



# ISO 9001—Its relevance and impact in Asian Developing Economies

**Based on Project TE/RAS/09/003**

A survey covering quality management system development, certification, accreditation and economic benefits



Norad





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In conjunction with:

International Organization for Standardization  
International Accreditation Forum  
Norwegian Agency for Development Cooperation



UNITED NATIONS INDUSTRIAL DEVELOPMENT ORGANIZATION  
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# PREFACE

## UNIDO

Since their initial publication in 1987, the ISO 9000 standards have undergone three revision cycles (in 1994, in 2000 and again in 2008/2009) and have had a great impact on the implementation of international trade and quality management systems by organizations throughout the world. In particular, the ISO 9001 standard has been applied in a variety of economic sectors, including industry, as well as regulatory frameworks established by governments in many areas. This standard focuses on the management of the processes needed for an organization to be able to demonstrate its ability to satisfy customer needs and expectations on a constant basis. Successful implementation of ISO 9001 by an organization requires the formal auditing of its quality management system by a certification body, which itself needs to be duly accredited. Whilst there are numerous certification bodies around the world, there is usually only one government-recognized accreditation body in any given country. These accreditation bodies provide recognition of each other's accredited certificates under the International Accreditation Forum's Multi-lateral Recognition Arrangement (MLA). This offers certified organizations a unique opportunity to improve their competitive advantage by gaining access to international markets and formal tenders where certification to ISO 9001 is often a pre-requisite.

In recent years, however, some concerns have been expressed in the Asian developing economies and elsewhere about whether accredited certification to ISO 9001 has been achieving the desired outcomes, and whether excessive attention to obtaining certification has shifted the focus away from the effectiveness of the quality management systems of the organizations involved. These concerns have also been shared by the ISO, the IAF and others. This publication represents an attempt to address these concerns in the context of business-to-business transactions in the manufacturing and construction sectors. It is the outcome of a project initiated by UNIDO, funded by Norad and supported with technical inputs by ISO and the IAF.

It is pleasing to see that the results have demonstrated (with some exceptions) that the implementation of ISO 9001 and the associated certification has been a good investment of resources, from both the perspective of the certified organizations and that of their customers (the major purchasing organizations in the region). The project has, however, highlighted some areas of weakness and we expect that all the parties involved will take the necessary actions to ensure continued improvements in the ISO 9001 implementation and certification process.



Kandeh K. Yumkella  
Director-General

## Norad

Over the last ten years there has been a rapid expansion of developing countries' interest in ISO 9001, but often the quest for certification has been limited by a lack of infrastructure and poor awareness among government and private sector organizations of what certification and accreditation actually mean. Norad has made significant investments in recent years to help selected Asian developing countries to develop such infrastructure and awareness by funding projects aimed at setting up accreditation bodies, certification bodies and other conformity assessment activities.

There has also been a debate on the effectiveness of accredited certification - whether the focus has shifted from one in which organizations strived to develop an effective quality management system that could subsequently be certified, to one in which the achievement of certification is the only goal, with a tendency to cut corners as necessary to achieve that goal. This debate centres on:

- whether organizations are deriving tangible benefits through ISO 9001 certification;
- whether certification bodies are carrying out the certification process effectively;
- whether the varied expectations from different stakeholders are being met.

Norad was therefore pleased to be able to provide funding for this project, which was aimed at obtaining objective evidence with which to be able to determine the true effectiveness of accredited certification and its value for the Asian developing economies. We can see from the results that the implementation of an accredited certification to ISO 9001 within the manufacturing and construction sectors do generally bring positive results both to the certified organizations and their customers, and ultimately to the economies themselves. Of course the system is not perfect, and this report has highlighted several areas of concern where improvements can be made to ensure the continued effectiveness and credibility of the accredited certification process.



Dag Larsson

Senior Adviser

## ISO

The International Organization for Standardization (ISO) develops standards in response to clearly identified demands for market and globally relevant solutions. ISO does not, however, provide certification services to assess compliance to the standards it develops. Instead it works with industry and with accreditation and certification bodies to encourage implementation of the standards in ways that meet the intent of the experts who wrote them.

Clearly, the use of ISO standards by those who will benefit from them is an objective of ISO and its members, one in each of 160 different countries. But ISO is neutral about how those who use the standards demonstrate compliance to them.

The ISO 9000 family of quality management standards are amongst the most widely-used and well known in ISO's catalogue of 18,600 standards. This study provides useful information about the take-up by and benefits for those in the countries covered by the survey who have decided to seek an accredited certification of their quality management system based on ISO 9001.

The increase in the numbers of those using the ISO 9000 family of standards is a global phenomenon, but the fastest growth in the uptake of these voluntary standards is in rapidly emerging countries. This is not an accident: there is a clearly demonstrated link between uptake of standards and economic growth, just as there is a link between standards and innovation.

The results of the survey also show that there is no reason for long discussions on policy nor for theoretical debate on the next steps to be taken to foster economic development. This survey shows, again, that the ISO 9000 family brings real benefits. A key next step must be for sustained international funding for quality improvement and economic development in the region. This can be achieved if such support is sustained, properly managed, and targeted through organizations and agencies, such as industry associations and standards and conformity organizations, that have a direct link to those who will benefit.

A handwritten signature in blue ink, appearing to read 'Rob Steele'.

Rob Steele

Secretary-General

## IAF

The Chair of IAF at the time this project was initiated was Dr. Thomas Facklam. I was then the Chair of the IAF Technical Committee and in this position I was supportive of the project because of the opportunity it gave to obtain some independent, objective, and reasonably representative information about accredited certification to ISO 9001.

This project has the potential to fill in one major missing element in the quest to improve the integrity, credibility and value of accredited certification to ISO 9001. This critical element is a methodology for evaluation/measurement of the overall effectiveness of the certification process.

As we seek to make improvements in accredited certification, it is important to evaluate/measure its status at a given point in time, implement improvements, and then re-evaluate/re-measure the status at an appropriate time in the future to determine if the interventions resulted in true improvements. Sound familiar? Sound like Plan-Do-Check-Act?

The results of this study are generally positive. They show that organizations do get value from accredited certification to ISO 9001; that users can rely on accredited certification to ISO 9001 as a reasonable basis for having confidence that the products or services provided by a certified organization will fulfil their expectations; and that, despite commercial and competitive pressures that can undermine the impartiality and effectiveness of audits and certification, the audits and certifications are, in most instances, effective and valuable.

The challenge now is to use this study to further improve accredited conformity assessment processes: to implement the Act part of the PDCA continual improvement cycle.



Randy Dougherty

Chair and President

# ACKNOWLEDGEMENTS

The project was carried out with extensive collaboration from the following people, at the international level:

Mr Rob Steele	ISO Secretary-General
Mr Sean MacCurtain	ISO Head of Conformity Assessment
Mr Olivier Peyrat	ISO/CASCO Chair
Mr Randy Dougherty	IAF President
Dr Thomas Facklam	IAF Immediate Past President
Mr B. Venkataraman	IAF/ILAC Development Support Committee Co-chair
Mr Roger Bennett	IAF Executive Committee member
Mr Graham Talbot	IAF Executive Committee member
Mr John Owen	IAF Secretary

In each of the participating countries, the project benefited from the hard work and dedication of a team of local consultants appointed specifically for this project, with support from their respective national standards bodies, local accreditation bodies, UNIDO offices and others. A complete list of participants is given in the annex.

The following individuals contributed their time, energy and professional experience by commenting on and validating the various questionnaires used in the project:

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This project was coordinated by Dr Nigel H. Croft, under the guidance of Mr Ouseph Padickakudi, Project Manager, and Dr Lalith Goonatilake, Director of the Trade Capacity Building Branch of UNIDO, with administrative support from Mr Mathias Schaetz, Mr Pradeep Paulose and Ms Ivana Najdanovic. The report was edited by Mr Malachy Scullion. The financial support from Norad and the active participation in the project of Mr Dag Larsson are gratefully acknowledged.



# ABBREVIATIONS AND ACRONYMS

AB	Accreditation Body
AFNOR	Association Française de Normalisation (France)
APG	Auditing Practices Group (Joint initiative of ISO and the IAF)
BAB	Bangladesh Accreditation Board
BIS	Bureau of Indian Standards
BoA	Bureau of Accreditation (Viet Nam)
BPS	Bureau of Product Standards (Philippines)
BSN	Badan Standardisasi Nasional (Indonesian National Standards Body)
BSTI	Bangladesh Standards and Testing Institution
BQSP	Bangladesh Quality Support Programme
CASCO Toolbox	Series of conformity assessment standards issued by ISO/CASCO
CAB	Conformity Assessment Body
CB	Certification Body
CRB	Certification/Registration Body (superseded terminology, but still referred to in some old IAF documents)
EMS	Environmental Management System
FCL	Foreign Critical Location
IAF	International Accreditation Forum
IAG	ISO 9000 Advisory Group (Multi-stakeholder group including ISO/TC 176, ISO/CASCO, ISO/COPOLCO and the IAF)
IEC	International Electrotechnical Commission
ILAC	International Laboratory Accreditation Cooperation
Inmetro	Instituto Nacional de Metrologia, Normalização e Qualidade (Brazil)
ISMS	Information Security Management System
ISO	International Organization for Standardization
ISO/CASCO	ISO Policy Committee on Conformity Assessment
ISO/COPOLCO	ISO Committee on Consumer Policy
ISO/TC 176	ISO Technical Committee 176 for Quality Management and Quality Assurance
KAN	Komite Akreditasi Nasional (Accreditation Body of Indonesia)

MLA	Multi-lateral Recognition Arrangement
MSMU/MED	Maldives Standards and Metrology Unit, Ministry of Economic Development
NABCB	National Accreditation Board for Certification Bodies (India)
NBSM	Nepal Bureau of Standards and Metrology
NAC	National Accreditation Council of Thailand (now NSC)
NSC	National Standardization Council of Thailand (formerly NAC)
Norad	Norwegian Agency for Development Cooperation
PAO	Philippine Accreditation Office
PDCA	The “Plan-Do-Check-Act” cycle (also referred to as the “Deming Cycle”)
PNAC	Pakistan National Accreditation Council
PSQCA	Pakistan Standards and Quality Control Authority
QCI	Quality Council of India
QMS	Quality Management System
OHSMS	Occupational Health and Safety Management System
SAARC	South Asian Association for Regional Cooperation
SDOC	Self-Declaration of Conformity
SLAB	Sri Lanka Accreditation Board for Conformity Assessment
SLSI	Sri Lanka Standards Institution
SME	Small or medium enterprise
SQCA	Standards and Quality Control Authority (Bhutan)
STAMEQ	Viet Nam Ministry of Science and Technology Directorate for Standards, Metrology and Quality
TISI	Thai Industrial Standards Institute
UNIDO	United Nations Industrial Development Organization
WTO	World Trade Organization
WTO/TBT	World Trade Organization Agreement on Technical Barriers to Trade

# EXECUTIVE SUMMARY

## Background

### What is ISO 9000?

The International Organization for Standardization (ISO) currently has a portfolio of over 18,500 standards, of which the ISO 9000 series relating to quality management is undoubtedly the best known. Within this series, ISO 9001:2008 [1] (“Quality management systems — Requirements”), is widely used by organizations around the world to demonstrate that they have a clearly defined and well managed set of processes that enable them to consistently provide products (including services) that meet customer and applicable statutory and regulatory requirements.

### What does “ISO 9001 Certification” mean?

A common way for organizations to show that they meet all the requirements of ISO 9001 is by using an independent third-party (a certification body (CB)) to carry out an audit of the organization, which, if successful, will result in the organization being issued with a certificate of conformity and the initiation of a programme of on-going surveillance by the certification body to ensure that the system is maintained in accordance with the standard. The value of certification is the degree of public confidence and trust that is established by an impartial and competent assessment by a third-party. The organization’s current and potential customers can be confident that their supplier (the certified organization) has indeed defined its processes and is managing them in a way that will consistently provide them with conforming products.

### Where does accreditation fit in?

Additional confidence is provided when the certification body is accredited by a recognized accreditation body (AB). Typically there is only one accreditation body per country. In the case of ISO 9001 certification, the accreditation process verifies the certification body’s conformity to the ISO/IEC 17021 standard [2] (at the time this project was carried out, this meant ISO/IEC 17021:2006 “Conformity assessment — Requirements for bodies providing audit and certification of management systems”, which has since been revised to ISO 17021:2011).

### How does accredited certification facilitate trade?

Accreditation bodies may choose to participate in multilateral recognition arrangements under the coordination of the International Accreditation Forum (IAF), to ensure that the criteria being used for accreditation are comparable around the world. This is intended to facilitate international trade by giving the corresponding accredited certification international validity and recognition, independent of the geographical location of the certified organization.

## Number of ISO 9001 accredited certificates

The countries involved in this project were Bangladesh, Bhutan, India, Indonesia, Malaysia, Maldives, Nepal, Pakistan, Philippines, Sri Lanka, Thailand and Viet Nam. The latest figures available from the ISO [3] (based on December 2009 data) show that there were 68,563 accredited certificates to ISO 9001 in these countries, representing 6.44% of the worldwide total of 1,064,785 certificates.

## Objectives of this study

The original project proposal [4] outlined three objectives of this study; it should provide:

- “Improved empirical evidence on the economic impact of management system certification in industries in SAARC and South East Asian countries;
- Improved knowledge base for national standards, certification and accreditation bodies, governments, regulators, ISO and IAF on management system certification and supporting schemes;
- Best practices and policy guidelines for improvement of functioning of management system certification and accreditation bodies.”

## Summary of the project methodology

The project methodology was agreed jointly by UNIDO, ISO and the IAF and is described in detail in the body of this report, but basically comprised the following phases:

### Survey of institutional purchasers

A survey was carried out of major institutional purchasing organizations (the customers and potential customers of ISO 9001-certified organizations). The aim was to assess the purchasers’ level of awareness and use of accredited certification to ISO 9001 as a supplier selection and evaluation tool, and the satisfaction of these major purchasers with the performance of their ISO 9001-certified suppliers.

### Interviews with selected purchasers

Face-to-face meetings were held with a small sample of purchasing organizations who had demonstrated their clear understanding of accredited certification (during the initial survey questionnaire) in order to obtain more detailed information about the performance of their suppliers.

### Survey of certified organizations

A survey of ISO 9001-certified organizations was conducted to assess (among other things) their reasons for implementing a quality management system and for seeking certification, their use of consultants, the selection criteria that they applied in choosing a certification body, their levels of satisfaction with the certification body, and their perceptions about the certification process.

### Visits to certified organizations

A series of one-day visits was made to 561 certified organizations. These were not formal audits but were characterized as “market surveillance” visits, carried out by experienced quality professionals and aimed at assessing the level of confidence in the effectiveness of the organization’s quality management systems and in the certification process.

### Sampling criteria and limitations/bias in the methodology

The project was intentionally limited primarily to manufacturing and construction-based industries involved in “business-to-business” transactions. Service sectors and “business-to-consumer” transactions were not targeted.

It is important to emphasize that participation in the project was necessarily voluntary and that organizations could not be required to take part.

## Key findings

### Economic benefits

There are clear empirical economic benefits to the effective implementation and accredited certification of quality management systems in the manufacturing sectors of the Asian developing countries in which the project was conducted.

### Credibility of ISO 9001

Overall, the perceptions of both the ISO 9001 standard and accredited certification to ISO 9001 in the region are good, though the role of accreditation is not well understood either by purchasers or by certified organizations.

### Purchasers’ perceptions of their ISO 9001-certified suppliers

The purchasers surveyed were mainly satisfied with the performance of their ISO 9001-certified suppliers (with some exceptions), and, in general, ISO 9001-certified suppliers performed “better” or “much better” than non-certified suppliers, based on a number of parameters. One area of concern that was identified, however, was the poor responsiveness of certified organizations to customer complaints.

### Lack of transparency in some certification bodies

A number of certification bodies in the region (mainly franchisees of overseas certification bodies) refused to provide any information about the organizations they had certified. This raised doubts about the level of transparency and openness of the certification bodies (one of the core principles mentioned in ISO/IEC 17021 [2] in order to promote confidence in accredited certification).

### Market surveillance of certified organizations

A “market surveillance” methodology involving short (one-day) visits to certified organizations was shown to be effective in distinguishing between superior and unsatisfactory performances of suppliers (as perceived by their customers), based on the subjective evaluation of a series of parameters related to the implementation of the quality management system.

### Performance of certified organizations

Overall, the performance of the 561 certified organizations that were visited was good, and demonstrated the effectiveness of the accredited certification process within that sample. However, a small percentage of the organizations visited demonstrated unsatisfactory results, which emphasizes the need to avoid complacency and to drive further improvements in the accredited certification process.

### Use of the quality management system to drive improvement

There is very little awareness in the region about the ISO 9004 guidance standard (ISO 9004:2009 — “Managing for the sustained success of an organization — A quality management approach”) [5]. This standard is not used for certification purposes but provides recommendations on how to use the quality management system to drive continual improvement and achieve long-term (“sustained”) success.

### Handling of customer complaints

There is a very low awareness among all users (purchasers, certified organizations, certification bodies, consultants and others) about the ISO 10002 standard (ISO 10002:2004 “Quality management — Customer satisfaction — Guidelines for complaints handling in organizations”) [6]. This is particularly important in light of the relative dissatisfaction of purchasers with the way in which their certified suppliers deal with complaints.

### Performance of small and medium enterprises

The results confirm that the level of confidence in the performance of small and medium sized enterprises (SMEs — organizations with less than 250 employees) is lower than for larger organizations.

### Use of consultants

The vast majority (over 80%) of the certified organizations surveyed had used the services of a consultant to help with the implementation of their quality management system. This was more pronounced for micro, small and medium organizations.

### Audit durations

Interestingly, in spite of previous anecdotal evidence to the contrary, the results indicate that certification bodies, in general, respect the audit durations prescribed by the IAF Mandatory Document MD5 [8]. In particular, audit durations for micro, small and medium enterprises tend to exceed the recommendations of IAF MD5.

## Weak areas of implementation of ISO 9001

The weakest areas of implementation that were identified during the visits to certified organizations were:

- A general lack of focus on preventive actions;
- Poor use of the “Plan-Do-Check-Act” approach (ISO 9001 Clause 4.1) to manage the quality management system (QMS) processes;
- Poor culture of continual improvement;
- Lack of adequate cause analysis and effective corrective action for process, product and system nonconformities;
- Little use of the “process approach” throughout the organization.

## Differences in performance of certification bodies and accreditation bodies

Notable differences were observed in the performance and level of confidence in organizations certified by different certification bodies and under accreditation from different accreditation bodies. Detailed information is being made available on an individual basis to those involved.

## Performance of local franchisees of foreign certification bodies

The survey clearly highlighted the relatively poor performance of organizations that had been certified by local franchisees of foreign certification bodies, when compared with local certification bodies or branch offices of international certification bodies.

## Time taken to implement and certify the quality management system

A clear trend was observed that showed that more recently certified organizations are achieving certification in shorter times than those that have been certified for longer periods. The visits to certified organizations confirmed, however, that the level of confidence in the quality management system of those organizations that had spent less than six months implementing their system was substantially lower than in that of those who had taken longer.

# 1. INTRODUCTION

## The ISO 9000 standards

The International Organization for Standardization (ISO) currently has a portfolio of over 18,500 standards, of which the ISO 9000 series is undoubtedly the best known. The current ISO 9000 series comprises more than 20 guideline and requirements standards related to quality management, and is developed and maintained by ISO's Technical Committee TC 176.

The standard that is used as a basis for certification is ISO 9001:2008 "Quality Management Systems — Requirements" [1], for which the stated objective (Clause 1.1) is:

"to specify requirements for a quality management system where an organization

(a) needs to demonstrate its ability to consistently provide product that meets customer and applicable statutory and regulatory requirements, and

(b) aims to enhance customer satisfaction through the effective application of the system, including processes for continual improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements".

ISO 9001 addresses the need for: the commitment of top management to the quality management system; a "customer focus" throughout the organization; a clear quality policy and policy objectives defined by top management; definition of the responsibility and authority of the various personnel involved in the quality management system and communication between them; ensuring the availability of resources (including competent personnel); appropriate levels of documentation; and control of the various operational processes, from sales through product design and development and manufacture (or service provision) to process monitoring, product inspection and after-sales support.

In order to ensure on-going conformity to ISO 9001 and continual improvement of the system, the standard further requires the organization to carry out its own internal audits and reviews of its system at regular intervals and to undertake corrective and preventive actions as needed.

ISO 9001 is based on two key concepts: a clear understanding of the organizational processes and their interactions to ensure product conformity; and the management of those processes and the system as a whole, using a "Plan-Do-Check-Act" methodology. It is applicable to any kind of organization — large or small, private or public, and in the manufacturing, service or other economic sectors.

As a result, ISO 9001 has been widely accepted around the world as a basis for organizations to provide confidence in their ability to understand customer and statutory/regulatory requirements, and to systematically provide products (including services) that meet those requirements. Its aim is an effective quality management system (one that achieves the expected outcome of "consistent,



conforming products”), but not necessarily an efficient one (which does so with the minimum waste of resources). Although efficiency may not be critical from the perspective of the certified organization’s customers, however, it is clearly important for the organization itself, and is a key topic of the guidance standard ISO 9004.

ISO 9004:2009 “Managing for the sustained success of an organization — A quality management approach” [5] goes beyond the basic requirements of ISO 9001, and guides organizations towards sustained success by identifying and meeting the needs and expectations not only of their customers but also of other interested parties over the long term and in a balanced way. This standard is specifically not intended for the purpose of certification, but may be used as a basis for self-assessment (by the organization) of the maturity of its quality management system. ISO 9004 addresses topics such as strategic planning, policy deployment, employee motivation, management of financial and natural resources, knowledge management and innovation that are not specifically covered in ISO 9001.

