QCI STUDY REPORT

On

Effectiveness of QMS

Of

ISO 9001:2000 CERTIFIED ORGANIZATIONS (INDIA)

Quality Council of India

CONTENTS

Abbreviation

ABs	Accreditation Bodies
ANOVA	Analysis of Variance
AQAP	Allied Quality Assurance Procedures
AQC	American Society for Quality Control
ASSOCHAM	Associated Chambers of Commerce
BHEL	Bharat Heavy Electricals Limited
BIS	Bureau of Indian Standards
BSI	British Standard Institute
CBs/CB	Certification Bodies/ Certification Body
CD	Critical Difference
CEO	Chief Executive Officer
CII	Confederation of Indian Industry
CP	Certification Process
CWQC	Company Wide Quality Control
EU	European Union
FICCI	Federation of Indian Chambers of Commerce and Industry
GATT	General Agreement of Tariffs and Trade
GOI	Government of India
HRD	Human Resource Development
IAF	International Accreditation Forum
IEC	International Electro technical Commission
IIQM	Indian Institute of Quality Management
IRCA	International Register of Certified Auditors
ISO	International Organization for Standardization
IVF	Independent Variable Factor
JUSE	Union of Japanese Scientist & Engineers
MLA	Multilateral Agreement

MRM	Management Review Meeting
NABL	National Accreditation Board for Testing & Calibration Laboratories
NASA	National Aeronautics & Space Administration
NATO	North Atlantic Treaty Organization
NCs	Non –conformities
NORAD	North America Aerospace Defence Command
Nos	Numbers
NPC	National Productivity Council
QA	Quality Assurance
QC	Quality Control
QCI	Quality Council of India
QMS	Quality Management System
Retd.	Retired
SPC	Statistical Process Control
SSI	Small Scale Industries
STQC	Standard Testing and Quality Certification
TBT	Technical Barrier to Trade
TQC	Total Quality Control
TQM	Total Quality Management
UK	United Kingdom
UNIDO	United Nations Industrial Development Organization
USSR	Union of Soviet Socialist Republic
w.r.t	With respect to
WTO	World Trade Organization

Abstract

International Standard ISO 9001:2000 specifies the requirements for a quality management system (QMS), where an organization must implement to:

a) demonstrate its ability to consistently provide products or services that meet customer and applicable statutory and regulatory requirements and
b) enhance customer satisfaction through the effective application of the QMS, including the processes for its continual improvement and the assurance of conformity to customer and applicable regulatory requirements

The Standard ISO 9001:2000 is one of the most widely used certification system in the world, against which more than 12, 00,000 organizations have been certified. The certificates are issued by Certification Bodies, after verifying that the organization (supplier of products) is complying with the requirements specified in ISO 9001:2000 Standard. The competency of the Certification Bodies is ensured through the process of accreditation, wherein a designated Accreditation Body grants the accreditation to the Certification Body, based on International Standard ISO Guide 62 .In addition, the International Accreditation Forum, a consortium of Accreditation Bodies', has established a mechanism of mutual recognition of accredited certification world over. By this process of accreditation or services products of a certified organization get global acceptance. Such a robust mechanism acts as a guarantee to the ultimate consumer that the product /services from the certified organizations would comply with the specified requirements. However, this guarantee has, of late unfortunately has eluded the ultimate user.

Field survey, the first of its kind undertaken to validate this hypothesis, on the certified organization, has revealed wide ranging inadequacies in the certification process. Analysis of the data conclusively indicates lack of consistency in the certification process adopted by different Certification Bodies, in spite of the fact that they are accredited and are expected to follow uniform practices.

The study provides a critical review of the audit process deployed by different Certification Bodies and thereby in assessing the effectiveness of Quality Management System based on ISO 9001:2000 standards.

1 INTRODUCTION

The term “quality” means different things to different people. For example, a quality automobile may be one, which has no defects and performs exactly as per our expectations. Such a definition matches with the oft-repeated definition given by J.M Juran (1988): "*Quality is fitness for use*." The concept of quality as "*conformance to specifications*" is often promoted by the manufacturing industry, presumably because the manufacturer cannot do anything to change the product design. Others promote wider views, which include that *quality means that a product or a service fulfils or even exceeds the expectations of the customer*. Going by this definition, quality is a judgment by the customers or users of a product or a service, which meets customer’s expectations and fulfills customer’s present needs as well as their unanticipated future aspirations. In a way, quality is meeting the customers stated as well as implied requirements.

The ISO 9000:2000 standards define quality as “*degree to which a set of inherent characteristics fulfils requirements*.” The requirements in this definition could be specified by the supplier, by the customer, or may also be legal. Looking from the customer’s perspective, this definition simply means that a product must have features, which meet customer’s needs and thereby provide customer satisfaction. Yet another simpler definition says; Quality means, satisfying/delighting customers on a continuous basis. Here onus has been put entirely on the supplier to keep on assessing the customer’s needs (which are dynamic) and make sure that products/services take care of such needs. Mere conformance to specifications may not match the customer needs and hence quality departments cannot relax by declaring that their products conform to the specifications. The departments need to continuously lookout and assess the varying needs or aspirations of the customers and incorporate them in the products.

Quality can be attributed to a product, a process, or even to an organization. A quality organization will have an established network of quality processes to deliver

the quality products. Even within an organization, every process will have a supplier and a customer, which are termed as internal supplier and internal customer. Likewise it may have external suppliers and external customers.

An entire organization can be broadly viewed as the process shown in the Fig. 1.1. External suppliers provide input to the organization and customers receive output from the organization. If one replicates this diagram many times, the entire operation of an organization can be represented. This model of an organization shows how the external suppliers and customers are related through the process of the organization.

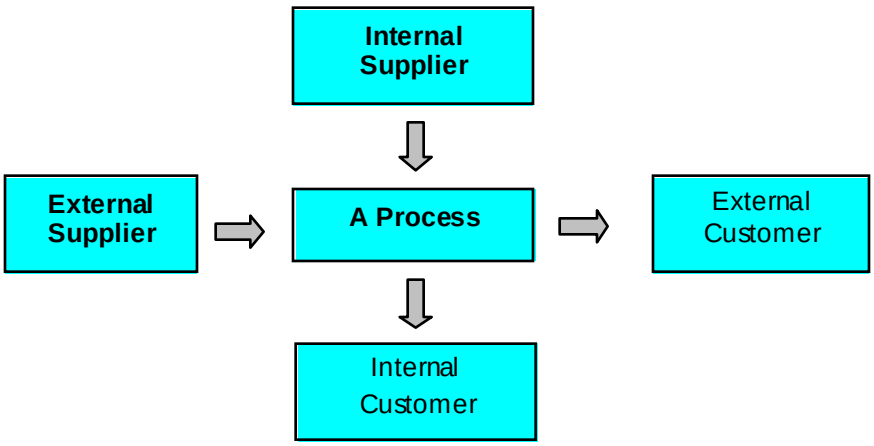


Figure 1.1: Customers, Suppliers and Process Relationship

Quality can be qualitative, quantitative, or both, and hence it is described on the basis of domain under consideration. For example, the Table 1.1 lists certain products/services relevant to our society and their quality-related indicators.

Table 1.1: *Related Indicators for Quality*

AREAS	EXAMPLES
Airlines	On-time, comfortable, low-cost service
Health Care	Correct diagnoses, minimum wait time, lower cost, security
Food Services	Good product, fast delivery, good environment, safe
Postal Service	Fast delivery, correct delivery, cost containment
Academia	Preparation for future, on-time knowledge delivery
Consumer Products	Defect-free, cost effective
Insurance	Payoff on time, reasonable cost
Military	Rapid deployment, up-to-date weapons and equipment
Automotive	Defect-free and dependable
Communications	Clearer, faster, cheaper service

The common denominator among these examples are four basic parameters; viz., cost, time, customer satisfaction, and defects. It is easy to see that some of these parameters in some areas are more important than others. For example, in health care sector, it is vitally important that defects be minimized. In all the cases, the bottom line is customer satisfaction. If you take an airline flight that is on time and inexpensive, you are satisfied.

Quality: The Historical Perspective

Quality is a timeless concept. It has been an inherent part of the human society, right from their creation. Somewhere down the line, we began to identify quality only with the manufacturing sector and accordingly link the quality evolution with the industry. Today, the clock has taken a full turn and quality is an inseparable entity in every thing we do, and hence It has truly become a way of life. Going by the literature, the quality movement originated with the work of artisans and craftsmen. The goods made by them were priced on the basis of their quality or the reputation of the individual

artisan/craftsman who created it. The competition among them soon resulted into formation of craftsmen unions called guilds. During the late 13th century, these guilds began to formally look into establishing specifications for the finished products as well as evolving the appropriate methods for their inspection and testing.

Quality through Inspection: The industrial revolution began in Europe during the mid-eighteenth century and gave birth to factories that soon outperformed the artisans and the guilds. The craftsmen became factory workers, and the quality was managed through the skills of craftsmen, and supplemented by in-house supervisory inspection which is termed as 'first party inspections'. Late in the nineteenth century, the United States broke the European tradition and adopted the concept of Taylor system of scientific management by separating planning from execution. The emphasis on productivity had a negative effect on quality. To restore the balance, a central inspection department came into being. For example, the Hawthorns Works of the Western Electric Company employed 40,000 people in the year 1928, out of which 5,200 people were in the Inspection Department.

Emergence of Quality Management Concept: During World War–II, the European and American industry was faced with the burden of producing enormous quantities of military products meeting their stringent requirements of time and quality. It saw emergence of new concepts in organizational management, including "*Quality Management*". Some of the pioneering works done in "*Statistical Quality Control*" in 1920s by Bell Telephone Laboratories (Dr. Shewart) and Hawthorn Works of Western Electric Company (Dr. Deming and Dr. Juran) got immense boost during and after World War II, and this led to the formation of American Society for Quality Control (ASQC). The post-World War II period witnessed dramatic developments of *Quality Management Tools* and their applications in different organizations. Most of the companies converted their Inspection Departments to the Departments of "Quality Control", or "Quality Engineering", or "Quality Assurance". As the things settled down, the manufacturing organizations adapted the concept of "Quality Assurance", which contained planned and systematic actions required to provide adequate confidence to

a customer that a product or service would satisfy the given quality requirements. This concept was largely based on "*process compliance*", where the process was viewed to be comprising of 7 Ms i.e.

1. Man
2. Material
3. Machine
4. Method
5. Milieu (Environment)
6. Measurement
7. Money (Resources)

The manufacturing processes were designed around these seven Ms. The inspection activity was limited to the monitoring (measurement) of process at certain vital points, which later came to be known as "*In-Process-Inspection*". This era of "*Quality Assurance*" also made use of *Statistical Process Control* (FORD –1965) and *Reliability Engineering* (Dr. Shewart)

The Japanese Initiative: While the Western world (USA and Europe) took an early lead in quality assurance in the post-World War–II era, the Japanese embarked on a course of achieving national goals by trade rather than by military means. They invited foreign Quality experts (Dr. Deming and Dr. Juran) to Japan for conducting training courses for their managers. The Japanese devised some unprecedented strategies from the inputs received from them for creating a revolution in quality, some of which were:

- The senior managers took charge of leading the 'quality' functions.
- All levels of employees underwent extensive training in 'quality'.
- Workers were involved in 'quality' through a unique concept of Quality Control Circles (1962).

Unlike in Western countries, where quality assurance (process compliance) was confined to manufacturing processes, Japanese applied the concept of quality

assurance (QA) on company-wide basis. This came to be known as "*Company Wide Quality Control*" (CWQC). This created a quality revolution in Japan and the salability of Japanese electronic products surpassed that of the West, around the year 1975 onwards. By applying the concept of QA to all the functions of an organization viz., purchasing, marketing, design, storage, and delivery etc., besides of course in manufacturing, the Japanese were able to produce quality products at a lower cost, due to which they quickly became the world leaders in electronics and automobile sectors. It will be relevant to mention here that this era of CWQC or CWQA is also known as the era of *Total Quality Control* (TQC). The work on TQC was done by Dr. Armand V. Feigenbaum, when he was the head of Quality at the General Electric Company, USA. Although, TQC was theoretically propagated in the USA, but the Japanese made use of it first, and hence it is identified more with Japan rather than the USA.

