified or calibrated in factories and county institutes. Furthermore, there are 16 special metrology centers which are responsible for verifying or calibrating instruments for measuring certain particular parameter (e.g. high voltage, large volume, parameters used in textile field, etc.). Figure 2 shows the metrological traceability system of China.

The main task to establish national primary standards is under the charge of the National Institute of Metrology (NIM) in China. NIM has established the primary standards for six SI base units (except "Mole"), which have participated international comparisons with good results in the past. There are also 113 kinds of national standards for different parameters established and maintained in NIM, except those in the field of chemical metrology. NIM has 12 technical divisions, 68 laboratories and 1600 staffs including 1000 technical persons, among them 300 are senior scientists and engineers. BIPM has maintained one set of electrical standard cells made in China and with good stability. NIM has developed platinum resistance thermometer for measuring high temperature with good performance. All of these make NIM be of international reputation in the field of metrology.

The National Institute of Measurement and Testing Technology (NIMTT) is the second largest metrology research and service body. NIMTT has established 17 national standards and 25 working standards. It has near 500 staffs. Together with NIM, NIMTT has provided experimental data for changing the value of unit of Volt in 1990 and that of photometry in 1979. More than 70,000 pieces of instruments have been verified or tested in NIMTT each year.

The National Research Center for Certified Reference Material (NRCCRM) is a state professional institute for the research and development of certified reference materials. NRCCRM is also engaged in the development of standards for chemical metrology. NRCCRM has 110 technical staffs and has developed 120 certified reference materials, which have been exported to some other countries. The office of the examination council for certified reference materials in China is also located in NRCCRM.

There are seven State Metrology Centers in Economical Cooperation Zones. For example, the North China Metrology and Testing Center, has 326 professional personnel and has established 161 reference standards. More than 110,000 pieces of instruments had been verified or tested in that center in 1992.

There are 18 State Metrology Centers in Special Fields, which contain more than 1166 scientific and technical personnel. They verified or tested near 79,250 pieces of instruments in 1993.

Besides, there are 24 provincial metrology institutes and approximately 3,600 regional metrology units in China. They contain 60,000 personnel. Up to 28,000,000 pieces of instruments are verified or tested by them each year.

### **3. Metrology Supervision Has Been Implemented in Four Fields**

Now, more than 2,000 metrology administrative units have been set up at the state level and county level in order to implement the metrology supervision. There are more than 17,000 certified metrology supervisors for market supervision and 3,000 certified assessors for laboratory accreditation now in the country. Metrology supervision has been implemented in the following four fields.

#### **3.1 Supervision on Instrumentr Manufacture and Foreign Supplier**

It is required that new type of instrument must pass the pattern approval before its production and sale. It is the manufacturer's responsibility to apply for pattern approval to the Metrology Administrative Department (MAD) at provincial level. The authorized institute carries out the testing on the samples according to the designation by MAD. After the testing, conformity certificate of pattern approval is issued and announced to the public by MAD if the samples meet the requirements of the national regulation concerned. Manufacturer needs only to

apply to MAD for sample examination if that type of instrument has been announced to the public by the MAD

For some kinds of imported instruments, the foreign supplier or his agency must apply for pattern approval to CSBTS. The list of these kinds of instruments has been published by CSBTS under the approval of the State Council.

In addition, CSBTS will carry out irregular supervision in the instruments in market in order to guarantee the quality of instruments.

### **3.2 Market Supervision**

Metrology supervisors are responsible for the market supervision in China. They must be trained, pass the examination and get the certificate issued by the CSBTS. Supervision covers mainly instruments used in the market, for example scales, gasoline dispensers etc. and small prepackaged goods. A document concerning requirements on the weighing of retail goods has been promulgated by the Ministry of Domestic Trade and CSBTS. It stipulates the accuracy of the instrument used and the error of weighing result permitted. Requirements on the trade of massive raw materials are going to be published soon.

### **3.3 Supervision on Instruments Subject to Compulsory Verification**

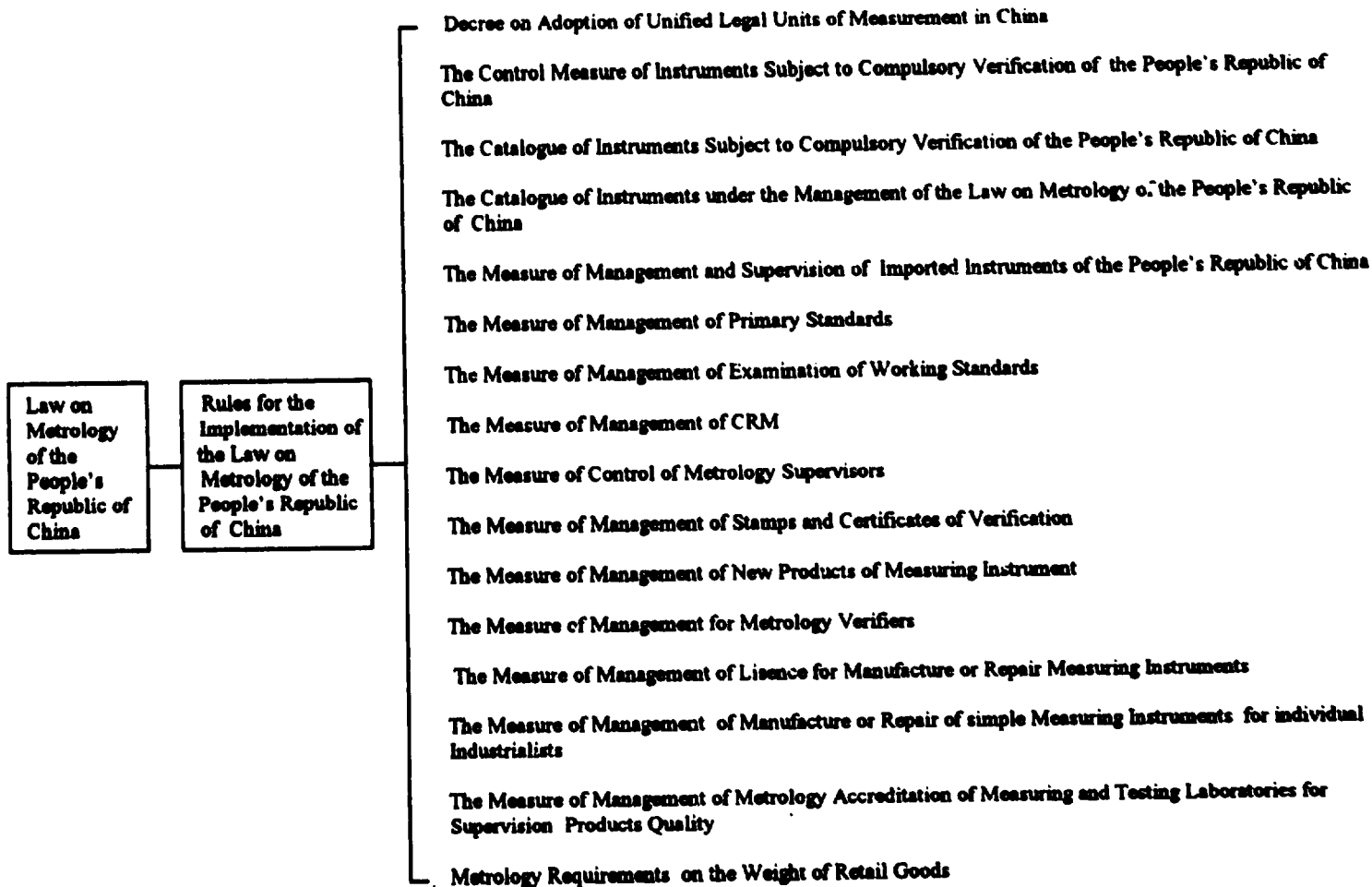
MAD has registered instruments subject to compulsory verification and conducted supervision regularly under its jurisdiction.

Anybody will be punished if he/she uses this kind of instrument which has not been verified and proved valid according to stipulation of "Rules for the Implementation of the Law on Metrology of the People's Republic of China".

### **3.4 Metrology Accreditation**

The supervision on measuring and testing laboratories is carried out by laboratory accreditation in China, which we call as Metrology Accreditation. MAD is responsible to implement metrology accreditation. ISO Guide 25 is adopted equivalently in principle as the criteria of accreditation. Assessments carried out by assessors and experts concerned. These laboratories are divided into two levels. Those that provide services only in the province are accredited by the MAD at the provincial level. Others that provide services in the whole country are accredited by the CSBTS. Metrology accreditation began in 1986.

Near 1100 laboratories which are affiliated to 30 ministries, have been accredited by CSBTS. Metrolog accreditation has been given high evaluation by these ministries. It improves the reliability and repeatability of test results and reduces disagreement between testing results.



**Fig. 1**

## The Metrological Traceability System of China

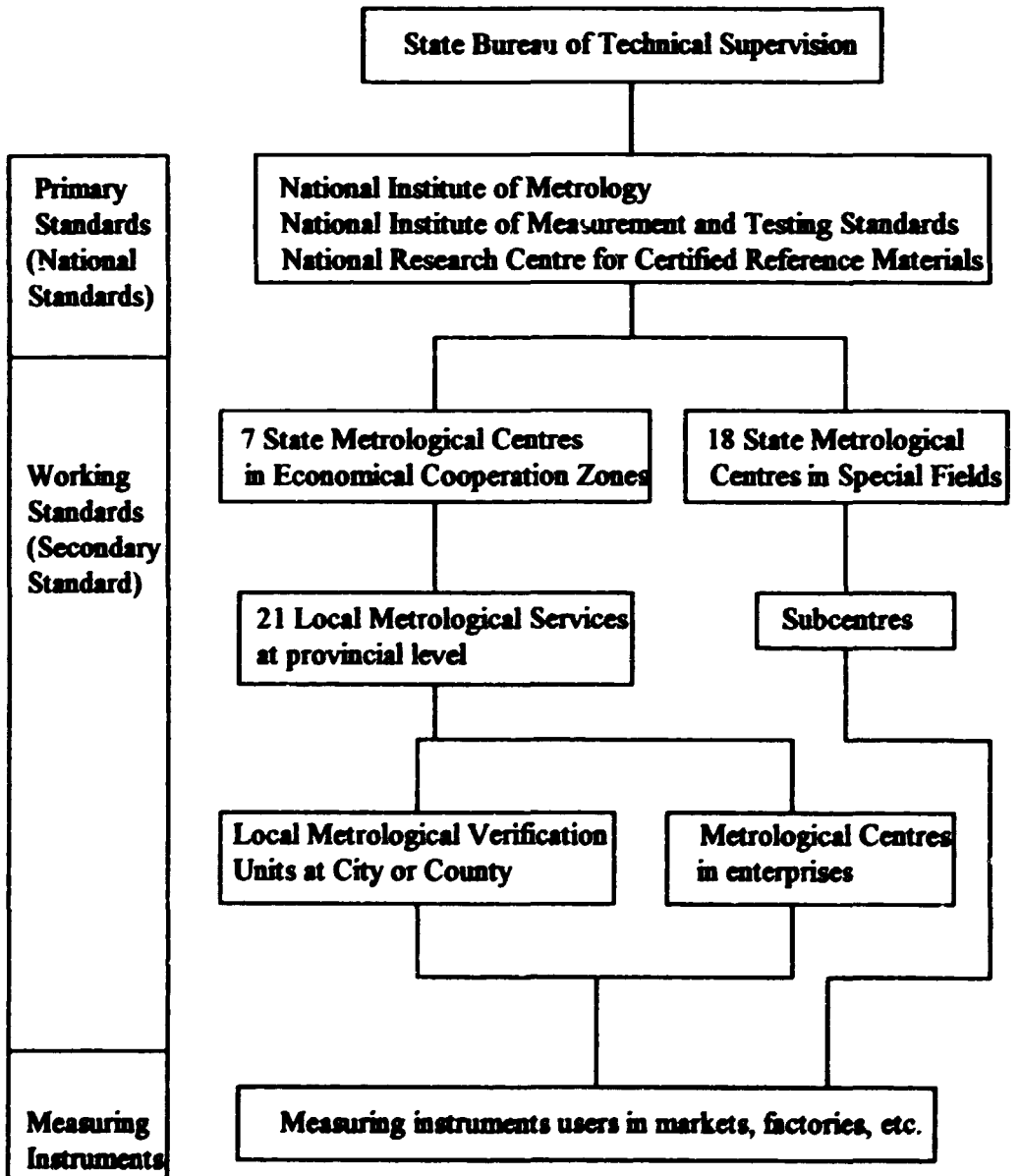


Fig. 2



# QUALITY SYSTEM REGISTRATION IN CHINA

Xiao Jianhua  
China National Accreditation Committee for  
Quality System Registration Bodies

## Abstract

The related standards of ISO9000 Family have been adopted identically into Chinese national standards. The national accreditation system for quality system bodies are being operated according to the appropriate Chinese law and international code. This article introduces the status on the implementation of quality system registration in China.

## 1. The Relative Law

The article 9 of the Law of the People's Republic of China on Product Quality defines:

“ The state shall practise a certification system of enterprise's quality system according to international generic quality system standards. An enterprise may on voluntary basis apply to a quality system certification body accredited or authorized by the department in charge of supervision and control over product quality under the State Council for quality system certification. The certification body shall issue a certificate of conformity of quality system to the enterprise whose quality system has been certified to conform with the specified requirements.”

This provision is the unique legal basis for managing quality system registration in China, which indicates that:

- a) our country practise a registration system of quality system with international standards of ISO9000 series which have been adopted identically into national standards of GB/T 19000 - ISO9000 series;
- b) the quality system registration should be voluntary for enterprises;
- c) the quality system registration body should be accredited nationally;
- d) the administration agency of national accreditation is the department in charge of supervision and control over product quality under the State Council.

## 2. The National Administration Agency

In accordance with the authority of the State Council and the Law mentioned above, CSBTS (China State Bureau of Technical Supervision) exercises the unified management of national conformity assessment, and is the national administration agency for quality system registration work in China.

Main functions of CSBTS in the unified management of national quality system registration are:

- a) to establish the national policies and provisions related to quality system registration;
- b) to authorize a national accreditation body, which is controlled by a committee consisting of members from related different interests, to implement a national accreditation of the quality system registration bodies;
- c) to supervise the accredited quality system registration bodies and their activities;
- d) to carry out the bilateral and/or multilateral cooperation with related foreign organizations.

### **3. The National Accreditation System for Quality System Registration in China**

#### **3.1 Accreditation Body**

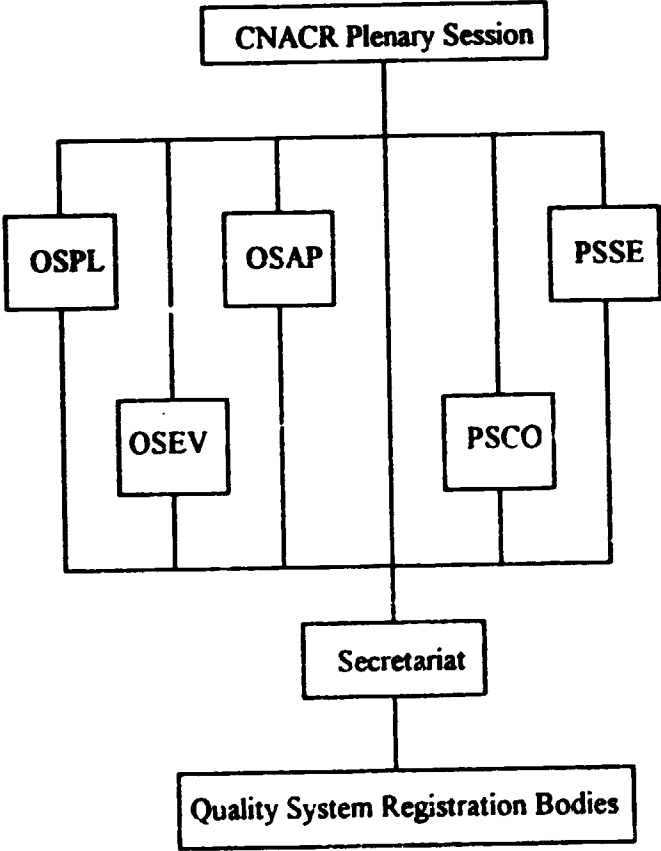
CNACR (China National Accreditation Committee for Quality System Registration Bodies) is the national accreditation body, authorized by CSBTS, which is solely responsible for implementing the national accreditation of quality system registration bodies in China.

The members of CNACR have been chosen from among those interests involved in the process of accreditation without any single predominating interest, including the State Economic and Trade Commission, Commission of Science, Technology and Industry for National Defence, Ministry of Machine-Building Industry, Ministry of Electronics Industry, Ministry of Metallurgical Industry, Ministry of Chemical Industry, Ministry of Internal Trade, Ministry of Construction, China National Council of Light Industry, China National Textile Council, China State Bureau of Technical Supervision, State Pharmaceutical Administration, State Bureau of Building Materials Industry, National Nuclear Safety Administration, China Quality Control Association, China Standardization Association, Shanghai Economic Commission, Shanghai Bureau of Technical

Supervision, Tianjin Economic Commission and Liaoning Provincial Bureau of Technical Supervision.

The organizational structure of CNACR is shown in Fig. 1

### The Organizational Structure of CNACR



- OSPL: Operational Subcommittee for Planning
- OSEV: Operational Subcommittee for Evaluating the Accreditation Assessors
- OSAP: Operational Subcommittee for Appeals
- PSCO: Professional Subcommittee for Construction Engineering
- PSSE: Professional Subcommittee for Services

Fig 1.