ISO 9001 and ISO 9004 were first published in 1987 and have since undergone three revisions (in 1994, in 2000 and again in 2008/2009) to incorporate the latest trends and philosophies in quality management. They are intended to be used separately or together, but it is important to emphasize the specific focus of each. Many of the perceived benefits that can be derived from an “ISO 9000-based quality management system” will not be achieved by implementing ISO 9001 alone. ISO 9001 focuses only on the management system requirements needed to ensure the provision of “consistent, conforming products” to customers, thereby enhancing customer satisfaction. Other organizational benefits — including improvements in efficiency — may be a by-product of ISO 9001 implementation but can only be ensured by the effective deployment of the long-term, multi-stakeholder approach promoted by ISO 9004, which is outside the scope of this project.

The development of the first edition of the ISO 9000 standards, published on 15 March 1987, was based on traditional quality assurance standards used in the manufacturing sector (specifically in the engineering, aeronautical, nuclear and military-related industries) that had been around since the 1950s. The “quality system” requirements standard, ISO 9001, (quality “management” was to come later) was developed to address contractual situations where the “supplier” had to demonstrate the ability to “design/develop, produce, install and service” its products. A minor revision to ISO 9001 was made in 1994 but without any significant change in focus.

In order to make the ISO 9000 standards more business-focused and easier to understand for those not involved in the manufacturing industries, however, ISO placed great emphasis during the development of the ISO 9000:2000 family of standards on defining and deploying throughout the standards a set of eight quality management principles. These principles had been developed during the mid-1990s and drew on the philosophies of recognized quality gurus such as Deming, Juran, Crosby, Ishikawa and Feigenbaum, among others. They are explained in detail in the ISO 9000:2005 standard (“Quality management systems — Fundamentals and vocabulary”[9]). They now provide the conceptual basis for both the ISO 9001 requirements standard and the ISO 9004 guideline standard. The principles are:

- Customer focus
- Leadership
- Involvement of people

- Process approach
- System approach
- Fact-based decision-making
- Continual improvement
- Mutually-beneficial supplier relationships

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***Conformity to ISO 9001 can be demonstrated by first, second or third-party assessments. Currently over 1,000,000 organizations worldwide hold accredited third-party certificates to ISO 9001.***

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In addition to a shift from “Quality Assurance” to “Quality Management”, ISO 9001:2000 also saw a change in focus from many “hard” engineering-based requirements to “softer”, more abstract people-focused requirements. Requirements related to management commitment and employee awareness were introduced, and, whilst these are much more appropriate for a modern organization, they are also more difficult to audit than some of the old black or white (yes/no) prescriptive requirements of the 1994 versions. The recently-published ISO 9001:2008 standard incorporated only a few small changes to existing (ISO 9001:2000) requirements and retained the eight quality management principles at its core.

It is not surprising, then, that most people tend to associate “ISO” with “ISO 9000”, and a certificate of conformity to the ISO9001 requirements standard has become commonly (but incorrectly) known as “ISO Certification”. ISO is not, however, directly involved in the ISO 9001 certification process, nor does it specifically promote or require certification as a means of demonstrating conformity to its standards. Its activities are essentially limited to the development and publication of international standards, including ISO 9001 and other requirements standards such as ISO/IEC 17021 [2] and ISO/IEC 17011 [10] (developed by ISO’s Conformity Assessment Committee ISO/CASCO) that relate to the certification and accreditation processes respectively. ISO does, however, maintain close contacts with the management system certification community through its liaisons with the International Accreditation Forum (IAF).

### **Accredited certification to ISO 9001**

A common way to demonstrate conformity to ISO 9001 is by using an independent third-party (a certification body) to carry out an audit of the organization, which, if successful, will result in the organization being issued a certificate of conformity. This is intended to provide confidence to the organization’s customers (and potential customers) that they can expect the organization to consistently provide them with conforming products. Although this is the most widely accepted method of conformity assessment for ISO 9001, it is not the only one, and indeed certification is not a required way of demonstrating conformity to any ISO standard. Other ways of demonstrating conformity include second-party evaluations of suppliers, carried out by the purchasers, and self-declarations of conformity (for example, by a corporate entity to ensure that its various divisions and plants around the world have a quality management system that meets not only ISO 9001 but also its corporate policies and objectives). ISO itself is neither directly involved in nor requires third-party certification.

In order to demonstrate its own competence to carry out the third party certification process, the certification body may choose to be accredited by an accreditation body; this accreditation will be based primarily on the requirements defined in ISO/IEC 17021 [2]. ISO/IEC 17021 is based on six core principles: impartiality, competence, responsibility, openness, confidentiality and responsiveness to complaints, and only those certification bodies that meet all the accreditation requirements are authorized to issue accredited certificates. Accreditation bodies may also choose to become signatories of the IAF's Multi-lateral Recognition Arrangement (MLA) for quality management systems, subject to a peer evaluation process based on the requirements of ISO/IEC 17011 [10]. In both cases (accreditation of certification bodies and peer reviews of accreditation bodies), the requirements of ISO/IEC 17021 and ISO/IEC 17011 are supplemented by IAF mandatory and guidance documents. One of the criteria for acceptance as an IAF MLA signatory is that the accreditation body must formally recognize accreditation granted by other MLA signatories as being equivalent to its own accreditation. In the context of trade capacity-building in the Asian developing countries, this multilateral recognition of certificates issued by accredited certification bodies is of vital importance in providing certified organizations with access to world markets without the need for multiple accreditations.

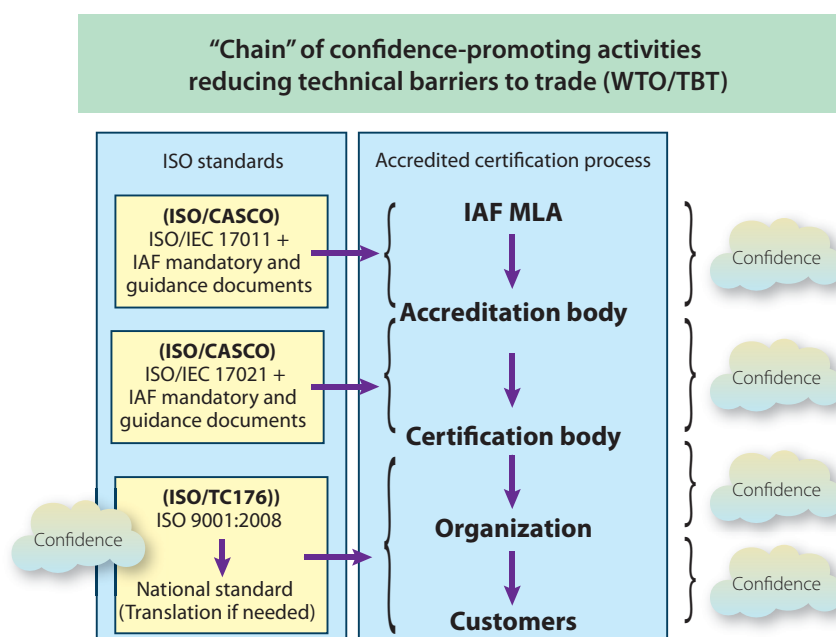
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*Membership of IAF is open to accreditation bodies and other stakeholders such as associations of certification bodies and industry groups. There are currently 56 countries with accreditation body members of the IAF (Source: IAF website [www.iaf.nu](http://www.iaf.nu))*

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The various interactions in the “conformity assessment supply chain” are shown in figure 1. The aim is to promote free trade by providing confidence throughout this supply chain so that customers (and, ultimately, consumers) can have a reasonable expectation of receiving conforming products from suppliers (the certified organizations) wherever in the world these are located. The ultimate objective is to achieve the goal of “Once certified, accepted everywhere”.

**Figure 1. Interactions within the “conformity assessment supply chain” aimed at providing confidence in ISO 9001 certification**



A certificate of conformity to ISO 9001 is not a “life-time award” but must be renewed at regular intervals by the certification body, typically every three years, with a periodic surveillance mechanism in between to monitor the on-going conformity and effectiveness of the system.

It is also important to recognize that ISO 9001 is not a “business excellence model”; its aims are quite basic — to give confidence in the organization’s ability to consistently provide conforming products to its customers. The way in which the organization manages its business in order to achieve this objective depends very much on its nature (size, type and economic sector, among others), and ISO 9001 provides some flexibility in how to meet its requirements. It is, however, important never to lose sight of this primary objective; irrespective of how many documented procedures and work instructions the organization has developed, how many hours of training it conducts, how many pieces of measuring equipment it calibrates, if the result does not provide confidence in the consistency of the product the organization provides, then the system is not effective. It is, of course, unrealistic to expect that any system will always be 100% effective, and for this reason ISO 9001 includes a requirement for organizations to “continually improve the effectiveness of their quality management system”.

In an effort to shift the (incorrect) focus of some organizations, consultants, auditors and others from concentrating only on the documentation and administrative requirements of ISO 9001, recent strategic initiatives by ISO and the IAF have placed a much greater emphasis on ensuring the effectiveness of the quality management system. A recent ISO/IAF joint communiqué, “Expected outcomes from accredited certification to ISO 9001” [11], was aimed primarily at emphasizing this point to accredited certification bodies and their auditors, and the mantra “Output matters!” is now part of the everyday lexicon of those involved in the conformity assessment of management systems.

The latest ISO statistics from December 2009 [3] show that there are now over a million organizations worldwide that are certified to ISO 9001. The majority of these have dedicated significant efforts and resources (often aided by the sensible use of competent consultants) to implementing robust systems capable of producing the desired outputs — “consistent, conforming products”. These systems, in turn, have been audited and certified by ethical, impartial certification bodies using competent teams of professional auditors. Croft and Dougherty [12] call all those involved in this process the “good guys”. They have done a good job and brought credit to the name of “ISO 9000”.

Unfortunately, in the late 1990s, disturbing trends began to emerge of less scrupulous players (“the bad guys” [12]) appearing on the scene (probably driven by the commercial factors surrounding the whole “business” of certification) and threatening to undermine the credibility of the ISO 9001 certification process as a whole. There is much anecdotal evidence that these “bad guys” are operating in Asian developing countries, but the extent of their activities has thus far not been clear, nor has their impact on the overall credibility and effectiveness of the certification process.

## 2. CONTEXT OF THE PROJECT

There are considerable differences in the level of maturity of ISO 9001 implementation and the associated conformity assessment infrastructure between the various countries in the Asian region that were included in this project. This can be seen to some extent in table 1, where it can be noted that the countries included in the study range from India (with almost 40,000 accredited certificates and a long history of standardization and conformity assessment) to countries, such as Bhutan, the Maldives and Nepal, where there are currently only a handful of accredited certificates and no formally constituted accreditation body.

**Table 1. Details of the standards and accreditation bodies in each of the participating countries, and the number of accredited certificates in each (according to the official 2009 ISO Survey[3]): countries involved in the project**

Country	Standards body	Accreditation body	Certs
Bangladesh	BSTI	BAB	852
Bhutan	SQCA	–	7
India	BIS	NABCB	37 493
Indonesia	BSN	KAN	5 476
Malaysia	Standards Malaysia	Standards Malaysia	6 463
Maldives	MSMU/MED	–	5
Nepal	NBSM	–	55
Pakistan	PSQCA	PNAC	2 112
Philippines	BPS	PAO	1 992
Sri Lanka	SLSI	SLAB	678
Thailand	TISI	NAC	6 097
Viet Nam	STAMEQ	BOA	7 333

*Note:* Numbers relate to the TOTAL number of certificates in December 2009, including those issued under overseas accreditations. (Data from ISO Survey)

**Table 2. Evolution of the number of accredited ISO 9001 certificates for the participating countries, according to the official 2009 ISO Survey[3]**

Country	Dec 2002	Dec 2003	Dec 2004	Dec 2005	Dec 2006	Dec 2007	Dec 2008	Dec 2009
Bangladesh	6	49	182	570	570	284	845	852
Bhutan	–	–	–	3	6	10	4	7
India	2 247	8 367	12 558	24 660	40 967	46 091	37 958	37 493
Indonesia	308	1 318	3 134	4 068	4 783	4 532	5 713	5 476

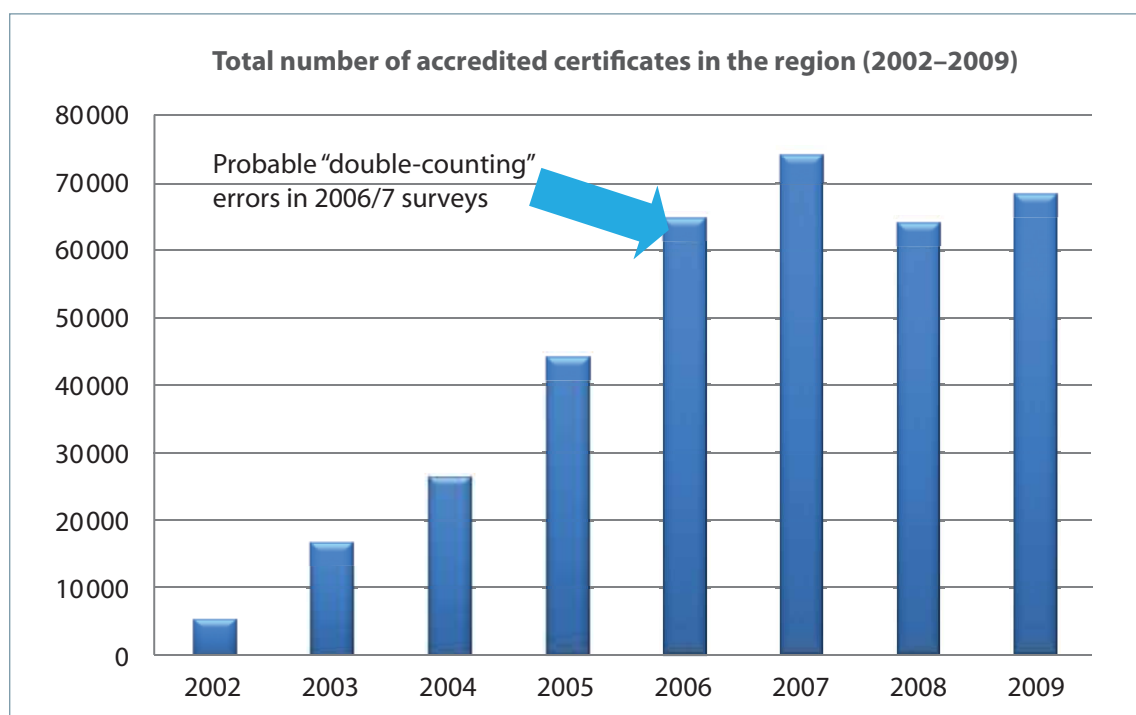
*continued*

Country	Dec 2002	Dec 2003	Dec 2004	Dec 2005	Dec 2006	Dec 2007	Dec 2008	Dec 2009
Malaysia	1 119	3 076	4 337	5 695	6 786	7 838	6 267	6 463
Maldives	-	1	1	1	1	2	4	5
Nepal	4	6	25	83	115	77	65	55
Pakistan	186	464	695	2 013	2 291	2 580	2 268	2 112
Philippines	270	456	1 108	1 414	2 007	2 199	2 412	1 992
Sri Lanka	34	90	148	244	318	496	549	678
Thailand	938	1 675	2 620	3 231	3 913	5 915	5 275	6 097
Viet Nam	354	1 237	1 598	2 461	3 167	4 282	3 071	7 333
<b>Total</b>	<b>5 466</b>	<b>16 739</b>	<b>26 406</b>	<b>44 443</b>	<b>64 924</b>	<b>74 306</b>	<b>64 431</b>	<b>68 563</b>

Note: A more detailed analysis of the latest trends in management systems certification and the latest versions of the ISO Survey of Certifications can be downloaded free of charge from [www.iso.org](http://www.iso.org)

Figure 2 shows the overall growth in accredited certification in the region from 2002 to 2009. It should be noted that the decrease in the number of certifications in some countries from December 2007 to December 2008 has been attributed by ISO to improvements in the data reporting and counting methodology used in their 2008 survey and onwards. This corrected previous over-estimates due to the double-counting of some certificates in earlier surveys (when the same certified organization was reported by two or more separate entities, for example by both the head office and branch office of the certification body, or by two accreditation bodies where the certification body had multiple accreditations).

**Figure 2. Data from the ISO Survey showing the overall increase in accredited certification in the countries involved in the project from 2002 to 2009**



The above statistics do illustrate, however, the more than tenfold increase in the number of accredited certificates between 2002 and 2009 in the region, which is evidence that SAARC and South East Asian countries look at the ISO 9001 standard as an important instrument for enhancing their trade and business.

It should also be noted that there are still apparent discrepancies in the number of certificates reported in the ISO Survey. In Nepal, for example, feedback during the local workshops at the end of the project suggests that the total number of accredited certificates in that country may be considerably more than the 55 reported in the ISO Survey for 2009. It has been suggested that, because many accredited certificates in Nepal are issued by Indian certification bodies (there are currently no active certification or accreditation bodies in Nepal), these may have been wrongly reported as Indian certificates.

### 3. PROJECT METHODOLOGY

#### Overall project planning (March–October, 2009)

Meetings were held at the international level with interested parties from UNIDO, ISO and the IAF to discuss and agree the overall project methodology, and, at the local level, a series of meetings and workshops was held in nine of the twelve countries involved in the project. The latter included discussions with senior management of the national standards bodies and accreditation bodies, interviews of potential local consultants for the project, and a half-day workshop with interested parties to explain the background and objectives of the project. These parties included:

- Standards body and accreditation body personnel
- Local UNIDO representatives
- Certification bodies
- Purchasing organizations
- Organizations certified to ISO 9001
- Consultants
- Industry and consumer organizations
- Chambers of trade and/or commerce
- Government (ministries of industry, science and technology, commerce, etc.)

Typical economic sectors that were covered in the project included:

Automotive	Machinery & equipment manufacture
Chemicals (including paint)	Oil and gas
Civil engineering	Packaging
Concrete and cement	Pharmaceuticals
Construction	Plastics
Defence	Public utilities (including power)
Electrical/Electronics	Railways
Food and beverages	Rubber
Garment and textile manufacture	Shipbuilding/ship-breaking
Health care	Steel and non-ferrous metals
Local/regional/national governments	Telecommunications

In terms of the national infrastructures for standardization, certification and accreditation, the involvement of national standards bodies fell into two main categories:



- Involvement in the establishment of an associated management systems certification body (with the appropriate “firewall” separation between the standardization and the certification activities). This is the traditional model adopted by many of the Asian developing economies and is usually based on pre-existing product certification activities.
- Involvement with (or close structural ties to) the local accreditation body.

Based on (subjective) observations during the planning and execution of this project, it became apparent that in several countries where there was a management system certification body associated with the national standards body, this had generated some friction between the national standards body and the local accreditation body. In order to enhance public confidence and the effectiveness of accredited management system certification, it is vital that those involved work together proactively in order to overcome such differences. ISO and the IAF should encourage close collaboration, mutual support and feedback mechanisms between national standards bodies and accreditation bodies in the same way that ISO and the IAF collaborate internationally through the IAF/ILAC/ISO Joint Working Group and the ISO 9000 Advisory Group.

## Survey of institutional purchasers (October 2009–March 2010)

The objective of this part of the project was to assess the level of awareness and use of accredited certification to ISO 9001 as a supplier selection and evaluation tool, and the satisfaction of major purchasers with the performance of their ISO 9001-certified suppliers.

The questionnaires used in this survey were developed by a consensus-building process that included experts from ISO and the IAF. Useful inputs were provided by Inmetro (Brazil), who had carried out a survey of Brazilian purchasing organizations’ perceptions of their ISO 9001-certified suppliers in 2006 [13].

Questionnaires were initially validated by asking a number of large institutional purchasers in other economies to complete a questionnaire and provide feedback, which was then incorporated prior to meeting with selected representatives of purchasers in the Asian developing countries for final validation.

The questionnaires were sent out to selected institutional purchasing organizations in each of the ten participating countries (Bhutan and the Maldives were not included in this part of the project) after initial contacts had been made between the UNIDO local consultants and the purchasing organizations. The consultants were requested to consult only “major purchasers” (in terms of purchasing power) in their country, regardless of those purchasers’ knowledge of ISO 9001.

## Interviews with selected purchasers (January–March 2010)

The objective of this part of the project was to obtain a control sample of certified organizations whose performance (as perceived by their customers, the purchasing organizations) was known.

Based on the results of responses to the questionnaires, purchasers were identified who had demonstrated their understanding of accredited certification and had implemented sound purchasing and supplier evaluation/feedback processes. A small sample of these “knowledgeable” purchasers was invited to participate in face-to-face interviews with the project consultants. These interviews, conducted at the purchasing organizations’ premises, included detailed discussions and a review of their supplier performance data. More detailed information about the performance of ISO 9001-certified suppliers was obtained, along with information about the “best” and “worst” performing suppliers (as perceived by the purchasers).

## Planning of visits to certified organizations (January–April 2010)

The intention in the initial project plan was to make a random sample of ISO 9001-certified organizations in the manufacturing and construction sectors in each participating country, using a sample size equal to the square root of the number of certified organizations in that country. In general, this number was achieved, as shown in table 3, which is based on the ISO Survey data for December 2008 [14] (the latest information that was available at the time the visits were being planned).