Emergence of Total Quality Management Concept: Total Quality Management (TQM) is a fundamental shift from the earlier phases of quality management evolution. TQM came into being during early 1980s, largely as a result of competition in the market place, world over. While TQC talked of compliance, the TQM era had more of technology, or what we call "*quality engineering"*. The TQM era realized that technology has its own limitations and the continuous improvement can not be achieved without harnessing the unlimited potential of human resource. Accordingly TQM established a very strong link (rather it overlaps) with the HRD functions within the organization. TQM organization is one where continuous improvement is the norm, where every one at all the levels and in all the functions is committed to the philosophy of "problem prevention" rather than "fire-fighting". In this quest for self-improving organization, cultural change, use of TQM tools, leadership, teamwork, all have a part to play. The organization is designed based on customer focused quality system and human resource management (HRD) principles. One of the definitions of TQM very appropriately comes from the people (employees) themselves: *"We are engaged in an ongoing journey of continuous measurable improvements, championed by empowered individuals at all levels of the organization. Our leadership philosophy*

inspires teamwork, trust, and belief in people, which results in an enjoyable and productive workplace, dedicated to the highest possible level of customer satisfaction." The key words about TQM are:

- Continuous improvement,
- Customer orientation, and
- Empowered employees.

The process of inspection looks at the product quality alone, whereas QA calls for quality of manufacturing process. The TQC stages integrate quality of all processes in the organization. The four stages are additive and progressive. Inspection is included in QA, which is included in TQC. The TQM stage encompasses TQC and takes the organization on a journey of continuous improvement, as shown in the Fig. 1.2.

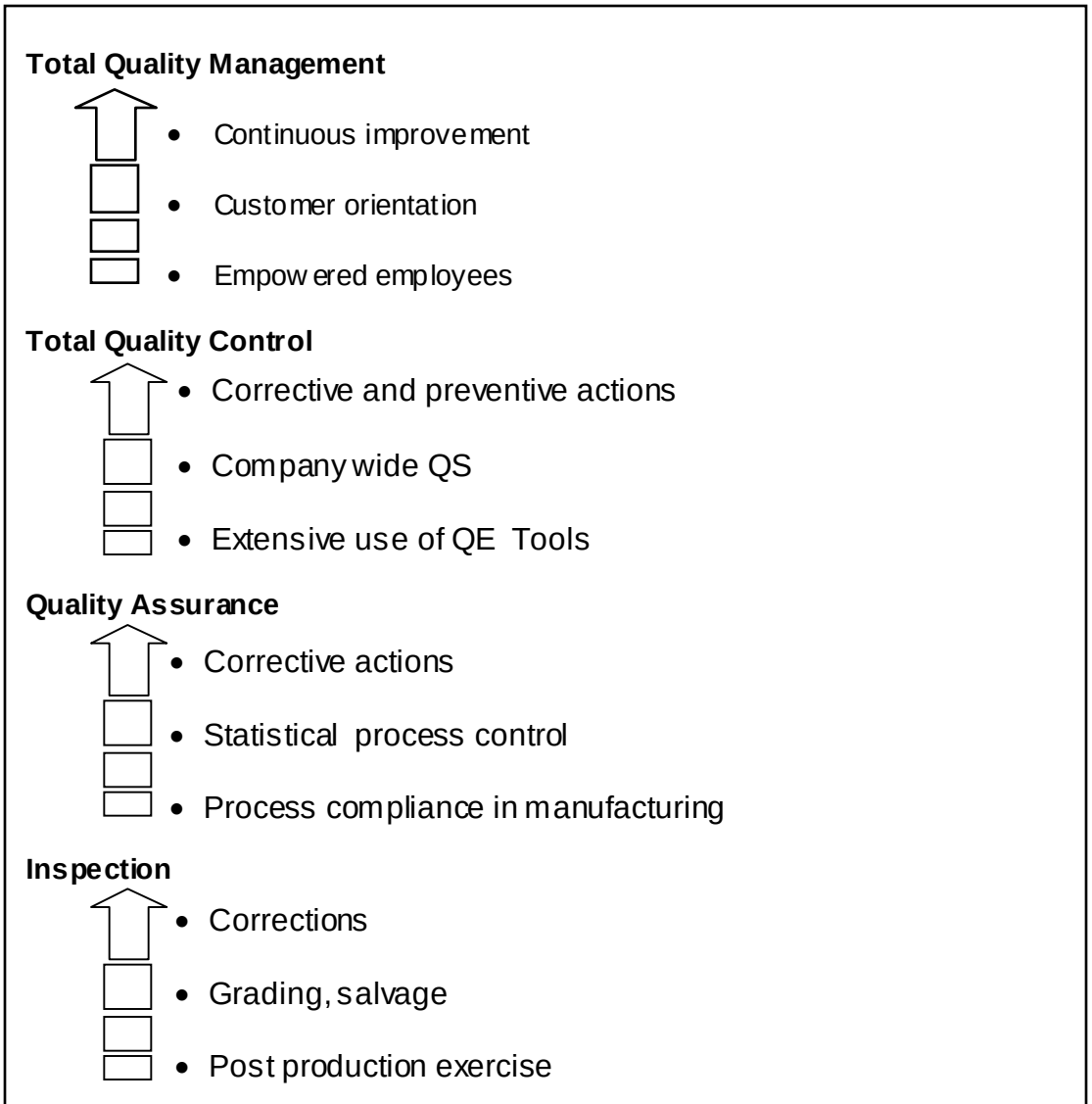


Figure 1.2: The four levels in the Evolution of Quality Management

Standards and Conformity Assessment

Standards are documented agreements containing technical specifications or other precise criteria to be used consistently as rules or guidelines to ensure that materials, products, processes or management systems are in conformity with these rules, guidelines or criteria covered therein.

International commercial exports and imports would be impossible for many industries if different countries have different standards for the same product or service. ISO 9001:2000 Standard, for example, defines the requirements where an organization needs to demonstrate its ability to provide products and services that meet customer and regulatory requirements and aims to enhance the customer satisfaction. Such standard helps the organizations in different parts of the globe to harmonize their management systems, thereby facilitating international trade between various countries. Organizations meeting the ISO 9000 Standards are certified by designated bodies, the procedure for which is discussed in detail in the Chapter 2.

Conformity assessment is the process by which a designated certification body known to be competent and credible, issues a certificate that a particular business or product complies with the particular standard. Role of conformity assessment in international trade is covered in detail in Chapter -3. The competence and credibility of a Certification Body is assured when it is accredited by an authoritative body. Such a system of conformity assessment, where a business is certified to, say, ISO 9001:2000 Standard by a competent and credible Certification Body and whose competency is further recognized by an authoritative Accreditation Body, should provide adequate guarantee to the ultimate user on the quality of the products / services delivered by the certified business. Of late, this guarantee has eluded the ultimate user. Ambiguities in the process of conformity assessment have been reported, which had been a matter of concern to the quality management experts in the world. However, no efforts have been made to isolate the causes of such a problem.

It was, therefore, decided to survey an adequate number of certified organizations and collect all the relevant information about them and the process of conformity assessment employed by the Certification Body in their certification. The data analysis of this survey and the conclusion drawn from this exercise are presented in Chapters 4 and 5.

2 Evolution of ISO 9000 Series of Standards

2.1 The Need for Quality Management System

In the present globally competitive environment, it is not just sufficient to achieve quality at any cost; it is necessary to achieve quality at a competitive cost to sustain the market forces. In this context, establishment of *Quality Management System* (QMS) provides a right framework for the organizations to harness their capabilities, direct their efforts to achieve the intended business results, and provide a basis for long-term growth and survival. QMS is commensurate with the benefit, cost, and risk considerations of an organization. The key objectives of QMS are to have effective management of internal processes to:

- Enhance customer / stakeholder satisfaction,
- Sustain business competitiveness, and
- Increase bottom line results and profitability with optimum use of resources.

The approach to develop and implement a Quality Management System consists of several steps, as shown in the Fig. 2.1. The need to have structured approach in managing system for quality resulted in development of an international set of standards, which came to be known as ISO 9000 series of standards.

2.2 Evolution of ISO 9000 Series of Standards

Quality by Second Party Inspection: During World War II, the United Kingdom faced a serious problem of accidental detonations in weapon factories that supplied ammunitions to the armed forces. To handle this problem, the UK's Ministry of Defence evolved guidelines, wherein it was essential that the supplier writes down the procedures for making a product, ensures that their workers strictly follow these procedures, and carryout internal inspection of their work. Finally, the complete method of working was inspected by a Government representative from the Ministry of Defence to ensure that only quality product comes out of the factory for supplying to

the forces. This was a small beginning for the evolution of the concept of *control and inspection,* which ensured that the quality is maintained and the products meet the desired specifications. This method of control was designed to ensure consistency of output. *Quality* became associated with "conformance" and "*quality assurance*", and implied that the *conformance has been assured through inspection*.

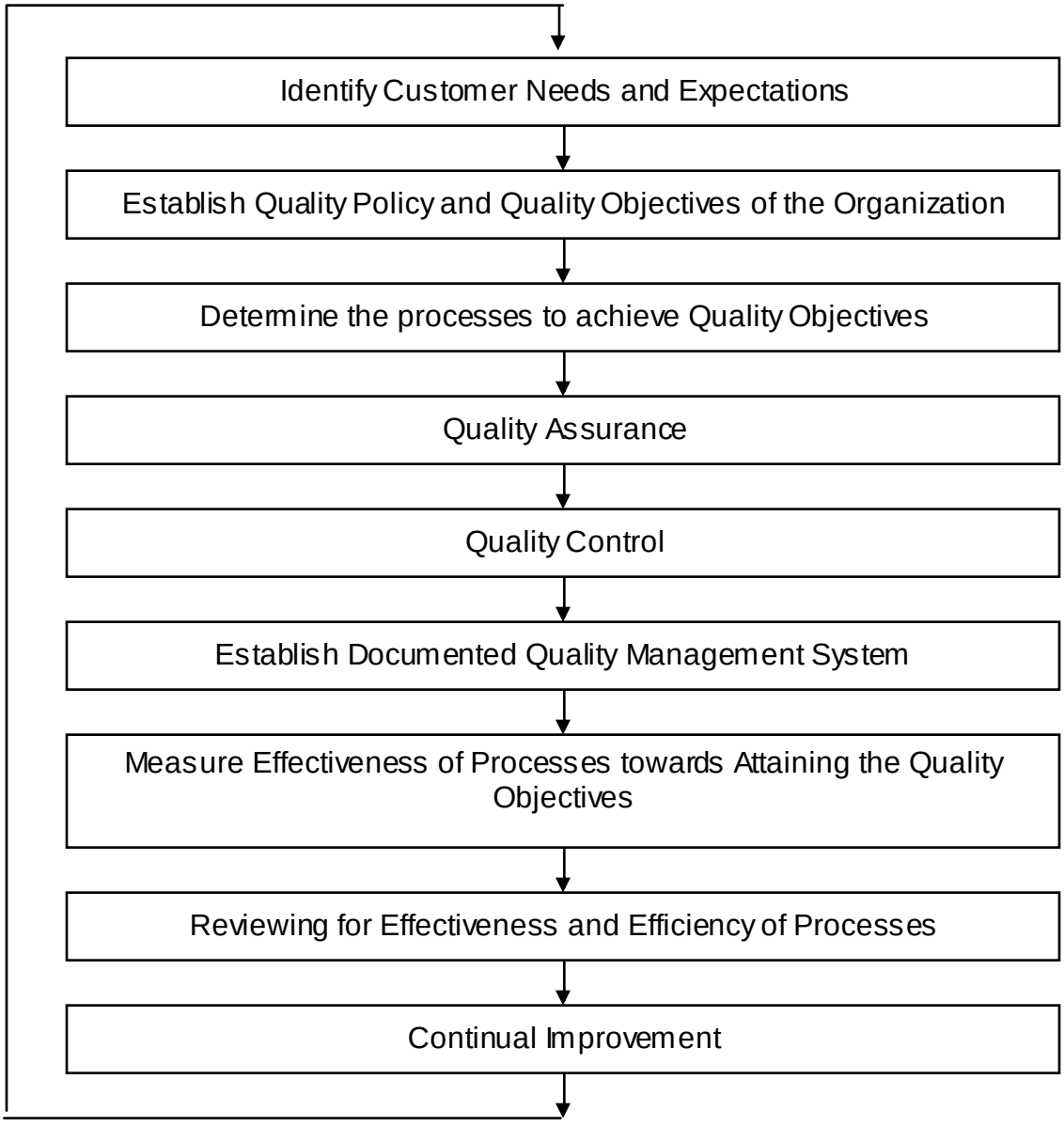


Figure 2.1: Implementation of Quality Management System

MIL-Standards (USA) and DEF Standards (UK): Development of quality standards reflected the desire to shift the burden of inspection by the Government inspectors