### 3.2 Accreditation Procedures

The accreditation procedures of CNACR is shown in Fig.2

#### The Accreditation Procedures of CNACR

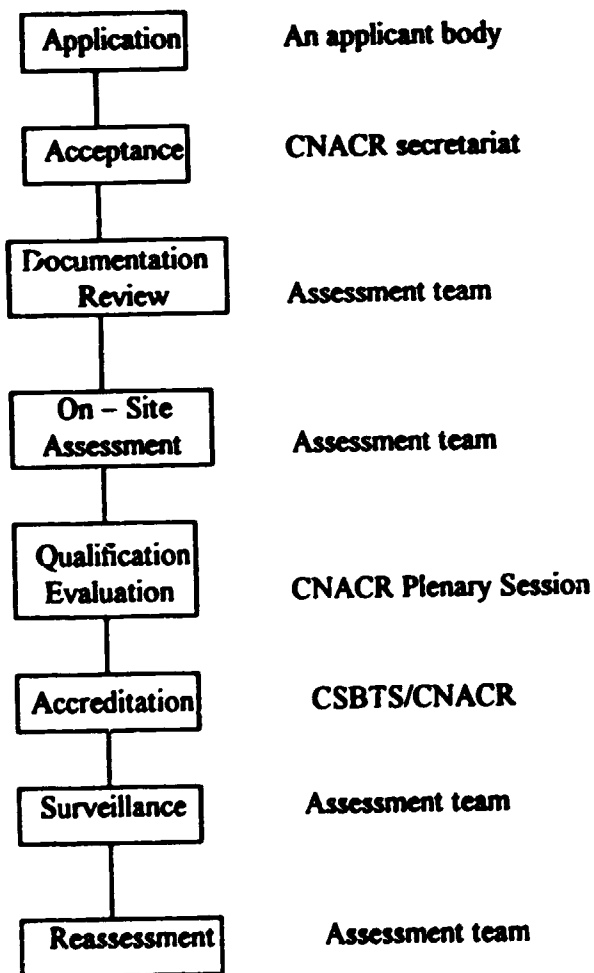


Fig. 2

### **3.3 Accreditation Measures and Criteria**

CNACR assesses the quality system registration bodies against the relative measures issued by CSBTS and criteria issued CNACR which incorporate the requirements specified in appropriate international and regional documents (e.g. ISO/CASCO 227, EN 45012).

According to the criteria of competence, a quality system registration body should:

- a) be a nongovernmental and nonprofit making legal entity;
- b) have a management committee with its members chosen from industries, consumers governmental departments, etc.;
- c) have adequate staff and registered auditors with the expertise in related technological and industrial sectors;
- d) have established and maintained its documented quality system;
- e) make a commitment that it will not provide any consultancy to firms for establishing their quality systems and etc.

### **4. The Present Situation and Future Tendency of the Quality System Registration in China**

By the end of 1994, substantial progress for the quality system registration in China has been achieved.

- On the basis of the assessment of CNACR and approval of CSBTS, 12 quality system registration bodies, which have been listed in the Directory of Quality System Registration Bodies (third edition) published by ISO, have received the National Accreditation Certificate, and an announcement has been made nationwide.
- The accredited quality system registration bodies have registered 140 firms against ISO9001-9003. The involved industrial sectors include machinery, electrical, basic metals, chemicals, aerospace, shipbuilding, construction, etc. Totally, about 220 Chinese firms have been registered by local or foreign quality system registration bodies.
- More than 260 people have been registered by CSBTS as quality system auditors in China.

· CNACR are discussing the feasibility and procedures for increasing cooperation with certain national accreditation bodies in the Asia/Pacific region and other regions. CNACR participates actively in the activities of IAF ( International Accreditation Forum ) as well as those concerned with ISO/CASCO conformity assessment, and also participates in discussions regarding the establishment of ISO/IEC QSAR ( Quality System Assessment Recognition).

The quality system registration has caught close attention of the Government and industries in our country and are being implemented effectively.

# **IMPACT OF EMERGING TECHNOLOGIES ON METROLOGY**

**Wang Lanxiang, Yang Xiaoren  
National Institute of Metrology, China**

## **I. Introduction**

Metrology is the science of measurement. It includes all aspects, both theoretical and practical, with reference to measuring methods and instruments, calibration and measurement standards, measurement results, etc., in whatever field of science and technology they occur. Metrology is essentially an applied science. It develops in pace with the development of science and technology; while, in return, it activates the further development of science and technology. Consequently, it is important and wise for metrologists, especially for those in developing countries, to keep keen eyes on the emerging technologies and make full use of them.

Emerging technologies may be understood as technologies that are undergoing fundamental changes and extending revolutionary applications; such as the high density integration and compound composition of semiconductor, the high temperature operation and sensitive magnetic behavior of superconductor technology, the laser and fiber optics applications of classical optics, the high resolution display and holographic imaging of video technology, the large volume data transfer and high speed data processing of microwave communication, the software application and intelligent performance of computer technology, the various transducer probing of non-electrical quantity measurement, the nanotechnology in dimensional measurement, etc. It may also be understood as applications of new physical effects, advanced mathematical methods and even new materials, such as the Josephson, Von Klitzing and single electron tunnelling effects, the ARIMA prediction and fuzzy estimation methods, the thermosetting polymer, ferrite, multilayer metal thin film, superlattice, etc.

## **II. On Measuring Methods and Instruments**

Measuring method determines the measurement capability, e.g., the range, sensitivity, uncertainty, etc., of the measurement, and is usually realized in the measuring instrument. Many measuring methods have been proved useful in the past: such as the transformation of the magnitude of the measurand into a easier

measurable (e.g. the frequency difference multiplication in frequency stability measurement, the synchronous integration in the retrieve of signal buried in noise, and many other power splitter, voltage divider, current shunt, ratio transformer, directional coupler, measuring amplifier, etc.) the transformation of the quantity to be measured into another easier measurable quantity (e.g. the change of voltage into frequency or digital value in digital voltmeter, the change of attenuation into distance in cut off attenuator, the change of phase difference into time interval in phase meter, and many other electrical measurements of non-electrical quantities), the transformation of the value of measuring frequency (e.g. the heterodyne method in measuring receiver, the DC and IF substitution method in power and attenuation measurement, and many other frequency division, multiplication and mixing techniques), the transformation of measuring domain ( e.g. the time domain, frequency domain and data domain). On the bases of the above mentioned means the applications of emerging technologies will surely promise more powerful measuring methods and higher performance measuring instruments.

### **III. On Calibration and Measurement Standards**

A measurement standard is a material measure, measuring instrument, reference material or measuring system used to define, realize, conserve or reproduce a unit or the value of a quantity, and calibration is a set of operations to establish the relationship between values represented by a measuring instrument and the corresponding measurement standard. All units are derived from the seven SI base units, so all measuring instruments and measurement standards should be traceable to the primary standards of the SI base units. In the past, some primary standards had been linked through physical theory to atomic or macroscopic quantum phenomena or fundamental physical constants, the immutability of which were proved to be much better than artefacts. They are the cesium beam time and frequency standard, the He-Ne laser length standard, the Josephson junction array voltage standard, the quantum Hall resistance standard, etc. With the applications of emerging technologies, the existing natural primary standards may be improved (e.g. the primary time and frequency standard may be improved by applying optical pumping, laser cooling, atoms or ions trapping, digital servo control, and new natural primary standards may be established (maybe the STM current standard and even the natural primary standard on mass). For calibration services, self-calibration and programmable calibration through computer softwares are being put into effect.

### **IV. On Measurement Results**



The result of a measurement is computed from a series of data processing and will be characterized by the corrected value and the uncertainty of measurement. In the past, various statistical methods had been applied, and the BIPM had issued an Recommendation while ISO had issued a Guide for the expression of measurement uncertainty so as to make the measurement results internationally comparable and acceptable. With the applications of emerging technologies, high density data storage, high speed data transmission and real time data processing will be realized while reliability analysis, fuzzy estimation and robustness determination will also be carried out.

## **V. Conclusion**

The human society is characterized by its integrity. The commercialization of emerging technologies into metrology will surely bring impacts to other fields of science and technology, to the national productivity, to the trade competitiveness and to the quality of human life. In the mean time, emerging technologies will pose various interesting measurement problems with themselves, awaiting for the metrologists to solve and enjoy.

# UNCERTAINTY AND RELIABILITY ANALYSIS

Liu Zhimin

National Institute of Metrology  
Beijing, China

## Abstract

this paper deals with uncertainty and reliability. In uncertainty analysis, the evaluation and report of uncertainty are discussed, examples are put forward. In reliability analysis, concepts, expressions and applications are illustrated.

## 1. Introduction

The uncertainty and reliability are very important and useful for quality, standardization and metrology. The standards on uncertainty and reliability are used in many fields.

Measurement must be carried out for recognizing the world. When reporting the result of a measurement, it is obligatory that uncertainty of the result be given so that the level of measurement can be assessed. Without such an indication, measurement results cannot be compared, either among themselves or to the reference values given in a specification. It is therefore necessary that there be a readily implemented, easily understood, and generally accepted standard- Guide for characterizing the quality of a result of a measurement, that is, for evaluating and expressing its uncertainty.

For Metrology Assurance Procedure (MAP), the uncertainty is necessary for explaining whether the value of a quantity is under control or not, and the uncertainty is used for expressing the level of control. In this case, the t-test and F-test are used.

In ISO/IEC Guide 25, the competence of calibration and testing laboratories must include uncertainty<sup>[1]</sup>. In ISO9001-4.11 for quality management and quality assurance. It is needed to ensure that the measurement uncertainty of equipment is known<sup>[2]</sup>. So the uncertainty is important for quality and standardization.

To ensure the use of product, its reliability is of great importance. In ISO9004-8.4, the reliability, durability and safety under expected storage and operational conditions should be considered; and in 9004-8.5.2 b, reliability requirement should be considered; also in 9004-15.3, the significance of a problem affecting quality should be evaluated in terms of its potential impact on reliability etc <sup>13)</sup>

Without reliability, the product can not be guaranteed against failure. Without reliability in metrology, the result of measurement can not be confident in its correctness.

## **2. Uncertainty Analysis**

### **2.1 The Guide**

In 1987, recognizing the lack of international consensus on the expression of uncertainty in measurement, the Comite International des Poids et Mesures (CIPM) requested the Bureau International des Poids et Mesures (BIPM) to address the problem in conjunction with the national standards laboratories and to make a recommendation. In 1980, The Recommendation INC-1 (1980) Expression of Experimental Uncertainties was developed.

The task of developing a detailed guide based on INC-1 was referred by the CIPM to the International Organization for Standardization (ISO). In 1986, the International Working Group on Uncertainty ISO/TAG4/WG3 was established. It was assigned to develop the Guide to the Expression of Uncertainty in Measurement <sup>14)</sup>. In 1993, this Guide was published by BIPM, IEC (International Electrotechnical Commission), IFCC (International Federation of Clinical Chemistry), ISO, IUPAC (International Union of Pure and Applied Chemistry), IUPAP (International Union of Pure and Applied Physics), OIML (International Organization of Legal Metrology).

This Guide establishes general rules for evaluating and expressing uncertainty in measurement that can be followed at various levels of accuracy and in many fields, including those required for

- maintaining quality control and quality assurance in production;
- complying with and enforcing laws and regulations;
- conducting basic research, and applied research and development, in science and engineering;

- calibrating standards and instruments and performing tests throughout a national measurement system in order to achieve traceability to national standards;
- developing, maintaining, and comparing international and national physical reference standards, including reference materials.

**The definition of uncertainty and related terms are:**

**(1) Uncertainty (of measurement)**

**Parameter, associated with the result of a measurement, that characterizes the dispersion of the values that could reasonably be attributed to the measurand.**

**Notes:**

**1) The parameter may be, for example, a standard deviation (or a given multiple of it), or the half-width of an interval having a stated level of confidence.**

**2) Uncertainty of measurement comprises, in general, many components. Some of these components may be evaluated from the statistical distribution of the results of series of measurements and can be characterized by experimental standard deviations. The other components, which also can be characterized by standard deviations, are evaluated from assumed probability distributions based on experience or other information.**

**3) It is understood that the result of the measurement is the best estimate of the value of the measurand, and that all components of uncertainty, including those arising from systematic effects, such as components associated with corrections and reference standards, contribute to the dispersion.**

**(2) Standard uncertainty**

**Uncertainty of the result of a measurement expressed as a standard deviation.**

**(3) Type A evaluation ( of uncertainty )**

**Method of evaluation of uncertainty by the statistical analysis of series of observations.**

**(4) Type B evaluation (of uncertainty)**

Method of evaluation of uncertainty by means other than the statistical analysis of series of observations.

**(5) Combined standard uncertainty**

Standard uncertainty of the result of a measurement when that result is obtained from the values of a number of other quantities, equal to the positive square root of a sum of terms, the terms being the variances or covariances of these other quantities weighted according to how the measurement result varies with changes in these quantities.

**(6) Expanded uncertainty (or overall uncertainty)**

Quantity defining an interval about the result of a measurement that may be expected to encompass a large fraction of the distribution of values that could reasonably be attributed to the measurand.

**(7) Coverage factor**

Numerical factor used as a multiplier of the combined standard uncertainty in order to obtain an expanded uncertainty.

**(8) Degrees of freedom**

The number of terms in a sum minus the number of constraints on the terms of the sum.

**2.2 Evaluating Standard Uncertainty <sup>[4][5][6]</sup>**

**2.2.1 The Measurement Model**

In most cases a measurand  $Y$  is not measured directly, but is determined from  $N$  other quantities  $X_1, X_2, \dots, X_N$  through a functional relationship  $f$ .

$$Y = f(X_1, X_2, \dots, X_N)$$

A best value (estimate) of  $Y$ , denoted by  $y$ , is obtained from equation above using best values (estimates) input of  $x_1, x_2, \dots, x_N$  for the values of the  $N$  quantities  $X_1, X_2, \dots, X_N$ . Thus the best value output  $y$ , which is the result of the measurement, is given by

$$y = f(x_1, x_2, \dots, x_N)$$

### 2.2.2 Type A Evaluation of Standard Uncertainty

In most cases, an input quantity  $X_i$  is determined from  $n_i$  equal-accurate independent measurements, and we obtain

$$x_{i1}, x_{i2}, \dots, x_{in_i}$$

The best value  $x_i$  is

$$x_i = \frac{1}{n_i} \sum_{k=1}^{n_i} x_{ik}$$

Its standard uncertainty is

$$u(x_i) = s(x_i) = \sqrt{\frac{1}{n_i(n_i - 1)} \sum_{k=1}^{n_i} (x_{ik} - x_i)^2}$$

with degrees of freedom  $\nu_i = n_i - 1$ .

Often an estimate  $x_i$  is obtained from Least Squares Method. For unknown vector  $Z_1$  ( $X_i$  is one component of  $Z$ , say, the first component), we measure vector  $L_{n_1}$  ( $n \geq t$ ). There is residual equation  $AZ = L_{n_1} - V$  ( $A_m$  is design matrix). Let weight of  $L$  be

$$P_{nn} = \begin{pmatrix} p_1 & & \\ & \ddots & \\ & & p_n \end{pmatrix}$$

the normal equation and estimate are

$$A'PA\hat{Z} = A'PL$$

$$\hat{Z} = (A'PA)^{-1}A'PL = (q_{ij})A'PL$$

From  $V = AZ - L$  we obtain

$$\hat{\mu} = \sqrt{\frac{1}{n-t} \sum p_i v_i^2}$$

We have  $x_i = z_1$ ,  $u(x_i) = s(x_i) = \hat{\mu}\sqrt{q_{11}}$  with degrees of freedom  $\nu_i = n-t$

### 2.2.3 Type B Evaluation of Standard Uncertainty

For an estimate  $x_i$  of an input quantity that has not been obtained from repeated observations, the  $u(x_i)$  is evaluated by scientific judgement based on all of the available information on the possible variability of  $X_i$ . The pool of information may include:

- (1) Previous measurement data
- (2) Experience with or general knowledge of the behaviour and properties of relevant materials and instruments
- (3) Manufacture's specifications
- (4) Data provided in calibration and other certificates
- (5) Uncertainties assigned to reference data taken from handbooks

The case to obtain standard uncertainty for Type B evaluation may be

(1) If the estimate is taken from a manufacturer's specification, calibration certificate, handbook or other source and its quoted uncertainty is stated to be a particular multiple of a standard deviation, the  $u(x_i)$  is the quoted value divided by the multiplier.

Example: A calibration certificate states that " the uncertainty is  $240\mu\text{g}$  at the three standard deviation level". Then we have  $u = 240\mu\text{g}/3 = 80\mu\text{g}$

(2) If it can be assumed that the distribution of possible values of  $X_i$  is normal (generally, this is a reasonable assumption).

1) The quoted uncertainty defines an interval having a 90, 95, or 99 percent level of confidence, the  $u(x_i)$  is obtained by dividing the quoted uncertainty by the factor 1.64, 1.96 or 2.58.

2) If there is a fifty-fifty chance that the value of  $X_i$  lies in the interval  $a_1$  to  $a_2$  (in other words, the probability that  $X_i$  lies within this interval is 0.5), then the estimate  $x_i$  can be taken to be the midpoint of the interval, and one can take  $u(x_i) = 1.48a$  ( $a = (a_2 - a_1)/2$ )

3) If there is about a 2/3 chance that the value of  $X_i$  lies in the interval  $a_1$  to  $a_2$ , one can take  $u(x_i) = a = (a_2 - a_1)/2$

(3) If it can be assumed that the distribution of possible values of  $X_i$  is uniform within  $a_1$  to  $a_2$ , we have

$$x_i = (a_+ + a_-) / 2$$

$$u(x_i) = a / \sqrt{3} \quad [a = (a_+ - a_-) / 2]$$

(4) If it can be assumed that the distribution of possible values of  $X_i$  is trapezoidal distribution having equal sloping sides, a  $[a_+, a_-]$  base of width  $a_+ - a_- = 2a$ , a top of width  $2a\beta$  where  $0 \leq \beta \leq 1$ , then we have

$$x_i = (a_+ + a_-) / 2$$

$$u(x_i) = a \sqrt{1 + \beta^2} / \sqrt{6}$$

which becomes for the triangular distribution ( $\beta=0$ )

$$u(x_i) = a / \sqrt{6}$$

(5) If it can be assumed that the distribution of possible values of  $X_i$  is projective distribution having limiting value  $\Delta$ , after we add correction  $-\Delta/3$  to estimate  $x_i$  of  $X_i$ , we have  $u(x_i) = 3\Delta/10$

Example: A 2-meter ruler is verified by standard ruler. The deviation angle between rulers is  $\alpha \leq 1'$ .