**Table 3. Planned and actual sample sizes for one-day “market surveillance” visits to certified organizations**

Country	No. of certificates (December 2008)	Planned sample (based on $\sqrt{\text{number of certificates}}$ )	Actual sample size
Bangladesh	845	29	30
Bhutan	4	2	4
India	37 958	195	204
Indonesia	5 713	76	77
Malaysia	6 267	79	77
Maldives	4	2	2
Nepal	65	8	10
Pakistan	2 268	48	25
Philippines	2 412	49	19
Sri Lanka	549	23	25
Thailand	5 275	73	38
Viet Nam	3 971	63	50
<b>Grand Total</b>		<b>647</b>	<b>561</b>

The selection criteria for the consultants to be hired by UNIDO for this part of the project were defined. A key challenge was to identify people with sufficient in-depth knowledge and experience in auditing ISO 9001-based quality management systems but at the same time having no conflicts of interest by performing work for or on behalf of any certification body.

A total of 28 consultants were contracted, and all participated in one of three intensive 5-day training courses that included a one-day “calibration” visit to a certified organization (to ensure consistency between the various consultants) and an examination.

Requests were sent out to all IAF accreditation body members asking for details of their accredited certification bodies that issued certificates in the participating countries. (*Note: as will be seen later, not all accreditation bodies provided this information.*)

The accredited certification bodies were then contacted to request details of the name, scope and geographical location of each of their ISO 9001-certified clients (in accordance with ISO/IEC 17021:2006 Clause 8.3), with the objective of compiling a full list of certified organizations in each country and then selecting a random sample of those organizations in the manufacturing/construction sectors. (*Note: again, as will be seen later, a significant number of certification bodies did not provide this information.*)

## Survey of certified organizations (February–June 2010)

An extensive web-based survey targeting ISO 9001-certified organizations was conducted in all 12 participating countries. This was based on a questionnaire that had been developed by a consensus process with ISO/TC 176, ISO/CASCO and the IAF, and validated by individual experts from those organizations.

## One-day visits to certified organizations (April–July 2010)

The methodology for the one-day visits to certified organizations was developed by a process of consultation and consensus, mainly within the IAF Technical Committee Task Force on “Accreditation Market Surveillance”, during meetings in Vancouver, Canada (Oct 2009) and Rio de Janeiro, Brazil (March 2010). There has been a close interaction with this group throughout the project, and the results will be important to the Task Force in developing future guidance for the possible implementation of similar methodologies within the IAF.

The following were key concepts in the one-day visits:

- The visits were not intended to be “repeat audits” and were not focused on “conforming/nonconforming” outcomes.
- The results of the visits were strictly confidential and were reported neither to the organization’s certification body nor to the respective accreditation body. This was considered essential in order to obtain agreement from the certified organizations to receive the visits.
- The visits were aimed at determining confidence levels related to various aspects of the organization’s quality management system and the overall level of confidence in the certification process. The full check-list covered the following 26 topics:
  1. Initial certification body audit duration
  2. Surveillance audit duration and frequency

3. Scope statement on the organization's certificate
  4. Justification for any exclusions (ISO 9001:2008 Clause 1.2)
  5. Top management commitment
  6. Internal communication
  7. Understanding and implementation of the "process approach"
  8. Use of PDCA to manage processes (ISO 9001:2008 Clause 4.1)
  9. Quality policy
  10. Meaningful objectives
  11. Quality manual as a true reflection of the quality management system
  12. Appropriate use of quality management system documentation
  13. Resource management (including human resources)
  14. Work environment
  15. Management of product realization processes
  16. Process monitoring and measurement
  17. Treatment of product nonconformities
  18. Cause analysis for nonconformities and effective corrective action
  19. Internal audits
  20. Management review
  21. Prevention of nonconformities
  22. Customer feedback and complaints handling
  23. Overall confidence in the ability to produce "consistent, conforming products"
  24. Continual improvement of quality management system effectiveness
  25. Overall confidence in the certification body's processes
  26. Overall confidence in the organization's implementation of ISO 9001
- It was found that all the consultants were able to discriminate between scores of 1–5 within a scale of confidence levels defined for each of the parameters as follows:

<b>Grade 1</b>	"Little or no confidence"	No evidence at all to support the implementation of this topic.
<b>Grade 2</b>	"Some evidence presented, but not at all convincing"	Some evidence was presented, but in the professional judgment of the consultant (based on experience), there would probably be evidence to support a nonconformity in an audit situation.
<b>Grade 3</b>	"OK — No reason to doubt that this is being addressed correctly"	This was the "default" grade, where there was no evidence to suggest reasons for concern, based on the consultant's experience and professional judgment.
<b>Grade 4</b>	"Clear evidence that this is being done and meets the intent of ISO 9001"	Sufficient objective evidence was available to provide a good level of confidence that the organization is meeting the intent of ISO 9001.
<b>Grade 5</b>	"We can be proud to use this organization as a benchmark for this topic"	It was emphasized during the training that "Grade 5" was to be reserved for truly excellent performance, and not to be awarded lightly.

## Analysis of results (August–September 2010)

The results were analysed using standard, simple, statistical tools. For the majority of the results, the use of graphical techniques such as pie charts, bar charts and histograms was found to be a satisfactory and user-friendly way of presenting the data.

In cases where more detailed analysis was found to be necessary, this was carried out by the Institute of Applied Statistics and Quality Management of Lucknow University, India.

No attempt was made to “rank” the performance of each country. This was considered to be outside the scope of the current project and, in view of the many variables involved, not a viable proposition.

## International and local (country-specific) feedback workshops (October 2010–March 2011)

Workshops to present the project results and promote feedback from interested parties were carried out as follows:

### International workshops

These were held in Shanghai, China and Paris, France (with a simultaneous webcast) and were attended by a total of approximately 150 participants from standards bodies, certification bodies, accreditation bodies and other interested parties.

### Local (country-specific) workshops

These were held during January to March 2011 in each of the participating countries (except Bhutan and the Maldives), with a total of over 900 participants, including all major interested parties.

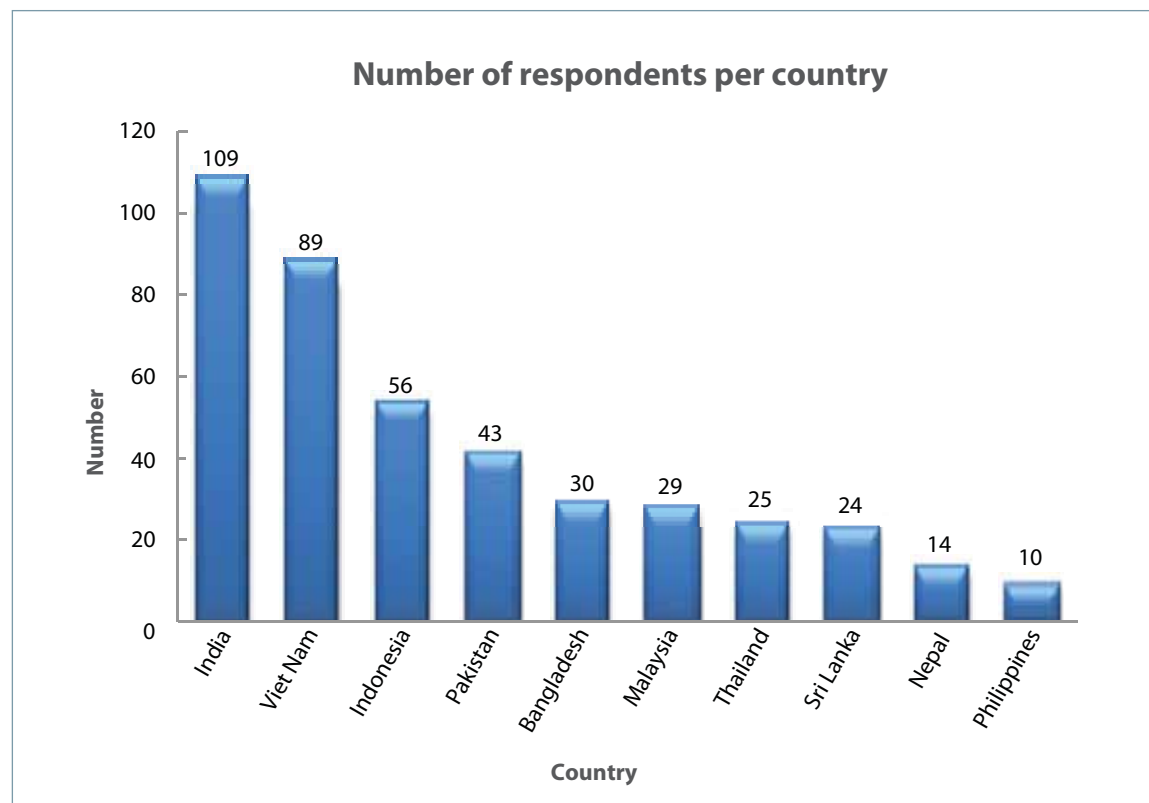
## 4. RESULTS OF THE SURVEY OF PURCHASERS' PERCEPTIONS OF ISO 9001-CERTIFIED SUPPLIERS

The questionnaire was replied to by 429 purchasing organizations in 10 countries (all the SAARC and SE Asian countries involved, with the exception of Bhutan and the Maldives, who participated only in the second part of the project). This represented a response rate of approximately 17% of the 2,513 purchasing organizations contacted.

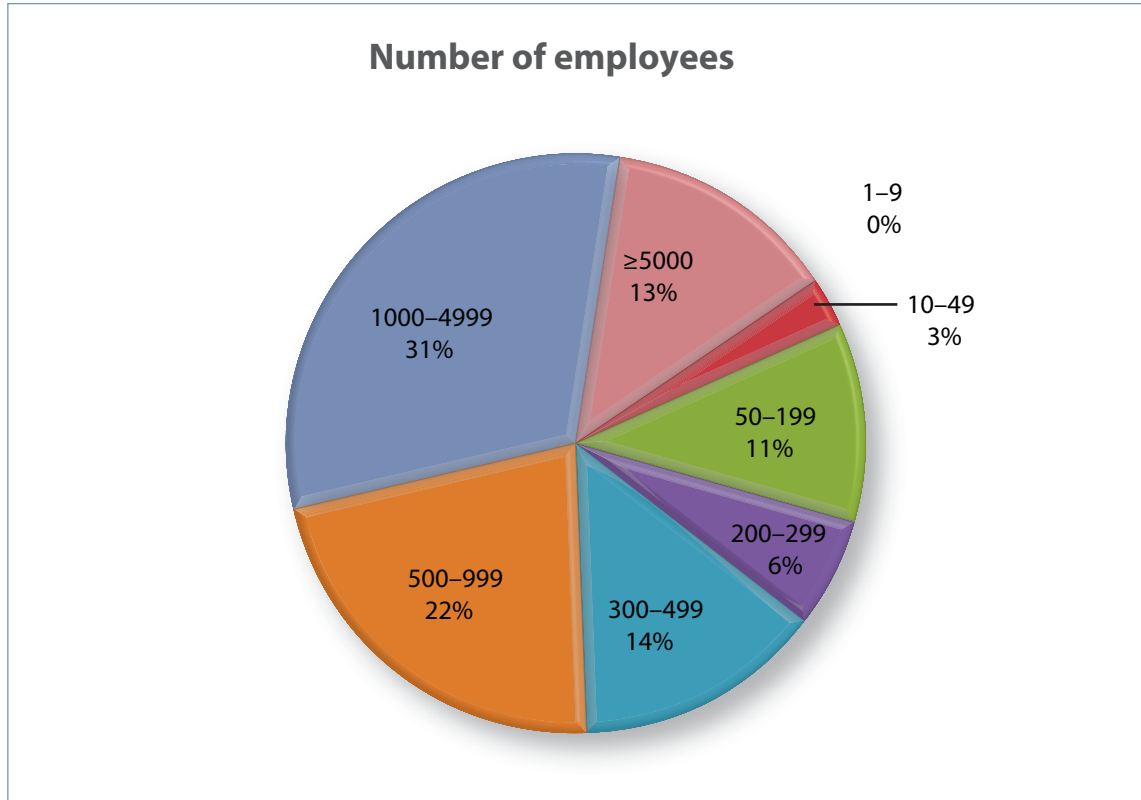
### Demographics of respondents

Demographic details of the respondents are given in figures 3 to 6.

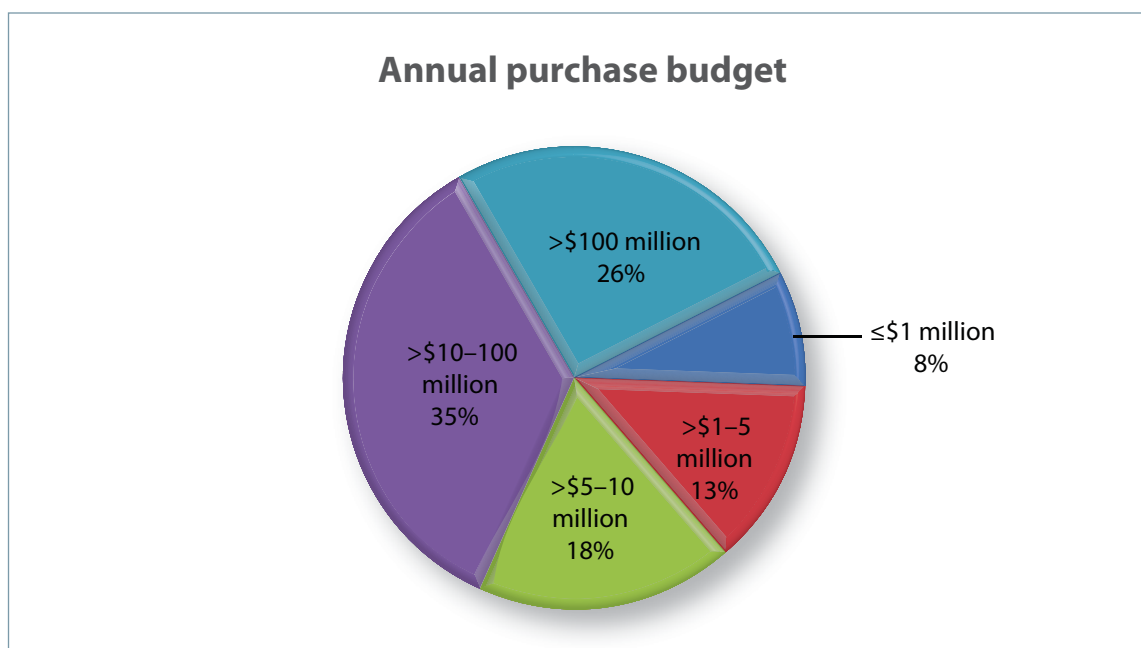
**Figure 3. Geographical distribution of the 429 purchasing organizations participating in the survey**



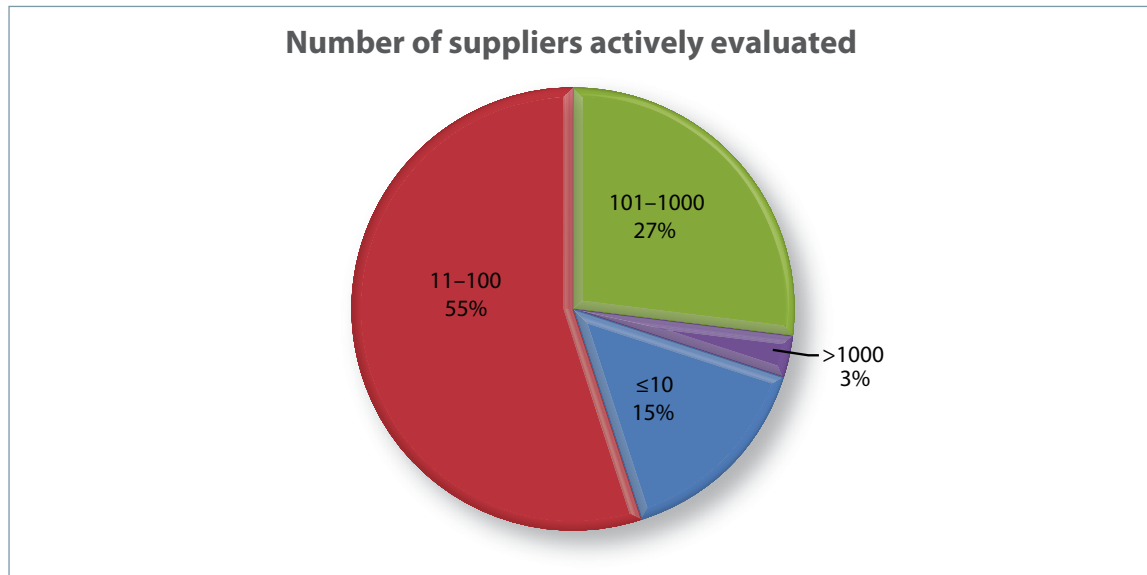
**Figure 4.** Size distribution of the 429 purchasing organizations who participated (by number of employees)



**Figure 5.** Size distribution of the 429 purchasing organizations who participated (by annual purchasing budget in US dollars)



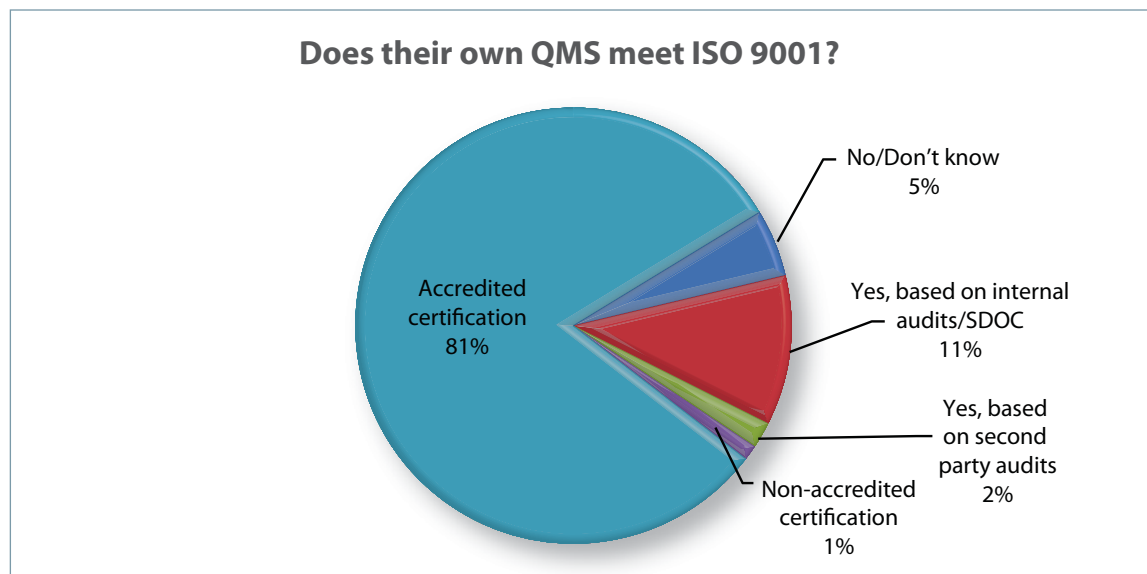
**Figure 6. Number of suppliers actively evaluated by each of the 429 purchasing organizations surveyed**



## Quality management systems of purchasing organizations

Figure 7 shows that 95% of the 429 respondents to the survey claimed that their organization had a quality management system that included the purchasing process and met the requirements of ISO 9001. Some 81% claimed to have an accredited certificate. This is interesting in light of the relatively low levels of awareness about certification and accreditation demonstrated by these purchasers (see later), but it does highlight the fact that many major organizations in the Asian developing countries (such as these purchasers) had already implemented ISO 9001.

**Figure 7. Responses from the 429 purchasing organizations about their own level of conformity to ISO 9001**

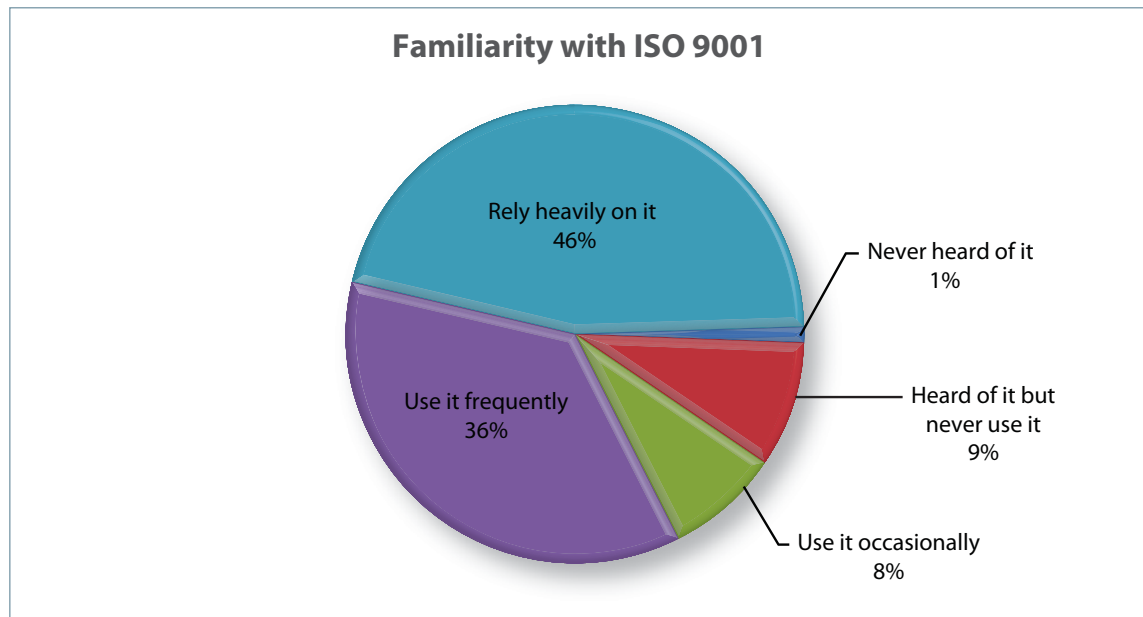




## Purchasers' familiarity with ISO 9001

The vast majority of purchasers who responded to the survey (82%) said they either “rely heavily” on ISO 9001 or “use it frequently” (see figure 8). Some 9% had heard of it but didn’t use it, whilst 1% (representing only 4 major purchasers in the region) claimed never to have heard of ISO 9001.