(*second-party inspection*) to *quality assurance* guaranteed by the supplier. In 1959, the United States developed "Quality Program Requirements", their first quality standard (Mil-Q-9858a) for military procurement, which laid down what the suppliers had to do to achieve conformance. By 1962, the NASA Space Programme also developed "quality system requirements" for their suppliers. In 1968, NATO adopted the *Allied Quality Assurance Procedures* (AQAP) specifications, the standards for procurement of NATO equipment. British Ministry of Defence released the Standards as 'DEF–STAN 05-20 series in 1969. By this time, the idea of quality assurance had spread beyond the military domain. In 1969, the UK's Central Electricity Generating Board and Canadian Ontario Hydroelectric organization developed their own quality assurance standards for their suppliers.

In 1966, the UK Government led the first national campaign for quality and reliability and made a slogan "*quality is everybody's business*". At this time, suppliers were being assessed by their customers, which was thought to be a wasteful effort, as it unnecessarily consumed resources. In 1969, Colonel G W Raby chaired a committee to prepare a report on the inspection and assessment of the UK's military quality systems. This committee's report reinforced the idea that suppliers should take the responsibility for quality assurance and recommended that their methods should be assessed against the generic standards of quality assurance. This opened the door to the third-party inspection; which also led to the creation of assessing organizations and made many Government (second-party) assessors redundant.

British Standards for Quality Assurance: In response to many problems that were occurring in their new electronics industry, the British Standards Institute (BSI) published their first Quality Assurance Standards – BS 9000 in 1971, *A Guide to Quality Assurance* - BS 4891 in 1972, and *Guidelines for Quality Assurance* - BS 5179 in 1974. These early documents were only guidelines and hence were not suitable for specifying the customer's requirements in contracts or for the assessment of a supplier's quality system. This led to major purchasing organization producing their own contractually binding versions of quality assurance measures. Such multiple

assessments led to a demand for a single national Standard and thus the BS 5750 – series of *Quality System Standards* were issued in 1979. The key industrial bodies agreed to drop their standards and instead use BS 5750 Standards, which provided a common contractual document to control their industrial production.

ISO 9000 Series of Standards: Following the lead taken by the UK, many national quality system standards were introduced in various parts of the world. Many of these Standards were copies of the British Standards, with certain modifications or a few additions. Increase in the global interest in Quality Management Systems resulted in the International Organization for Standardization (ISO) developing and publishing the ISO 9000 - Series of International Standards on Quality Management System in 1987.

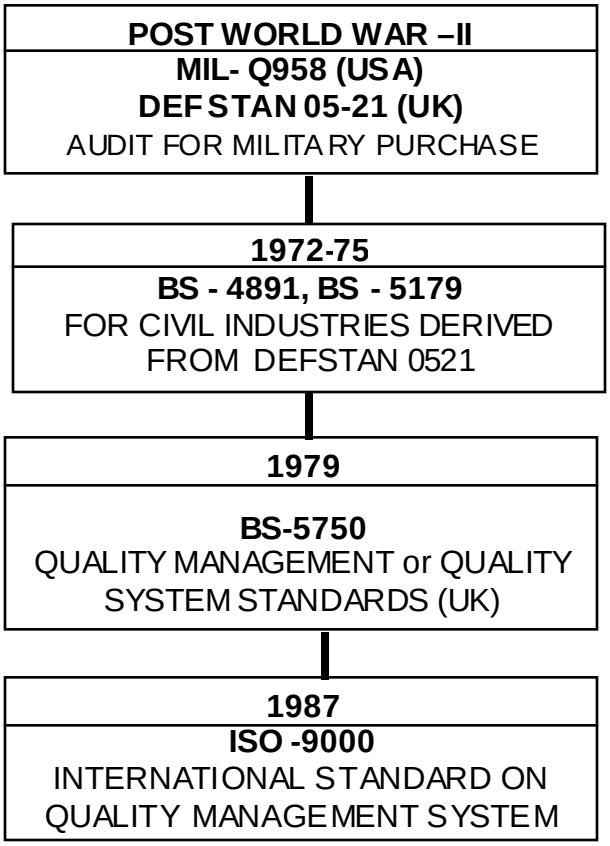


Figure 2.2: Evolution of ISO 9000 Series of Standards.

2.3 Structure of ISO 9000:2000 Series of Standards

The ISO 9000:2000 series of Quality Standards basically comprises of the following three Standards:

- ISO 9000: 2000 Quality Management Systems – Fundamentals and Vocabulary
- ISO 9001:2000 Quality Management Systems – Requirements
- ISO 9004:2000 Quality Management Systems– Guidelines for Performance Improvements

The ISO 9000:2000 Standard defines the principles and fundamental concepts and terms used in the ISO 9000 series of standards; ISO 9001:2000 defines the requirements where an organization needs to demonstrate its ability to provide products and services that meet customer and regulatory requirements and aims to enhance the customer satisfaction. ISO 9004:2000 provides guidelines for improving the performance of organization and enable them to satisfy all interested parties. Of these only ISO 9001:2000 is being used for contractual and certification purposes. There is yet another related standard, which is taken as member of extended family of ISO 900 series i.e. ISO 19011:2002. This standard provides guidelines for quality and/or environment management systems auditing.

The ISO 9000:2000 standard has now been revised and published as ISO 9000:2005 document. This has been done to align with the terminology relating to audit used in ISO 19011:2002.

The ISO 9001: 2000 Standard: As stated earlier, the ISO 9001:2000 standard defines the requirements where an organization needs to demonstrate its ability to provide products and services that meet customer and regulatory requirements and aims to enhance the customer satisfaction. These are the standards, which the desiring organizations should implement for their “certification”. About 250 requirements of the ISO 9001 can be condensed into the following 5 linked requirements. ISO 9001 basically requires the organization to:

- Determine the needs and expectations of customers and other interested parties.
- Establish policies, objectives and a work environment necessary to motivate the organization to satisfy these needs.

- Design, resource and manage a system of interconnected processes necessary to implement the policy and attain the objectives.
- Measure and analyze the adequacy, efficiency and effectiveness of each process in fulfilling its purpose and objective.
- Pursue the continual improvement of the system from an objective evaluation of its performance.

The focus is, therefore, on the results and the processes that produce these results. This means that there has to be a link between the needs of the interested parties, the organization's objectives, the processes for achieving these objectives and the results being produced.

2.4 Certification to ISO 9001: 2000

ISO, as the publisher of standard, does not issue certificate of conformity to ISO 9001:2000. Certificate of conformity to standard is issued by Certification Bodies, which are independent of ISO as well as the organization they certify. There are about 700 Certification Bodies worldwide. Certification assures users and customers that the organization has quality management system in place that complies with requirements specified in standard ISO 9001:2000. To maintain compliance on continuous basis, organizations are being monitored by Certification Bodies through regular surveillance.

In order to ensure that the Certification Bodies have necessary competency to issue certification, an authoritative (accreditation) body gives formal recognition to them. Accreditation bodies are established in many countries, often by the Government or with encouragement of the Government, to ensure that functioning of the certification bodies in the country are regulated. International Accreditation Forum (IAF), an association of accreditation bodies, ensures equivalence of accreditation and thereby of global certification, facilitating the international trade, details of which are covered in Chapter -3.

3 Conformity Assessment

ISO/ IEC 17000: 2004 defines conformity assessment of an organization as demonstration that the specified requirements relating to a product, process, system person or body are fulfilled. The conformity assessment includes activities such as testing, inspection, certification as well as accreditation of laboratories, inspection agencies, certification bodies (CBs). The accreditation accordingly is defined in ISO/IEC 17000: 2004 as " third party attestation, relating to a conformity assessment body, conveying formal demonstration of its competency to carry out specific conformity assessment tasks. Accreditation, in a way, is the highest echelon of conformity assessment.

Globalization and World Trade Organization (WTO) agreements have resulted in marketing of goods and services across the international borders comparatively easier. The boundaries of the market for the organization in a country changed from its own country to the world. In this process, while the organizations got access to the world market, they had to face the competition in domestic market from the organizations in other parts of the world. Trade within a country as well as across border requires mechanism to ensure that the quality of goods and services being traded is of acceptable levels. Conformity assessment and related international standards, that cover product quality, management systems, environmental systems etc., provide such mechanisms.

The impact of conformity assessment on both domestic and international trade was taken cognizance of in the 1994 agreement of Technical Barriers to Trade (TBT Agreement) of the international General Agreement on Tariffs and Trade (GATT) of WTO. The TBT Agreement recognized that **conformity assessment activities could expedite or seriously hinder** the free-flow of goods in the international commerce. To ensure that non-tariff barriers to trade do not hamper the world trade, Article 6 of the TBT agreement refers to the mechanism of recognition of conformity assessment

schemes. Article 6 on recognition of conformity assessment by Central Government Bodies states; *Members shall ensure, whenever possible, that results of conformity assessment procedures in other member countries are accepted, even when those procedures differ from their own, provided they are satisfied that those procedures offer assurance of conformity with applicable technical regulations or standards equivalent to their own procedures. Adequate and enduring technical competence of the relevant conformity assessment bodies in the exporting members, so that confidence in the continued reliability of their conformity assessment results can exist; in this regard, verified compliance, for instance through accreditation, with relevant guides or recommendations issued by international standardizing bodies shall be taken into account as an indication of adequate technical competence.*

The TBT agreement also emphasizes that the technical competence of a body undertaking conformity assessment needs to be ensured through the process of accreditation. Accreditation by definition is the formal recognition of the technical competence of an organization to carry out conformity assessment activities in the specified areas.

3.1 International Recognition and Equivalence of accreditation

Keeping the WTO / TBT requirements in view, appropriate mechanisms for mutual recognition of conformity assessments have been established by the **International Accreditation Forum (IAF).** The membership of IAF is open to all accreditation bodies and other stakeholders like association of Certification Bodies and the industry representatives etc. IAF has also prepared guidance documents for uniform interpretation of the international standards and has established a process of "Multilateral Arrangement (MLA) of Mutual Recognition", through which the accredited certificates issued get global recognition and the need for multiple accreditation is avoided. To be a member of IAF and also be part of MLA, all members are required to give an undertaking that they would comply with the applicable international standards and guidance documents issued by IAF from time to time. It also makes it mandatory for the members of IAF to recognize accreditation granted by other MLA signatories

as equivalent. The process of becoming MLA signatory requires that member accreditation body makes a formal application to IAF MLA Management Committee (MLA-MC) and confirms that it is complying with the international standards and IAF guidance documents. After the application is accepted, IAF sends a team of expert assessors from accreditation bodies of two different countries to carry out a "peer assessment". The peer assessment involves assessment at the office of the applicant accreditation body and also the observation of the assessors of the applicant body during an assessment of the Certification Body by the applicant.