The projective error is  $\delta = l \cos \alpha$ . Its limiting value is

$$\Delta = 1 - \cos 1' \approx (1/2) (1/3438)^2 = 4.2 \times 10^{-8}$$

The expectation and standard deviation of  $\delta$  are

$$E = \Delta / 3 = 1.4 \times 10^{-8}$$

$$\sigma = 3\Delta / 10 = 1.3 \times 10^{-8}$$

For the length  $x_i$  of 2-meter ruler after we add correction  $-1.4 \times 10^{-8} \times 2\text{m} = -28\text{nm}$  the uncertainty is  $u(x_i) = 1.3 \times 10^{-8} \times 2\text{m} = 26\text{nm}$

For a standard uncertainty evaluated by Type B, the degrees of freedom is



$$v = 1 / 2 \left( \frac{\sigma(u(x_i))}{u(x_i)} \right)^2$$

## 2.3 Determining Combined Standard Uncertainty and Expanded Uncertainty

### 2.3.1 Combined Standard Uncertainty <sup>[7]</sup>

The standard uncertainty of y is

$$u_c^2(y) = \sum_{i=1}^N \left( \frac{\partial f}{\partial x_i} \right)^2 u^2(x_i) + \sum_{i < j} \frac{\partial f}{\partial x_i} \cdot \frac{\partial f}{\partial x_j} u(x_i, x_j)$$

Where  $u(x_i, x_j)$  is the estimated covariance associated with  $x_i, x_j$ .

Introducing estimated correlation coefficient

$$r(x_i, x_j) = \frac{u(x_i, x_j)}{u(x_i)u(x_j)} \in [-1, 1]$$

we obtain

$$u_c^2(y) = \sum_{i=1}^N \left( \frac{\partial f}{\partial x_i} \right)^2 u^2(x_i) + 2 \sum_{i < j} \frac{\partial f}{\partial x_i} \cdot \frac{\partial f}{\partial x_j} r(x_i, x_j) u(x_i) u(x_j)$$

We introduce uncertainty component

$$u_i = \left| \frac{\partial f}{\partial x_i} \right| u(x_i)$$

If every  $r(x_i, x_j) = 0$ , we have

$$u_c(y) = \sqrt{\sum u_i^2}$$

That is, if all component pairs are uncorrelated, the quadratic combined method is used.

If every  $r(x_i, x_j) = 1$  and if the signs of  $\partial f / \partial x_i$  are the same, we have

$$u_c(y) = \sum u_i$$

That is, if all component pairs are fully correlated, the linear combined method is used.

For simplicity,  $u_c(y)$  may be written as  $u_c$ .

### 2.3.2 Expanded Uncertainty

Although  $u_c(y)$  can be universally used to express the uncertainty of a measurement result, in some commercial, industrial and regulatory applications, and when health and safety are concerned, it is necessary to give expanded uncertainty.

The expanded uncertainty is <sup>(4)</sup>

$$U = k u_c(y) \quad (k \text{ is coverage factor})$$

The result of a measurement is then expressed as  $Y = y \pm U$ , which is interpreted to mean that the best estimate of the value attributable to the measurand  $Y$  is  $y$ , and that  $y-U$  to  $y + U$  is an interval that may be expected to encompass a large fraction of the distribution of values that could reasonably be attributed to  $Y$ .

We have

$$k = t_p(v)$$

where  $t_p(v)$  is critical value of  $t$  distribution with level of confidence  $p$  and degrees of freedom  $v$ .

Here  $v$  is the degrees of freedom of combined standard uncertainty

$$v = u_c^4(y) / \sum (u_i^4 / v_i) \quad (v_i \text{ is the degrees of freedom of } u(x_i))$$

If  $v$  is not known, one may take  $k = 2 \sim 3$ .

**Table 1 Value of  $t_p(v)$**

$\nu$ \ P	0.95	0.9545	0.99	0.9973
1	12.71	13.97	63.66	235.80
2	4.30	4.53	9.92	19.21
3	3.10	3.31	5.84	9.22
4	2.78	2.87	4.60	6.62
5	2.57	2.65	4.03	5.51
6	2.45	2.52	3.71	4.90
7	2.36	2.43	3.50	4.53
8	2.31	2.37	3.36	4.28
9	2.26	2.32	3.25	4.09
10	2.23	2.28	3.17	3.96
15	2.31	2.18	2.95	3.59
20	2.09	2.13	2.85	3.42
50	2.01	2.05	2.68	3.16
100	1.984	2.025	2.626	3.007
$\infty$	1.960	2.000	2.576	3.000

## 2.4 Reporting Uncertainty

When the measure of uncertainty is  $u_c(y)$ , it is preferable to report it as ( the quantity whose value is being reported is assumed to be a nominally 100g standard of mass  $m$ ): The combined standard uncertainty of  $m$  is

$$u_c = 0.35 \text{ mg}$$

When the measure of uncertainty is  $U$ , it is preferable to report it as: The expanded uncertainty of  $m$  is

$$U = 0.79 \text{ mg}$$

(  $U$  determined from a combined standard uncertainty  $u_c = 0.35\text{mg}$ , coverage factor  $k = 2.20$  calculated from the  $t$  distribution critical value with  $\nu = 9$  degrees of freedom,  $p = 0.95$  level of confidence)

If  $\nu$  is not known, in parentheses, the “ calculated from the  $t$  distribution ... ” may be omitted.

The numerical values of  $y$  and  $u_c$ ,  $U$  should not be given with an excessive number of digit . It usually suffices to quote  $u_c$ ,  $U$  to at most two significant digit, although in some cases it may be necessary to retain additional digit to avoid round-off errors in subsequent calculations. Output estimate  $y$  should be rounded to be consistent with their uncertainties. For example, if  $y = 10.05762 \Omega$  with  $u_c = 27\text{m} \Omega$ ,  $y$  should be rounded to  $10.058 \Omega$

## 2.5 Example

### 2.5.1 Digital Voltmeter

A manufacturer’s specifications for digital voltmeter state that between one and two years after the instrument is calibrated, its accuracy on the  $1\text{V}$  range is  $14 \times 10^{-6}$  times the reading plus  $2 \times 10^{-6}$  times the range.

Consider that the instrument is used 20 months after calibration to measure on its  $1\text{V}$  range a potential difference  $V$ , and the arithmetic mean of a number of independent repeated observations of  $V$  is found to be  $\bar{V} = 0.928571\text{V}$  with a Type A standard uncertainty  $u_1 = s_1 = 12.0\text{mV}$ . One can obtain the standard uncertainty associated with the specifications from a Type B evaluation by assuming that the stated accuracy provides symmetric bounds to an additive correction to  $V$ .  $\Delta \bar{V}$ , of expectation equal to zero and with equal probability of lying anywhere within the bounds. The half-width  $a$  of the symmetric uniform distribution of possible value of  $\Delta \bar{V}$  is then  $a = (14 \times 10^{-6}) \times 0.928571\text{V} + (2 \times 10^{-6}) \times 1\text{V} = 15\mu\text{V}$ . And we have  $u_2 = 15\mu\text{V} / \sqrt{3} = 8.7\mu\text{V}$  ( Type B standard uncertainty ). Because of  $\Delta \bar{V} = 0$ , the estimate of the value of the measurand is given by

$$u = \bar{V} + \Delta \bar{V} = 0.928571\text{V}$$

Its uncorrelated uncertainty components are as Table 2

Table 2

No.	uncertainty		
	source	symbol	value( $\mu\text{V}$ )
1	repetition correction	$u_1$	12.0
2		$u_2$	8.7

We obtain combined standard uncertainty

$$uc(v) = \sqrt{u_1^2 + u_2^2} = \sqrt{12.0^2 + 8.7^2} \mu\text{V} = 15 \mu\text{V}$$

Report: The combined standard uncertainty of  $v$  is  $u_c = 15 \mu\text{V}$

### 2.5.2 End - gauge

The length of nominally 50mm end gauge is determined by comparing it with a known standard of the same nominal length. The direct output of the comparison of the two end gauges is the difference  $d$  in their lengths:

$$d = l(1 + \alpha\theta) - l_s(1 + \alpha_s\theta_s)$$

where

$l$  is the measurand, that is, the length at  $20^\circ\text{C}$  of the end gauge being calibrated,

$l_s$  is the length of the standard at  $20^\circ\text{C}$  as given in its calibration certificate,

$\alpha_1, \alpha_s$  are the coefficients of the thermal expansion, respectively, of the gauge being calibrated and the standard,

$\theta, \theta_s$  are the deviations in temperature from the  $20^\circ\text{C}$  reference temperature, respectively, of the gauge and the standard.

The measurand is given by

$$l = \frac{l_s (1 + \alpha_s \theta_s) + d}{1 + \alpha \theta} = l_s + d + l_s (\alpha_s \theta_s - \alpha \theta)$$

Introducing  $\delta\theta = \theta - \theta_s$ ,  $\delta\alpha = \alpha - \alpha_s$ , we have

$$\begin{aligned} l &= f(l_s, d, \alpha, \alpha_s, \theta, \delta\alpha, \delta\theta) \\ &= l_s + d - l_s \theta \delta\alpha - l_s \alpha_s \delta\theta \end{aligned}$$

It is assumed that the  $l_s$ ,  $\alpha$ ,  $\alpha_s$ ,  $d$ ,  $\theta$ ,  $\delta\alpha$ ,  $\delta\theta$  are uncorrelated and  $\delta\alpha$ ,  $\delta\theta$  are estimated to be zero. we have

$$u_c^2(l) = u^2(l_s) + u^2(d) + l_s^2 \theta^2 u^2(\delta\alpha) + l_s^2 \alpha_s^2 u^2(\delta\theta)$$

The uncertainty components are as follows.

### (1) Uncertainty of the Calibration of the Standard

The calibration certificate gives the expanded uncertainty of the standard  $U=0.075\mu\text{m}$  and states that it was obtained using a coverage factor of  $k = 3$ . The standard uncertainty is

$$u(l_s) = 0.075\mu\text{m}/3 = 25\text{nm}$$

The calibration certificate states that the degrees of freedom of the combined standard uncertainty from which the  $U$  was obtained is  $\nu(l_s) = 18$ . we have

$$u_1 = s_1 = u(l_s) = 25.0\text{nm}, \quad \nu_1 = 18$$

### (2) Uncertainty of the Repeated Difference Observations

The experimental standard deviation characterizing the comparison of  $l$  and  $l_s$  was determined from the variability of 5 independent repeated observations of the difference of two gauges and was found to be 13nm. The standard uncertainty associated with the mean of these reading is

$$u_2 = s_2 = 13\text{nm} / \sqrt{5} = 5.8\text{nm}$$

Its degrees of freedom is  $\nu_2 = 5 - 1 = 4$

### (3) Type A Evaluation of Uncertainty of Length Comparator

According to the certificate of the comparator used to compare  $l$  with  $l_s$ , its uncertainty due to Type A is  $0.01\mu\text{m}$  at a level of confidence of 95% and is based on 6 replicate measurements; thus the standard uncertainty using  $t_{0.95}(5) = 2.57$  is

$$u_3 = s_3 = 0.01 \mu\text{m} / 2.57 = 3.9\text{nm}$$

Its degrees of freedom is  $\nu_3 = 5$

### (4) Type B Evaluation of Uncertainty of Length Comparator

The uncertainty of the comparator due to Type B is given in the certificate as  $0.02\mu\text{m}$  at the three sigma level. The standard uncertainty from this cause is

$$u_4 = 0.02 \mu\text{m} / 3 = 6.7\text{nm}$$

The  $0.02\mu\text{m}$  uncertainty may be assumed to be reliable to 25%, and thus the degrees of freedom is

$$\nu_4 = \frac{1}{2(25\%)^2} = 8$$

### (5) Uncertainty of Difference in Expansion Coefficient

The estimate bounds on the variability of  $\delta\alpha$  are  $\pm 1 \times 10^{-6} \text{ } ^\circ\text{C}^{-1}$  with an equal probability of  $\delta\alpha$  having any value within those bounds. Using uniform distribution, the standard uncertainty is

$$u(\delta\alpha) = 1 \times 10^{-6} \text{ } ^\circ\text{C}^{-1} / \sqrt{3} = 0.58 \times 10^{-6} \text{ } ^\circ\text{C}^{-1}$$

Because of  $\theta = 19.9 - 20.0 = -0.1 \text{ } ^\circ\text{C}$ , we have

$$u_5 = |1, \theta| u(\delta\alpha) = 2.9\text{nm}$$

The estimated bounds of  $\pm 1 \times 10^{-6} \text{ } ^\circ\text{C}^{-1}$  on the variability of  $\delta\alpha$  are deemed to be reliable to 10%. This gives

$$v_5 = \frac{1}{2 (10\%)^2} = 50$$

**(6) Uncertainty of the Difference in Temperature of the Gauges**

The standard and the test gauge are expected at the same temperature, but the temperature difference could lie with equal probability anywhere in the estimated interval  $-0.05^\circ\text{C}$  to  $+0.05^\circ\text{C}$ . The standard uncertainty is

$$u(\delta\theta) = 0.05^\circ\text{C} / \sqrt{3} = 0.0289^\circ\text{C}$$

Because of  $\alpha_s = 11.5 \times 10^\circ\text{C}^{-1}$ , we have

$$u_6 = |\alpha_s| u(\delta\theta) = 16.6\text{nm}$$

The estimate interval  $-0.05^\circ\text{C}$  to  $+0.05^\circ\text{C}$  is believed to be reliable only to 50%. we have

$$v_6 = \frac{1}{2 (50\%)} = 2$$

The uncorrelated uncertainty components are as Table 3.

Table 3

No	uncertainty			degrees of freedom	
	source	symbol	value(nm)	symbol	value
1	standard	$u_1$	25.0	$v_1$	18
2	repeated difference	$u_2$	5.8	$v_2$	4
3	Type A of comparator	$u_3$	3.9	$v_3$	5
4	Type B of comparator	$u_4$	6.7	$v_4$	8
5	difference in expansion	$u_5$	2.9	$v_5$	50
6	difference in temperature	$u_6$	16.6	$v_6$	2

The combined standard uncertainty is



$$u_c = \sqrt{\sum u_i^2} = 31.7 \text{ nm} \approx 32 \text{ nm}$$

It degrees of freedom is

$$v = \frac{31.7^4}{\frac{25.0^4}{18} + \frac{5.8^4}{4} + \frac{3.9^4}{5} + \frac{6.7^4}{8} + \frac{2.9^4}{50} + \frac{16.6^4}{2}} = 16.8$$

Taking  $v=16$ ,  $p=0.95$ , we have  $t_{0.95}(16) = 2.12$ . The expanded uncertainty is

$$U = t_{0.95}(16)u_c = 2.12 \times 31.7 = 67 \text{ nm}$$

Report : The expanded uncertainty of  $l$  is

$$U = 67 \text{ nm}$$

(  $U$  determined from a combined standard uncertainty  $u_c = 31.7 \text{ nm}$ , coverage factor  $k = 2.12$  calculated from the  $t$  distribution critical value with  $v = 16$  degrees of freedom,  $p = 0.95$  level of confidence )

### 3. Reliability Analysis

#### 3.1 Some Concepts

The reliability is important for quality of product and measurement. Lots of standard concerns reliability.

The reliability is defined as " The ability of an item to perform a required function under stated conditions for a stated period of time ". The term " reliability" is also used as a reliability characteristic denoting a probability of success or a success ratio. So the reliability may be used in two case: one is to express the qualitative concept, another is to express quantitative measure.

Loss of required function is called " failure". The failure may be, for example, the cases:

(1) One or more parameter cannot maintain within the required range. For metrology instrument, it means that error exceeds the maximum permissible error given by specification, regulation etc

(2) The element of product will be damaged

The type expressing failure is called failure mode, it may be (1) construction failure (2) incorrect position (3) failure to close (4) failure to open.

The inherent reason caused by change of physical or chemical condition and making failure is called failure mechanism, it may be (1) temperature (2) humidity (3) oxidation.

### 3.2 Expression of Reliability

#### (1) Reliability (Probability) Function $R(t)$

Reliability Function  $R(t)$  is defined as the probability to perform a required function under stated conditions for a stated  $t$  of time. Obviously,  $R(t)$  will be changed with  $t$ , and

$$0 \leq R(t) \leq 1$$

Example: There are 1000 instruments. From beginning to 500h, 100 instruments fail. For beginning to 1000h, 500 instruments fail. Then the estimates of  $R(t)$  are

$$\hat{R}(500h) = \frac{1000 - 100}{1000} = 0.9$$

$$\hat{R}(1000h) = \frac{1000 - 500}{1000} = 0.5$$

#### (2) Failure (Distribution) Function $F(t)$ and Failure (Distribution) Density $f(t)$

The failure function  $F(t)$  and Failure density  $f(t)$  are defined, respectively, as

$$F(t) = 1 - R(t)$$

$$f(t) = \frac{d}{dt} F(t)$$

The failure time  $t$  is a variate, so the  $f(t)$  is the probability distribution density of  $t$ .