**Figure 8. Responses from the 429 purchasing organizations to the question “Are you familiar with the ISO 9001 quality management system standard?”**



## Use of ISO 9001 as a supplier evaluation tool

Of the purchasers who took part in the survey 79% claimed they used ISO 9001 as a component of their supplier evaluation process.

## Purchasers' awareness of roles of ISO, accreditation bodies and the IAF

Despite the large percentage of purchasing organizations that claimed to use ISO 9001 as a basis for supplier evaluations, their awareness of accreditation and the roles of ISO and the IAF was very poor.

Only 38% of the respondents were aware of the fact that ISO's role in ISO 9001 certification is limited to that of standard-writer. Some 9% believed that ISO actually certifies organizations who meet the requirements of the standard, whilst the majority (53%) believed that ISO is responsible for accrediting certification bodies to carry out certification.

Overall, awareness among the purchasing organizations about the role and importance of accreditation was very disappointing. Only 32% overall could name their local accreditation body (after excluding from the analysis those countries where there is no accreditation body). This compares with 37% who were able to name any foreign accreditation body.

Some regional variations were apparent, however (See table 4), with recognition of the local accreditation bodies being greatest in the following countries:

- Indonesia (KAN — 70%)
- Thailand (NAC (now NSC) — 64%)
- Pakistan (PNAC — 53%)

With the exception of Indonesia, the Philippines and Thailand, a higher percentage of purchasers in all the other countries were able to name a foreign accreditation body than could name the local accreditation body.

**Table 4. Level of name recognition of local and foreign accreditation bodies by purchasing organizations in the participating countries**

Country <sup>a</sup>	Local AB	Percentage of purchasers who could correctly name the local AB	Percentage of purchasers who could correctly name any foreign AB
Bangladesh	BAB	23	37
India	NABCB	26	40
Indonesia	KAN	70	64
Malaysia	Standards Malaysia	29	45
Pakistan	PNAC	53	62
Philippines	PAO	40	20
Sri Lanka	SLAB	10	21
Thailand	NAC (now NSC)	64	24
Viet Nam	BoA	6	16

<sup>a</sup> Excludes Bhutan, Maldives and Nepal, where there is no local accreditation body.

Perhaps of even greater concern is the low level of awareness about the IAF among major purchasers. Only 34% of the respondents claimed to know about the IAF and what it does; 31% had heard of the IAF but didn't know what it does; and 35% had never heard of it.

This is particularly relevant if the IAF is to promote the use of its MLA mark in order to provide confidence in accredited certification around the world. Although no developed economies were included in this project, informal feedback obtained during the international workshops would indicate that the levels of awareness are not much greater in those countries than in the Asian developing economies.

Overall, this lack of awareness of major institutional purchasers about accreditation is of great concern in the Asian developing countries for two reasons:

- For exporters, it is vital that overseas customers are able to derive confidence from ISO 9001 certificates provided by suppliers in the Asian developing countries. It is unlikely (and unrealistic to expect) that these customers will know and recognize each of the developing countries' accreditation body name or logo when it appears on a certificate, so the use of a single, recognizable IAF MLA mark is key for trade capacity-building.
- For importers in the developing countries, it is important to be able to recognize what is and what is not a valid accredited certificate when presented by a potential supplier. Whilst an importer might recognize the accreditation mark of its local accreditation body, it is unrealistic to expect them to be able to verify the authenticity of accreditation marks from all the other countries in which their overseas suppliers may have achieved accredited certification. This leaves space for less scrupulous players (often via local agents) to present falsified certificates when bidding for purchase contracts. This practice was evidenced during the initial visits to the Asian developing countries and is very difficult for the "intelligent layman" purchaser to identify.

## Purchasers' awareness of conformity assessment methodologies

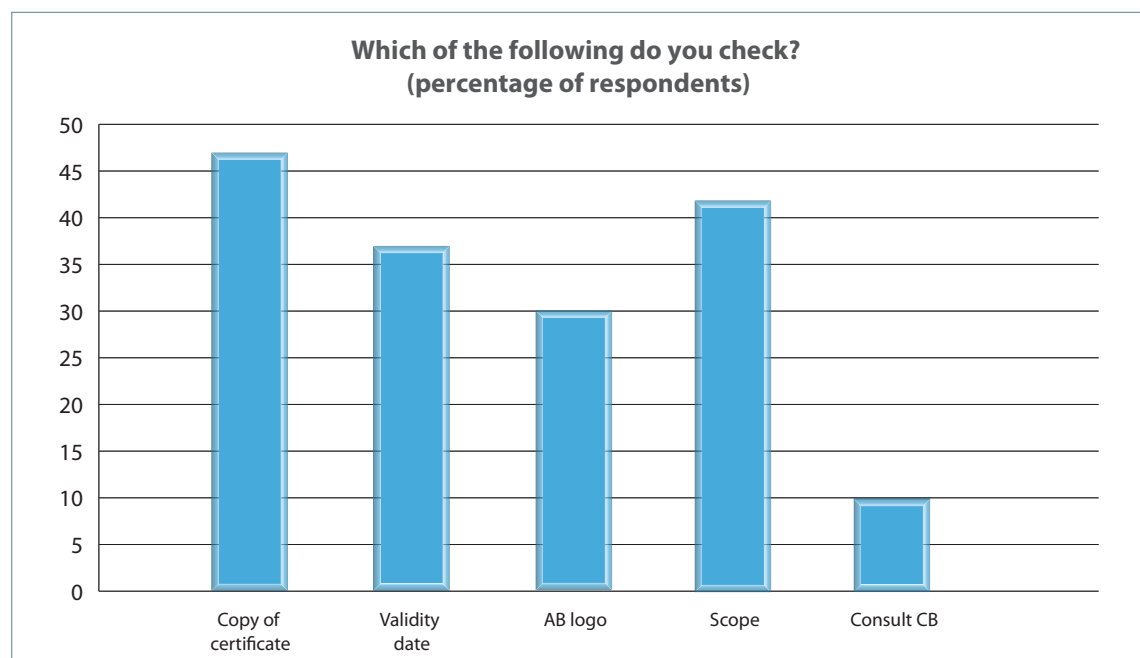
Conformity to ISO standards such as ISO 9001 may be demonstrated by first, second or third-party attestations, [15, 16] and not all certification bodies (who make third-party attestations of conformity) choose to demonstrate their competence by seeking accreditation. Interestingly, whilst a significant majority of the respondents knew about and used the concepts of self-declarations of conformity, second-party auditing, and accredited certification, only 23% knew about and had experience with unaccredited certification. This further supports the need for a significant awareness-building campaign by accreditation bodies and the IAF in order to promote the added levels of confidence that accreditation can provide.

## Purchasers' verification of suppliers' ISO 9001 certificates

Given the high dependence that the purchasers place on ISO 9001 as a basis for supplier evaluation, it is surprising how little they check the evidence of this. Figure 9 shows that:

- Only 47% ask for a copy of their suppliers' certificates when supplier selection has been based on ISO 9001.
- Only about 37% check the validity date on certificates presented by their suppliers.
- Only 30% look for the accreditation body logo (and, based on the low awareness about accreditation in general, are probably not sure what they are looking for anyway).
- Only 42% check that the scope of certification is appropriate for the products they are purchasing.
- Less than 10% have ever contacted their supplier's certification body to check the validity of the certificate presented.

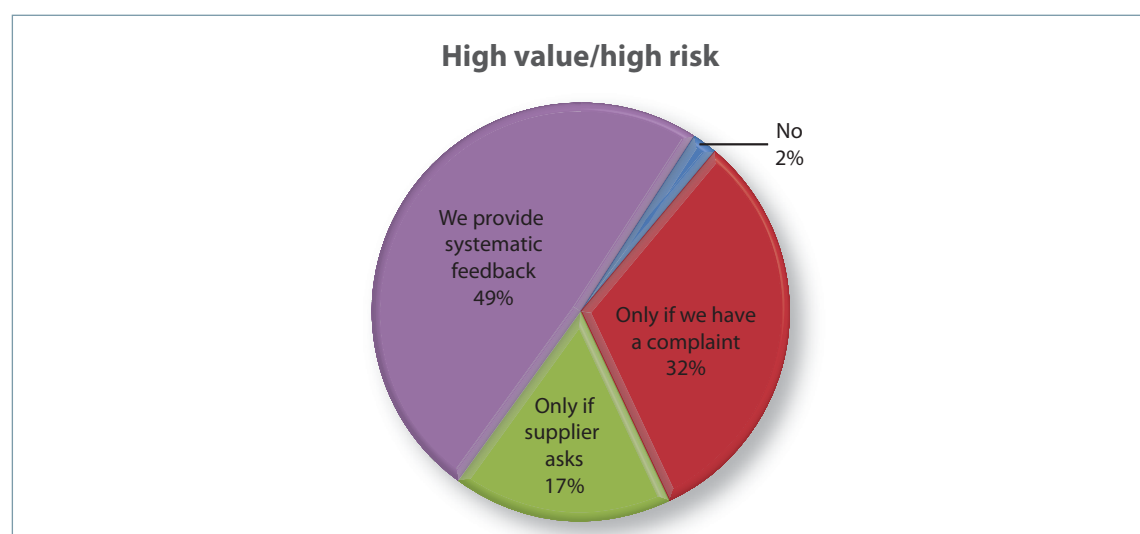
**Figure 9. Percentage of the 429 purchasing organizations who verify the validity and relevance of their suppliers' certificates**



## Supplier feedback

It can be seen from figures 10 and 11 that the percentage of purchasers who systematically provide feedback on supplier performance varies from 49% (for “high value” and/or “high risk” purchases) to 22% (for “low value” and/or “low risk” purchases). This is encouraging and should enable certification bodies to obtain valuable inputs into the audit process by requesting their certified clients to provide this information from customers, as required by ISO 9001:2008 Clause 8.2.1 (Customer satisfaction).

**Figure 10. Details of the 429 purchasers' levels of feedback to suppliers of “high value/high risk” products**



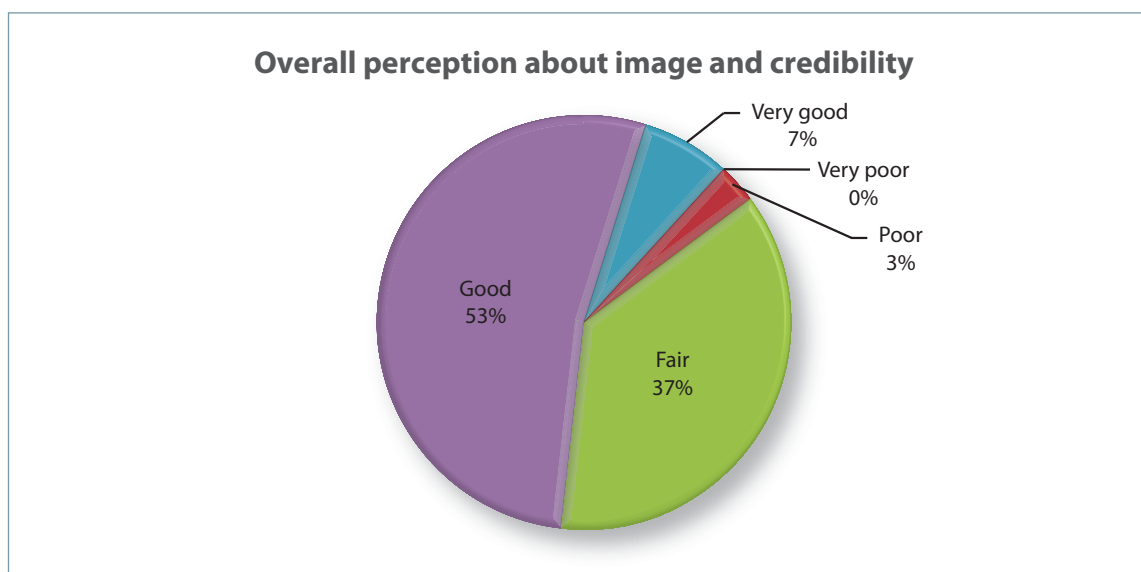
**Figure 11.** Details of the 429 purchasers' levels of feedback to suppliers of "low value/low risk" products



## Purchasers' confidence in and opinions of ISO 9001 certification bodies

Figure 12 shows that the overall perception by the 429 purchasing organizations of the image and credibility of accredited certification bodies was good (7%: "very good"; 53%: "good" and 37%: "fair"). Only 3% considered the credibility to be "poor" and only one of the purchasers surveyed (signifying 0.23% of the total) considered it to be "very poor".

**Figure 12.** Perceptions of 429 purchasers of the image and credibility of accredited certification bodies in the region



The purchasers were asked for their opinions of several aspects of their ISO 9001-certified suppliers' performance, and the results are shown in figure 13, presented in order of decreasing level of satisfaction.

They were also asked to compare the performance of their ISO 9001-certified suppliers with that of uncertified suppliers (or the same supplier prior to becoming certified) for the same set of criteria. These results are shown in figure 14.

In general, the levels of satisfaction in terms of a range of criteria are good, and certified suppliers perform significantly better than non-certified suppliers. Highlights that are of particular interest are:

- Satisfaction with the intrinsic quality of the products being supplied by the ISO 9001-certified organization was highest of all the criteria, with a 96% satisfaction level (85% of purchasers were "satisfied" and 11% "very satisfied"). When making the comparison with uncertified suppliers, it can also be seen that certified suppliers perform significantly better in comparison (13% of the suppliers surveyed considered certified suppliers to perform "much better" and 63% "better" than uncertified suppliers for this criterion). This is consistent with the results reported in a similar study carried out in Brazil in 2006 by Inmetro [13], where 70% of the purchasers of industrial products surveyed considered their certified suppliers' performance to be "better" than uncertified suppliers.
- There was a high level of satisfaction with the ease of communication during the purchasing process (94% of purchasers were either "satisfied" or "very satisfied") and with the accuracy of promotional and marketing information (93% of purchasers were either "satisfied" or "very satisfied").
- In terms of the suppliers' "ability to consistently provide conforming products" (the principal objective of ISO 9001 certification!), 13% of the purchasers were "very satisfied", and 79% were "satisfied", but it is important to note that as many as 8% were "dissatisfied". When making the comparison with uncertified suppliers, however, it can be seen that, despite this 8% level of dissatisfaction, the overall perception is that certified suppliers perform significantly better in comparison (12% of the suppliers surveyed considered certified suppliers to perform "much better" and 64% "better" than uncertified suppliers for this criterion).
- Two topics that should be of concern to certified organizations and to certification bodies are that the highest levels of dissatisfaction among purchasers relate to their suppliers' ability to meet delivery commitments (10% "dissatisfied" and 1% "very dissatisfied") and their responsiveness to customer complaints (13% "dissatisfied" and 1% "very dissatisfied"). In both cases, however, certified suppliers were found to perform significantly better than non-certified suppliers. In the context of customer complaints handling, it would seem appropriate for certified organizations to make more use of the guidance standard that specifically addresses this topic (ISO 10002:2004 "Quality management — Customer satisfaction — Guidelines for complaints handling in organizations" [6]). From the feedback workshops conducted at the conclusion of the project, however, it is clear that this standard is not well known, and special efforts should be made by both ISO and national standards bodies to promote greater awareness of it. It is also recommended that ISO and the IAF consider developing guidance for certification body auditors on how to effectively audit certified organizations' customer complaints handling processes; this could be done via the Auditing Practices Group.\*

*\*The ISO 9001 Auditing Practices Group (APG) is an informal group of quality management system (QMS) experts, auditors and practitioners drawn from the International Accreditation Forum (IAF) and the ISO Technical Committee 176 Quality Management and Quality Assurance (ISO/TC 176)[17].*

Figure 13. Levels of satisfaction of the 429 purchasers with certified suppliers for various criteria



Figure 14. Performance of certified suppliers compared to the performance of non-certified suppliers (or the same supplier prior to certification), in order of greatest to smallest improvement



## Purchasers' opinions of the ISO 9001 standard and certification

Figure 15 shows that the general level of satisfaction with the ISO 9001 standard is good. Some 18% of those 429 purchasers who participated in the survey considered it to be “excellent”, 57% said it was “good”, and 22% thought it “reasonably good”. Only 3% considered the standard to be “inadequate” and no respondents considered it to be “very poor”. It is worth noting that ISO is continually seeking feedback from users on how it can improve its standards, and the comments received during this project will be taken into consideration when developing future versions of ISO 9001.

**Figure 15. Opinions of the 429 purchasers about the ISO 9001 standard (without considering certification issues)**

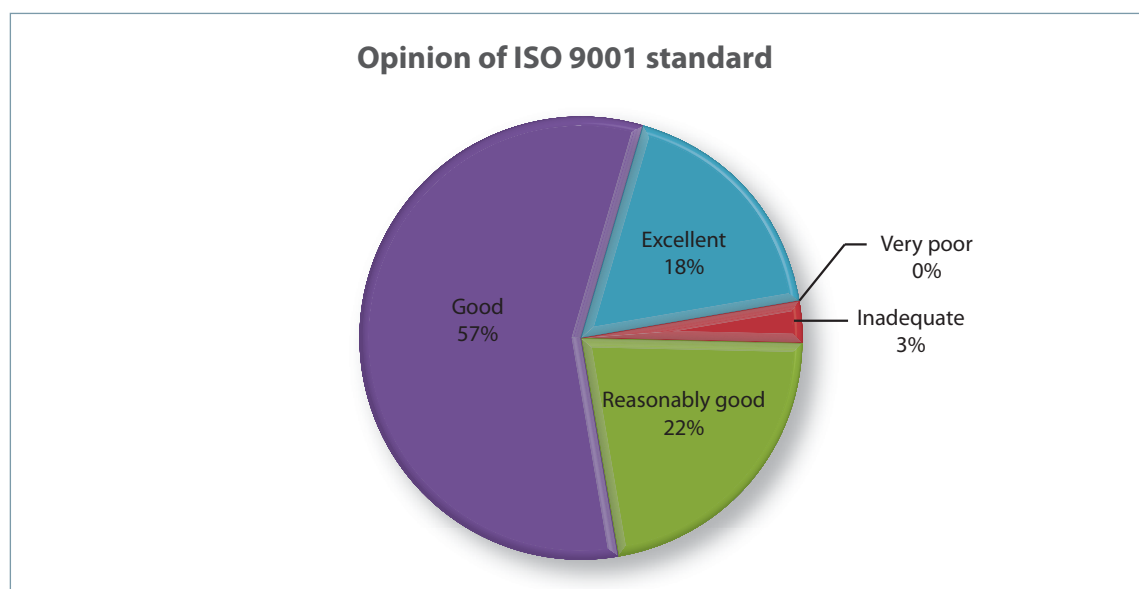


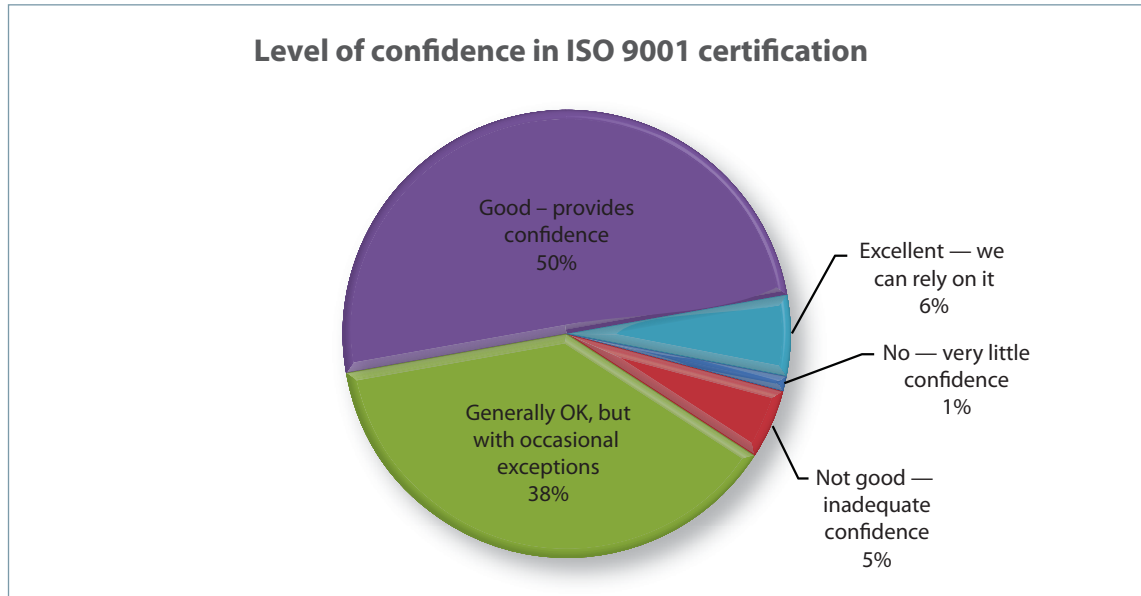
Figure 16 shows the responses obtained from the 429 purchasers about their confidence in the ability of accredited certification to demonstrate their suppliers' ability to “consistently provide products that meet customer requirements, as well as applicable statutory and regulatory requirements”. Confidence levels were generally good, but with some exceptions noted. Some 94% of the respondents were generally satisfied (6% considering their level of confidence to be “excellent”, 50% “good”, and 38% “generally OK, but with occasional exceptions”).

These are very encouraging results, but conversely, however, this means that 6% (or a total of 25 of the 429 purchasing organizations surveyed) said they had “inadequate” (5%) or “very little” (1%) confidence in accredited certification. There is still ample scope for improvement!