3.2 Role of a Certification Body:

A Certification Body that is accredited by a single (or multiple) accreditation bodie(s), based on its compliance to the applicable standards and the competence of their managerial and technical resources can issue accredited certificates with the logo of the accreditation body (choice of the organization seeking certification). These certificates are issued by them only after they have physically verified that the organization is complying with the requirements of ISO 9001 standard or other applicable standards and the scope of the certificate is part of their scope of accreditation. After the initial audit and verification for their initial compliance to ISO 9001 standard, the Certification Bodies have to carry out surveillance audits at regular intervals (not later than once in a year) to ensure the continued compliance.

At the time of initial audit, if the organization is not found to be complying with the standard in certain respects, specific non-conformities (NCs) are communicated to them and they are allowed time to complete the corrective actions. The certificate is issued only on satisfactory completion of the corrective actions. If some of the non conformities are observed during the surveillance audit, depending on their severity, suitable actions are taken by the Certification Body that could be allowing time for corrective action, follow-up audit, suspension or withdrawal of certificate.

3.3 Certification scenario in Developing Countries

ISO 9000 standard based on the British standard BS 5750 was first issued in 1987. The certification to BS 5750 was initially started in UK and subsequently the standard was adopted as ISO 9000 by the international community. The certification activity was mainly led by the organizations that were involved in third party certification like ship registrars, third party inspection bodies etc. Later the Certification bodies established in UK and Europe realized that it would be easier to operate through branch offices set up in the developing countries.

As the awareness in the market spread and the thrust by the European countries that ISO 9000 certification would help improve the exports potential of developing countries, number of organization started looking at the ISO 9000 series of standards. The Certification Bodies took this as business opportunity and began to look at various options to expand their operations. They started having partnership or tie-up with appropriate agencies in the developing countries. Simultaneously it gave rise to local CBs coming into being and seeking accreditation from the overseas ABs in the developed countries. This was because most of the developing countries, at that point of time, did not have their own accreditation bodies. Proliferation in certification brought in competition and with inadequate control of foreign Accreditation Bodies on the Certification Bodies, resulted in considerable dilution of the certification process. The controls on the (a) organization that get certified to ISO standards, (b) the certification bodies that certify and (c) the accreditation bodies that accredit the certification bodies are graphically represented in Figure 3.1.

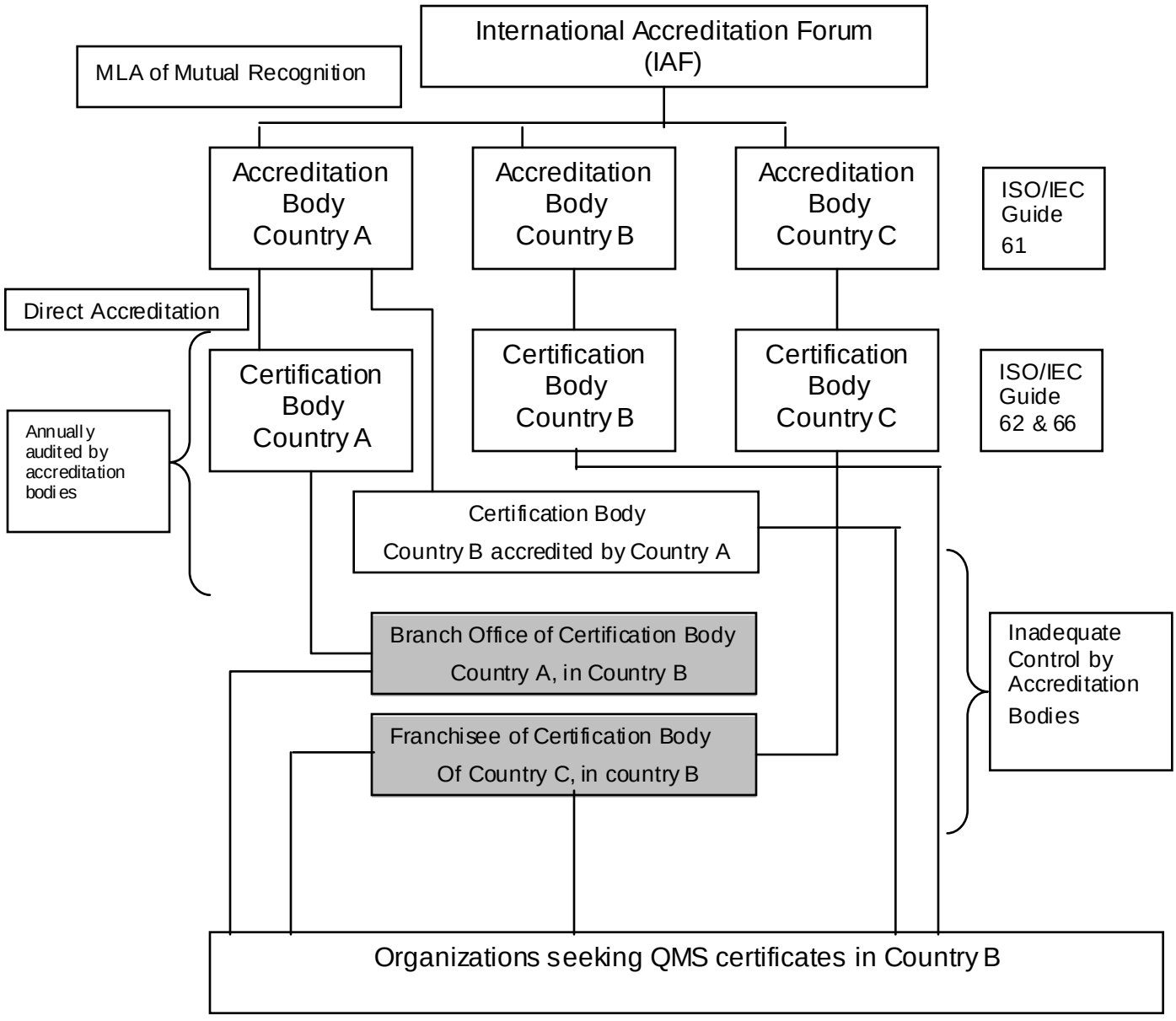


Figure 3.1: Control Structure of QMS Certification Process

It is mandatory for the Accreditation Bodies to carry out a regular surveillance assessment of the Certification Bodies at least once a year. Similarly the Certification Bodies will carry out a regular audit at least be once a year on the certified organizations to ensure continued compliance. One of the main reason for dilution of the standards of certification process is inadequate control of the Accreditation Bodies on the Certification Bodies that are operating through the branch offices, franchisee or through representation. The certification bodies (CBs) operating in most of the developing countries fall into following three categories;

Category A: Certification Bodies having direct accreditation from the National Accreditation Body.

Category B: Certification Bodies operating under foreign Accreditation Bodies (ABs)

Category C: Certification Bodies operating through branch offices, Franchisee or through representation of foreign Certification Bodies (CBs)

The CBs in the categories 'A' and 'B' undergo mandatory annual surveillance by their ABs, as provided in the IAF guidelines. This ensures regular monitoring & control over the functioning of CBs. The CBs in category 'C' are in fact the ones, which have largely been responsible for dilution in the certification process, mainly because of lack or absence of monitoring and control. Many CBs in this category have never been subjected to the surveillance by the concerned ABs.

3.4 Crises of Credibility

The ISO 9000 series of quality standards work on the premises that Customers require products with characteristics that satisfy their needs and expectations, collectively referred to as customer requirements or product specifications. The quality management system (QMS) approach encourages organizations to analyze the customer requirements, define a process that contributes to the achievement of a product, which is acceptable to the customer, and keep these processes under

control. Some organizations have used the ISO 9000 series of standards to develop quality management systems that are integrated into the way they do business are useful in helping them to achieve their strategic business objectives and add value for the organization. On the other hand, many other organizations have simply created a set of bureaucratic procedures and records that do not reflect the way the organization actually works. Setting up such elaborate procedures simply adds costs, without providing any value additions to the product or process.

Many companies generally feel that they have been benefited from the ISO 9000 certification. However, most of this initial benefit has been due to the creation of well-defined documentation of work processes, assimilation of data and maintenance of records. Many of such companies also recognize that benefit has not gone beyond adding any value into the internal system by way of improvement in efficiency and cost reduction etc. Most of the audit schedules focus only on determining whether documented procedures are being implemented in practice. Few procedures, however, define what the process they describe are designed to achieve or how these are to be measured. The audits in many cases fail to ascertain whether the process is suitable to deliver products that meet defined requirements and whether the process has realized the quality objectives of the organization. Consequently, most of the audit efforts reinforce the status quo and do little to identity the scope for business improvement. Many consider such audits merely as bureaucratic, low value to the company, and a necessity only to retain certification.

The effectiveness of quality management system certification is based upon the **credibility of the certification process.** Commercial considerations, incompetence or indifference on the part of a certification body would result in poor quality of certification and eventually the credibility of the whole process would be lost. The present research study is aimed at assessing this very effectiveness of QMS certification process.

4 Objectives and Methodology of the Research Study

4.1 OBJECTIVES OF THE STUDY

The ISO 9001:2000 Standard set out the criteria that apply to the management of an organization in determining needs and expectations of the customers and supplying products and services that satisfy the customers. Customers need confidence that they can select a supplier of specific products/services by assessing their capabilities on the basis of a professional "third party" certification. The role of a Certification Body (CB) is to carryout on–site assessment of an organization to verify that their quality management system complies with the requirements specified in ISO 9001:2000 Standards. While assessing an organization, the Certification Body is expected to follow the ISO Guide 62 and the applicable IAF guidance documents. The credibility of such certification solely rests on the competence and integrity of the third party, viz., the Certification Body. However, it has been noticed that gap has consistently existed between what has been specified in the guidelines and the actual practices being followed by various CBs. This is an extremely important lacuna in the ISO 9001 certification process, which needs an in-depth analytical study, so that appropriate remedial measures could be formulated and promulgated. The problem of the credibility of certification process has international ramifications, as mentioned in Chapter-3, and hence needed a detailed study. The principle objective of this research study has been to empirically analyze and critically assess the effectiveness of ISO 9001:2000 based QMS certification of different organizations and bring out the deficiencies that led to the crisis of credibility (Chapter-3). In view of this, sample of certified organizations in the country has been studied to:

- Verify, whether the CBs comply with the applicable guidelines in the certification process.
- Assess on ground by way of validating compliance of ISO 9001:2000 requirements in the certified organizations.

- Critically analyze the certification process on the basis of objective data collected from validation study.
- Identify the key areas, which are responsible for effectiveness (or in-effectiveness) of the certification process?
- Provide feedback to the CBs, and the relevant stake holders in the supply chain (Fig. 4.1) to highlight the gaps in the certification audit process.
- Suggest corrective measures to make the certification process more effective, the overall objective of which is that the ultimate consumer derives intended benefits while receiving the quality products/ services.