#### (3) Failure Rate function $\lambda(t)$

The failure rate function  $\lambda(t)$  is defined as "for instruments which have not been failure at time  $t$ , failure probability at unit time after time  $t$ ".

We have

$$\lambda(t) = \frac{-1}{R(t)} \cdot \frac{dR(t)}{dt} = \frac{f(t)}{R(t)}$$

In early failure period,  $\lambda(t)$  is larger and decreases with time. In random failure period,  $\lambda(t)$  is small and is approximately a constant. The time in this period is the normal work time. In wear-out failure period,  $\lambda(t)$  increases, and at last the instrument cannot be used.

### 3.3 Life Characteristic

#### (1) Mean Life $\theta$

The mean life  $\theta$  is the mean time before failure. We have

$$\theta = \int_0^{\infty} t \cdot f(t) dt = \int_0^{\infty} R(t) dt$$

that is

$$\theta = E t$$

It means that  $\theta$  is the mathematical expectation of  $t$ .

Making experiment, if the lives of  $n$  samples of instruments are  $t_1, t_2, \dots, t_n$ , the estimate of  $\theta$  is

$$\hat{\theta} = \bar{t} = \frac{1}{n} \sum_{i=1}^n t_i$$

#### (2) R - reliability Life

Given reliability  $R$ , the solution  $t_R$  of equation

$$R(t_R) = R$$

is called R- reliability Life.

When  $R = 0.5$ , the  $t_R$  is called Medium Life

### (3) Life Standard Deviation $\sigma$

The life standard deviation  $\sigma$  is the standard deviation of  $t$ . We have

$$\sigma = \sqrt{\int_0^{\infty} (t - \theta)^2 f(t) dt}$$

Making experiment, if the lives of  $n$  samples of instruments are  $t_1, t_2, \dots, t_n$ , the estimate of  $\sigma$  by Bessel Method is,

$$s = \sqrt{\frac{1}{n-1} \sum (t_i - \bar{t})^2}$$

### 3.4 Failure Distribution.

The failure conforms with exponent distribution, Weibull distribution and other distributions.

#### (1) Exponent Distribution

$$f(t) = \lambda e^{-\lambda t}$$

$$R(t) = e^{-\lambda t}$$

$$F(t) = 1 - e^{-\lambda t}$$

$$\lambda(t) = \lambda \text{ (constant)}$$

$$\theta = 1/\lambda$$

$$\sigma = 1/\lambda$$

For distribution density  $f(t)$ , its skewness coefficient  $\gamma_1$  ( $= \mu_3 / \sigma^3$ ,  $\mu_i$  is  $i$ -th central moment) and kurtosis coefficient  $\gamma_2$  ( $= (\mu_4 / \sigma^4) - 3$ ) are

$$\gamma_1 = 2, \quad \gamma_2 = 6$$

Its  $R$  - reliability life is

$$t_R = -\frac{\ln R}{\lambda} = k_R / \lambda = k_R \theta$$

The  $k_R$  is listed as Table 4.

**Table 4**

R	0.999	0.99	0.95	0.90	0.50	0.37
k	0.001	0.010	0.051	0.105	0.693	i

The medium life is  $t_{0.50} = 0.693$ . The reliability of mean life  $\theta$  is  $R = e^{-1} \approx 0.37$ .

The instrument is always used in random failure period with  $\lambda(t) \approx \text{constant}$ , so the exponent distribution is always used.

**(2) Weibull Distribution <sup>(8)</sup>**

$$f(t) = \frac{m}{t_0} t^{m-1} e^{-t^m/t_0^m}, \quad \theta = t_0^{1/m} \Gamma\left(\frac{1}{m} + 1\right)$$

$$R(t) = e^{-t^m/t_0^m}, \quad \sigma = t_0^{1/m} \left\{ \Gamma\left(\frac{2}{m} + 1\right) - \Gamma^2\left(\frac{1}{m} + 1\right) \right\}^{1/2}$$

$$F(t) = 1 - e^{-t^m/t_0^m}$$

$$\lambda(t) = \frac{m}{t_0} t^{m-1}$$

Where  $\gamma$  : position parameter,  $m$  : shape parameter,  
 $t_0$  : scale parameter

When  $\gamma = 0$ , we have

$$\gamma_1 = \frac{\Gamma\left(1 + \frac{3}{m}\right) - 3\Gamma\left(1 + \frac{2}{m}\right)\Gamma\left(1 + \frac{1}{m}\right) + 2\Gamma^2\left(1 + \frac{1}{m}\right)}{\left\{ \Gamma\left(1 + \frac{2}{m}\right) - \Gamma^2\left(1 + \frac{1}{m}\right) \right\}^{1/2}}$$

$$\gamma_2 = \frac{\Gamma\left(1 + \frac{4}{m}\right) - 4\Gamma\left(1 + \frac{1}{m}\right)\Gamma\left(1 + \frac{3}{m}\right) + 6\Gamma^2\left(1 + \frac{1}{m}\right)\Gamma\left(1 + \frac{2}{m}\right) - 3\Gamma^3\left(1 + \frac{1}{m}\right)}{\left\{ \Gamma\left(1 + \frac{2}{m}\right) - \Gamma^2\left(1 + \frac{1}{m}\right) \right\}^{1/2}}$$

The distribution reflects that when instrument is constructed by many parts, the life is determined by weak part. It is used in fine conditions.

When  $m = 1, \gamma = 0$ , the weibull distribution becomes exponent distribution

**3.5 Verifictaion Period <sup>(9)</sup>**

To obtain reliable value, the measuring instrument should be verified after a period.

How long is the period?

There are two basic criteria when deciding on period of each measuring instrument. These are:

- reliability, that is, the risk of a instrument going out of tolerance when in use should be as small as possible,
- minimum costs, that is, the verification costs should be kept to a minimum.

A large number of factors influence the frequency of verification and should be taken into account by the testing laboratory and by the accrediting authority. The most important factors are:

- uncertainty of measurement sought,
- type of equipment,
- manufacturer's recommendation,
- trend data obtained from previous verification records,
- recorded history of maintenance and servicing,
- extent and servity of use,
- tendency of wear and drift,
- frequency of cross-checking against other reference standards,
- frequency and quality of in-house check calibrations,
- environmental conditions (temperature, humidity, vibration, etc)

The period may be determined by reliability function.

If the mean life  $\theta$  and reliability function  $R(t)$  are given by:

$$t = \theta \{ - \ln R(t) \}$$

we can obtain the work time  $t$ . According the mean work time under usage condition, we can determine the verification period  $T$ .

**Example:** A instrument is of  $\theta = 5000\text{h}$ . Given  $R(t) = 0.95$ , we obtain  $t = 5000\text{h} \{ - \ln 0.95 \} = 256\text{h}$ . The mean work time of this instrument is  $40\text{h/month}$ , so the verification period is

$$T = \frac{256}{40} \text{ month} \approx 6 \text{ month}$$

### 3.6 Reliability for Combined Equipment

#### (1) Series Connection

The  $n$  independent equipments, each of which is of reliability function  $R_i(t)$ , work together. The reliability function of combined equipment is

$$R(t) = \prod_{i=1}^n R_i(t)$$

Using exponent distribution and assuming  $\lambda_1 = \lambda_2 = \dots = \lambda_n$ , for the mean life we have

$$\theta = \theta_1 / n$$

#### (2) Parallel Equipment

The  $n$  independent equipments, each of which is of Reliability function  $R_i(t)$ , work together. The reliability function of combined equipment is

$$R(t) = 1 - \prod_{i=1}^n \{ 1 - R_i(t) \}$$

Using exponent distribution and assuming  $\lambda_1 = \lambda_2 = \dots = \lambda_n$ , for the mean life we have

$$\theta = \theta_1 ( 1 + 1/2 + \dots + 1/n )$$

If  $n = 2$ , we have  $\theta = 3 \theta_1 / 2$

### 3.7 Design of Reliability

The design should provide evaluation at significant stages. Such evaluation can take the form of analytical methods, e.g. FTA, FMEA.

FTA is Failure Tree Analysis. We make the tree to reflect the relation of failure factors. According minimum cut set, we obtain the failure probability relating failure sources, and then we can obtain the degrees of importance as example:

Example:

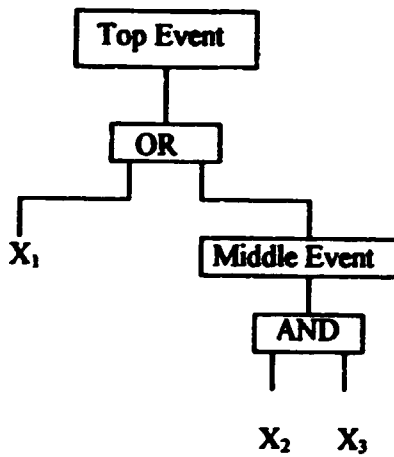


Fig. 1

The bottom events  $X_i$  conform with exponent distribution of

$$\lambda_1 = 0.001 / h$$

$$\lambda_2 = 0.002 / h$$

$$\lambda_3 = 0.003 / h$$

The failure function of top event is

$$\begin{aligned} F(t) &= 1 - \{ 1 - F_1(t) \} \{ 1 - F_2(t) F_3(t) \} \\ &= 1 - e^{-\lambda_1 t} \{ 1 - (1 - e^{-\lambda_2 t})(1 - e^{-\lambda_3 t}) \} \\ &= 0.1374 \end{aligned}$$

Where  $F_i(t)$  is the failure function of  $X_i$ . We have

$$\frac{\partial F(t)}{\partial \lambda_1} = t e^{-\lambda_1 t} \{ 1 - (1 - e^{-\lambda_2 t})(1 - e^{-\lambda_3 t}) \} = 86.260$$



$$\frac{\partial F(t)}{\partial \lambda_2} = t e^{-\lambda_1 t} e^{-\lambda_2 t} (1 - e^{-\lambda_1 t}) = 19.295$$

$$\frac{\partial F(t)}{\partial \lambda_3} = t e^{-\lambda_1 t} e^{-\lambda_2 t} (1 - e^{-\lambda_1 t}) = 12.055$$

The degrees of importance of  $X_i$  is defined as

$$I_i(t) = \frac{\lambda_i}{F(t)} \cdot \frac{\partial F(t)}{\partial \lambda_i}$$

we have  $I_1(t) = 0.682$ ,  $I_2(t) = 0.281$ ,  $I_3(t) = 0.263$

Because of  $I_1(t) > I_2(t)$  and  $I_1(t) > I_3(t)$ , the part  $X_1$  is more important than part  $X_2$ ,  $X_3$ .

FMEA is Failure Mode and Effects Analysis. It defines the function of system, finds the failure probability and lists the failure mode, mechanism and effect. Also, the failure proof method can be found.

## References

- [1] ISO/ IEC Guide 25, General Requirements for the competence of Calibration and Testing Laboratories, 1990
- [2] ISO 9001, Quality System — Model for Quality Assurance in Design/ Development, Production, Installation and Servicing, 1987
- [3] ISO 9004, Quality Management and Quality System Elements — Guidelines, 1987
- [4] BIPM, IEC, IFCC, ISO, IUPAC, IUPAP, OIML, Guide to the Expression of Uncertainty in Measurement, 1993
- [5] Liu Zhimin, Principle of Uncertainty, Chinese Metrology Press, 1993
- [6] Liu Zhimin, The Evaluation of Uncertainty and the Adjustment of Fundamental Constants, CIPM, 420- 421, 1988
- [7] Liu Zhimin, Measurement Uncertainty and Its Correlation Combination, Proceeding of ISEM, 196-207, 1993
- [8] Liu Zhimin, The Applied Method of Weibull Distribution in Product Life Research, Mathematics in Practice and Theory No.3, 32-39, 1979
- [9] Liu Zhimin, Determining Verification Period of Measuring Instrument by Statistical Method, Measurement Technique No 8 1-2, 1989

## **ISO 9000 • METROLOGY • QUALITY**

**Chen Weidong  
Qingdao Haier Group  
Qingdao, China**

The technology and equipment for producing refrigerator were introduced from Lieber Haier, West Germany by Qingdao Refrigerator General Factory in 1985. This was the first enterprise in our country which introduced, manufactured, and became effective in the same year, and produced the first generation of refrigerators with grade four stars. In recent years, the aim in our production and management is : to stress product quality as a heart; to establish famous brand strategy, to insist the starting on the high point, to keep good quality, to carry out omnibearing management . As a result, the enterprise has been developing rapidly. There are workers and staff: 1,540, fixed assets: 139.16 millions Yuan (RMB) including fixed metrological assets: 7.2 million (RMB), taking 5.2% of the total. In 1992, the gross industrial output value: 603.98 million Yuan (RMB), profits and tax: 59.40 million (US\$).

Since we stress on technical basic work in the enterprise, so we have established the principle "Quality is factory's life, metrology is quality's spirit". Management level of metrology work in the enterprise has been raised by a new step every year. In 1990, we gained the title-first-class unit of metrology in China. This ensures the enterprise developing speedily: "Qingdao Lieber Haier" gained the first gold medal in refrigerator history in China. For 7 years, the products were chosen as the most acceptable products by consumers in all over the country. In order to enter the international market smoothly, we have got certifications UL, CSA, VDE for entering U.S., Canada, Germany markets respectively. We have also got the European Green Mark approval for the first one to reduce freon by 50%. Our metrological management level meets requirements of international standards speedily. For this reason we have laid solid foundations for the enterprise to become an acceptable supplier in the world . Here, we would like to talk about the effect of metrology on improving product quality and economical benefits and how to connect with ISO9000 standard.

### **1. Metrological Management Model:**

Metrology & Testing Center is a leading division in Qingdao Haier Group, under the leadership of the Deputy General Manager. It governs the whole measuring

work in the Group. Following the measurement regulations and its practice, we conduct internal verifications for all of the measuring gauges and instruments in the General Factory by force. In the entire life time of the gauges from buying , verification, putting in store, taking out and using, entering into the account book, periodic verifications, sampling-verifications, to reporting as worthless, all of those things are controlled by the Center. The Center covers physical-chemical test , refrigerator practice experiment, metrological management including all of the measurement work as a whole. So, variety of data inspected and tested would be controlled effectively.

Our metrological management model adopts the contents requirements stipulated by the CSBTS. We absorb and use the experience of specification in international quality certification and ISO9000 series by using modern microcomputer management , adopting classification management marks, stressing data management, holding product quality as a key point and improving verification level continuously. We have laid a solid foundation for developing new products and improving product quality in pace with metrological management constantly. At first we enhanced the hardware level by establishing 21 sets of measuring reference standards and purchasing up to over 5,000 sets of gauges and instrumentation to meet the demands for production and test. Secondly, according to requirements of production and profession features, we organized technicians to study and compile over 20 calibration procedures for special instruments and measuring gauges and reported to the China State Bureau of Technical Supervision for approval , so the production quality is effectively assured. In recent two years, we joined the current metrological work to the measurement requirements for certification of quality management and assurance system so that our present metrological management model is adapted to the international competition.

## **2. How to Connect Metrology with International Approval**

ISO9000 is resulted from commercial economy. It is a quality assurance system in an enterprise, in order to make the enterprise "International". Our factory has gained the certification of ISO9001. In the certificating process, the original metrological work was transformed in forms and detailed in contents, stressing event proof and effectivity. During the assessment for ISO9001, certification requires a high level metrological work, that is, the special attention was paid to the metrological work. We consider that the following measures has to be emphasized:

**(1) Keeping and improving the metrological management of the enterprise to a first-class level in the country.**

**(2) On the basis of the above mentioned objective, some transformation work has to be done. The major work is to transform relative regulations into program files, that is to reflect the work we already did into relative records, so that , every thing has written proof.**

**(3) Stressing the measurement traceability. In the certification, the traceability of quantity value transfer and the verification validity are checked strictly. Every verification of gauges and instruments must be traceable to the national and international standards**

**(4) Corrective action is very important**

**International certification is just certificating the quality assurance system. All measurements in an enterprise are controlled and each measuring step should be rechecked. If there is anything wrong, correction must be made and then put in notes. For example, if an incorrect gauge is found, an immediately rechecking of the parts which have been measured by that gauge should be measured again with another correct gauge. For complete product, requalification or tracking is needed.**

**(5) Stressing the training of the personnel who conduct the verification or use the measuring instruments. In this way, those personnel could master the main specifications, the correct operating and the repairing and maintenance of instruments. Daily checking and keeping notes will ensure the control of the measuring instruments.**

**(6) In ISO9000 system , the effect is primary and the form is supplementary. During certificating and reexamining , we realized that there was no same form, no same model and no standard details, so it is even more flexible, adaptable and effectual, during reviewing, the head assessor might have some view points on the ways of doing adopted by the enterprise, but he did not interfere. He only used the effect to decide if the ways could be accepted and to examine whether the process could be controlled. They let the enterprise itself understand what was the was the primary purpose of the work and realize how to do things well. Therefore, each enterprise can create different models, ways, according to its superior and inferior positions. However, the aim is the same — meeting criteria and users' demands.**

(7) Auditors, who are in charge of ISO9000 examining, did not emphasize only oral or written form. They audited in the work-site primarily, reviewed randomly and examined not only the present but also the past work. It is important that the unit being examined would immediately reply to problems found, make correction and improvement and give satisfactory answers before the auditors leave. Now I would like to introduce briefly the process of reviewing through ISO 9001 certification:

(a) Visit the work-site, examine the status of measuring instrumentation and take notes.

(b) Look over total instrumentation account book, selectively examine one or two set of gauges and check if there are verification records, certificates of acceptance, as well as regulations for calibration.

(c) Look over the total account book of the gauges sealed up and discarded as useless.

(d) Look over the account book of new gauges bought lately.

(e) Visit the verification laboratory.

After the above steps, the unit being examined would execute correction and reformation according to the examination. If the result is accepted, then the unit would be passed.