In terms of the performance of accredited certification bodies, figure 17 shows that over half of the purchasing organizations considered the certification bodies operating in their country to be either “equally good” or “good, but with some small variations”. Some 33% had no data on which to form an opinion. Conversely, however, this means that 12% considered there were “major variations” from one certification body to another, and 1% (4 purchasers) considered the certification bodies to be “equally bad” in terms of performance.



**Figure 16. Level of confidence in ISO 9001 certification (429 purchasers who responded to the survey)**



**Figure 17. Opinions of the 429 purchasers regarding any systematic differences observed in the performance of accredited certification bodies operating in their country**

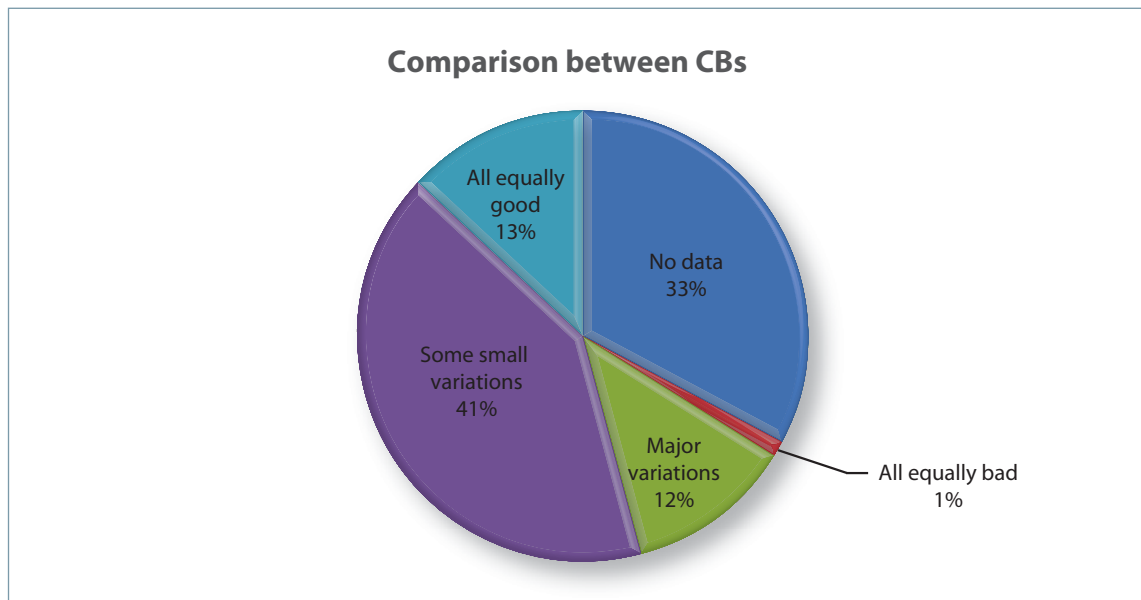


Figure 18 shows that the majority of purchasers surveyed (57%) do not carry out second-party evaluations of their ISO 9001-certified suppliers.

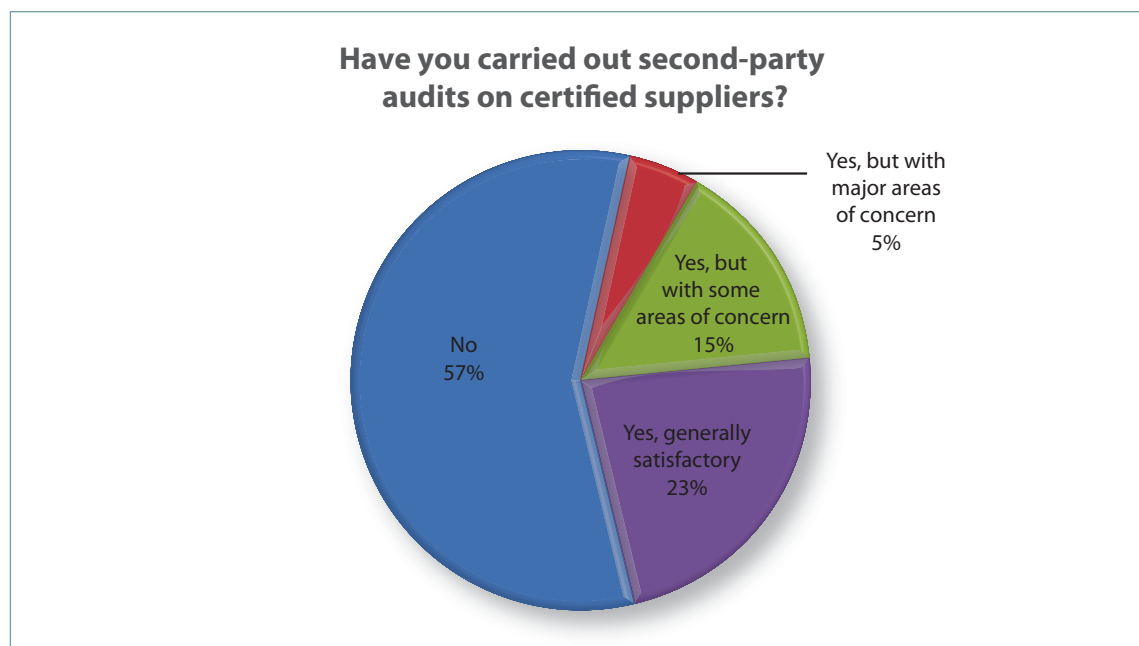
Of those who do carry out audits of their ISO 9001-certified suppliers:

- 53% (23% of the total number of purchasers surveyed) found generally satisfactory results.
- 35% (15% of the total number of purchasers surveyed) had carried out assessments with

“some areas of concern”, indicating that they had identified nonconformities in the quality management system.

- 5% (12% of the total number of purchasers surveyed) had found “major areas for concern”, indicating that they had doubts about the validity of the suppliers’ certification.

**Figure 18. Purchasers’ use of second-party supplier evaluation audits and the results when these are carried out on ISO 9001-certified suppliers**



In terms of complaining to the suppliers’ certification body, figure 19 shows that only 7% of the purchasing organizations consulted had ever done so (3% with satisfactory outcomes and 4% who were dissatisfied with the outcome) and a further 9% would have liked to, but didn’t know how to do so. Some 25% of the respondents didn’t know they could submit a complaint to the suppliers’ certification body, whilst 59% never felt the need.

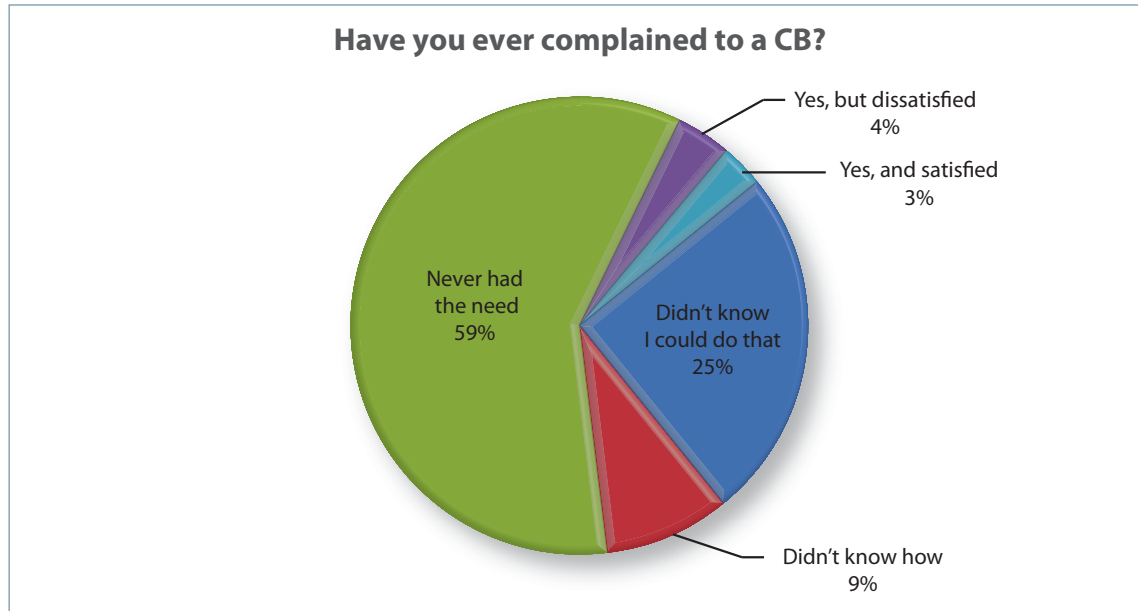
Similar results were found in relation to complaints to accreditation bodies (figure 20), either as a result of the escalation of complaints about suppliers or regarding the performance of a certification body.

During the feedback workshops, there was a general consensus among certification bodies that they would welcome such feedback from customers of their certified clients, since poorly-performing ISO 9001-certified organizations also reflect badly on the reputation of the certification body that issued the certificate. It is important, though, to emphasize that sporadic, minor complaints about nonconforming products should be dealt with between the purchaser and their supplier; only cases of repeated nonconforming products or indications that there are problems with the supplier’s quality management system should be brought to the attention of the certification body.

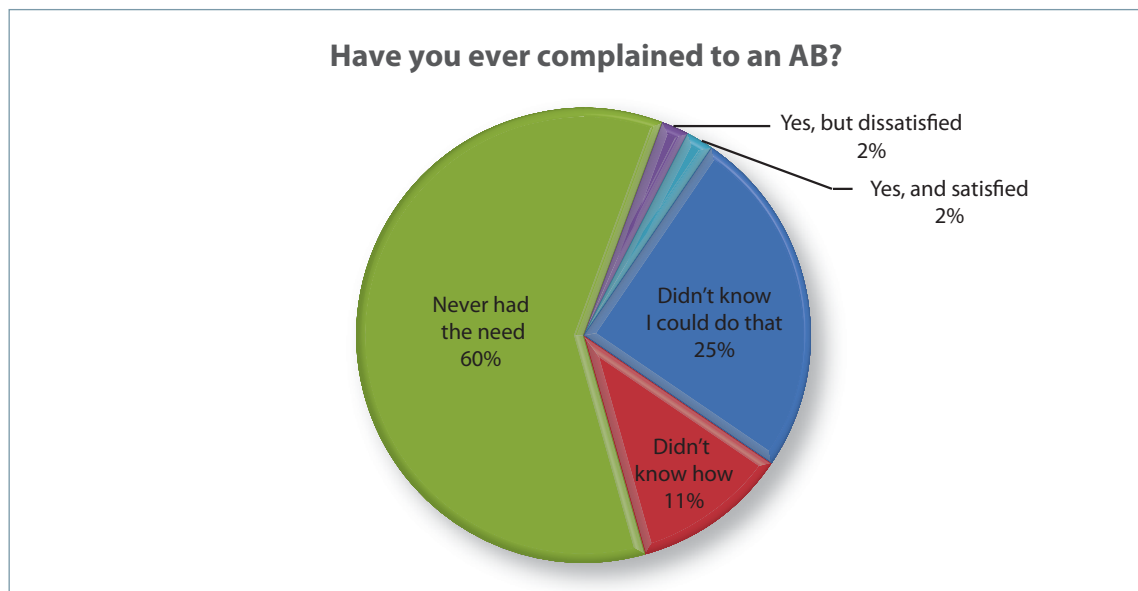
In view of the fact that a quarter of the purchasers surveyed were unaware that they could complain to their suppliers’ certification body, greater prominence needs to be given to the guidance for purchasers available on the ISO website (“ISO 9001 — What does it mean in the Supply Chain?”

[15,16]). This explains the concepts of quality management systems, how conformity to ISO 9001 may be demonstrated and the role of accredited certification, and gives guidance on how purchasers can provide feedback in cases of dissatisfaction with the performance of their suppliers.

**Figure 19. Percentage of the 429 purchasers complaining to a certification body**



**Figure 20. Percentage of purchasers complaining to an accreditation body about their suppliers or about their suppliers' certification body**

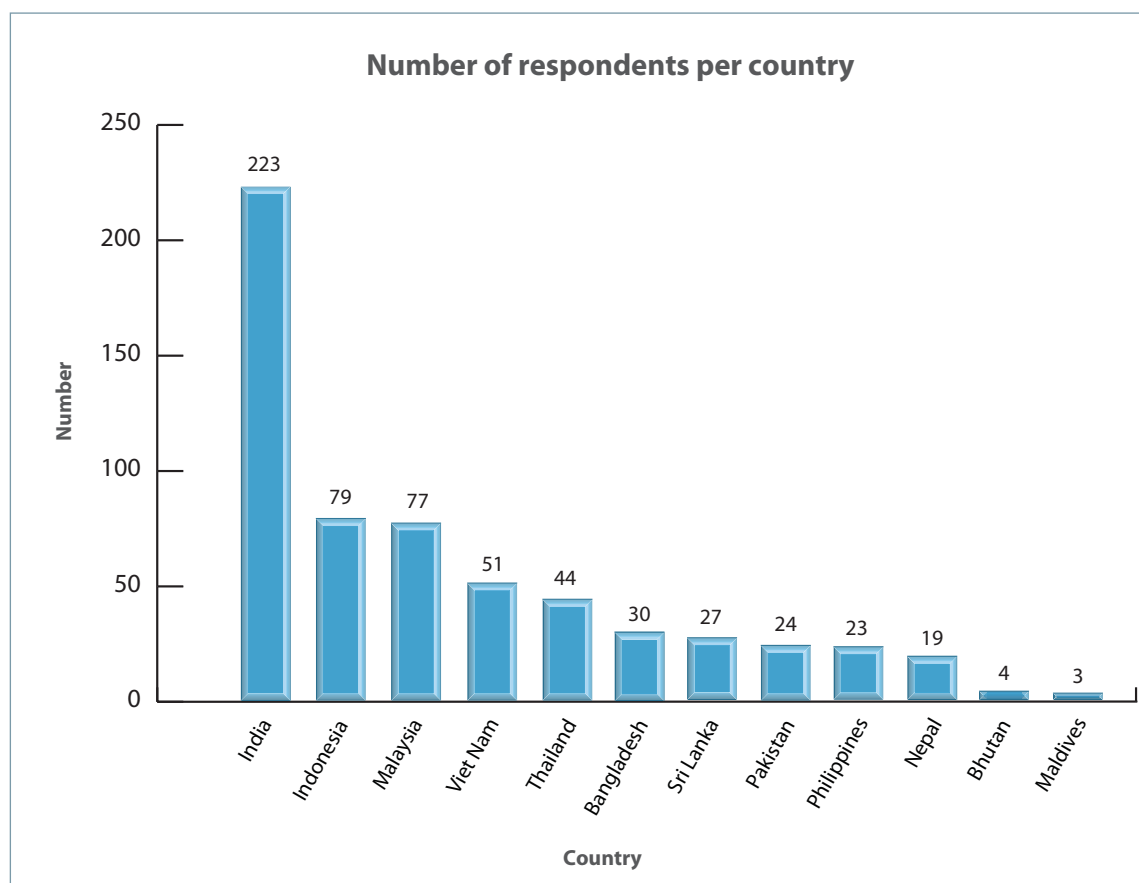


## 5. SURVEY OF CERTIFIED ORGANIZATIONS

This survey used a web-based questionnaire for all ISO 9001-certified organizations to fill out details of their motives for implementing a quality management system, their experiences during implementation, and their overall satisfaction with the results (including the certification process). In fact the spontaneous level of response to this on-line survey was very low, and the vast majority of the questionnaires were filled out by the respondents during visits by our teams of UNIDO-appointed consultants. Note that some questionnaires were filled out on-line by interested organizations, and these organizations were not necessarily included in the visit programme.

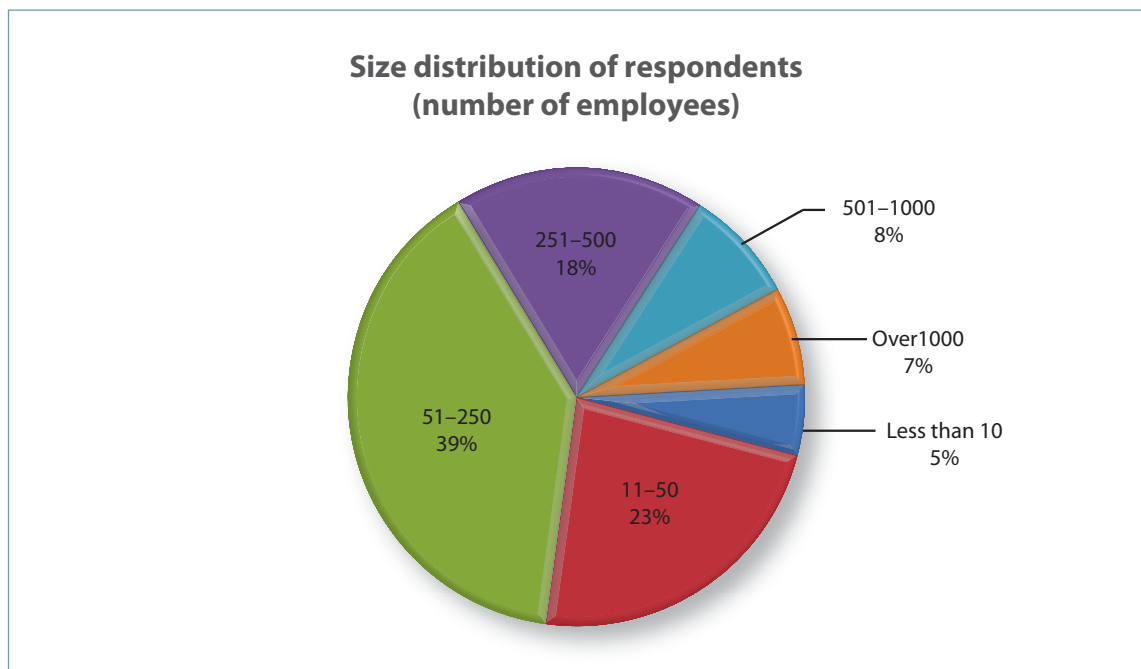
A total of 604 organizations completed the survey, distributed among the various countries as shown in figure 21.

**Figure 21. Geographical breakdown of the number of respondents to the questionnaire for certified organizations**



Respondents included a good sample of micro-, small, medium and large organizations, as shown in figure 22. Although definitions of micro-, small and medium enterprises vary in different economies, it is generally considered that organizations with less than 250 employees fall into this category. See, for example, the European Commission Recommendation 2003/361/EC [18]. This means that 67% of the organizations who responded to the survey fall into the category of “SME”, based on their number of employees.

**Figure 22. Size distribution of respondents (number of employees)**



There was also a good spread in the periods of time that organizations had been certified to ISO 9001:

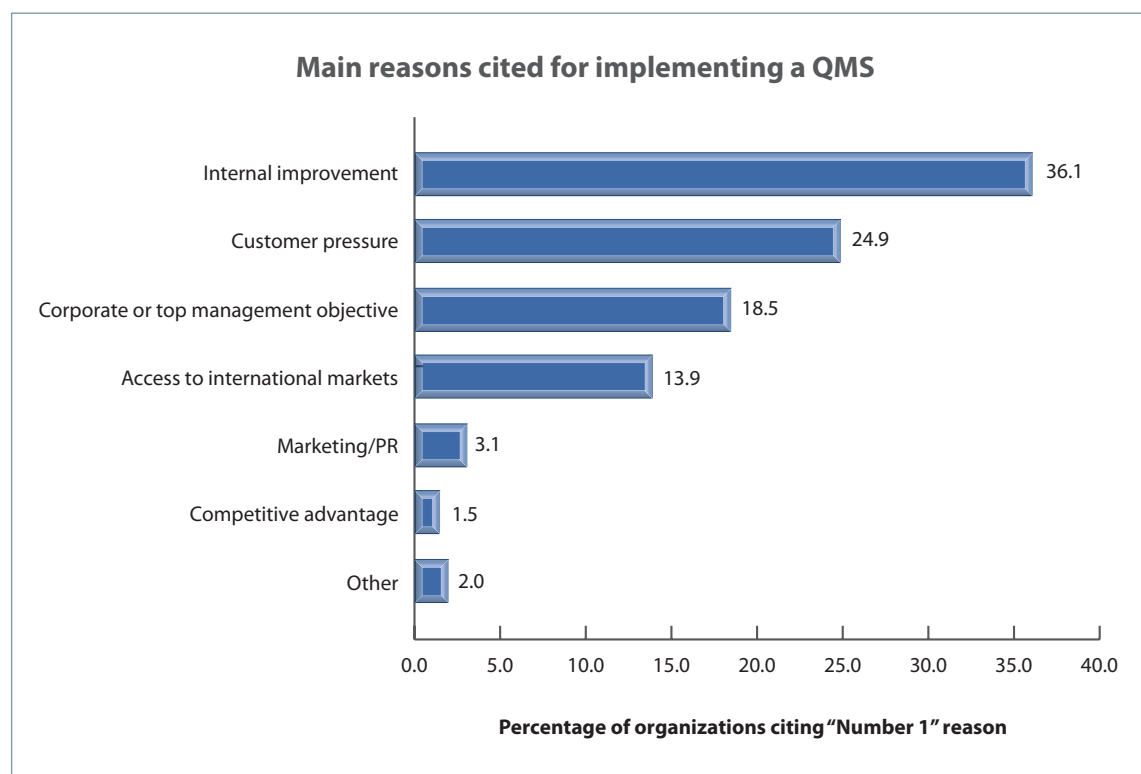
- 26% of the respondents had been certified for 10 years or longer, meaning that they had first implemented their quality management system based on the 1987 or 1994 versions of ISO 9001 (or, in some cases, the old versions of ISO 9002 or even ISO 9003), before the introduction of the “process approach” model adopted in ISO 9001:2000. They had therefore had to make the transition to this new approach during the period 2001–2003.
- 48% of the respondents had been certified for a period of 4–10 years, which means they had undergone at least one full certification cycle (initial audit, followed by periodic surveillance audits and a recertification audit).
- 26% of the respondents had been certified for 3 years or less, meaning that they had not yet been through one full certification cycle.