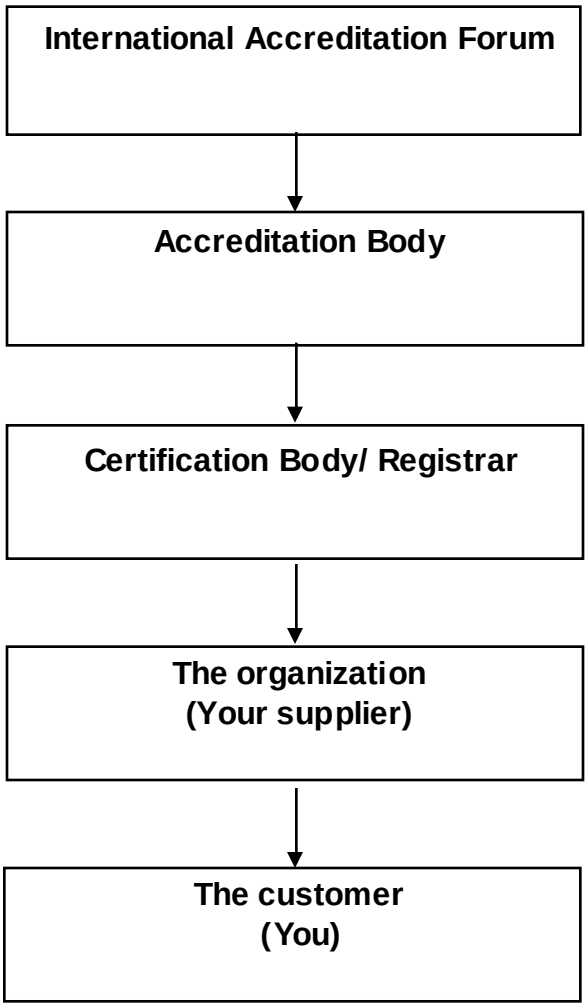


Figure 4.1: The Conformity Assessment Chain

4.2 THE RESEARCH METHODOLOGY ADOPTED

As discussed earlier, the Certification Body is the key player in the chain of activities for conformity assessment of those organizations, which seek ISO 9001 certification. The organization seeking certification approaches a particular Certification Body and the initial dialogue takes place, through which the latter gathers the requisite information about the organization and plans for the *modus operandi* of the assessment.

The Certification Body is expected to follow the ISO Guide 62 in getting the requisite information from the organization and plan for the assessment. One part of the research study has been focused on this aspect of the assessment process. A checklist was evolved on the basis of the requirements stipulated in the ISO Guide 62 and IAF guides. Data was collected from certified organizations to ascertain whether the CBs have followed the specified guidelines.

The second part of this study looks at the QMS status of the certified organizations. A checklist, largely based on the ISO 9001:2000 requirements was prepared, and data has been collected by way of actual assessment at the premises of the certified organizations to ascertain the extent to which QMS complies with the requirements of this Standard.

The effectiveness score is computed based on the survey results from number of organizations certified by a particular Certification Body. The average effectiveness score on the certified organizations relating to a particular Certification Body is taken as effectiveness index for that particular CB. The checklists were supported by guidelines for scoring various characteristic elements listed therein. Pilot assessment of seven certified organizations was also carried out, on the basis of which checklists and guidelines were finalized for use during the field survey on 429 organizations. Appropriate statistical tools were used to analyze the data obtained from the field survey. Three additional surveys were carried out to validate the results derived from the survey, while checklists in all the surveys broadly cover common parameters for

certification process and QMS status, a few minor changes have been made on the basis of experience gained from the preceding surveys.

4.3 QMS Certification Effectiveness Survey

The survey presented in this thesis has been conducted in two phases, spread over a period of about 2 years. The main survey (Phase –I) was carried out on 429 organizations, whereas the validation surveys were carried out in three parts on 112, 185 and 105 organizations. Details of organizations certified during a particular period were obtained from the respective CBs for each phase, out of which 10% certified organizations were picked up on a random sampling basis. While selecting the sample, the zonal representation and type of industry (small, medium, large) has also been taken into consideration. Some of the prominent CBs are covered in all the surveys to ascertain consistency and normalization of the empirical data. The number of organizations covered during the survey is given in the Table 4.1.

Table 4.1: Summary of Different Phases of the Survey

Phase	Number of Organizations Studied	Period of Survey	Period of Certified Organizations covered under Study
I	429	May – July 2005	Random Selection
II- A	112	May –June 2006	January – March 2006
II- B	185	September – October 2006	April –June 2006
II- C	105	May – July 2007	July – September 2006

4.4 Credibility of the Empirical Data

All the data used for the statistical analysis in the current study has been collected during the actual visits to the site and is based on objective evidence. The lists of certified organizations, obtained directly from the Certification Bodies, were further verified during the field visits. Due care was taken for the data collection to ensure that the conclusions drawn on the basis of such data remains objective. A common approach was followed for data collection in all the surveys.

4.5 Survey of ISO 9000:2000 Certified Organization (Phase –I)

As mentioned earlier, 429 ISO 9000:2000 certified organizations were surveyed during the Phase –I. The organizations covered in terms of the geographical areas of

North, South, East and West were 185, 134, 28 and 84 respectively. They represent 30 sectors and 31 certification bodies pertaining to 293 small scale industries, 116 medium scale industries and 20 large scale industries. The period of survey was May 2005 to July 2005.

The study focus mainly on two areas; i.e. Certification Process, where Certification Body interacts with the industry before audit and on actual QMS status, which looks into compliance of the standard within the organization. The data were analyzed using various Statistical tools including ANOVA (*Analysis of variance*; *this is a statistical test for comparing the means of more than two populations or group)* for -

a) Certification Process
b) QMS Status

In this study, data of only 5 Certification Bodies were analyzed, which had greater representation. Results of the study are given in Table 4.2.

Table 4.2: Effectiveness of Certification Process with respect to Category (Large, Medium or Small)

STAT GENERAL ANOVA		**Means(pavni-cb-cat1.sta)** F(8,318)=1.14;p<.3371
Var3	**Var4**	**Var5**
CB-1	LARGE	4.023809
CB-1	MEDIUM	4.061111
CB-1	SMALL	3.875000
CB-2	LARGE	3.500000
CB-2	MEDIUM	3.537879
CB-2	SMALL	3.593750
CB-3	LARGE	2.833333
CB-3	MEDIUM	2.642857
CB-3	SMALL	2.074324
CB-4	LARGE	4.333333
CB-4	MEDIUM	4.119048
CB-4	SMALL	4.178161
CB-5	LARGE	3.944444
CB-5	MEDIUM	3.122222
CB-5	SMALL	3.030864

Table 4.3: Effectiveness of QMS Status with respect to Category (Large, Medium or Small)

Stat. General Anova		**Means (pavni_cb_cat1.sta)** F(8, 268) =0.71 ; p< 0.6835
Var 3	Var 4	Var 6
CB-1	Large	3.714286
CB-1	Medium	3.724138
CB-1	Small	3.475325
CB-2	Large	3.547619
CB-2	Medium	3.033613
CB-2	Small	3.005495
CB-3	Large	3.464286
CB-3	Medium	2.360714
CB-3	Small	2.272059
CB-4	Large	4.571429
CB-4	Medium	3.619048
CB-4	Small	3.642857
CB-5	Large	4.023809
CB-5	Medium	3.104762
CB-5	Small	2.840909

4.6 Survey of ISO 9000:2000 Certified Organizations (Phase –II)

Three additional surveys have been carried out in the second phase to validate the results of phase –I

Results of Phase- II A

Phase-II A survey comprises of 112 organizations. This survey has been carried out with focus on the areas of Certification Process and QMS Status. The main objective of this survey is to analyze the status of two factors i.e. how the CB's are functioning during the pre audit phase and the status of QMS in the certified organizations. The survey carried out during May 2006 to June 2006 covered 23 sectors has been covered and 23 certification bodies. In terms of geographical locations, 54 organizations from North zone, 23 organizations from South zone, 16 organizations from East zone and 19 organizations from west zone have been surveyed in this phase. Out of 112 organizations surveyed in this phase 87 organizations pertains to small scale sector, 16 organizations to medium scale sector and 9 organizations to large scale sector.

In this survey only those CB's were considered for analysis which has four or more sample. Based on the analysis following results were obtained

Table 4.4: Effectiveness of Certification Process with respect to Certification Bodies

S.No.	Certification Body	Average on Scale of five
1	CB-6	4.02381
2	CB-7	3.533333
3	CB-1	4.06
4	CB-2	3.65
5	CB-3	2.491
6	CB-8	3.08
7	CB-9	3.7
8	CB-10	3.2
9	CB-11	3.777778
10	CB-12	3.218824
	Overall Effectiveness	3.313419

Table 4.5**: Effectiveness of QMS Status with respect to Certification Bodies**

S.No.	Certification Body	Average on scale of five
1	CB-6	3.330952
2	CB-7	3.183333
3	CB-1	3.742735
4	CB-2	3.625
5	CB-3	2.441345
6	CB-8	2.897436
7	CB-9	2.895833
8	CB-10	2.988889
9	CB-11	3.463675
10	CB-12	3.273002
	Overall Effectiveness	3.074197

Results of Phase – II B survey

The second survey phase-IIB consisted of 185 organizations. This survey was carried out to find out the homogeneity in functioning of different Certification Bodies with respect to Certification Process and QMS Status.

This survey was conducted from September 2006 to October 2006 wherein 28 Certification Bodies participated and 26 sectors were covered. . In terms of geographical locations 70 organizations were from North zone, 37 organizations from South zone, 32 organizations from East zone and 46 organizations from West zone. There were 148 organizations from small scale sector, 31 organizations from medium scale sector and 6 organizations from large scale sector.

The data analysis shows that the CBs fall in five different groups in respect to homogeneity in Certification Process while it comes to six different groups in case of QMS Status. This indicates that large variation exists in the functioning of Certification Bodies.

Table 4.6: Certification bodies in homogenous groups (Certification Process)

Group	**First Group**	**Second Group**	**Third Group**	**Fourth Group**	**Fifth Group**
Range of average response	4.35 – 4.60	3.50 -3.87	3.05 -3.40	2.60 – 3.03	2.30
Certification Bodies	CB-13 CB-14	CB-1 CB-6 CB-11 CB-15 CB-4 CB-2 CB-16 CB-17	CB-12 CB-18 CB-19 CB-5 CB-10 CB-20 CB-21 CB-22 CB-23 CB-24	CB-8 CB-25 CB-9 CB-3 CB-26 CB-27 CB-28	CB-29

Table 4.7: Certification bodies arranged in homogenous groups (QMS Status)

Group	First Group	Second Group	Third Group	Fourth Group	Fifth Group	Sixth Group
Range of average response	4.24	3.61 – 3.28	3.01 – 3.21	2.65 - 2.93	2.38 – 2.59	1.42
Certification Bodies	CB-13	CB-17 CB-1 CB-6 CB-15 CB-14 CB-11	CB-12 CB-2 CB-18 CB-26	CB-27 CB-16 CB-8 CB-23 CB-5 CB-20 CB-22 CB-10 CB-4 CB-19 CB-3	CB-9 CB-21 CB-24 CB-29 CB-25	CB-28

Results of Phase II-C survey

The third survey of phase-II consisted of 105 organizations, representing 11 certification bodies. In terms of geographical locations, 50 organizations were from north zone, 32 organizations from south zone, 12 organizations from east zone and 11 organizations from west zone. There were 92 organizations from small scale sector, 10 organizations from medium scale sectors and 3 organizations from large scale sectors covered in this survey.

The difference between the second and third survey of phase II is that in the present survey apart from the homogeneity, we also tried to find out the areas where CBs needs to improve in their performance and where is a need to make improvement in their variability i.e. where CB has to reduce their variability. Results of the analysis are tabulated below –

Table 4.8: Certification Bodies in homogenous groups (Certification Process)

Group	First Group	Second Group	Third Group
Range of average response	3.77 – 3.48	3.22 -2.76	2.52 – 2.31
Certification Bodies	• CB-1 • CB-5 • CB-12 • CB-23	• CB-8 • CB-2 • CB-3 • CB-11 • CB-9	• CB-21 • CB-29

Table 4.9: Certification Bodies in homogenous groups (QMS Status)

Group	First Group	Second Group	Third Group	Fourth Group	Fifth Group
Range of average response	3.89	3.53 – 3.34	3.25 – 3.05	2.97 – 2.84	2.44 -2.25
Certification Bodies	• CB-1	• CB-5 • CB-12 • CB-23	• CB-2 • CB-3 • CB-8	• CB-11 • CB-9	• CB-21 • CB-29

Performance Evaluation – Combining Mean and Variance- CP Process

Performance of certification bodies are evaluated for average and variance separately. Some certification bodies' averages are high but variances are not small and similarly there are certification bodies with low average and low variance. These are not very good performance level. Good performance is one where average performance is high and variability is small. This aspect cane be examined easily by the quantity known as coefficient of variance where ratio of standard deviation to mean is considered, i.e.

$$cv = \frac{s}{\overline{X}}$$

where cv is the Coefficient of Variance

s is Standard Deviation

$\overline{X}$ is the Mean

Comparison of Certification Bodies with respect to mean, variance, and cv is given in Table 4.10.