Last year, the Air-conditioner Factory under the Group passed the first-class metrological check. This year, the Freezer Factory is required to pass the same check. There is a plan in which every primary factories under the Group have to reach the national level in two or three years.

### **3. Relation Between Metrology, Quality and Profits:**

Metrology is related with quality and economical profits directly. Through practice in these years, we realize that perfect metrological management can make product quality stable and improving constantly and the more input for metrology, the more economical profits will be gained by the enterprise. 2.39 million Yuan (RMB) was invested for metrology by Qingdao Refrigerator General Factory in 1992. Two major projects were set up, one was a big test board with high precision for compressor which was imported from Japan, another was a refrigerator measuring line controlled by micro-computer, which

was designed and installed by the help of the Shandong University. For these two projects, the total investment is 1.5 million Yuan (RMB). Besides, we also input nearly 0.9 million Yuan (RMB) to increase some key instruments. In the past, the compressors imported from abroad had to be sent to other organization for sampling check, which took a lot of time and money, and could not ensure the quality of all compressors. In 1992, after the import of the compressor-testing board, we could test 17 items of the compressor so as to assure that every technical parameters could reach the national-class level. Thus, the product quality was guaranteed, which brought more economical benefits. According to the preliminary estimation, because of this project the enterprise can get profits over 500 thousand Yuan (RMB) each year.

In order to improve the refrigerator quality, to ensure every item of measuring data accurate, we use "a refrigerator measuring line controlled by micro-computer", which is advanced in domestic. There are three advantages with this line:

- (1) The measuring uncertainty of the line is  $\pm 0.5^{\circ}\text{C}$ , four times better than the previous measuring with glass-liquid thermograph.
- (2) The working efficiency can be raised by 20%, which means 2.0 million Yuan (RMB) more can be gained each year.
- (3) Faults and problems in the production of refrigerator can be predicted and determined using the curves drawn by the computer, so that the product-retrieving rate can be decreased and the product quality can be guaranteed.

Input for metrology promotes the technical reformation to a great extent. For example in the spraying line, since the impurity in compressed air was formerly rather higher, the acceptance rate of the parts sprayed was only 60%. With the cooperation of the Measuring Detection Center, we analyzed the reason through many measurements, we found that there were too much oil and water in the compressed-air. After the improvement, the acceptance rate for the sprayed parts was immediately raised from 60% to 93.5% consequently 2.115 millions Yuan (RMB) can be saved each year with this item only.

#### **4. Some Actions to Further improve the Metrological Work Future:**

- (1) The Measuring Detection Center will pass the provincial class laboratory accreditation by the end of this year.

**(2) 20 million Yuan (RMB) will be invested to improve the measurement hardware and a comprehensive metrological center will be established in 1995. This project includes 3 sub-items and provides 31 sets of key instruments used for product-developing, process testing, as well as product-testing. The sub-items are:**

**(a) Introduce from abroad two sets of full-performance-testing laboratory for refrigerators and freezers.**

**(b) Prepare to set up a research laboratory to study noise and vibration in household appliance.**

**(c) Set up a test laboratory for safety testing on heat and electricity.**

# STUDY ON EVALUATION OF QUALITY SYSTEM

Lang Zhizheng  
Beijing Institute of Technology

## Abstract

For the purpose of assessing, improving and comparing an organization's quality system, this paper puts forward a way which, using the elements of the quality system as evaluation indexes, makes comprehensive evaluation of the quality system in a scientific and practicable way, based on the fuzzy mathematics and through the evaluation of the elements of each quality system.

\*\*\*\*\*

How to evaluate an organization's quality system after it is established and put into operation is of vital importance. The purpose of the quality system mainly consists of the following:

- a. To assess the operation of the organization's existing quality system;
- b. To transform the organization's existing quality system;
- c. To make qualifications of the organization's existing quality system's adaptability when internal and external conditions change;
- d. To make comparison among the quality systems of different organizations.

For evaluation of the quality system, the following bodies may be included:

- a. The organization itself;
- b. The second party;
- c. The third party;
- d. The administrative department.

It is determined by the quality system's requirements and the present conditions of the organization to use which of the aforementioned aspects. It is possible for all of them to be adopted in evaluating the organization's quality system.



In light of the different aspects of the purpose of evaluation and different main bodies of evaluation, it is necessary to find a universal way to evaluate the quality system.

## **I. Establishment of the Evaluation Index System of the Quality System**

The first thing in evaluating the quality system is to choose evaluation index. Only through the evaluation of each element of the quality system can the comprehensive evaluation of the quality system be fulfilled. That is why the elements of the quality system are chosen as the evaluation index. It is based on the following factors that the system's elements are chosen as the evaluation index.

### **a. Elements that the quality system comprises of and depends on**

The quality system is composed of certain interactive and interrelated basic elements, which are the basic units that comprise the quality system. The quality system is sustained by those elements because the system comes into being after the assembly of certain elements. From Chapter 20 of the Element Standard in ISO9004 Quality System on, 17 system elements are provided, which give a quick-guide for the establishment of organizations and the improvement of the quality system.

### **b. Elements of the quality system present in the process**

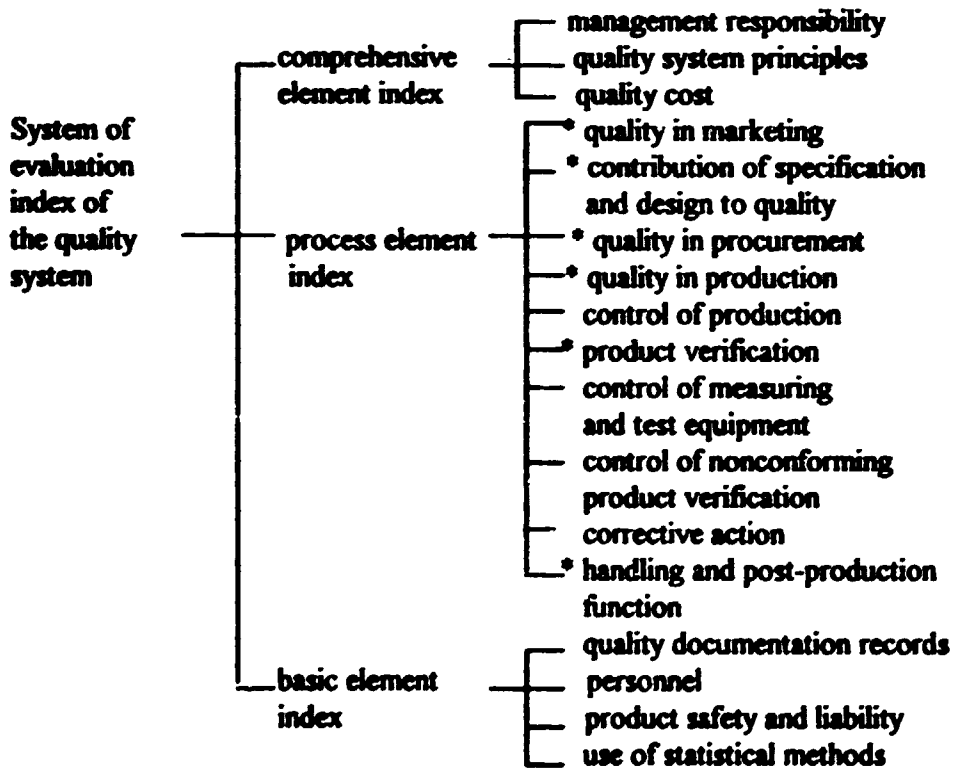
The quality system aims at fulfilling the quality requirements through the supplier's process, through whose control the administration of quality is reached. On the other hand, the quality system consists of elements which can be divided into several tiers and unfolded one by one, and whose end use is the activities related to quality. Each element of the quality system can be dissolved into one or a group of quality-related activities which must be completed in the process. In this way, the quality system consists of a series of elements carried out through processes.

It is reasonable to choose system elements as evaluation indexes and possible to make effective and comprehensive evaluation according to the analysis above.

General conditions, instead of specific structure, shall be first taken into account when establishing the evaluation index of the quality system. In this way, the

system of evaluation index of the quality system can be established according to ISO9004's requirements based on the abovementioned 17 elements.

Table 1: System of evaluation index of the quality system



The system of evaluation index of the quality system can be established (see Table 1 above ) on the basis of the quality system's elements and their interrelationship. Those with a "\*" in Table 1 indicate the fundamental process elements while others are supplementary process elements

system. This paper makes an initial study on the Fuzzy mathematics's comprehensive evaluation applicable to the evaluation of a quality system.

a. Introduction of the mathematical model

The evaluation criteria of the quality system of the demanding party is not simply "Good" or "Bad", between which exists a kind of intermediary and fuzzy relationship.

If "U" is the set made up of the quality system's evaluation index (as elements), "V" is the set of organization elements, the following formula indicates the fuzzy relationship between "U" and "V":



The "R" in the formula indicates a UxV's fuzzy sub-set which is represented by  $\underline{UR}: U \times V \rightarrow [0, 1]$ , the subordinate function  $\underline{UR} (U_0, V_0)$  is called the degree of subordination to the fuzzy relationship "R", i.e. an index's degree or level in V, the organization.

U, V are both limited, i.e.:

$$U = (U_1, U_2, \dots, U_m)$$

$$V = (V_1, V_2, \dots, V_n)$$

so "R" can be represented with fuzzy matrix "R":

$$R = \begin{bmatrix} r_{11} & r_{12} & \dots & r_{1n} \\ r_{21} & r_{22} & \dots & r_{2n} \\ \vdots & \vdots & \ddots & \vdots \\ r_{m1} & r_{m2} & \dots & r_{mn} \end{bmatrix} \begin{bmatrix} U_1 \\ U_2 \\ \vdots \\ U_m \end{bmatrix}$$

whose abbreviation is :

$$R = (r_{ij})_{max}$$

$$r_{ij} = \underline{UR} (U_i, V_j) \quad r_{ij} \in [0, 1]$$

$$i = 1, 2, \dots, m, \quad j = 1, 2, \dots, n$$

With the help of fuzzy matrix R and through appropriately assigning indexes of each quality system, a comprehensive evaluation of M indexes of each organization of field V can be achieved.

Taking into account of the importance of the indexes of the quality system to ascertain its weighted average, weighted vector A of the indexes of the quality system can be worked out, i.e.

$$A = (a_1 \ a_2 \ \dots \ a_m) \quad \sum_{i=1}^m a_i = 1$$

formula  $Q = AR$  can be calculated by common matrix multiplication, i.e.

$$Q = (Q_1, Q_2, \dots, Q_n) = (a_1, a_2, \dots, a_m) \begin{bmatrix} r_{11} & r_{12} & \dots & r_{1n} \\ r_{21} & r_{22} & \dots & r_{2n} \\ \vdots & \vdots & \ddots & \vdots \\ r_{m1} & r_{m2} & \dots & r_{mn} \end{bmatrix}$$

Linear matrix  $Q = (Q_1, Q_2 \dots Q_n)$  represents the degree or level that each index in field V reached. If  $n = 1$ , to one organization, one exceptional case is the following:

$$R = \begin{bmatrix} r_1 \\ r_2 \\ \vdots \\ r_m \end{bmatrix} \quad r_i = U_{ij} (U_i)$$

$$Q = (a_1 \ a_2 \ \dots \ a_m) \begin{bmatrix} r_1 \\ r_2 \\ \vdots \\ r_m \end{bmatrix} = \sum_{i=1}^m a_i r_i$$

#### b. Steps for comprehensive evaluation

- (1) To define the set of evaluation elements
- (2) To define the set of comments
- (3) To define the weighted average of the degree of comments
- (4) To get the subordinate level of secondary index through fuzzy evaluation statistics.
- (5) To define the weighted coefficient of the indexes
- (6) To calculate the comprehensive fuzzy evaluation
- (7) To calculate the index's comprehensive evaluation value at each stage

Note: All of the mathematical derivation in steps for comprehensive evaluation are omitted.

### **III. Application Example**

Table 2 indicates the application of the above mentioned methods.

This paper elaborates how to choose the evaluation index of the quality system, and how to apply the comprehensive evaluation method of fuzzy mathematics to an evaluation of the quality system. Attention should be paid to the following aspects in evaluating the quality system:

1. It is emphasized that this paper probes the quality system's ration evaluation of general purpose. No matter what the purpose or subject of the quality system's evaluation is, the method can be applied.
2. The quantity of chosen elements is not fixed when establishing the evaluation index of the quality system. The 17 elements provided in ISO9004 are only a guide to the establishment and improvement of the quality system in an organization and not a standardization of the quality system of that organization. On the basis of the types and characteristics of its products, different organizations can choose corresponding elements whose quantities can be different. In this way, the evaluation index defined according to elements of the system is not always the same.
3. The difference of different organizations' specific conditions in the market conditions they face, the types of products, the specific production and the demand of customers determine the difference of different organizations in choosing elements and their degree of application when establishing the quality system of their own, and also determine the different positions of the elements in

different organizations. The reality of each organization has to be taken into account during the evaluation of fuzzy mathematics, and in this way different weight is determined for each element's index. In many cases, the "expert evaluation" mentioned above can be adopted instead of subjective decision when defining the weighted index. The more experts taking part in the evaluation, the more accurate the defined weighted index will be.

4. What deserves attention is that the quality system's elements can be divided into activities related to quality. To facilitate narration, this paper only establishes bi-polar evaluation index according to the 17 elements provided by ISO9004. In fact, the elements of the quality system must be based on activities related to quality. Each system element can be divided into an activity or a group of activities related to quality, thus, when making an evaluation of the quality system using the methods mentioned above, Level 3, even Level 4 evaluations index can be established according to the specific conditions of the organization and the subdivision of the particular element into activities related to quality. The evaluation of the quality elements can be conducted and the end purpose of comprehensively evaluating the quality system can be fulfilled through the evaluation of activities related to quality.

5. The evaluation of process is emphasized. It is clear from the above analysis that, the quality system is made up of elements which can be sub-divided into quality-related activities, which must be fulfilled through process. In general, the quality system consists of a series of elements fulfilled through process. In this way, the evaluation of the quality system must be carried out finally through the evaluation of process. The following three aspects shall be taken into account when evaluating process:

- a. Has the process been defined? Has the procedures of process been appropriately transformed into document?
- b. Has the process been carried out fully and implemented as required in the document?
- c. Is the process effective with respect to providing desired results?

Respective and correct answers to these three questions in regard with method, implementation and results play a decisive role in the effectiveness of the evaluation.

**Table 2: Application Example of the Comprehensive Evaluation of the Quality System**

No.	Evaluation Index Quality	Weighted Coefficient	Degree of Subordination				Degree	Comprehensive Evaluation Value
			Poor	Fair	Good	Exc.		
1	Responsibility	0.05	0	0.5	0.25	0.25	Fair	75
2	Principles of Quality System	0.02	0.25	0.25	0.5	0	Fair	62.5
3	Quality Cost	0.08	0	0.25	0.5	0.25	Good	80
$\sum_{i=1}^3$	Comprehensive Elements	0.15	0.0333	0.333	0.4167	0.2167	Good	76.003
4	Marketing Quality	0.06	0.15	0.35	0.45	0.05	Fair	66.5
5	Quality of Design & Specification	0.05	0	0.3	0.55	0.15	Good	77
6	Purchasing Quality	0.1	0.2	0.55	0.15	0.1	Fair	61

7	Production Quality	0.1	0	0.35	0.5	0.15	Good	76
8	Control of Production Process	0.15	0	0.1	0.65	0.25	Good	83
9	Product Evaluation	0.05	0	0.3	0.55	0.15	Good	77
10	Control of Measurement & Experiment Equipment	0.05	0.15	0.45	0.25	0.15	Fair	66.5
11	Disqualified Control	0.02	0.02	0.3	0.4	0.28	Good	78.6
12	Corrective Measures	0.05	0.08	0.3	0.3	0.32	Good	78.6
13	Transportation & Post-Production Function	0.02	0.1	0.15	0.3	0.45	Good	81



13 $\Sigma$ 4	Process Elements	0.65	0.066	0.3155	0.44	0.1825	Fair	74.12
14	Quality Documents & Records	0.1	0.14	0.25	0.45	0.16	Fair	71.2
15	Personnel	0.07	0.15	0.4	0.3	0.15	Fair	67.5
16	Product Safety & Responsibility	0.01	0.08	0.15	0.45	0.32	Good	79.4
17	Application of Statistics	0.02	0.1	0.35	0.45	0.1	Fair	70
17 $\Sigma$ 14	Basic Elements	0.2	0.1365	0.3075	0.3975	0.1585	Fair	70.069
17 $\Sigma$ 1	Quality System	1	0.0752	0.314	0.428	0.1828	Fair	73.616

# **HOW DOES OUR WORKS IMPLEMENT THE QUALITY SYSTEM CERTIFICATION**

**Yu Lizheng  
Shanghai Turbine Works**

In July 1992, the related departments under the State Council convened a national certification meeting. Arranged by the State Bureau of Technical Supervision, the quality certification works were started under the state unified control and reviewed by the authorized certification organization. In order to suit the needs of market economy and invigorate the enterprise, our Works took the lead in applying the registration of quality system certification. In March 1993, our Works passed the on-job audit by the Shanghai Quality System Audit Center. In April of the same year, admitted by the Technology Commission of the Shanghai Quality System Audit Center, the State Bureau of Technical Supervision sent related persons-in-charge to attend the full-course on-job inspection activities as observers, and confirmed that all the audit procedures conform to international conventions. The audit activities were performed by a third party who is fair and has independent legal rights. So, it is fair, independent and scientific. On June 11, 1993, Director Wu Jizhi from the Quality Certification Office of the State Bureau of Technical Supervision made a special trip to Shanghai Turbine Works to attend the issuance ceremony awarded by the Shanghai Quality System Audit Center. The number of the registered Certificate is 0193A001. This is the first quality system certificate issued by the first domestic quality system certification organization performed, based on the general quality certification policy and trial-run schedule formulated by the state after the publication of the national "Product Quality Acts". This shows the first encouraging step of the quality system certification work of our country and this also shows that the quality management and quality assurance of our Works has reached the level of the domestic & international standards. Now, I would like to give a brief summing up of the quality system certification implementation procedures of our Works.