## Reasons for seeking certification

The top three “Number 1” reasons for implementing a quality management system and seeking certification are shown in figure 23. It can be seen that over 54% had “internally-motivated” reasons

(including “internal improvement” and “corporate or top management objective”), whilst 39% had “externally motivated” reasons (including “customer pressure” and “access to international markets”).

**Figure 23. Main reasons cited for choosing to implement a quality management system**

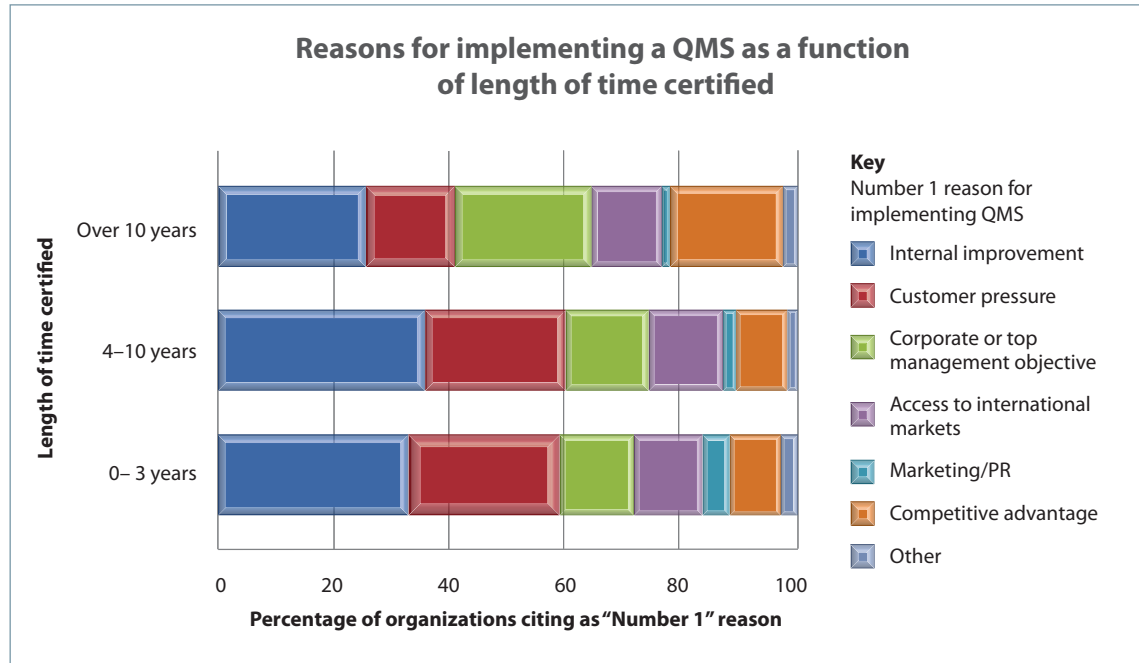


It is interesting to see how the “Number 1” reasons for implementing a quality management system have changed over time. Figure 24 shows the various reasons cited as a function of the length of time the respondent had been certified. The following trends can be observed:

- An increase over time in the percentage of respondents claiming that their “Number 1” reason for implementing a quality management system was to respond to customer pressure.
- A decrease over time in respondents claiming that their “Number 1” reason for implementing a quality management system was to gain a competitive advantage, or to meet corporate or top management objectives.

It can therefore be concluded that the implementation of a quality management system is no longer considered to offer a significant competitive advantage, but as certification becomes more of an entry criterion in order to become a supplier to many purchasers, to compete in international markets and to participate in tenders, it is the lack of certification that becomes a competitive disadvantage. This in turn has led to an increase over time in the percentage of organizations citing “customer pressure” as their number one reason for implementing their quality management system, and an increasing focus on “getting the certificate” rather than on implementing a sound, effective quality management system. This in turn has resulted in a quest for shorter implementation times and the subsequent deleterious effects on system effectiveness, as will be shown later in this report.

**Figure 24. Main reasons cited for choosing to implement a quality management system, as a function of the length of time certified**



## Implementation time

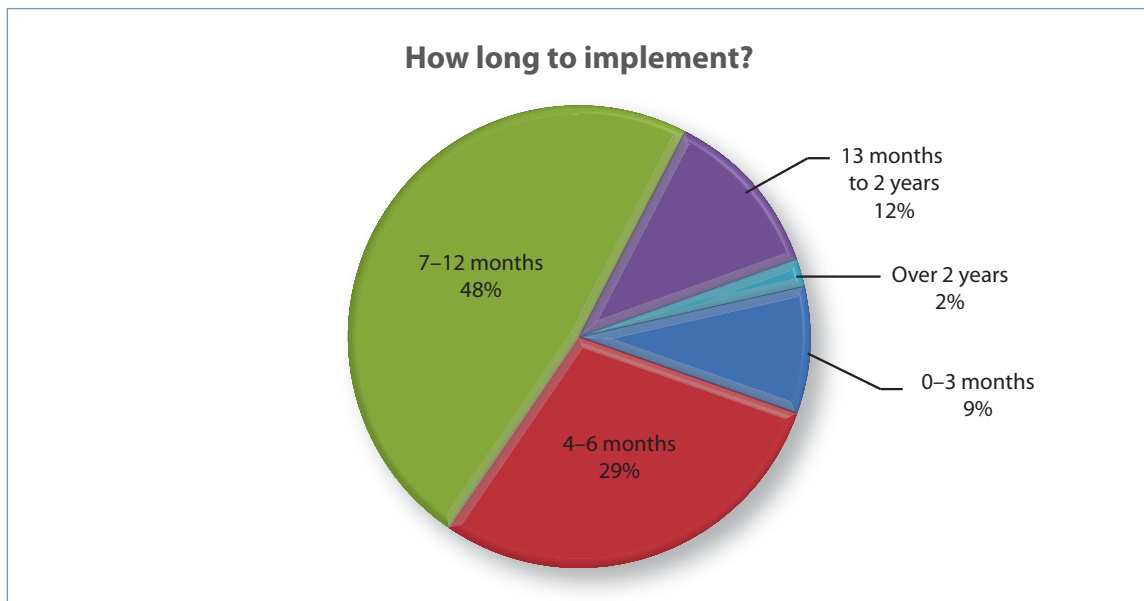
It can be seen from figure 25 that most organizations (60% of the 604 respondents) took between 7 months and two years from the time they decided to start implementing the quality management system until they obtained certification. In some cases, however, the time taken was surprisingly short, with almost 29% claiming to have become certified within four to six months after their decision to begin implementing the quality management system, and a further 9% claiming to have done so in less than three months. Although there might be special circumstances that facilitate such short implementation periods (for example, if the organization is part of a larger entity that already has a corporate quality management system), it is unlikely that the potential benefits to be derived during implementation have been fully achieved in such cases.

As shown in figure 26, there has been an increasing trend in recent years in the percentage of organizations taking 6 months or less to implement and certify their system. For those organizations that had been certified for over 10 years, only 26% had taken 6 months or less to implement the system and achieve certification and only 3% had done it in 3 months or less. This compares to 36% of organizations certified in the last 3 to 10 years who implemented and achieved certification in 6 months or less (with 9% doing so in 3 months or less), and 51% of organizations certified in the last 3 years implementing the system and achieving certification in 6 months or less (with 15% doing so in 3 months or less).

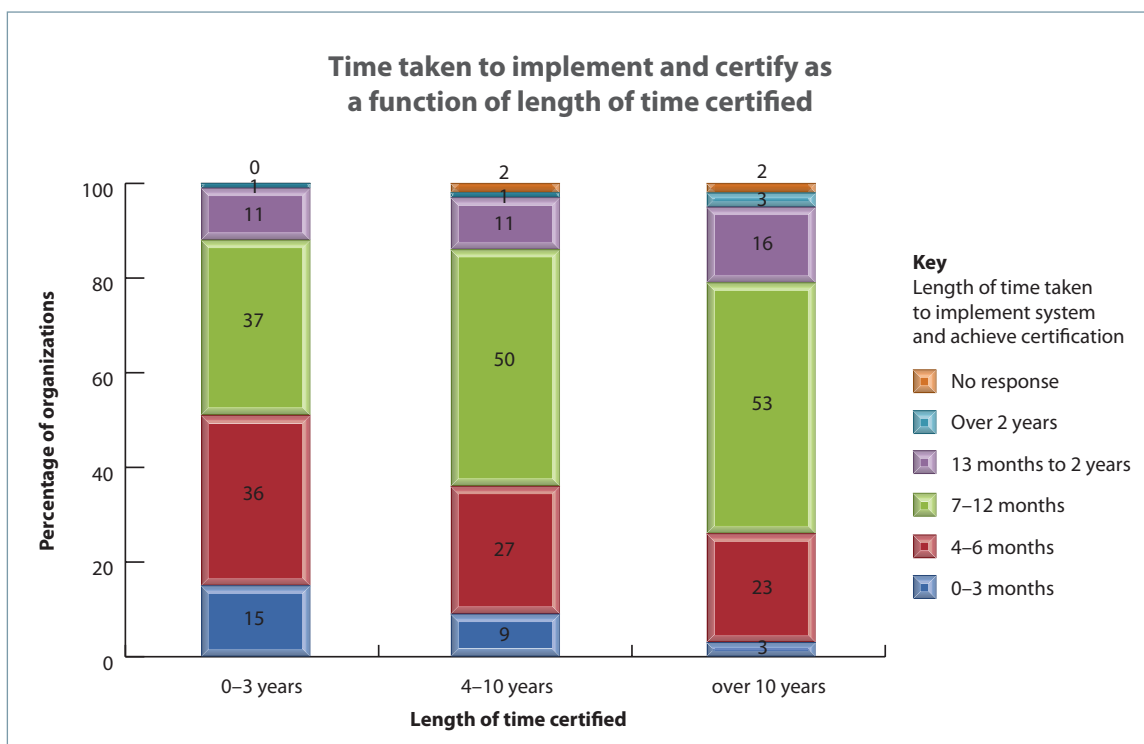
It is highly improbable that a fully operational and effective quality management system can be implemented in such short periods of time, and can have achieved sufficient maturity for a competent audit to be carried out. Realistically, before being audited, the quality management system should have passed through at least one complete Plan-Do-Check-Act cycle, including the process definitions and preparation of the appropriate documentation, effective implementation and deployment,

followed by a cycle of internal audits, corrective actions as needed and at least one management review. The negative impact of an unrealistically short implementation time on overall performance of the quality management system will be reported and discussed in more detail later in this report.

**Figure 25. Length of time taken to achieve certification after making the decision to begin implementation of the quality management system (604 respondents)**



**Figure 26. Length of time taken to achieve certification as a function of time since certification was achieved (based on responses from 604 certified organizations)**



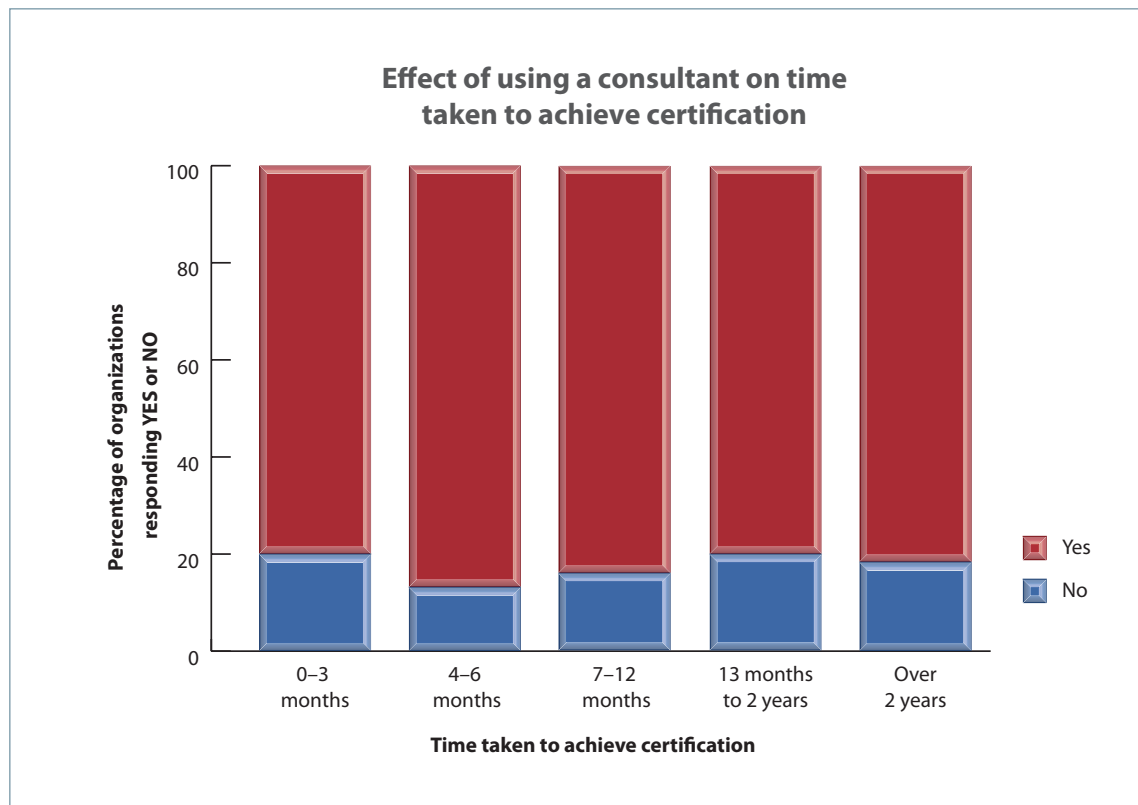


## Use of consultants

Although there is no requirement for organizations to use a quality management consultant to help with the implementation of their quality management system, 81% of the certified organizations surveyed chose to do so.

Interestingly, no trend was observed to show that the use of a consultant was associated with a shorter implementation time. As shown in figure 27, there was no statistically significant variation in the percentage of organizations using a consultant as a function of the time taken to achieve certification.

**Figure 27. Percentage of respondents who used a consultant during implementation of their quality management system, as a function of the time taken to achieve certification**



What could be observed, however, (see figure 28) was an increasing trend for more recently-certified organizations to use a consultant than did organizations certified for more than 10 years.

Figure 29 also shows that micro, small and medium enterprises had a greater tendency to use consultants than had larger organizations.

Figure 28. The increasing tendency among respondents from more recently certified organizations to have used a consultant

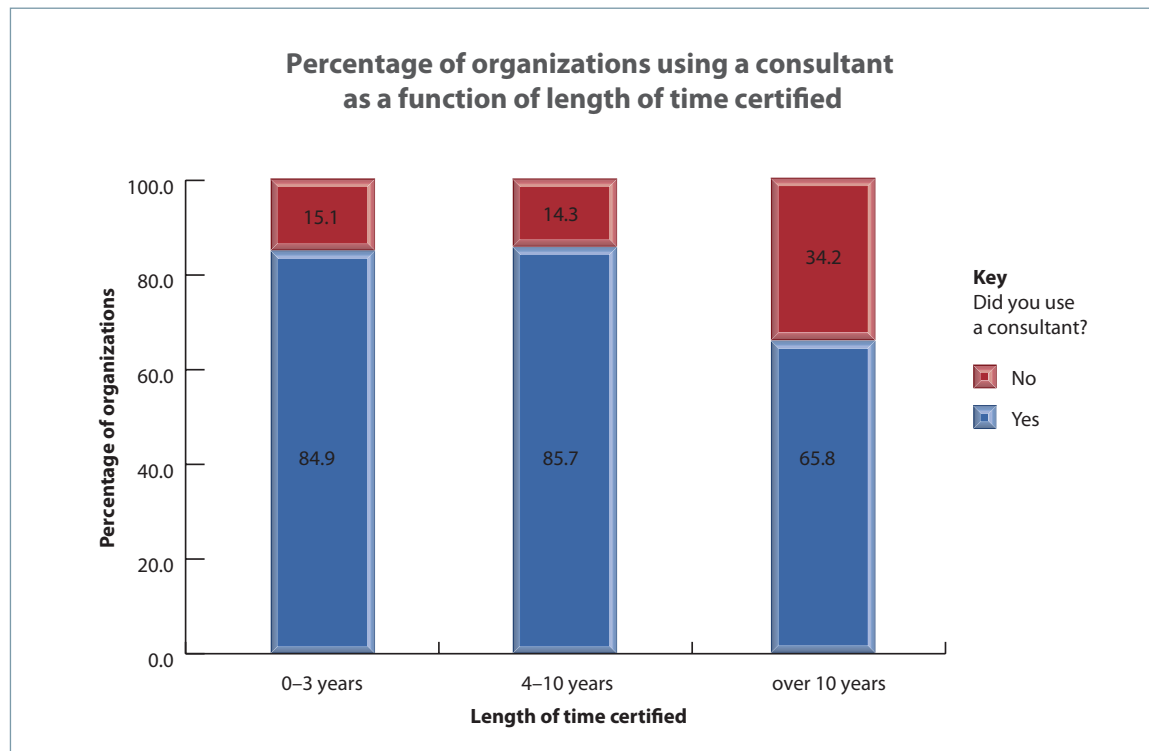
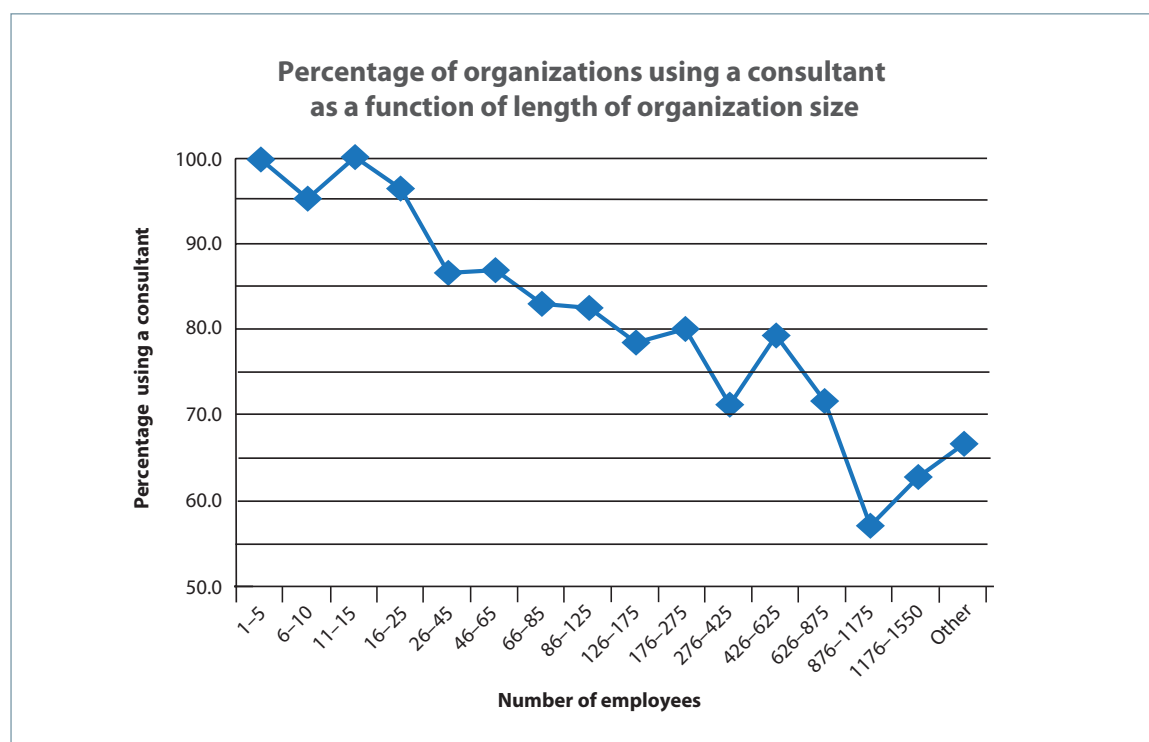


Figure 29. The decreasing percentage of respondents using a consultant as a function of the organization size (number of employees)



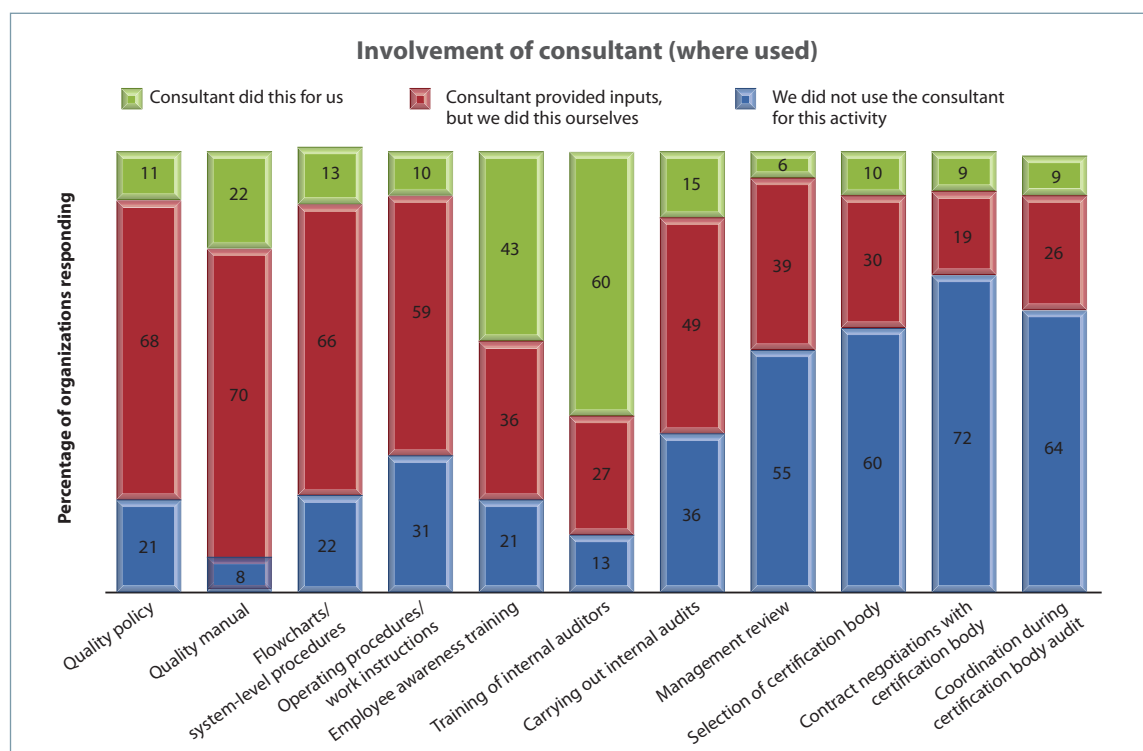
This can be explained by the fact that larger organizations are more likely to have access to their own resources, and may already have an existing management system (not necessarily meeting all the requirements of ISO 9001) before beginning implementation.