Table 4.10: Comparative performance of certification bodies

Certification Body	Average	Variance	Coefficient of Variation
CB-1	3.77	0.71	0.22
CB-5	3.61	0.78	0.24
CB-12	3.50	0.99	0.28
CB-23	3.48	0.77	0.25
CB-8	3.22	1.20	0.34
CB-2	3.13	1.10	0.34
CB-3	2.99	1.37	0.39
CB-11	2.97	1.17	0.36
CB-9	2.76	1.11	0.38
CB-21	2.52	0.78	0.35
CB-29	2.31	0.79	0.39

Performance of CB-1 is the best, as it has a high average and low variability which is also seen from cv value. Next best CBs are CB-5, CB-23 and CB-12. Rest of the certification bodies need to improve their average performance as shown in Table 4.13.

Performance Evaluation combining Mean and Variance- QMS Status

Performances of Certification Bodies are separately evaluated for average and variance. Some certification bodies' averages are high but variances are not small and similarly there are certification bodies with low average and low variance. These are not very good performance level. Good performance is one where average performance is high but the variability is small. This aspect can be examined easily by the quantity known as coefficient of variance where ratio of standard deviation to mean is considered, i.e.

$$cv = \frac{s}{\overline{X}}$$

where cv is the Coefficient of Variance

s is Standard Deviation

$\overline{X}$ is the Mean

Comparison of Certification Bodies with respect to mean, variance, and cv is given in Table 4.11.

Table 4.11: Comparative performance of Certification Bodies

Certification Body	**Average**	Variance	**Coefficient of Variation**
CB-1	3.89	0.65	0.21
CB-5	3.53	0.61	0.22
CB-12	3.44	0.91	0.28
CB-23	3.34	0.85	0.28
CB-2	3.25	0.77	0.27
CB-3	3.17	1.33	0.36
CB-8	3.05	1.16	0.35
CB-11	2.97	0.79	0.30
CB-9	2.84	1.00	0.35
CB-21	2.44	1.09	0.43
CB-29	2.25	1.57	0.56

Performance of CB-1 and CB-5 are the best among various Certification Bodies. They have a high average and low variability which is also seen from cv value (0.21 and 0.22). Next best are CB-23, CB-2 & CB-12. Rest of the CBs need to improve their average performance as shown in Table 4.13.

Table 4.12: Overall comparison of certification bodies for CP and QMS Status characteristics with respect to mean and variance

CP Characteristics				
Average	**Variance**			
	Level / Level	**Low**	**Medium**	**High**
	Low	CB-21, CB-29	-	-
	Medium	CB-2, CB-9	-	CB-8, CB-3, CB-11
	High	CB-1, CB-5, CB-23, CB-12	-	-
QMS Status Characteristics				
Average	**Variance**			
	Level / Level	**Low**	**Medium**	**High**
	Low		CB-11 CB-9	CB-21, CB-29
	Medium	CB-2	CB-8, CB-3	
	High	CB-1, CB-5	CB-23, CB-12	-

Table 4.13: Area for improvement

Certification Bodies	CP		QMS Status	
	Average	Variance	Average	Variance
CB-2	√		√	
CB-23			√	
CB-12			√	
CB-11	√	√	√	√
CB-9	√		√	√
CB-8	√	√	√	√
CB-3	√	√	√	√
CB-21	√		√	√
CB-29	√		√	√

5 Results and Findings

The main objective of the research study has been to assess the effectiveness of QMS certification process. Field study on 429 certified organizations followed up with three validation studies were undertaken on ISO 9001:2000 certified organizations during 2005 -2007. Each study has two components, one where data was collected on how the certification body plans an audit and whether it followed the applicable standards and Guides. This part has been referred as Certification Process (CP). In the second component, all the certified organizations were assessed to verify the compliance of requirements of ISO 9001:2000. This is referred in the study as QMS status. In both parts, results have been analyzed with respect to the certification bodies, industry sector (Large, Medium, and Small).

Not withstanding that all certification bodies are accredited to same international standard ISO Guide 62, there is vast difference in their performances and many ambiguities have been identified in the certification process. The key findings from the study are appended below –

5.1 The overall effectiveness of certification bodies in respect of certification process varies from 2.21 to 4.60. The results achieved in all four phases show similar pattern.

Table 5.1: Overall Effectiveness of Certification Bodies in respect of CP

	Study –I		**Study –II-A**		**Study –II-B**		**Study III-C**	
	Minimum Average	**Maximum Average**	**Minimum Average**	**Maximum Average**	**Minimum Average**	**Maximum Average**	**Minimum Average**	**Maximum Average**
	2.21	4.17	2.49	4.06	2.30	4.60	2.31	3.77
Overall Effectiveness	**3.40**		**3.31**		**3.29**		**3.11**	

5.2 The overall effectiveness of certification bodies in respect of their performances as viewed with respect to QMS Status show similar trend. The variation has been from 1.42 to 4.24.

Table 5.2: Overall Effectiveness of Certification Bodies in respect of QMS Status

	Study I		Study II-A		Study II-B		Study III-C	
	Minimum Average	Maximum Average	Minimum Average	Maximum Average	Minimum Average	Maximum Average	Minimum Average	Maximum Average
	2.31	3.67	2.44	3.46	1.42	4.24	2.25	3.89
Overall Effectiveness	**3.13**		**3.07**		**2.94**		**3.11**	

5.3 A positive correlation has been noticed between CP and QMS status effectiveness which demonstrates that if certification bodies does good audit planning (CP) the corresponding QMS status compliance is also good. The correlation realized in the four set of studies is computed below –

Table 5.3: Correlation between CP and QMS Status in four studies

Particulars	Study I	Study II-A	Study II-B	Study II-C
Correlation	0.79	0.74	0.76	0.86

5.4 Effectiveness of QMS has been found to be better in large scale industries as compared to medium and small scale industries. Data collected during studies I, II-A and II-B are given in Table 5.4 and 5.5 for CP process and QMS status respectively. This demonstrates that the large scale industries are better informed about usage of QMS certification.

Table 5.4: Large, Small and Medium Scale of Industry- CP Process

Category	Study –I	Study II-A	Study II-B
Large Scale	4.17	3.89	3.24
Medium Scale	3.44	3.66	3.48
Small Scale	3.32	3.19	3.60

Table 5.5: Large, Small and Medium Scale of Industry- QMS Status

Category	Study –I	Study II-A	Study II-B
Large Scale	3.78	3.83	3.43
Medium Scale	3.16	3.46	3.56
Small Scale	2.95	2.90	3.07

5.5 Besides the large variation in effectiveness of CBs, the test of significance (t-test) undertaken for the data collected during the study II-B and Study II-C show the behavior of CBs in terms of how homogenous are CBs with respect to each other. Table 5.6 below shows that CBs fall into relatively large number of non-homogenous groups in CP process as well as QMS status. The fact that all CBs are accredited to the same standard, this is an alarming pattern.

Table 5.6: Certification Bodies in Homogenous group – Study II-B – CP Process

Group	First Group	Second Group	Third Group	Fourth Group	Fifth Group
Certification Bodies	CB-13 CB-14	- CB-1 - CB-6 - CB-11 - CB-15 - CB-4 - CB-2 - CB16 - CB-17	- CB-12 - CB-18 - CB-19 - CB-5 - CB-10 - CB-20 - CB-21 - CB-22 - CB-23 - CB-24	- CB-8 - CB-25 - CB-9 - CB-3 - CB-26 - CB-27 - CB-28	- CB-29

Table 5.7: Certification Bodies in Homogenous group – Study II-B – QMS Status

Group	First Group	Second Group	Third Group	Fourth Group	Fifth Group	Sixth Group
Certification Bodies	- CB-13	- CB-17 - CB-1 - CB-6 - CB-15 - CB-14 - CB-11	- CB-12 - CB-2 - CB-18 - CB-26	- CB-27 - CB-16 - CB-8 - CB-23 - CB-5 - CB-20 - CB-22 - CB-10 - CB-4 - CB-19 - CB-3	- CB-9 - CB-21 - CB-24 - CB-29 - CB-25	- CB-28

Table 5.8: Certification Bodies in Homogenous group – Study II-C – CP Process

Group	First Group	Second Group	Third Group
Certification Bodies	• CB-1 • CB-5 • CB-12 • CB-23	• CB-8 • CB-2 • CB-3 • CB-11 • CB-9	• CB-21 • CB-29

Table 5.9: Certification Bodies in Homogenous group – Study II-C – QMS Status

Group	First Group	Second Group	Third Group	Fourth Group	Fifth Group
Certification Bodies	• CB-1	• CB-5 • CB-12 • CB-23	• CB-2 • CB-3 • CB-8	• CB-11 • CB-9	• CB-21 • CB-29

5.6 As a test case, the data on four prominent CBs has been compiled for all the four studies (CB-5 did not figure in study II-A). The effectiveness score has been generally consistent except in case of CB-3, which has minimum effectiveness out of the four CBs shown.

Table 5.10: Performance of 4 CBs in 4 studies – CP Process

CB's	Study -I	Study II-A	Study II-B	Study II-C
CB-1	3.93	4.06	3.87	3.77
CB-2	3.56	3.65	3.53	3.13
CB-3	2.21	2.49	2.87	2.99
CB-5	3.12		3.15	3.61

The above results have been graphically shown in the figure 5.1

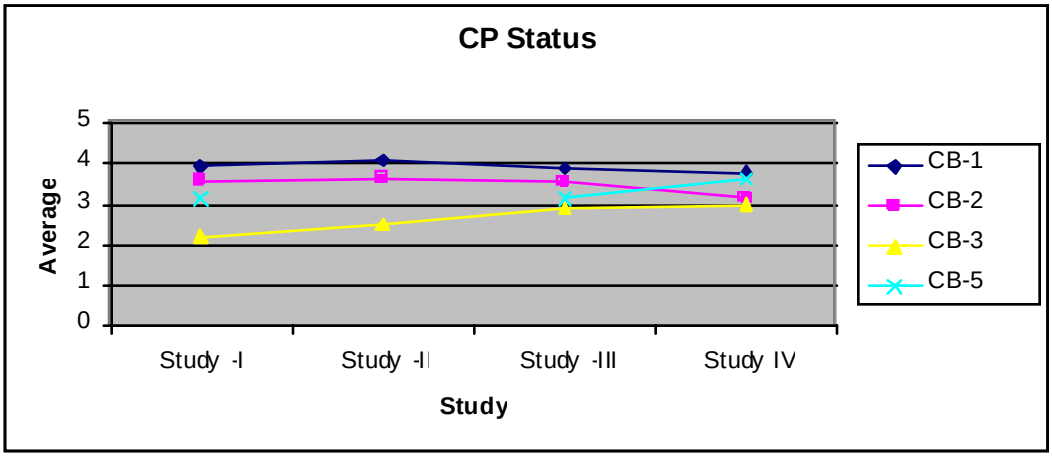


Figure 5.1: Performance of 4 CBs in 4 studies –CP Process

Table 5.11: Performance of 4 CBs in 4 studies – QMS Status

CB's	Study -I	Study II-A	Study II-B	Study II-C
CB-1	3.57	3.74	3.5	3.89
CB-2	3.07	3.62	3.08	3.25
CB-3	2.32	2.44	2.65	3.17
CB-5	3.03		2.87	3.53