## **I. Preparation for Application**

### **1. Select Suitable Quality System Certification Organization:**

Before the application, the enterprise must carefully select a suitable and reliable certification organization as an audit entity. If the contract or customer has no definite requirement, the enterprise can select according to its own characteristics and needs based on the voluntary principle. According to the

regulation of "Product Quality Certification Management Rules" published by the State, the domestic certification work will be unitarily controlled by the product quality supervision management department, and performed by the certification organization set up or authorized by the said department. So, the enterprise should consider an independent legal third party authorized by the State as its auditor. Such audit organization, in accordance with the principle of state universal management and certification level and the principle of international convention, may be acknowledged by the international bilateral or multi-lateral certification organizations.

## **2. Fill in Application Documents:**

The enterprise who applies for the quality system certification (applicant) should first fill in the formal application letter and provide the investigation sheet in which the necessary information of the enterprise is included. The contents of the application letter should include:

- \* The applicant's name, address, postal code, legal representative, the name of the liaison person, his occupation, telephone, telefax, cable etc.
- \* The quality assurance model of the applied certification and the business scope of the certification system etc.

The investigation sheet should include:

- \* Briefing and scale of the works
- \* Products related to the certification
- \* Production situation related to the certification

## **II .Choice of QA Model and Review of System Documentation**

1. Select suitable QA model: while applying for the quality system certification and handing in the system documentation, the quality assurance model of the applied certification and the scope of the covered product must be carefully considered and selected. Following factors are the bases for the correct selection of the quality assurance model.

- \* Complexity of the design
- \* Maturity of the design
- \* Complexity of manufacture
- \* Characteristics of the product
- \* Safety and economy consideration

If the requirement of the safety of the design, manufacture, and the product characteristics is relatively high , the first QA model (i.e. GB/T19001-ISO9001) should be selected. But, the higher the QA degrees, the more the expenses will be. So, if the design maturity is quite high and the products covered are not new products, or if the customer does not need design control, the second QA model (GB/T19002-ISO9002) is usually selected . About 60% to 70% of the foreign companies who have applied for system certification select the second QA model. For example, when a foreign company signed a trade-back purchasing contract with us , they required us to implement the ISO9002 model . The third model is mostly applicable to relatively simple products with no need to check the design, procurement and procedure control. Figure 1 shows the relationship between the standard content of the various QA models. Figure 2 shows the selection programme for various QA models.

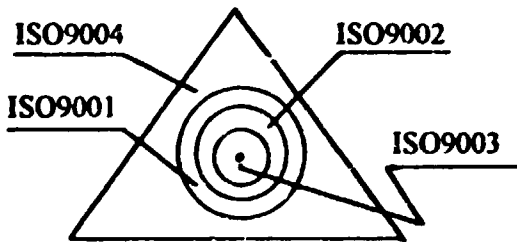


Fig.1 The relationship between the standard content of Various QA models

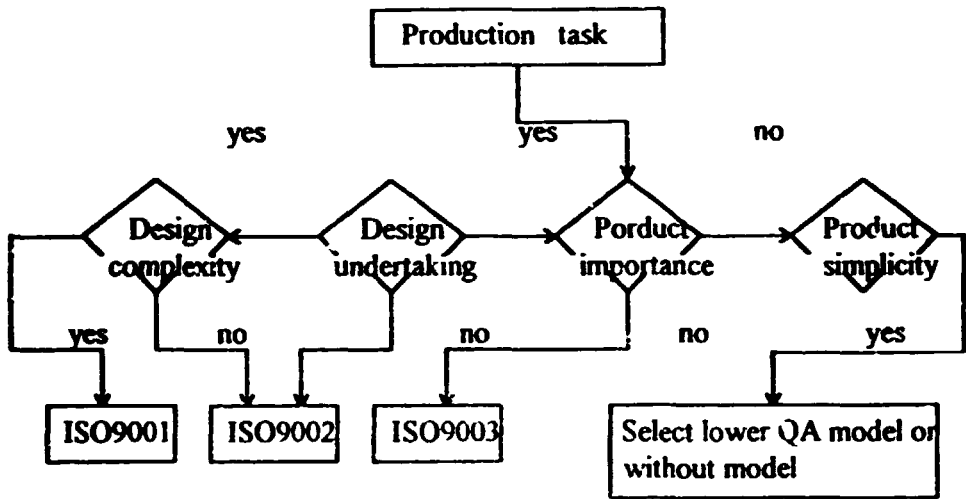


Fig. 2 Selection program for various QA models

It is beneficial for both the supplier and customer to select a proper QA model. A mutual agreement can be reached for the selection of the model according to specific conditions and requirements. Some developed countries have set up selection standards of QA models, e.g. CSA299 in Canada and MIL-Q — 9858A in U.S.A. Only a few products need to select high level QA requirement (ISO9001). Our works selected ISO9001 QA model because of the high economics value, high requirement of safety & reliability, and the complexity of the turbine product as well as its importance and significance in the national economy.

The covered scope of the product is the base for the backing of specific QA model, and is also the application of the quality system embodied in the said product. So, when an enterprise is determining whether the quality system is in conformity with the QA model standard, it should also consider what kind of product the said quality system will apply to. Because the quality system itself includes all activities of interaction related to product or service quality, running through every period from the initial determination of the quality requirement and customer needs of the product to the final satisfaction of these requirement and needs. For example, when we are determining the covered scope of the products, we make it clear that the turbine product with introduced technology is selected. So, nonturbine products and domestic -ally designed turbines are not

included in the control scope of the said QA model . The production of the turbine with introduced technology is the base for handing in all documentation and witness materials or during on-job inspection.

## **2. Review the Documentation System:**

After the enterprise has applied for the quality system certification , the QA documentation (including quality manual, quality system procedure document, etc.), which is in conformity with the standards of application model, must be handed over to the audit organization. At the same time, the related verification information should be fully prepared to verify that the quality system of the enterprise is in conformity with the requirement of the QA standards; the relative procedure documents should fully support and cover the stipulations of the quality manual. All quality records (forms, reports and records ) should show that the stipulated quality requirements have been reached and the quality system is being operated effectively.

The quality manual handed over should describe the quality policy of the enterprise and the quality system documents used for external quality assurance. In ISO/DIS10013 (guideline for drawing up quality manual), it is defined as quality assurance manual, which can be provided for an external third party review or customer usage. It should be noticed that the QA manual handed over should meet the requirement of all elements of the related QA standards (e.g. ISO9001). From the viewpoint of the system audit and review, any intentionally omitted related section of the system element should be explained. For example, as our Works does not need many goods and materials from the customer, the element of " the goods and materials provided by customer" is deleted from the original QA manual . It was found during the review of the system documentation that the reason should be explained for the deletion. Besides, though there is no unified requirement for the format of the quality manual , the control procedures of each element should be described clearly and correctly, so that the requirement for standards can not be misunderstood or distorted. For example, in the element of contract review in our original quality manual and procedure document, only the contract review for new product is stipulated. This runs contra to the stipulation of "supplier should review every contract" in clause 4.3, contract review element of ISO9001. The problems found by the audit organization during the document review should be corrected by the enterprise. Not only should the document system be revised and corrected, but also, which is more important, the revision should be strictly followed at the time of implementation . Another example is that during our implementation of the element of statistical techniques, there was no related " selected procedure

stipulation" in the original document. During the document review, it was requested that the selected procedure of statistical techniques be supplemented according to turbine manufacturing characteristics.

In a word, before the on-job inspection, the applicant must revise and supplement the part of system documentation which was omitted or not in conformity with the standard requirement .

### **3. Prepare the Verification Information**

Based on the system documentation review, the applicant must fully inspect and provide enough records to show that these documents have been implemented, the required quality has been reached and the quality system is being operated effectively. The general evidence should be provided at least half a year before the on-job inspection.

All verification information to be provided should be appended with marks, index for collection, files and storages. These information, forms and records (reports) are generally named quality records. There are two levels of management for these information in our Works: one is the concentrated management by the related archives department, the other is the management by other concerning departments. During the process of implementation for the quality system certification, it is made clear that 7 categories (more than 200 types covered in 87 procedure documents of 20 elements in GB/T19001) are concentratively managed by the headquarters. The verification information managed by various departments can be drafted by the department itself according to the management principle "Quality record management procedure" set up by the headquarters. But the methods, place, and person-in-charge etc for various quality records collection and storage should be stipulated so that the management for all verification information will be standardized. Records can be in the forms of hard copy or other media. All written quality records must be clear and standardized, convenient for storage and indexing. During the preparation for certification, we made an all-round rectification for the related quality records, which were found, during the on-job inspection, non-standardized as the time limit for storage, place or methods have not been clearly stated.

### **III . Internal System Audit to Improve Quality System**

Before external quality system audit, it is necessary to carry out an all-round internal system audit for every system element based on the drafted system

documentation . Through internal audit, the status of completeness and practicality of a quality system element can be fully verified and the ability of the quality system to achieve the set quality target can be verified. If this is not done, some audit organizations may regard the system as ineffective. Then it may be voted down and not allowed to be registered

The internal audit should be carried out in a well organized and planned way, once or twice a year . The auditors should be qualified personnel and authorized by the director . During the audit for a certain element , the person directly in charge of the element should participate

The internal auditors of our Works consist of the director , chief engineer, manager of each department and related quality management personnel. These auditors have all been systematically trained in the Works or in other units. They understand well enough the GB/T19000 standard series and have passed the examination (director is not exempted) organized by the quality management department. The names of these formal authorized persons are put on files after approval by the director so as to ensure the authority and legality

Before internal audit, related personnel in the quality management department should be responsible to draw up inspection item sheets for audit . Usually, one week before audit, these item sheets should be sent to each auditee department and the time, items and scopes of the audit, including the degree of importance of item )should be informed in advance so that the auditee department can prepare according to the requirement. One internal audit before our QS certification was presided over by the director himself and implemented per 20 quality elements. As some elements were related to several departments, the auditee unit was "division". So, the division managers (usually they are deputy directors) can coordinate the related work in various departments within the division, and the correction measures can be put into effect. A detailed arrangement for an internal audit activities is listed in table 1



**Table 1**

No.	Auditee department	Main audit element	Audit time
1	<b>Market Division</b> (Sale Dept. Purchase Dept. Market Planning Dept.)	<b>Contract Review</b> <b>Procurement</b> <b>Handling</b> <b>Storage</b> <b>Packing &amp; Delivery</b> <b>After-Sale Service</b>	one day
2	<b>Technical Division</b> (Research Dept. Design Dept. Process Dept. Metallurgical Dept. Archive Dept.)	<b>Design Control</b> <b>Document Control</b> <b>Process Control</b> <b>Quality Records</b> <b>Statistical Techniques</b>	one day
3	<b>Manufacturing Div.</b> (Related Workshops, Production Planning Dept.)	<b>Product Marks &amp; Traceability</b> <b>Quality Records</b> <b>Nonconformity Control</b> <b>Corrective Action</b> <b>Training &amp; Process Control</b>	one day
4	<b>QA Division</b> (QC Dept. Meterage Dept.)	<b>Inspection &amp; Test</b> <b>Inspection, Measuring &amp;</b> <b>Test Facilities</b> <b>Inspection &amp; Test Status</b> <b>Nonconformity Control</b> <b>Training &amp; Quality Records</b>	one day

The core of the internal audit is to find out nonconformity in comparison with the current standards, quality manuals, procedure documentation and other quality documents. Then, trace and implement corrective actions. Fig. 3 shows the indefinite circulation of the three elements: Documentation Control, Internal Audit and Corrective Actions. The quality system is being perfected during the process of circulation.

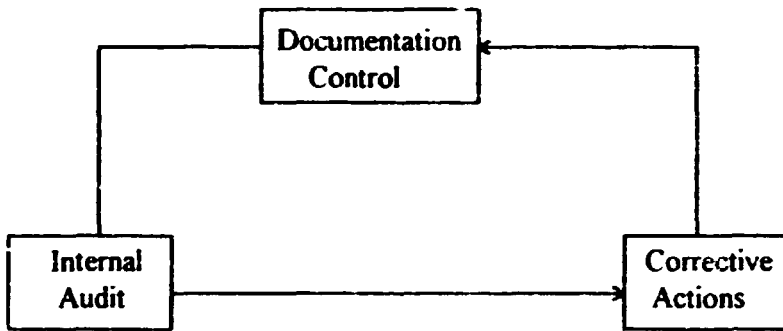


Fig 3 The core of ISO9000

After the audit is completed, the quality management department is responsible to fill in the audit report, write down the audit status and the existing problems, and evaluate whether improvement or corrective actions are needed. If there is any nonconformity item, the notice of corrective action should be issued. During the process of internal audit, it may be found that a certain quality action was actually done, but no complete records or other evidences could be shown. For example, it was found that the inspected parts were not stamped, re-check was incomplete for the repair parts, the recall of old drawings was not complete in signature and date etc. The above situations should also be regarded as disposition of nonconformity during internal audit and should be mentioned out in the audit report.

The trace of the corrective action is very important. If one is content only with the problems found and do not pay attention to the tracing and supervision, the internal audit may become a mere formality. So, the notice for corrective action should be numbered and cared by specific person to ensure that every item is disposed. After disposition of corrective action tracing, every notice will be verified by the quality management chief to ensure that the correction measure is

really taken from the root cause. In a word, the purpose of the internal audit and is to keep the quality system effective and improved gradually.

#### **IV. On-job Audit**

##### **1. Prepare for On-job Audit:**

Before on-job audit, the itinerary arrangement should be negotiated with the inspection group to make sure that the top directors of the works and chief department managers are present during audit. After the itinerary is determined, the enterprise should draw up detailed on-job audit schedule, and list the date, time, inspection items, inspection departments, main participants, location and audit elements etc. for the whole course of on-job audit. When the inspection group is auditing in the workshop, many elements are usually related, including product marks, traceability, procedure control, inspection & test status, inspection, test & measuring equipment, quality records, nonconformity control, and corrective measures, etc.. The elements of partial documentation control and quality record can also be included. So, it should be assured that the concerning leaders and the related persons who are familiar with them and the leaders are present.

After the itinerary arrangement, the Works should hold an internal meeting on how to meet the inspection and let the managers of each department know when, who, where to receive the inspection. It is also made clear that who will be in charge during auditing. As our Works is very large, the inspection group is divided into two sub-groups A and B. So the enterprise arranges correspondingly the responsible person from the quality management department as liaison between each sub-group, and deal with on-job situation. When a nonconformity item is found, that person will sign on the nonconformity report as auditee witness.

According to the concrete itinerary allocation for each department, the well prepared information should be relatively concentrated, the related management documentation and witness materials should be included. The related persons who are responsible to meet the inspection should understand and be familiar with GB/T19001 standards. They should also be able to explain clearly how the requirements of the standards are implemented in the Works, and evidences should be shown to demonstrate by what forms or means these quality actions are expressed. So the person qualified with above requirements is usually the top manager in each department. When the completion of some elements are involved with several departments, one manager must be selected to meet the

reception. For example, for the element of handling, packaging, storage and delivery, the departments of transportation, production, sales, design, process, etc. are involved. It is made clear that the sales department is in charge to fully understand each quality activity and requirement of the said element as well as the interface of each quality activity.

## **2. Receive the On-job Audit**

To receive the on-job audit is the key link in gaining quality system certification for an enterprise. It is generally divided into five steps:

### **1) Initial meeting**

Initial meeting is the first link of the on-job inspection. Presided over by the inspection group chief, the main purpose of the meeting is to introduce group chief, group members, inspection scope, method, requirement, limit as well as to clarify some other problems. It is usually a short meeting, but the main leaders, chief engineer of the Works and the managers, quality management staff of different departments should be present at the meeting. So that, the persons in different levels of the enterprise could fully understand the intention and working method of the inspection group, and do their cooperation work. At the beginning of the meeting, director can make a brief welcoming speech and introduce to the inspection group the main leaders of the Works and the chiefs who will accompany the inspection group. As this is the first acquaintance for both sides, the 'Style' and 'Keynote' of the on-job audit will be determined in this meeting, and the rules and regulations will be clarified. So it should be regarded as a very important meeting. The Works will do his best to ensure that all persons who should be present do attend on time. According to international conventions, the agenda is compactly arranged. So, any style of being late and dilatory will leave impression of poor management on the inspection group.

### **2) Tour of the Works**

In order to give the inspection group a general impression and visual understanding of the enterprise on its products, production and control, usually a general tour activity is arranged before the formal on-job inspection as a preparation for further inspection. Before the tour, an optimized route should be arranged by the works as a reference for the inspection group. Of course, the decision for the tour route will be finally made by the inspection group. As the time for the tour is limited, instead of whole works, only some main workshops, storehouses, laboratories, archives and test rooms could be considered as tour

objectives . During the tour, the characteristics of the products of the works will be introduced to the inspection group so as to let the inspection group know more about the enterprise.

### 3) On-job inspection

The on-job inspection is implemented according to pre-arranged inspection schedule and list (of course, the auditee is not informed of the schedule and list). The following tactics are usually made:

- from above to below
- from below to above
- random
- transversal
- lengthwise

The above tactics can be implemented in turn. The inspection procedures for sub-group A are: documentation control — contract review — service — design — meterage — workshop — handling, storage, packaging and delivery — internal audit — corrective actions — training.

The inspection procedures for sub-group B are: documentation control — procurement — buyer- provided materials & parts — material & parts incoming inspection — workshop — nonconformity control — corrective actions — quality records.