Figure 30 provides details of how and for which activities consultants were used. It can be seen that, for the initial phases of implementation, consultants were used primarily to assist the organizations to develop their quality policy, quality manual, system level procedures and operating procedures/work instructions. In a small percentage of cases, however, the consultant actually prepared these documents for the organization, and as many as 22% of the organizations who used a consultant said that the consultant had written their quality manual for them. This is not actually wrong, but does not help to induce a sense of “ownership” of the quality management system by the organization’s own personnel.

As might be expected, consultants were quite extensively used for employee awareness raising and internal auditor training, and 15% of the organizations responding used the consultants to carry out internal audits on their behalf.

Although the majority (55%) of the organizations carried out their management review without any involvement of their consultant and a further 39% used the consultant to provide inputs, it is worrying to see that 6% (a total of 30 organizations using consultants) responded that the consultant “had done the management review for them”. Clause 5.6 1 of ISO 9001 is very clear — “Top management shall review the organization’s quality management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness” — and this is not something that can be delegated to a consultant. Also of concern are the approximately 10% of organizations who responded that the consultant had conducted all negotiations with the certification body, negotiated the contract with the certification body, and coordinated activities during the certification body’s initial audit.

**Figure 30. The ways in which the respondents had used the services of their consultant**



Although there is no requirement for organizations to use a consultant, it is well known that the competence of quality management system consultants and the ways in which they are used by an organization can be key to the successful implementation of ISO 9001, particularly in SMEs. Although there were no questions about its use in the current survey, it is recognized that the ISO 10019 standard (“Guidelines for the selection of quality management system consultants and use of their services”[7]) is not widely known or utilized. This was evident from the reaction of participants in the various international and local feedback workshops that were conducted at the end of the project. ISO 10019 explains the various criteria that organizations may adopt when choosing a consultant, and how to use the consultant’s service wisely and to maximum benefit without creating an ongoing dependency (and cost). If this standard is to achieve the desired impact, though, it is vital that organizations considering implementing a quality management system are made aware of its existence before they enter into any contract with a consultant, and national standards bodies should be encouraged to promote ISO 10019 among potential users. Consultants themselves might also find it useful to make potential clients aware of the content of this guidance, in order to help them to make an informed choice about this important element, should they choose to use a consultant to help implement their system.

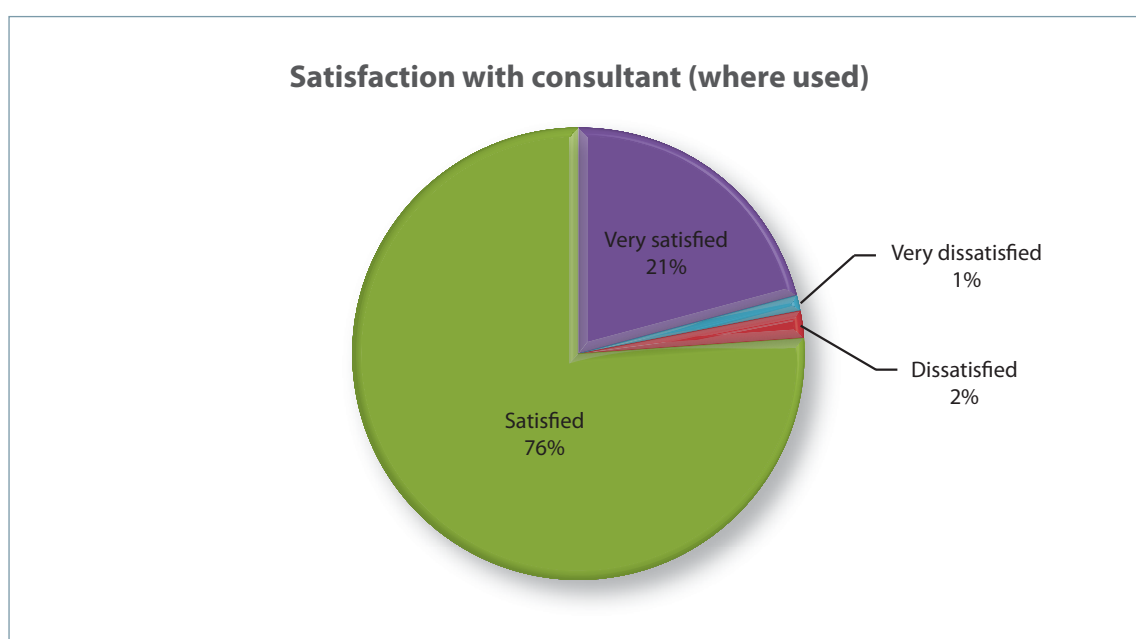
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***Organizations need to be made aware of the guidance in ISO 10019 before they enter into a contract with a QMS consultant.***

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Overall, figure 31 shows that the level of satisfaction with the consultants was very high (97% rated “Very good” or “Good”), but it must be remembered that this survey was carried out among organizations that had achieved certification and so it is very likely that they would be satisfied with their consultants’ performance.

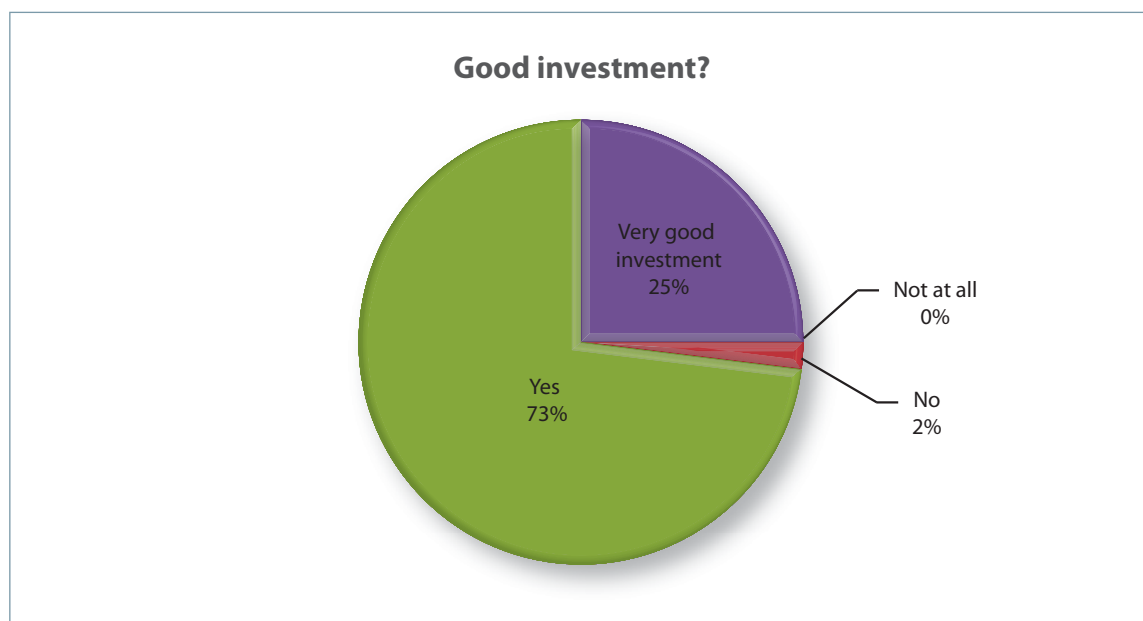
**Figure 31. The level of satisfaction with QMS consultants used by the 604 certified organizations that participated in the survey**



## Economic impact and return on investment

It proved impossible to extract meaningful data from the question on the survey about the actual costs of implementation and certification, in view of the widely varying size and complexity of the organizations involved, the various currencies, the length of time elapsed since many had achieved certification, and the absence of reliable records to take into account internal costs such as employee time spent during implementation and on-the-job training. There was, however, a very important and encouraging result to a more generic question. Of the 604 organizations surveyed, figure 32 shows that 98% responded that, independent of the amount they had invested, they considered the return on their investment to have been “Good” (73%) or “Very good” (25%). Only 2% considered the implementation of ISO 9001 not to have been a good investment, and none of the respondents considered it to have been a complete waste of money.

**Figure 32. The responses of 604 certified organizations to the question “Regardless of whether you can quantify the total costs, do you consider that the investment (in your QMS) was worthwhile?”**



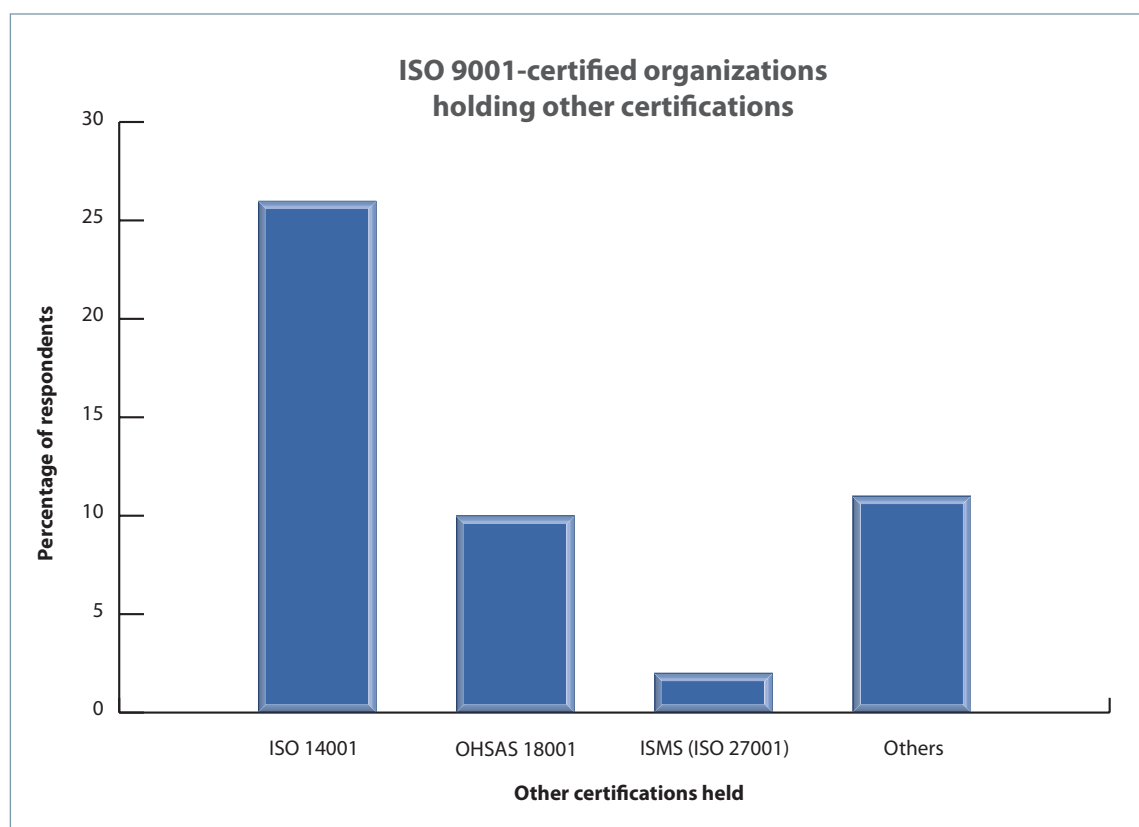
The difficulties involved in isolating the effect of ISO 9001 certification on the financial performance of organizations and economies are well documented in the literature (see, for example, the work of Heras, Dick and Casadesús [19]). Although Corbett et al [20] have shown that certified organizations do indeed tend to out-perform non-certified organizations in similar industry sectors, it is not clear whether certification is the causal factor for the superior performance. In other words, does ISO 9001 implementation and certification enable organizations to enhance their financial performance, or is it that the better-performing organizations choose to seek ISO 9001 certification?

Regardless of these deliberations, the responses to the present survey on the overall return on investment, coupled with the opinions expressed by certified organizations later in this report (see table 8), provide significant empirical evidence of the positive economic impact of ISO 9001 implementation and certification.

## Compatibility of ISO 9001 with other management system standards

Figure 33 shows that 26% of the ISO 9001-certified organizations that responded to the survey also had an environmental management system certified to ISO 14001. Less than 10% had occupational health and safety management systems meeting the requirements of OHSAS 18001 [21], and less than 2% had information security management systems certified to ISO 27001 [22]. Other certifications held by the organizations surveyed included various product certifications and, in some cases, sector-specific certifications to standards such as ISO/TS16949 (for the automotive industry) [23].

**Figure 33. Percentage of respondents holding certifications to other standards**

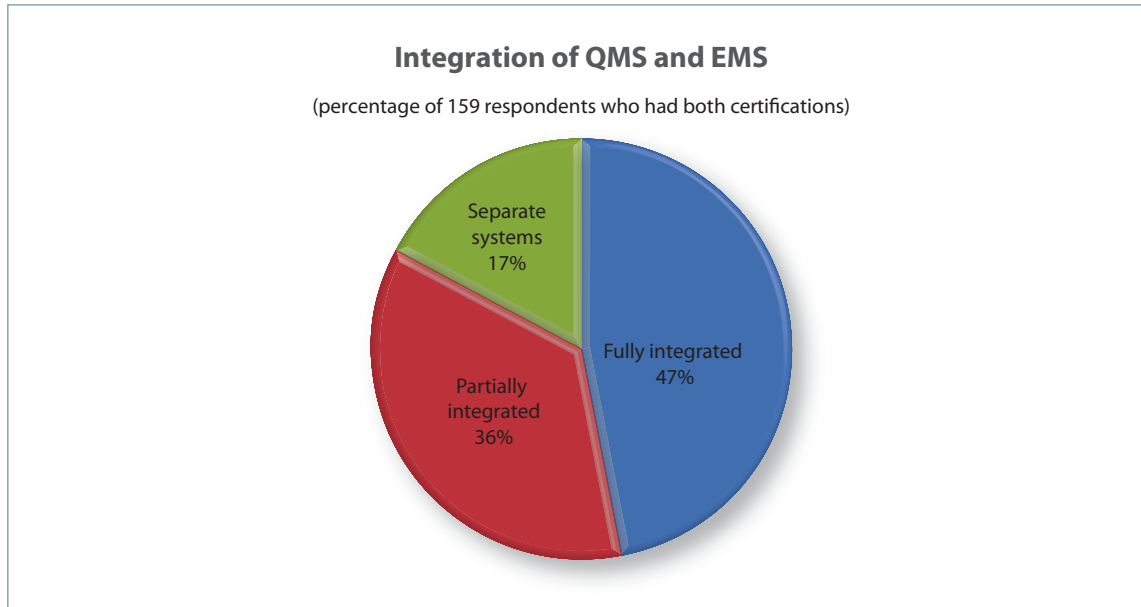


It was interesting to note that of the 159 organizations certified to both ISO 9001 and ISO 14001, 91% were satisfied with the current level of compatibility between the two standards.

As seen in figure 34, almost half of these 159 organizations had implemented the two standards as a single, integrated system. Some 36% said their systems were only “partially integrated” and only 17% had implemented the two standards as completely separate systems.

One very disappointing result of the survey was the low level of awareness and utilization of the ISO 9004 guidance standard [5] among ISO 9001-certified organizations. Only 17% of the 604 respondents said they “know and use” ISO 9004. Some 42% had heard of the standard, but didn’t

**Figure 34. Level of integration of QMS and EMS among the 159 organizations holding certification to both ISO 9001 and ISO 14001**



use it and a surprising 42% were not even aware of its existence. As mentioned in chapter 1, ISO 9004 goes beyond the basic requirements of ISO 9001, and guides organizations towards sustained success by identifying and meeting the needs and expectations not only of their customers but also those of other interested parties over the long term and in a balanced way. If organizations in the Asian developing economies are to derive the maximum benefit from their quality management systems, it is imperative that they be encouraged to look “beyond certification”. Although it is recognized that many organizations in these countries need ISO 9001 certification for trade capacity-building purposes, such certification should be a consequence of a well-implemented quality management system, and not an end in itself.

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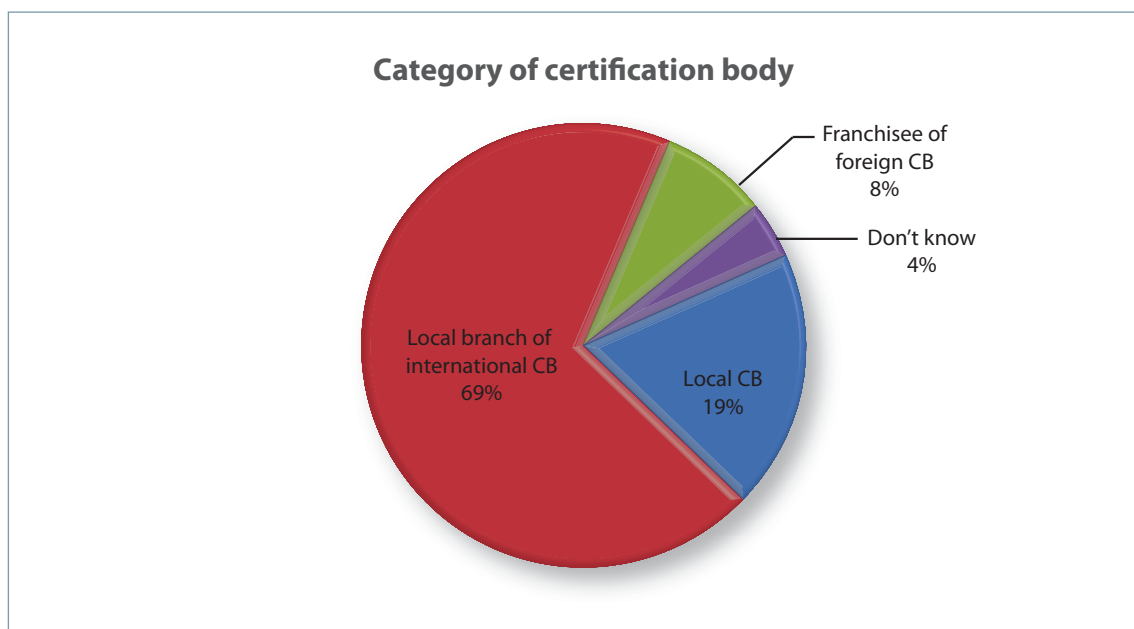
***National standards bodies, consultants, certification bodies and accreditation bodies all have a responsibility to make ISO 9001-certified organizations aware of the economic benefits of looking beyond certification towards “sustained success”, using the certified quality management system as a starting point.***

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## Selection of certification bodies by ISO 9001-certified organizations

As shown in figure 35, almost 80% of the organizations surveyed had chosen certification either by a branch office or a local franchisee of a foreign certification body. Less than 20% were certified by local certification bodies. Interestingly, almost 20% of the organizations surveyed had changed certification body at some stage. Some of the factors that influence the choice of certification body are examined later in this chapter.

**Figure 35. Category of certification body used by the 604 certified organizations who participated in the survey**



As was the case with the purchasers (chapter 4), knowledge and awareness of the role of accreditation was poor among certified organizations. Although most of the organizations (72%) were able to correctly name the accreditation body who had accredited their own certification body (and whose name appears on their certificate!), only 40% were able to name the local accreditation body in their own economy and only a similar number (39%) were able to name any accreditation body.

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*Awareness of the IAF was also very low, with only 13% of the certified organizations consulted saying that they had heard of the IAF and knew what it did, and 53% saying they had never heard of it.*

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## Criteria used to select the certification body

The results presented in table 5 relate to the criteria and methodology used by the respondents to select their certification body. In each case, the certified organizations were asked to comment on their level of agreement or disagreement with a series of statements, and the distribution of the results is shown. No attempt has been made to perform a statistical analysis of these results, in view of the different nature and format of the distributions observed, but the tendencies can be clearly identified simply by observing the responses in the form of histograms. Where comments have been made, these are as a result of the relative and cumulative frequency of the various responses.



Table 5. Opinions of 604 certified organizations about their certification body selection process

Statement about the criteria for selecting the certification body	Level of agreement with the statement (604 responses)	Comments
(1) “We had no input — our consultant negotiated with the certification body on our behalf.”		There was no great tendency for consultants to choose the certification body on behalf of the organization. This correlated well with the results shown in figure 30, where only a small percentage of the organizations surveyed said that contract negotiations with the certification body were handled exclusively by their consultant.
(2) “We made the decision (about which certification body to use) purely on our own.”		This corroborates the result in (1). Organizations in general were making their own decisions about which certification body to select.
(3) “We took into consideration recommendations from major customers.”		A range of responses, showing that approximately 50% of the organizations did consider using the same certification body as their major customers.
(4) “We checked to see which certification body had the best reputation in our own country/industry sector.”		Strong tendency for organizations to place importance on the certification body's reputation in the local country and in the industry sector.
(5) “It was important for the certification body to have an international reputation.”		Very strong tendency for organizations to place importance on the certification body's international reputation.
(6) “We chose the certification body because we heard they were the easiest.”		Organizations tended to deny choosing the certification body on the basis of reputation for being “easy”.
(7) “We chose the certification body because they were the cheapest.”		Organizations in general maintained that they did not choose the certification body based only on price.
(8) “We didn't care whether the certification body was accredited or not.”		Accreditation was generally considered to be important (despite the low level of awareness of what accreditation actually means).