The above results have been graphically shown in figure 5.2

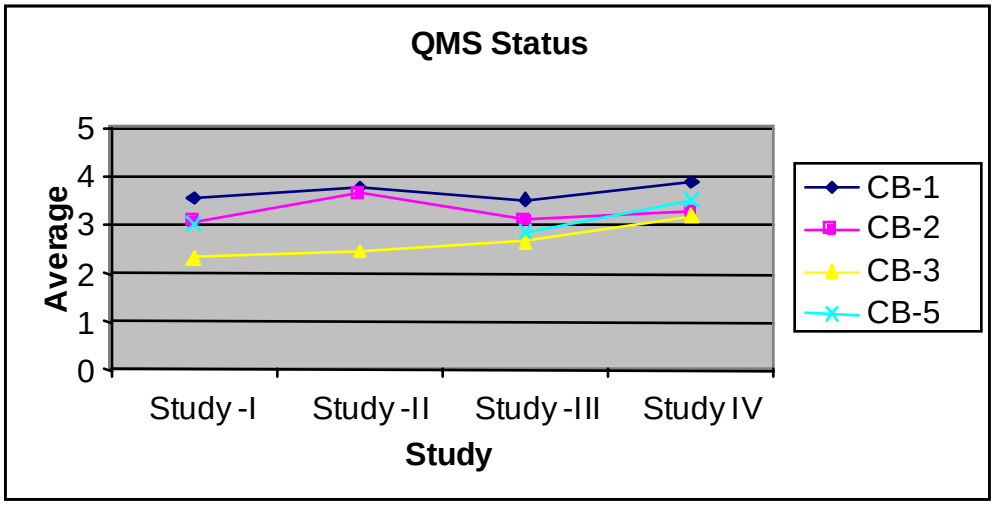
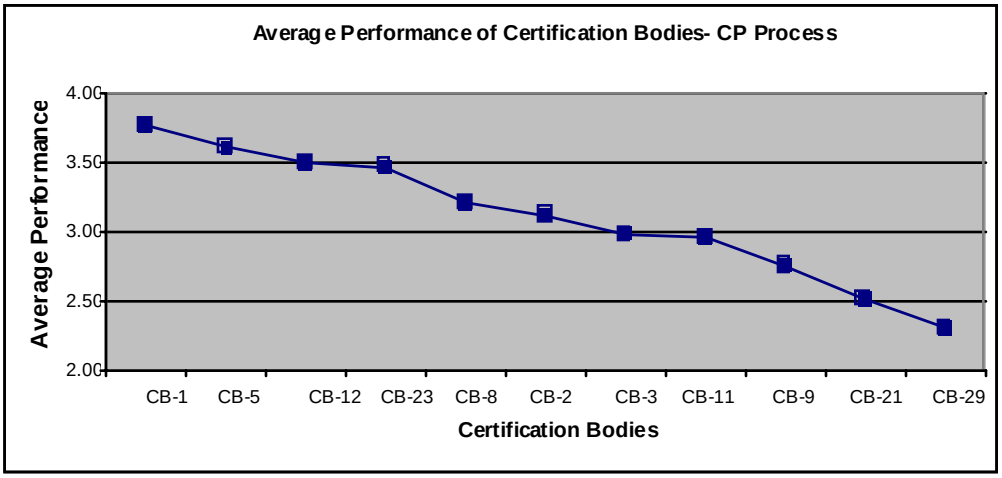


Figure 5.2: Performance of 4 CBs in 4 studies –QMS Status

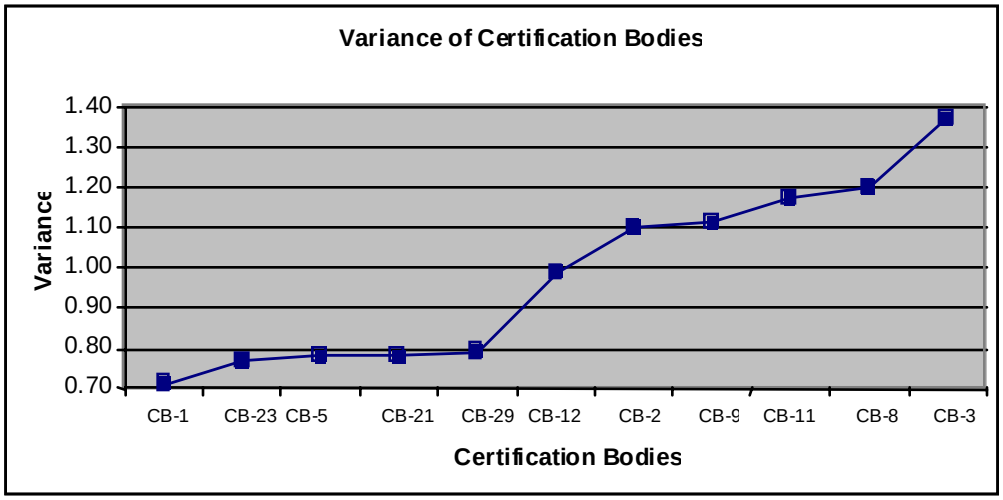
5.7 In study II-C we have calculated variance and coefficient of variance for 11 certification bodies for Certification process as well as for QMS Status. Variance indicates the measure of spread of data within the CB. Coefficient of variance combines the result of variance and overall average effectiveness (mean). Results for CP process and QMS Status are given in Fig. 5.3 and 5.4 respectively.

Certification Process

Certification Body	Average
CB-1	3.77
CB-5	3.61
CB-12	3.50
CB-23	3.48
CB-8	3.22
CB-2	3.13
CB-3	2.99
CB-11	2.97
CB-9	2.76
CB-21	2.52
CB-29	2.31



Certification Body	Variance
CB-1	0.71
CB-23	0.77
CB-5	0.78
CB-21	0.78
CB-29	0.79
CB-12	0.99
CB-2	1.10
CB-9	1.11
CB-11	1.17
CB-8	1.20
CB-3	1.37



Certification Body	Coefficient of Variation
CB-1	0.22
CB-5	0.24
CB-23	0.25
CB-12	0.28
CB-2	0.34
CB-8	0.34
CB-21	0.35
CB-11	0.36
CB-9	0.38
CB-29	0.39
CB-3	0.39

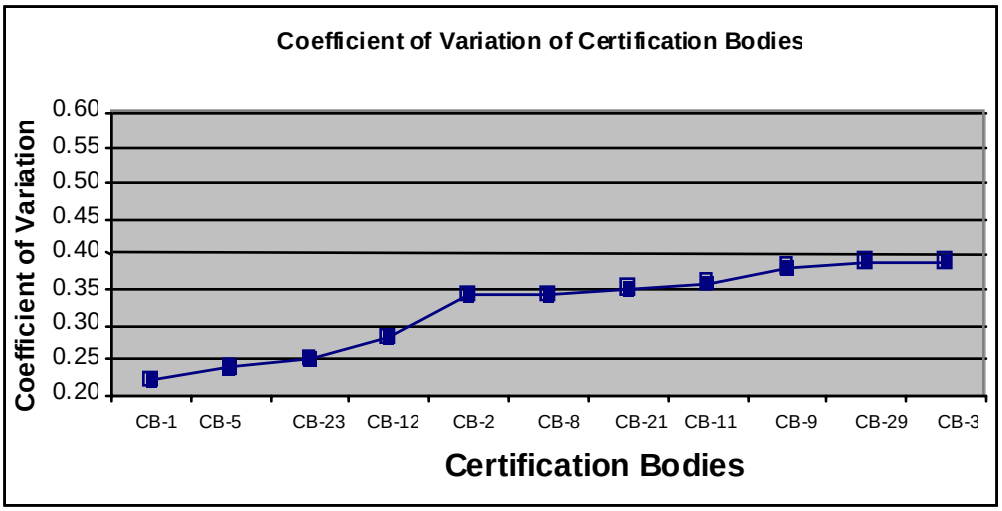
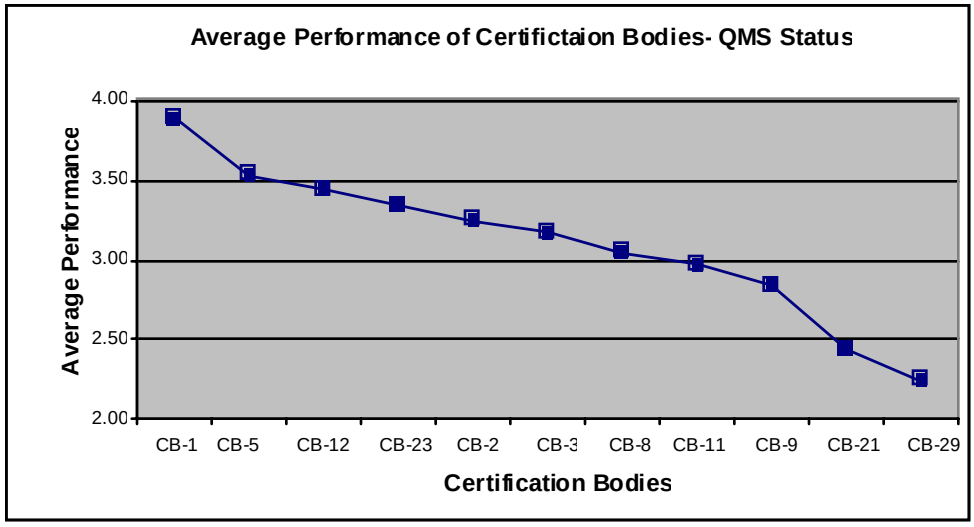


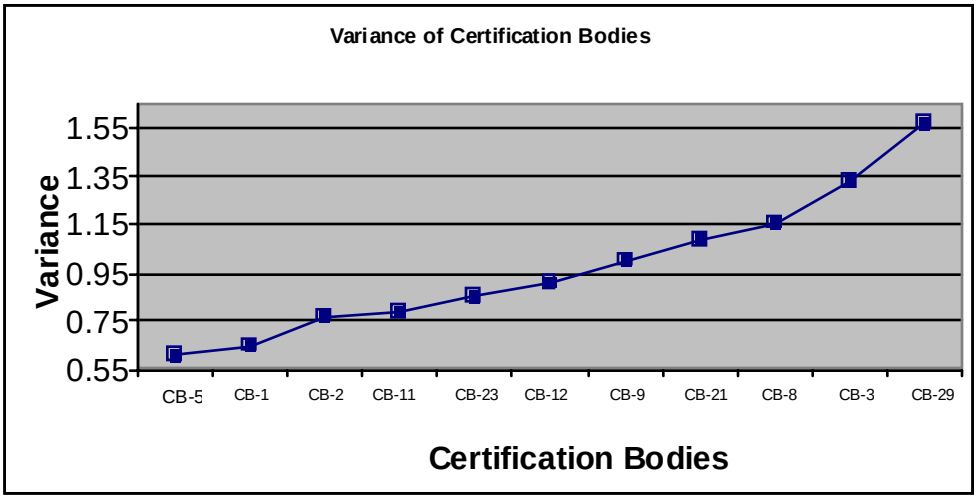
Fig. 5.3 : Average , Variance and Coefficient of Variance for Certification Process

QMS Status

Certification Body	Average
CB-1	3.89
CB-5	3.53
CB-12	3.44
CB-23	3.34
CB-2	3.25
CB-3	3.17
CB-8	3.05
CB-11	2.97
CB-9	2.84
CB-21	2.44
CB-29	2.25



Certification Body	Variance
CB-5	0.61
CB-1	0.65
CB-2	0.77
CB-11	0.79
CB-23	0.85
CB-12	0.91
CB-9	1.00
CB-21	1.09
CB-8	1.16
CB-3	1.33
CB-29	1.57