The inspection methods are generally as follows.

\* Selective inspection: This is a kind of inspection method most commonly used. For example: according to the documentation list provided by the enterprise, several kinds of documents (including reproducible drawings) could be selectively inspected . The record for document issuance & recall, approval procedures, revision procedures and revision consistency could also be inspected. When the acceptance status of the incoming goods are inspected, random check at the storehouse for several stored goods could be performed, e.g. their purchase order, procurement documentation, inspection report are reviewed to see whether they are in conformity with the stipulation of the quality manual, or whether they can meet the requirement of design and technical specification. When the product storehouse is inspected, several stored products could be selected to check their issuance & recall records, delivery procedures

inspection records and quality records, etc.. The on-job nonconformity parts will be traced to see whether there is any marks or isolations, and the nonconformity notice should be called out to check whether the specified approval procedures are implemented, the re-work parts are re-inspected and their records are completed. When the calibration of the meterage instrumentation is inspected, part of the instruments could be inspected for their numbers, certificates, calibration cycles, effective dates, uncertainties, traceability, etc.

\* Check: At the workshop production site, the inspection and test facilities are checked item by item according to the standards to see whether they can meet the requirements specified by the standards. Specific operators could also be checked to see whether they are qualified and have relevant operation certificates.

\* Examination: The qualification of the personnel is usually examined. For example, an impromptu examination is given to the reception personnel on his understanding and implementation of the works quality policy and GB/T19001 standards, and an on-job examination is given to the related personnel on his working capability.

The inspection group will make full use of the limited time and space to gain the evidence of related objective facts. During the time of audit, only the testimony of the person in direct charge of the department can be regarded as the evidence. So, it is very important that the reception persons at inspection site must be those in charge of various departments.

Sometimes, the objective evidence is the fact seen by the inspection group. For example: lack of status explanation, or lack of signature, protection, label, or lack of records or test items, etc..

The process of on-job inspection is a process to collect facts & evidence through record review, visit, conversation, inspection or check, and then to make a judgement. In order that the inspection group could gain evidence effectively, the auditee should fully understand, support and cooperate with the group. As the action of certificate application is a self requirement of the enterprise, just like a patient seeing a doctor, the existing situation must be explained or described honestly according to the fact, so that the inspection group can make a fair and objective judgement for the enterprise.

As the on-job inspection is randomly sampled, some small-chance-rate events may happen. Moreover, since the inspection group has only limited time and

limited understanding of for the enterprise, in order to help the inspection group to determine the existing problems in the management, and facilitate the perfection of the system, the reception persons should take active and realistic attitude in making response to the inspection group so as to make the inspection more efficient.

During on-job inspection, some faults on the enterprise quality system may appear. But the auditee should not be afraid of the auditor, and what is more, should not conceal any existing deficiency. He should clearly understand that problems may exist in an effective system and the perfection and improvement for any quality system are endless. It is through the audit that deficiencies can be discovered and corrected thenceforth.

#### 4) Evaluation:

Evaluation is the judgement made by the inspection group according to the inspection results to the related system elements. The comprehensive evaluation and conclusion finally made to the whole system is : "qualified", "waiting for improvement" or "not qualified". The basis of the comprehensive evaluation is determined by the existing nonconformity items.

The nonconformity items may have one of the following three reasons:

- a. The written procedures are not in conformity with the requirements of GB/T19000/ISO9000.
- b. The procedures practised do not follow those described.
- c. The practices (which are actually being implemented) have no effect or do not generate the required output.

When the auditor finds out a nonconformity item, he will address to the auditee. At this time, the auditee should cooperate with the auditor with sincere attitude. Of course, some explanations and descriptions to the facts are necessary. Some contentious facts could be rechecked by the auditor when necessary to ensure that the inspection results are true and the evaluation is appropriate. However, such explanation and clarification should not be any quibble, nor should the standards or procedures be violated. The problem existed in the department should not be shifted to its superior, or to its subordinate. When fact is irrefutable, any explanation or excessive description is unnecessary, and the notice for nonconformity items should be signed. When some minor

nonconformity items happen due to accidental fault or coincidence and is of no significance, they could be corrected right away. Then, if the auditor agrees, the nonconformity item report may not be issued.

Finally, evaluation is made by the inspection group that whether the complete system or part of it is ineffective according to the amount, size, characteristics and degree of importance of the nonconformity items. Then, the conclusion is made. The orientation of further improvement and enhancement may be pointed out for those "qualified". The nonconformity should be made clear and the orientation of correction with its time limit should be pointed out for those "waiting for improvement", and the nonconformity may be verified again after corrective actions have been taken. The reason of failure should be explained and the orientation of future efforts should be pointed out for those "not qualified", and the enterprise could be re-audited only after a new application.

#### **5) Sum-up meeting**

After the evaluation is completed, the audit group announces the results of the on-job inspection, and reports the overall situation of the complete process of the on-job audit, including the persons they observed and visited, the samplings they drew, the nonconformity items they found, the characteristics of nonconformity items, the major or minor ineffective belongings to the main or subordinate system, the comments of final evaluation results, and whether the enterprise passed or failed in the audit, etc.. The summing-up meeting is a conclusive meeting of the on-job inspection and it has great significance for the enterprise to improve its future work. So, it is a very important meeting. Medium and high level leaders as well as the related personnel of the enterprise should attend the meeting as far as possible. The summing-up meeting is presided over by the inspection group chief. After the audit results are announced, the leader of the enterprise may make a brief statement of his stand.

Before the summing-up meeting, the related nonconformity item report is documented and signed by the inspection group, and it is effective after it is signed by the person in charge of the auditee department. The nonconformity item report is duplicated, so that the inspection group takes one as the attachment to the inspection report for future supervision and the other is kept in the enterprise.

### **V. System Perfection, Approval & Registration, And Successive Supervision**



Necessary correction and perfection should be taken by the enterprise according to the given corrective actions and time limits in the nonconformity item report and audit report. After correction, it should be reported to the inspection group. The tracing records for implementation should be sent to the audit organization as a feedback. The audit organization could make partial or full evaluation and confirmation to the revised system.

If no major nonconformity item is found during on-job inspection, the audit group may decide that the product and quality system of the enterprise is in conformity with the requirements of the related QA model standards, and the operation is effective. Then, a recommendation for passing the certification will be handed over together with the audit report to the audit organization. After the discussion and confirmation by the technical commission of the audit organization, it is approved and registered. And the registration certificate will be issued.

Beside the seal and sign from the quality system certification organization, there should be also the approval and sign from the certification management organization, i.e. the State Bureau of Technical Supervision, in the registration certificate.

The effective period after the registration for quality system certification is 3 years. Within the 3 years, the enterprise is successively supervised and controlled by the certification organization according to the ISO/IEC guideline 48 so as to verify that the original requirements are continuously followed. During the effective period, a nonperiodic supervision once every half year will be performed to the enterprise, and a report will be made whether the supervision result conforms to the registration standards.

The enterprise, after it has obtained the registration certificate of quality system certification, will provide a reliable quality information to the society and the second party repeating audit is not necessary. This is advantageous in the breakthrough of foreign technology barrier and in the sale of the products to the world market. But, with the success of quality system certification, one can not be content because the requirement of GB/T19000-ISO9000 standard series does not include the whole and complete contents for the enterprise to unfold the quality management. So, during the time of implementation of the standards, the enterprise can not slacken its total quality management. The enterprise should unfold quality management creatively and efficiently according to the customer and its own needs.

# **Strengthening Data Management to Improve Metering Management**

**Liu Wenmei**  
**Beijing Organic Chemical Plant**

Metering work is an important basis of technology and management in the national economy. It is manifested mainly in the manner of technical guarantee and technical supervision. To organize and manage better a modern production plant, we must rely on the precise information, in particular, precise metering data which are taken as basis for policy-making control and management of enterprises. Coming along a big tide of economic reform and subsequently deepening of metering work, how to improve the management, authentication and supervision of metering data becomes an important work in the metering management of the chemical enterprise. The following is our experiences on metering management in our plant.

## **1. The Current Management of Metering Data in Our Plant**

The management of metering data of the whole Plant is divided into two phases: direct data control as one phase; supervision and authentication as the other.

The important metering data of the whole Plant, for instance, the quantity of acetylene which have direct influence on the production and benefit of the complex are under control of the instrument department of the Plant. Acetylene was the major raw material for production in our Plant. The hourly consumption during full load production was approximately 1500 m<sup>3</sup>. Owing to various reasons such as different locations of flow-meters, different methods of measurement, and different accuracies of measuring meters, etc. there was usually big deviation between the meters of the neighbouring Beijing No.2 Chemical Plant and our Plant. Sometimes the difference was as big as 12%. Therefore, much more money than expected had to be paid to Beijing No. 2 Chemical Plant, our acetylene supplier. Although the flow-meter of Beijing No.2 Chemical the Plant must be used for the account settlement, the instrument department, BOCP had still actively tried to find other reasonable solutions. Through the co-ordination of Beijing Municipal Technical Monitoring Bureau and Beijing Chemical Industry Group Corporation, an agreement had been reached. We had kept making measurement once every 5 days. The result was reported to the production departments and Plant directors. If readings on both meters were found different from each other, adjustment would be made in time

within the possible scope, so that the deviation of metering data between the two Plants could be controlled at the minimum. The unnecessary expenses of BCCP would be cut down, too. The metering report by the instrument department was always taken as the basis for calculation of production cost, settlement of accounts, especially in co-ordinating with Beijing No.2 Chemical Plant. It has conspicuously had great economic effect to the Plant.

The major energy consumed in our plant is steam from Beijing Thermal-Power Generation Company. The steam consumption is approximately 2000 tons/day in winter, and 1500 tons/day in summer. In the last few years, owing to the shortage of energy supply, its price has been moving up year by year. Therefore, how to save on steam has been an important task for us in cutting down energy consumption of the plant. The availability of steam measurement in our Plant is 100%. There are special people dedicated to writing down the primitive data from all steam gauges in the whole Plant regularly every day. The figures are input the computer. The calculated steam consumption of each unit and the total measured amount of the whole Plant are printed out in itemized tables which are sent to the Plant directors in charge and the various departments concerned such as production section, business management section, enterprise management office, etc. These reports will enable the directors and people in charge of production equipment and energy to judge whether the plant production is normal on the basis of daily consumption of steam. If any abnormal condition occurs, it can be adjusted in time. The instrument department will make its own judgement whether instruments and meters are running normally according to daily steam record. If any abnormality arises, the cause will be promptly found out. If instruments and meters themselves go wrong, it should promptly be handled and have them restored so as to ensure that the metering data are accurate.

There are also water, ethylene, nitrogen, oxygen, etc. under the direct data control, all which the instrument department is responsible to write down and send as the basis for cost accounting to every department of the Plant.

The other part of the management is supervision and authentication which includes the quantity check and measurement of materials, stocktaking, inspections for quality, weight and package of ex-factory products, as well as measurement of noise level and waste water discharge, etc. These data are respectively managed by the supply and marketing section, quality control section, and safety and environment protection section. The instrument section assigns his people to supervise and authenticate the metering work. The metering management worker-in-charge participates every month in making an

inventory of stock, and supervises reliability of measurement data and correct use of the metering apparatus.

The inspection for ex-factory products is an important link because the quality of products has a direct influence on the reputation of a factory. Therefore, our Plant pays very close attention to product quality control. Despite of being equipped with advanced equipment, the instrument department also assigns special management workers to carry out authentication of the measurement data, to sum up, and to have them printed out every month, in order that measurement and test for quality, safety and environment protection is 100% sure.

The computer is applied for carrying out the comprehensive management. The measurement data for energy, meterial, process, quality, safety and environment protection, etc. are unanimously filed, and are summed up and sorted out in time, Finally, these data are tabled, printed and sent to the various departments concerned.

## 2. Flow Diagram of Data Management:

According to the practice of our Plant, data management is divided into three parts as follows:

(1) Direct data management (the instrument department is responsible for):

Data collecting → Summing up & Sorting out → Table formation &

top management level

print out —↑→ application



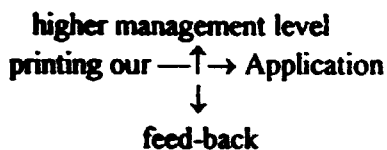
feed-back

(2) Authentication (for various departments as of quality, process, safety and environment protection, etc.):

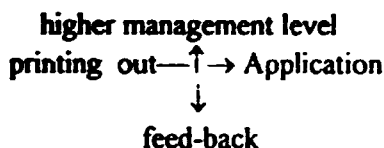
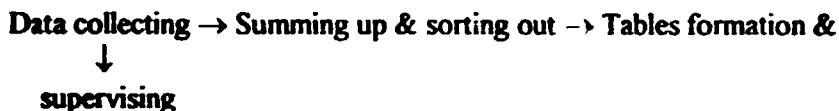
Data collecting → Summing up & sorting out → Tables formation &



authentication



**(3) Supervision (for departments as of material supply ,supply & marketing):**



**3. Experiences on How to Improve Data Management:**

**(1) Special attention paid by leaders of the Plant:**

The leaders of the Plant should attach importance to two aspects. hardware and software.

First of all, the plant leaders in charge of metering work should have rich knowledge about measurement, a deep understanding of metering work and sense of ruling laws and regulations. Only when he notices the importance of investing on metering equipment, can the metering data be made precise and reliable, and really play the role of technical guarantee and technical supervision. In the last few years, in order to guarantee that the metering data collected are reliable and accurate, our plant has renewed the outdated built-in platform scale and installed a 30-ton electronic truck weighing bridge manipulated by computer. The management of goods & material flow has been strengthened. A large number of flowmeters have been imported from abroad. Measurement points for material flow have been set up in the various production workshops. Measurement accuracy has been assured. Meanwhile, We have paid great attention to applications of new technologies. The control level of the plant production has been improved continuously. In order to enhance product quality control, the quality assurance section of the plant has been equipped with a number of imported instruments and advanced electronic balances. With these

advanced equipment, we are more confident technically. They enable us to smoothly carry out our work to meet the requirements as stipulated. This is the hardware for data management which can make metering data collection more reliable.

The leader's care about software is to pay more attention to the application of metering data. If the accurate and reliable metering data could not be applied in the management of production, they would lose their fundamental significance and become only dull and useless figures. The plant leadership has therefore given the instrument department full administrative power that a measuring department normally has. The metering data issued by the instrument department are taken as the basis for settlement of account, trade, calculation of production cost and the management of energy resources and materials. The instrument department also partakes in account settlements every month. In this way, series of figures are closely linking together with production, business operation, production cost, economic benefit and even the life of the Plant, and they have become an intergral part of the production activities of the Plant.

## (2) Complete management setup and strict management rules

A complete management system is indispensable for the accomplishment of any work, especially for the work of measurement. What the transference of data information relies on is just the administration. There is a metering management network going on well in our Plant. In the network, the instrument department takes full responsibilities. Under the leadership of the Plant director, the instrument department keeps close contact with other departments. Within the department, everybody has his own assignments and responsibilities. The division of work is clear. In other departments of the Plant, concurrent posts for metering work are setting up. The concurrent metering worker is responsible for coordination with the instrument department during the periodic check and test of metering apparatus. He would have to collect metering data, and supervise execution of the metering work in his own department. The close contact and good cooperation between the professional measurers and the concurrent metering workers surely improve the management work.

The strict management rules are the best guarantee for the perfectness of the management and authentication of the metering data. The post responsibility system has clearly defined the responsibility and obligation of each individual and the working standard. Everyone knows what to do and what the requirement for the work is. As for how to do? Everybody has to bring his own talent into full play. For achieving the best performance and implementation of the various rules

and the workers' consciousness. The explicit rewards and punishment on the basis of the strict assessment are also indispensable.

Nowadays, large and medium- sized enterprises, under the situation of reform and opening up, shall change their own mechanism of business operation to reactivate themselves as soon as possible. However, the metering work will still play an important role in the input of capitals, manoeuvre of personnel, and distribution of benefits, etc.

In short, the International Standard ISO9000 recognized by the various countries in the world, is an important measure for raising qualities of products, and is a laissez-passer to the international market. We, the whole enterprise, will try our best working towards this direction.

# **INTERNAL QUALITY SYSTEM AUDIT FOR AN ENTERPRISE**

**Liang Chengfa  
Shanghai Petrochemical Co.,LTD  
– No. 2 Chemical Factory**

The implementation of GB/T19000-ISO9000 series of quality management and quality assurance standards so as to achieve the certification of quality system is not only the result of marketing economy development, but also the major approach for an enterprise to go into the market. During the last three years, the Shanghai Petrochemical CO.,LTD-No.2 Chemical Factory has done much in this aspect. At the end of last year, we accepted field auditing for the GB/T19002-ISO9002 quality system certificate carried out by the Shanghai Quality System Auditing Centre, and passed the certification finally. Experience showed that internal quality system audit was a key means to correct deficiencies in quality activities and to ensure effective operations of the quality system.

In the GB/T6583-92-ISO8402-86"Quality-Vocabulary", it is defined that quality audit is a systematic and independent examination to determine whether quality activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives. Quality audit typically applies, but is not limited, to a quality system. Such audit is often called "quality system audit". It is required to be carried out by staff not having direct responsibility in the body being audited but, preferably, working in cooperation with the relevant field. The purpose of a quality system audit is to evaluate the need for further improvement or corrective action. An audit shall not be confused with "surveillance" or "inspection" activities. Quality audits can be conducted for internal or external purposes.



In order to complete a quality system and to pass the field audit for obtaining a quality system certificate, it is required to have in advance a thorough comprehension of the quality system audit concept and to undertake systematic, independent and conformable internal quality system audit. During last several years, with reference to the GB/T19002-ISO9002 "Quality System--Model for quality assurance in production and installation", we have established and completed such a quality system. But it is only limited to documents, and the effectiveness of which should be verified through practices. A planned internal quality system audit can have a supervision effect on the durable, effective implementation of quality system documents and so is a basis for quality system completion.