Certification Body	Coefficient of Variation
CB-1	0.21
CB-5	0.22
CB-2	0.27
CB-23	0.28
CB-12	0.28
CB-11	0.30
CB-9	0.35
CB-8	0.35
CB3	0.36
CB-21	0.43
CB-29	0.56

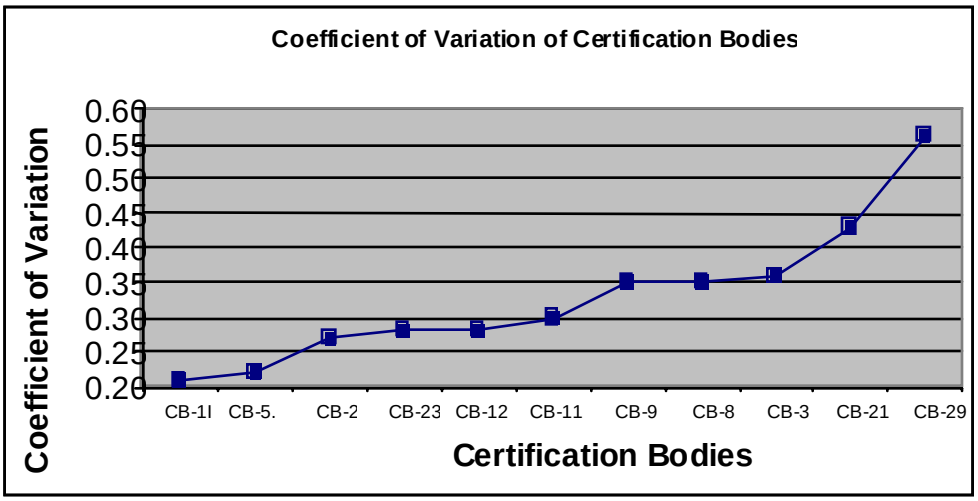


Fig. 5.4 : Average , Variance and Coefficient of Variance for QMS Status

Conclusions

ISO 9001:2000 has been most widely used management system standard. Over 1 million certificates have been issued all over the world. The standard played key role in national and international trade across the globe. Beginning 21st century, concerns have been raised on the credibility in QMS certification process, all over the world and more so in the developing economies.

The validation study conducted on total of 831 ISO 9001:2000 certified organizations to assess the effectiveness in certification process is the first of its kind, not only in India but in the world over. The study has conclusively established that ambiguities exit in the process of certification for ISO 9001:2000.

Conclusive evidence has emerged that there is large variation between processes adapted by different certification bodies although they are all expected to follow common standard. The compliance status of standard ISO 9001:2000, as validated by field visits on 831 certified units show wide variations. In other words, the ultimate consumer is deprived of degree of assurance that certified organization has the ability to consistently provide products that meet specified requirements.

When we look at the effectiveness in small, medium and large sectors, the findings are interesting. While the effectiveness index is low in small scale industry sector, the dispersion between CBs is low in the same sector. In case of medium/large scale, the overall average effectiveness is better but the dispersion is found to be relatively higher. This indicates that for small sector CBs collectively do not handle certification process effectively, whereas in large scale, it has been found that some CBs handle the activity more seriously than others.

The study has established mechanism to assess the relative effectiveness of a CB by evaluating the effectiveness index as well as working out its own dispersion.

Finally the study has gone in detail to identify the weak areas, where CBs should focus to improve effectiveness in certification.

6 Recommendations

To answer the increasing concerns by the end-users and other stake-holders about the value and credibility of accredited ISO 9001 certifications, Accreditation Bodies (ABs) & Certification Bodies (CBs) need to identify mechanism to determine if and how far the ISO 9001 certified organizations are able to consistently provide products (or services) meeting customer and regulatory requirements. The research study by way of validating and analyzing data from 831 ISO 9001 certified organizations has conclusively established that a wide variation exists in the certification process and practices adapted by various accredited Certification Bodies. The study has adequately provided remedial measures to be taken on improving the effectiveness of the accreditation – namely the ability of ABs to continuously ensure the observance of applicable standards and guides by the Accredited Certification Bodies. The value and credibility of the accredited attestations of CBs can be strengthened by acquiring appropriate feedbacks from the certified organizations. The following recommendations emerged from the current research study for various stake holders in the conformity assessment chain:

I. Recommendations Specific to International Organization for Standardization (ISO)

- ISO 9000 series of standards are periodically revised. ISO may consider preparing guidelines document to provide detailed interpretation of ISO 9001:2000 requirements. Alternatively, ISO can also incorporate necessary changes in the new version of ISO 9001, with focus on outcome.

- ISO 17021 (General requirements for bodies operating assessment and certification of management systems) has been released to replace ISO Guide 62. Market surveillance as a requirement, may be included as a requirement in ISO 17021. ISO

should expedite bringing out ISO 17021 (Part 2) on CB competencies, which up to some extent will ensure harmonized practices among different CBs.

- ISO Advisory Group should engage stakeholders in conformity assessment chain, including IAF, to have continuous feedback on effectiveness of Certification in meeting the expectation of the end user.

- ISO may bring out guidance document on 'What is a good audit' and 'What would be considered as a good audit report' – as an adjunct to ISO 19011:2002 (Guidelines for quality and/or environmental systems auditing).

- ISO should organize regional level programs through CASCO/ DEVCO on conformity assessment tools with a focus on improving the effectiveness of certification.

- ISO may actively look at the other methods (including one covered in the present research study) to get a feedback from the market about the effectiveness of certification, may be through an annual survey on a sample basis.

II. Recommendation Specific to the International Accreditation Forum

- International Accreditation Forum (IAF) is the custodian of ABs in the fields of management systems, products, personnel and other similar programmes of conformity assessment. With this mandate, they must assert that all the ABs follow uniform practices, and more importantly, accredit only the competent CBs. IAF may facilitate and establish regional forums comprising of ABs, CBs, industry representatives, and consumer groups for open discussions on the certification issues and interpretations of the Standard. It is also a good idea to open on FAQ box (Frequently Asked Questions), which can be made available to the public.

- ABs normally operate from a national base to provide accreditation of CBs for their domestic market. However, there are certain cases where some CBs seek foreign accreditation. In many cases even a foreign CB may set up a branch office in other economies, which weaken's the control on CBs by AB. IAF has come out with a policy of cross-frontier accreditation, which encourages CBs to have local accreditation whenever it is available. The policy provides that ABs should have an assessment that covers all the critical locations of its accredited CBs. The policy requires foreign ABs to accept assessors from the local AB. Once this policy is implemented by all the ABs, the control on CBs, particularly those operating as a branch office of foreign CBs, will significantly improve. **IAF need to enforce this policy in a fast track mode.**

- One of the key findings from the study has been that the CBs are generally found to deploy lesser audit man-days (audit time), which adversely affects the effectiveness of certification. If the audit is done in a hasty manner, many shortcomings of the organizations are likely to be inadvertently skipped. IAF Guidance document ISO/IEC 62 provides that CBs shall demonstrate that it has appropriate criteria in place to ensure that it provides necessary manpower resources, based on risk assessment and other applicable elements. IAF should come out with explicit guidelines to deal with this issue. IAF can possibly make software for minimum audit time to be used for contract review available.

III. Recommendations Specific to the Accreditation Bodies (ABs)

- Each AB, on its website, should provide the details of CBs accredited by them and the organizations certified by the respective CBs. This has become more important after the passage of "Right to Information" Bill in the country.

- ABs in their contracts with CBs should incorporate that they maintain a web-based database of their clients, comprising of details of active and invalid certificates etc., which may be accessible to the public for their information. This would ensure transparency of the process of ISO 9001:2000 Certification and increase the public awareness.

- Based on the findings of this research work, it is strongly recommended that ABs undertake validation audits directly on the certified organizations on a sample basis. This may necessitate inclusion of appropriate provisions in the contract between ABs & CBs and also between CBs and the organizations to be certified. The results of such audits should be shared with the respective CBs. The feedback results should also be fed into the AB's surveillance and decision making processes for the respective CBs to ensure effective performance.

- ABs may have a system of publicizing the good work done by CBs to encourage others to emulate. Simultaneously, ABs should publicize the suspended or withdrawn status of CBs on their web-site for general awareness. This would go a long way to ensure effectiveness compliance of the Standards.

- While auditing CBs, ABs need to focus on resource adequacy, resource planning and resource utilization of CBs.

IV. Recommendations Specific to the Certification Bodies (CBs)

- CBs may form an association in a country / zone and share their common concerns, common problems, and the remedial measures undertaken..
- CBs must organize regular meetings of their auditors to share information and counsel those needing attention.

- CBs should evolve an effective performance appraisal system for auditors. The system should take into consideration the quality of audit report and auditee feedback.

V. Recommendations Specific to the Industries

- The industry associations should have periodic programmes to enlighten their members about the importance of effective implementation of ISO 9001 standard, rather than merely having the 'certificate on the wall'.

- Industries need to educate themselves that the non-conformities raised by CBs are opportunities for improvement and, therefore, should support CBs in carrying out exhaustive and value-added audits.

- Industries should select consultants and the CBs strictly on the basis of merit and not only on the financial grounds alone.

- Top management in the industry must demonstrate understanding of requirements of ISO 9001 Standard and actively participate in maintenance of quality system through regular Management Reviews.

- Industry should offer the system for certification only after Quality Management System has fully been implemented and has also attained adequate maturity.

VI. Recommendations Specific to the Consumers

- The conformity assessment chain begins with the IAF and ends with the consumer/ultimate user. However, very little evidence is available to show that the user is playing any active role in the process of accreditation or certification. As a first step, IAF and ABs need to launch massive campaign to educate the users on their expectations from the accreditation certificates. Only empowered consumer

would be able to demand quality and thereby forcing / motivating CBs and industry to comply with the standards effectively.

- The general public is best represented by the recognized consumer organizations. Initially, these groups may not have a clear understanding of the conformity assessment responsibilities, practices or requirements, but are often best placed to provide first-hand feedback on the performance of certified organizations. The ABs should undertake lead role in educating the consumer organizations for such an exercise.
- Large purchasing groups such as Government departments, public and private utilities, and wholesalers have very good information about the supplier's capabilities. However, they may not differentiate between the activities of suppliers with accredited certification and those with un-accredited certifications or no certification. ABs/CBs can best utilize such groups and educate them to play key role in building effectiveness in the certification process.
- Industry group and scheme owners are also the key participants with a direct interest in the conformity assessment chain and are good sources of information about the quality of products and services they acquire and the effectiveness of accredited conformity assessment activities they rely upon. These groups, usually, have a high level of awareness about the accredited certification and can offer quantitative purchasing data. It is recommended that ABs/CBs establish formal arrangement with these groups for sharing this data.

VII. Recommendations Specific to the Government

- Accreditation provides assurance that the accredited certifications of Quality Management System (quality, environment, information security, occupational health and safety, and food safety etc.) are the reliable indicators of the capability of certified organizations to consistently meet the objectives of the Standard. World wide, the ISO 9001:2000 certifications exceed 1,000,000 and induced great expectations in the socio-economical context. The risks of deceiving such expectations are very high. In such a scenario, the Government has to play a very

active role, not withstanding that the accreditation and/or certification of management systems are voluntary in nature.

- Government need to allocate adequate budget for quality promotion in the country. It should educate citizens on their rights to appeal, whenever deficiencies are noticed in using a product/service from an ISO 9001:2000 certified organization.
- Government need to enact appropriate regulations to penalize the CBs, which are found to be resorting to un-ethical practices.
- Government can introduce regulations that all consultants should conform to the minimum acceptance criteria.
- Government should withdraw the monetary benefits given to an organization for certification, in case AB suspends accreditation to the concerned CB or when the CB suspends the certification.