We are sticking to ensure the standardization, rapid and fair implementation of internal quality system audit. For the first step, we invited personnel from the Shanghai Quality System Auditing Centre to set up an internal auditors' training course. Twenty trainees, who finally got the certifications, were assigned to be part-time internal auditors by our director. Then, our quality management department formulated the "Internal quality system audit plan" and organized an overall audit in totally 13 areas on the whole production processes of our main products, with the purpose of evaluating whether all quality related activities comply with corresponding regulations, documentary and standards. This internal quality system audit made an objective and fair evaluation on our quality system. As a result, we totally documented 15 non-compliance reports covering 7 quality system essences. Corrective actions were taken timely and their implementations were monitored by internal auditors. Consequently, a continuous quality system self-completion is ensured.

The internal quality system audit practice has shown its efforts in the following three aspects:

1. Supplying the director with a clear operation status of the enterprise quality system, its potentiality and a reliable strategic planning basis;

2. Find out non-compliances timely, correct deficiencies in the quality activities and revise quality system documents;
3. Ensure the effective operation of quality system as well as make ample preparations for quality system field audit.

The effective operation of internal quality system audit activity should include the following procedures:

**(1) Draft an internal quality system auditing plan**

The quality management department should draft an auditing plan at the right beginning which includes areas and activities to be audited, time schedule, organization of auditors and auditing bases.

**(2) Pre-auditing organization and coordination**

Each time before carrying out auditing, it is necessary for all auditors to exchange opinions with each other so as to edit an auditing outline in the form of an inspection list. In order to raise the efficiency, the auditing time schedule and plan should be brought to the attention of the personnel taking responsibility in the area to be audited, so as for him/her to make arrangement and coordination.

**(3) Field auditing**

Auditors conduct field sampling inspections with their individual auditing tricks, and record their audit findings following the inspection list. Generally, four steps are taken:

- A. Verify the effective bases of a certain quality activity;
- B. Hearing the execution report on this quality activity;
- C. Check the implementation record of this quality activity;
- D. Compare "record" with "bases" in order to determine whether this quality activity complies with required standards.

During the field auditing, auditors should shall exchange opinions timely with personnel taking responsibility in the audited area in order to attain ample, objective and fair evidences.

**4. Internal quality system audit report**

After completion of field audit, auditors should make assessments and non-compliance reports. The quality management department should edit the audit report on the basis of auditors' records. Both non-compliance and audit report should be issued with the approval of the auditing leader, who will be responsible for their accuracy, reliability and completion.

#### 5. Corrective action and traceability

The personnel responsible for the audited area should take timely corrective actions on the deficiencies found by the audit. Internal auditors should trace to ensure that corrective actions have been taken and are effective before the next audit.

However, this quality system inspection and assurance takes a long time. We shall further improve and shorten the period of our internal quality system audit.

# **STANDARDS, METROLOGY AND QUALITY ASSURANCE OF MASS MEASURING INSTRUMENTS IN CHINA AND THE IMPLEMENTATION IN SHANGHAI YAMATO SCALE CO., LTD**

**Pei Yuji**

**National Institute of Metrology (Mass Laboratory)**

**Yang Zengquan**

**SHANGHAI YAMATO SCALE CO., LTD**

## **Abstract**

The management and macro control of the standards, metrology and quality assurance of mass measuring instruments are described as viewed from the whole country. Taking an advanced enterprise as the example, this paper introduces the work they have done on standards, metrology and quality assurance, and the preliminary effect they have achieved.

## **1. Standards, Metrology and Quality Assurance of Mass Measuring Instruments in China**

To speed up the development of national economy, strengthen the international exchange and enter into the international market, China has accomplished the following jobs in standards, metrology and quality assurance:

1). Having taken an active part in the popularization and adoption of the international standards and based on the situation in China, converted the OIML IR into corresponding China's laws and regulations and popularize the OIML Certificate System.

The related ministries and commissions, such as the National Economy and Trade Commission and the State Bureau of Technical Supervision, popularize and encourage all the departments, enterprises and institutions to adopt the international standards. In the mass measuring instruments, China has, on the principle of active adoption and laying stress on the actual effect and the situations in China, referenced to or equivalently adopted the corresponding international standards, especially converted the related OIML IR into the corresponding recommended standards or regulation documentations of compulsory implementation.

Weights are the material tools of mass measuring instruments which are used to calibrate or measure other weighing instruments to determine whether their

metrological performances meet the requirements. Therefore, China has adopted the OIML IR for weights when stipulating regulation documentations, and combined No.1, No.2, No.25 (all corresponding to the new R111 of OIML), No.33, No.47 and No.52 in OIML into a unified class of weight through analysis and study. The allowance table of this class of weight can be seen in Table 1, which has already been written in JJG99-90 Metrology Verification Regulation for Weights. The allowance table has solved the problem of interface disagreement of the OIML IR for weights and is identical to the concerned parts of R.111 published later.

We have referenced and adopted the corresponding OIML IR for the weighing instruments used outdoors (which are also called scales, including the railway track scales), based on the situations in China. As for the non-automatic weighing instruments, we have mainly adopted and made additive stipulations due to the situations in China.

For the non-automatic weighing instruments used indoors (which are also called balance in China), we have equivalently adopted the OIML IR for the balance with  $e \geq 1\text{mg}$  in consideration of the situation in China, and through analysis and study, combined No 3 and No 28 in OIML into a unified balance regulation, which is basically in accordance with the later R76. We have made some stipulations for both the balance with  $e \leq 1\text{mg}$  and the mechanical balance which has been used for a long time, and made their accuracy classes in accordance with those of OIML. Concerning the Verification Regulation for Weights in China,  $e \neq d$  is also allowed besides  $e = d$ , where  $d < e \leq 10d$  and  $e \leq 10^4\text{kg}$ . All kinds of balances (except the mechanical balances of Class I and Class II which should meet the requirements laid down in the additive stipulations) should be, without any exception, in accordance with corresponding stipulations for non-automatic weighing instruments recommended by OIML. For this purpose, we have made some coordinations in methods and specifications with OIML. The balance classification can be seen in Table 2 and the maximum permissible errors of other balances in Table 3.

For being in line with the international standards, both the non-automatic balance and the non-automatic scales in China, belonging to the new products that should be subject to "pattern evaluation" according to the documentation laid down by the State, should apply for "pattern evaluation". The technical articles and requirements laid down in the "pattern evaluation" should equivalently adopt the stipulations of R76-1 and R76-2 of OIML. Consequently, new products will firstly be in line with the international standards, thus promoting the whole mass measurement profession. Besides, China plays an active part in the popularization of OIML Certificate System and encourages local enterprises to apply for OIML Certificate so as to enhance their reputation and expand the markets abroad and at home.

2) Having propagated and implemented ISO 9000 Series Standards, and encouraged enterprises to perfect their own quality assurance systems on a voluntary basis.

The State Bureau of Technical Supervision has equivalently adopted ISO9000 Series Standards, and issued in the form of GB/T 19000 Series Standards, which has already come into force since January 1, 1993. The series standards and the support standards have been well popularized and implemented in the mass speciality. In this way enterprises have further perfected the quality assurance system, strengthened the quality management and control mechanism, improved the product quality and enhanced the market competition. Many enterprises that have well implemented the standards and enjoyed higher prestige and benefit have sprung up in China and SHANGHAI YAMATO SCALE CO., LTD. is one of them.

## **2. How Did The Shanghai Yamato Scale Co., Ltd. Insist on the Adoption of OIML R76, on the Implementation of ISO9000 Series Standards and on the Ensurance of The Quality of Electrical Weighing Instruments?**

1). Paying special attention to quality management, implementing ISO 9000 Series Standards and ensuring the quality of products. For this reason, the Company has done the following jobs:

### **(1) To pay attention to quality awareness**

Man is the first factor of quality management. The Company should, therefore, test the persons who come for employment and provide training to the personnel from time to time in order to strengthen and enhance their quality awareness.

### **(2) To pay attention to quality management organization**

Organization is the pillar for quality management. Individual capability is limited while the mass capability is unlimited. The Company keeps on exploring the best combination of the organization to improve and develop all kinds of jobs including the quality job.

### **(3) To pay attention to the standard of quality management**

The mode of quality management is the guide for quality management and ISO 9000 Series Standards is the Company's best mode of quality management and quality assurance. The Company has set up the quality management system and quality assurance system based on ISO9000 Series Standards, making sure that all links in the production, such as design, development and after-sales service, be under the control, and applied for quality system accreditation, making sure that the quality system is continuously improved and meets the needs of the customers.

#### **(4) To pay attention to technical equipment**

The Company has paid much attention to its technical equipment, as they are the material bases for quality assurance. With the development of the enterprise, technical equipment has been updated, eg. the adoption of processing centre, strain gauge technique, computer compensation. Meanwhile, the test and measurement equipment such as the 2t balance, standard signal source with high precision, precise voltmeter, thermostat, CPU board test device, base measuring device, measuring device for temperature compensation at zero point, load measuring device, LCR tester, static discharge tester, rf interferometer and pulse string interferometer have been replenished in production line.

#### **2) To insist on the adoption of OIML R76 and apply for the OIML Certificate so as to ensure the technical superiority of products**

"Quality standards internationalization" is the first criterion of the five quality policies stipulated by the YAMATO Company. Now the country is in the period of reform, and the trend is to coincide with the international conventions. A high starting point and the adoption of OIML R76 are needed for the products to "be in the lead at home and abroad." To ensure the technical superiority of products and let the Company's products stand the tests at the national or international market, the Company has accomplished the following two jobs:

##### **(1) To insist on the adoption of OIML R76**

a. Organizing cadres, engineers and technicians to study and master the OIML R76 step by step, and using it to guide the development and design of products.

b. Formulating or revising the enterprise standards of the Company in accordance with the related stipulations of OIML R76 so that the quality of products will come up to the advanced international level and will possess certain technical superiority.

## **(2) To apply for the OIML Certificate**

With products being in accordance with OIML R76 as the prerequisite, the Company applies for OIML Certificate enthusiastically. With the support of OIML secretariat in China and the State Bureau of Technical Supervision, 9 prototypes of the ACS price counting scale provided by the Company have all reached the specifications stipulated in OIML R76 and passed the evaluation assigned by the State Bureau of Technical Supervision. YAMATO is the first company that has obtained the OIML Certificate in China. The OIML issued the approved registration of ACS series of SHANGHAI YAMATO COMPANY CO., LTD. in OIML Bulletin No.2, 1994.

## **3). The preliminary effect**

(1) The Dongchang Plant (the predecessor of the Company) has become the first enterprise manufacturing all kinds of electrical weighing instruments. Now, it has products of five series and more than a hundred models with a weighing range from 300g to 300t. The annual output includes 30000 electrical weighing instruments, 40000 load cells and 5000 display instruments. Among which, the electrical weighing instruments of 120t and 300t are the biggest ones in Asia. Our small size scale has occupied 50% of the market in China and has been exported to more than 20 countries and regions, such as USA, Germany, France and Switzerland.

(2) The total sale amount per year is over 60 million yuan(RMB).

(3) The electronic price counting scale and the resistance strain gauge were appraised as one of the top quality products and were awarded the title of famous brand product in Shanghai in 1991. The electronic track scale was appraised as the product compared to that in the world and was awarded the title of famous brand product in Shanghai.

(4) The Company was appraised as Shanghai advanced enterprise in technology, advanced enterprise of quality management and advanced weighing scale enterprise of the China Weighing Instrument Association.



TABLE 1 MAXIMUM PERMISSIBLE ERRORS

nominal mass value	± mg								
	ClassE <sub>1</sub>	ClassE <sub>2</sub>	ClassF <sub>1</sub>	ClassF <sub>2</sub>	ClassM <sub>1</sub>	ClassM <sub>1,1</sub>	ClassM <sub>2</sub>	ClassM <sub>2,2</sub>	ClassM <sub>3</sub>
5t				7.5x10 <sup>4</sup>	2.5x10 <sup>5</sup>	5x10 <sup>5</sup>	7.5x10 <sup>5</sup>	1.5x10 <sup>6</sup>	
3t				4.5x10 <sup>4</sup>	1.5x10 <sup>5</sup>	3x10 <sup>5</sup>	5x10 <sup>5</sup>	9x10 <sup>5</sup>	
2t				3x10 <sup>4</sup>	1x10 <sup>5</sup>	2x10 <sup>5</sup>	3x10 <sup>5</sup>	6x10 <sup>5</sup>	
1t				1.5x10 <sup>4</sup>	5x10 <sup>4</sup>	1x10 <sup>5</sup>	1.5x10 <sup>5</sup>	3x10 <sup>5</sup>	
500kg				7.5x10 <sup>3</sup>	2.5x10 <sup>4</sup>	5x10 <sup>4</sup>	7.5x10 <sup>4</sup>	1.5x10 <sup>5</sup>	
200kg				3x10 <sup>3</sup>	1x10 <sup>4</sup>	2x10 <sup>4</sup>	3x10 <sup>4</sup>	6x10 <sup>4</sup>	
100kg				1.5x10 <sup>3</sup>	5x10 <sup>3</sup>	1x10 <sup>4</sup>	1.5x10 <sup>4</sup>	3x10 <sup>4</sup>	
50kg	2.5x10	7.5x10	2.5x10 <sup>2</sup>	7.5x10 <sup>2</sup>	2.5x10 <sup>3</sup>	5x10 <sup>3</sup>	7.5x10 <sup>3</sup>	1.5x10 <sup>4</sup>	2.5x10 <sup>4</sup>
25kg					1.2x10 <sup>3</sup>		3.7x10 <sup>3</sup>		1.2x10 <sup>4</sup>
20kg	10	3.0x10	1x10 <sup>2</sup>	3x10 <sup>2</sup>	1x10 <sup>3</sup>		3x10 <sup>3</sup>		1x10 <sup>4</sup>
10kg	5	1.5x10	5x10	1.5x10 <sup>2</sup>	5x10 <sup>2</sup>		1.5x10 <sup>3</sup>		5x10 <sup>3</sup>
5kg	2.5	7.5	2.5x10	7.5x10	2.5x10 <sup>2</sup>		7.5x10 <sup>2</sup>		2.5x10 <sup>3</sup>
2kg	1.0	3.0	10	3x10	1x10 <sup>2</sup>		3x10 <sup>2</sup>		1x10 <sup>3</sup>
1kg	0.5	1.5	5	1.5x10	5x10		1.5x10 <sup>2</sup>		5x10 <sup>2</sup>
500g	0.25	0.75	2.5	7.5	2.5x10		7.5x10		2.5x10 <sup>2</sup>
200g	0.10	0.30	1.0	3.0	10		3x10		1x10 <sup>2</sup>
100g	0.05	0.15	0.5	1.5	5		1.5x10		5x10
50g	0.030	0.10	0.30	1.0	3		10		3x10
20g	0.025	0.08	0.25	0.8	2.5		8		2.5x10
10g	0.020	0.08	0.20	0.6	2.0		6		2x10
5g	0.015	0.05	0.15	0.5	1.5		5		1.5x10
2g	0.012	0.04	0.12	0.4	1.2		4		1.2x10
1g	0.010	0.03	0.10	0.3	1.0		3		10
500mg	0.008	0.025	0.08	0.25	0.8		2.5		
200mg	0.006	0.020	0.06	0.20	0.6		2.0		
100mg	0.005	0.015	0.05	0.15	0.5		1.5		
50mg	0.004	0.012	0.04	0.12	0.4		1.2		
20mg	0.003	0.010	0.03	0.10	0.3		1.0		
10mg	0.002	0.008	0.02	0.08	0.2		0.8		
5mg	0.002	0.006	0.02	0.06	0.2				
2mg	0.002	0.006	0.02	0.06	0.2				
1mg	0.002	0.006	0.02	0.06	0.2				

TABLE 2

Accuracy class	Verification scale interval $\epsilon$	Number of verification scale interval Max $n = \frac{\text{Max}}{\epsilon}$	
		min.	max.
Special I	$\epsilon \leq 5 \mu\text{g}$ $10 \mu\text{g} \leq \epsilon$	$1 \times 10^3$ $5 \times 10^4$	unlimited
High II	$\epsilon \leq 50\text{mg}$ $0.1\text{g} \leq \epsilon$	$1 \times 10^2$ $5 \times 10^3$	$1 \times 10^6$ $1 \times 10^7$
Medium III	$0.1\text{g} \leq \epsilon \leq 2\text{g}$ $5\text{g} \leq \epsilon$	$1 \times 10^2$ $5 \times 10^2$	$1 \times 10^4$ $1 \times 10^4$
Ordinary IIII	$5\text{g} \leq \epsilon$	$1 \times 10^2$	$1 \times 10^3$

TABLE 3

Maximum permissible errors (expressed by verification scale interval $\epsilon$ )		loads $m$ (expressed by verification scale interval $\epsilon$ )			
newly produced newly imported in service	the repaired	class I	Class II	Class III	Class IIII
$\pm 0.5$	$\pm 1$	$0 \leq m \leq 5 \times 10^4$	$0 \leq m \leq 5 \times 10^3$	$0 \leq m \leq 5 \times 10^2$	$0 \leq m \leq 50$
$\pm 1$	$\pm 2$	$5 \times 10^4 < m \leq 2 \times 10^5$	$5 \times 10^3 < m \leq 2 \times 10^4$	$5 \times 10^2 < m \leq 2 \times 10^3$	$50 < m \leq 2 \times 10^2$
$\pm 1.5$	$\pm 3$	$2 \times 10^5 < m$	$2 \times 10^4 < m \leq 5 \times 10^4$	$2 \times 10^3 < m \leq 1 \times 10^4$	$2 \times 10^2 < m \leq 1 \times 10^3$