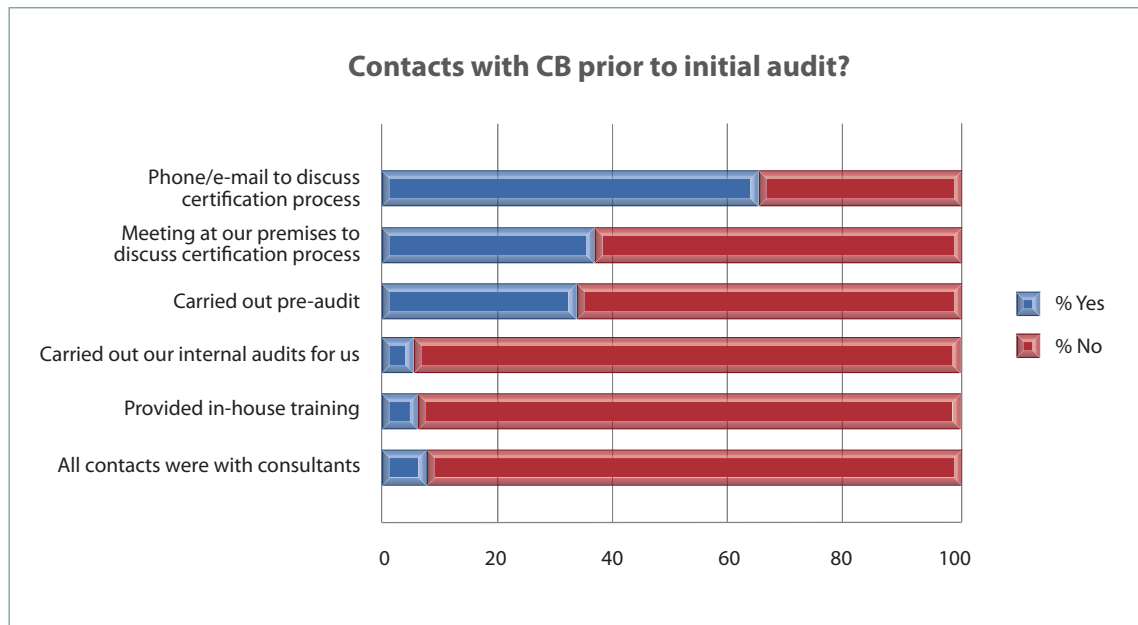
Statement about the criteria for selecting the certification body	Level of agreement with the statement (604 responses)	Comments
(9) <i>“It was important for the certification body to be accredited by our national accreditation body.”</i>		Local accreditation of the certification body was only considered to be important by 50% of the certified organizations surveyed.
(10) <i>“It was important for the certification body to be accredited by a foreign accreditation body.”</i>		More organizations gave importance to foreign accreditation than to local accreditation.
(11) <i>“It was important for the certification body to be accredited by a member of the IAF (International Accreditation Forum).”</i>		There were mixed responses about the importance of the certification body having accreditation from an IAF MLA signatory (which is hardly surprising, given the low level of awareness about the IAF).

## Contacts with the certification body prior to the initial audit

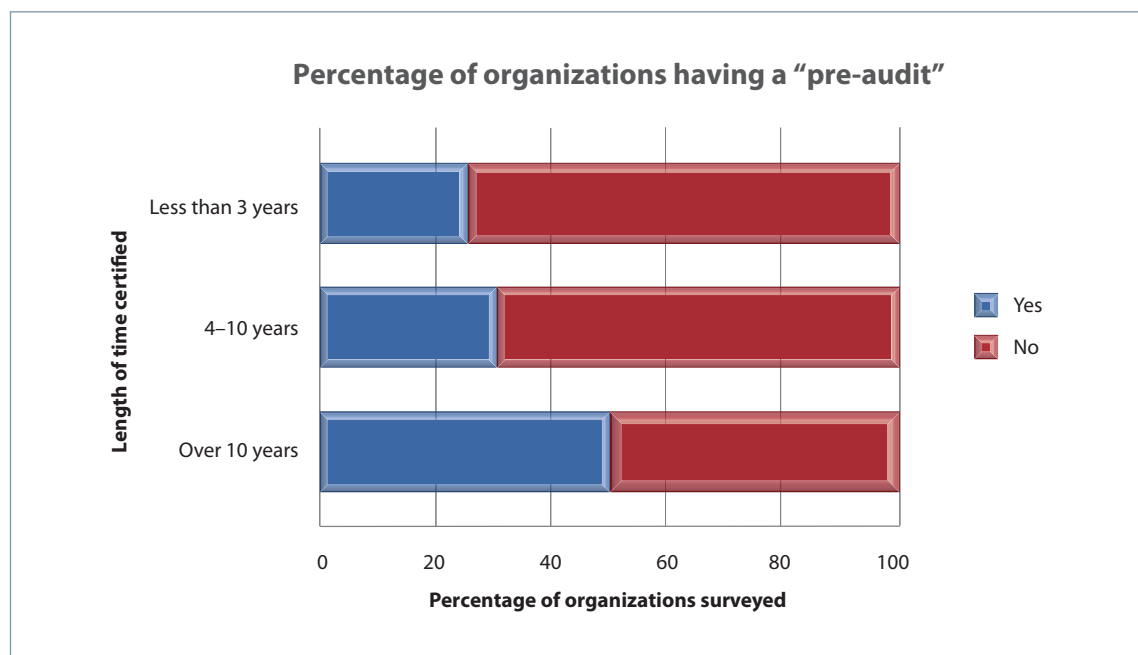
In figure 36, it can be seen that in the contacts with the certification body prior to the initial certification audit, it was common for organizations to have telephone discussions (65% of the respondents) or meetings at the organization's premises (37%) to discuss the certification process. Of the 604 organizations surveyed, 34% had hired the certification body to carry out a pre-audit (or “gap analysis”) before initiating the certification audit process. It is important to remember that ISO 17021:2006 [2] had not been published at the time that many of the organizations surveyed went through the certification process, and a two-stage audit was not mandatory. It can be seen in figure 37 that the percentage of organizations opting for a pre-audit by their certification body in recent years has decreased compared to the percentage of organizations certified for longer periods of time who did so.

Although the numbers in absolute terms were low (6% of those surveyed), it was disturbing to see that a number of certification bodies were performing in-house training (which, according to ISO/IEC 17021, might be acceptable provided it is limited to the provision of generic information that is freely available in the public domain and does not provide company-specific solutions) or were actually carrying out the organization's internal audits on their behalf (which is not acceptable, according to ISO/IEC 17021 Clause 5.2.6). As noted in previous sections of this report, a small percentage of the organizations surveyed had no contact at all with their certification body prior to the initial audit, with all contacts being made via the consultants.

**Figure 36.** Analysis of the kind of contacts between the certified organization and the certification body prior to the initial certification audit (based on the 604 responses from certified organizations)



**Figure 37.** The decreasing tendency for more recently-certified organizations to have undertaken a pre-audit by their certification body (based on the 604 responses from certified organizations)



## Audit durations

Interestingly, in spite of previous anecdotal evidence to the contrary, the results showed that (based on the responses of the 604 certified organizations who responded to the survey) certification bodies, in general, respect the audit durations prescribed by the IAF Mandatory Document MD5 [8].

Figure 38 shows the actual number of auditor-days reported by the certified organizations for the latest full (initial or recertification) audit plotted against the theoretical number of auditor-days (according to IAF Mandatory Document MD5 [8]) as a function of organization size. It is reasonable to expect that the number of auditor-days reported by the organizations is accurate since they are unlikely to be familiar with the detailed content (or even the existence!) of IAF MD5 and there was no evidence to suggest they had been “coached” by their certification body before providing their responses.

For each organization’s size category, the calculated theoretical audit duration took into consideration the length of time the organizations in that category had been certified — for organizations that had been certified for more than three years, the recommended duration for a recertification audit was considered.

$$\text{Theoretical audit days} = \frac{\sum \text{MD5 auditor-days (orgs certified } \leq 3\text{yrs)} + 2/3 \sum \text{MD5 auditor-days (orgs certified } > 3\text{yrs)}}{\text{Number of organizations in size category}}$$

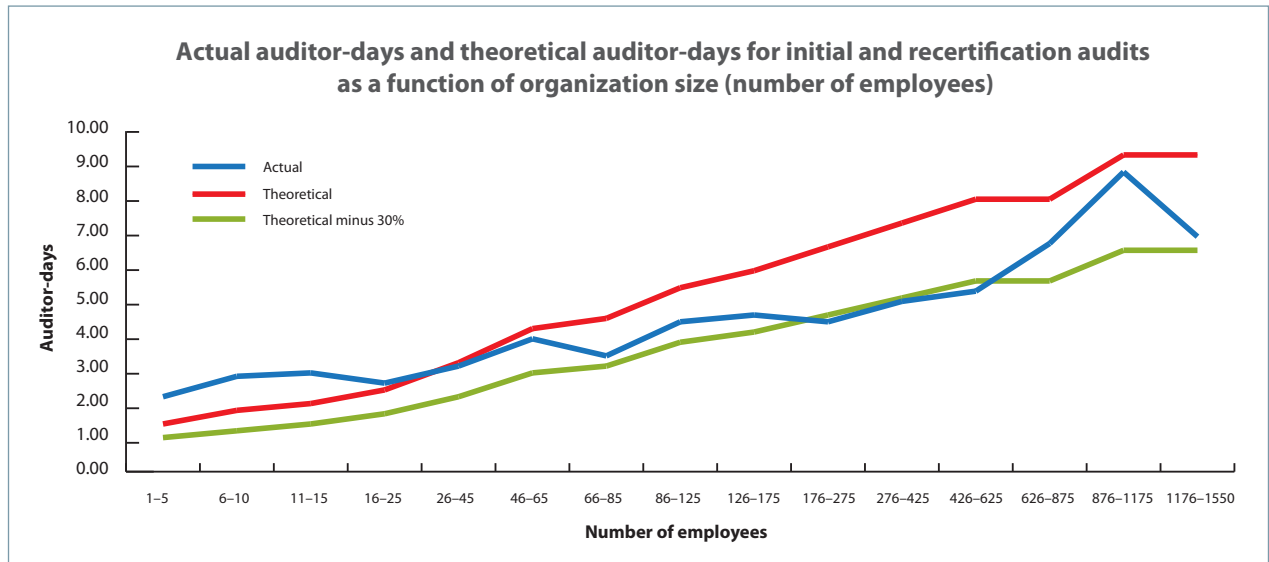
$$\text{Actual audit days} = \frac{\sum \text{actual auditor-days}}{\text{Number of organizations in size category}}$$

It is important to note, however, that ISO 17021:2006 does not prescribe the number of auditor-days based on the size of the organization; it requires only that the certification body defines “the time needed to plan and accomplish a complete and effective audit of the client’s management system.” This can vary depending on a number of factors, including:

- The requirements of the relevant management system standard;
- The size and complexity of the organization;
- The technological and regulatory context;
- Any outsourcing of any activities included in the scope of the management system;
- The results of any prior audits;
- The number of sites and multi-site considerations.

Also included in figure 38 is the theoretical audit time minus 30%, which is the maximum reduction permitted by IAF MD5 [8] to take into consideration organizations with excluded ISO 9001 requirements, simple and/or repetitive processes, and other factors that might justify a reduction in audit duration.

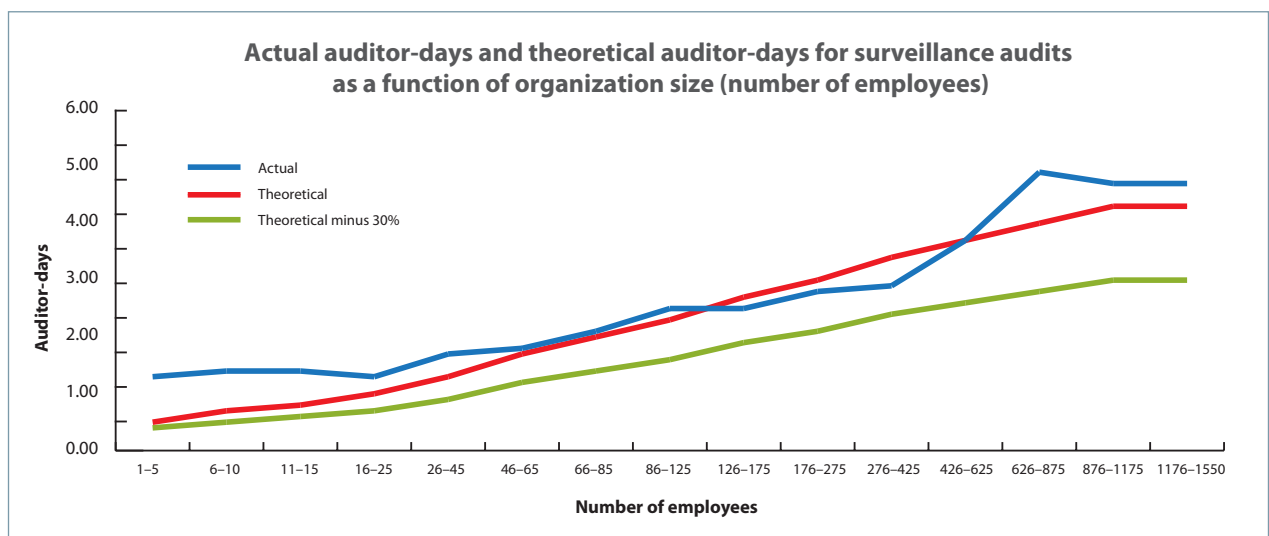
**Figure 38.** The variation of actual auditor-days compared to the theoretically calculated number of auditor-days (according to IAF MD5 [8]) for full (initial or recertification) audits, based on the responses from 604 certified organizations



It can be seen that for micro- and small organizations (below 25 employees), the IAF guidelines are actually exceeded. For larger organizations, the actual audit durations are below those prescribed in IAF MD5 but generally within the limits of the 30% reductions in duration that may be permitted.

A similar pattern emerged for surveillance audits (figure 39), but in this case the actual audit durations were higher than those recommended by IAF MD5 for organizations below approximately 125 employees in size and above 625. In no cases did the number of auditor-days fall below the maximum 30% reduction allowed by IAF MD5 for surveillance audits.

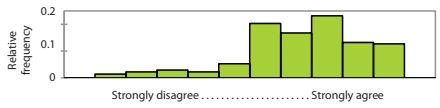
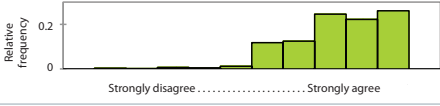
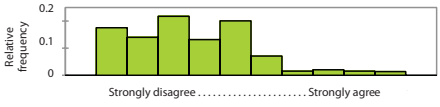
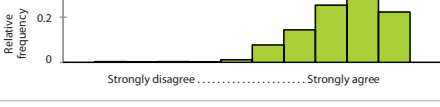
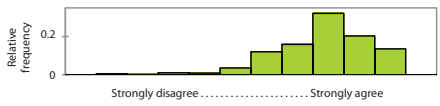
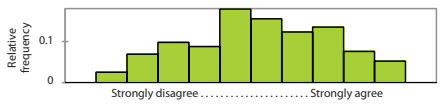
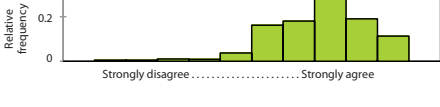
**Figure 39.** Graph showing the variation of actual auditor-days compared to the theoretically calculated number of auditor-days (according to IAF MD5) for surveillance audits, based on the responses from 604 certified organizations

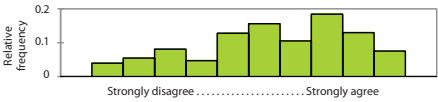
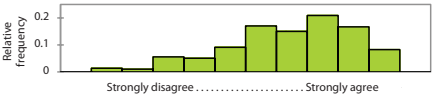

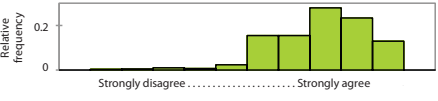
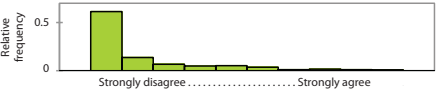


## Initial certification process

Regarding the initial audit process, the certified organizations were asked to comment on their level of agreement with a series of statements, as reported in table 6.

**Table 6. Opinions of 604 certified organizations about the initial certification audit**

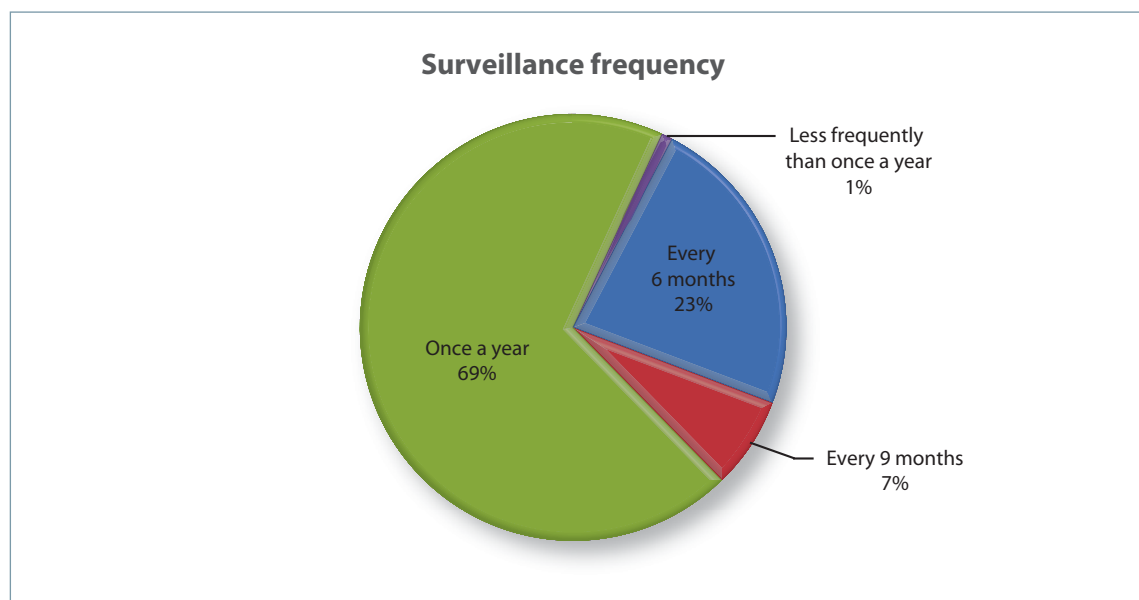
Statement about the initial certification audit process	Level of agreement with the statement (604 responses)	Comments
(1) <i>"The audit process was challenging."</i>		The majority of the certified organizations surveyed considered that the audit process was challenging, with only 10% disagreeing.
(2) <i>"The audit process was fair and impartial."</i>		There was strong consensus that the initial audit process was fair and impartial.
(3) <i>"The audit was too easy."</i>		There was strong consensus that the audit process was not "too easy", with only 10% of the respondents disagreeing. This is consistent with the results of Item 1.
(4) <i>"The auditors were professional and competent."</i>		In general, there was good agreement that the auditors were professional and competent in their approach.
(5) <i>"The auditors had a good understanding of our business and processes."</i>		The certified organizations generally agreed that the auditors had a good understanding of their business processes. This is interesting, and contradicts some of the anecdotal evidence that has often been cited.
(6) <i>"The auditors spent most of their time looking at procedures and records."</i>		There were mixed opinions about whether or not the auditors spent most of their time looking at documentation, with half of the respondents agreeing, and half disagreeing. It is clear, however, that some auditors need to pay attention to this concern, and to focus less on documentation.
(7) <i>"The auditors were keen to observe our processes in operation, and to talk to the employees involved."</i>		In some ways, this contradicts the previous topic, and organizations confirmed that auditors were observing processes in operation, and talking to the appropriate employees.

Statement about the initial certification audit process	Level of agreement with the statement (604 responses)	Comments
(8) <i>“The auditors told us what they thought we should be doing.”</i>		There were mixed responses to this topic, but it is clear that a significant percentage of auditors were perceived to be “giving advice” which, if it is specifically directed towards providing instructions or solutions, is considered by ISO/IEC 17021 Clause 3.3 to be consultancy and is not permitted.
(9) <i>“The auditors spent enough time interviewing our top management.”</i>		There was a clear tendency to agree that auditors were spending enough time talking to top management, although as many as 8% of the organizations surveyed disagreed quite strongly.
(10) <i>“The auditors rarely left the management representative’s office.”</i>		There was a strong tendency to confirm that auditors were not spending too much time only talking to the management representative, although this was the case in approximately 8% of the respondents.
(11) <i>“The auditors were able to identify problem areas in our system and raise the appropriate non-conformities.”</i>		There was good agreement that auditors were able to identify problems in the system and were raising the appropriate nonconformities.
(12) <i>“Our consultant answered most of the auditors’ questions.”</i>		Certified organizations strongly disagreed that their consultant answered most of the auditors’ questions.

## Surveillance audits

Figure 40 shows that the most commonly reported surveillance frequency was yearly (69%), but with 25% maintaining a six-monthly frequency and 7% reporting a 9-monthly cycle (to include an initial or recertification audit plus 3 surveillance audits during a 3-year certification cycle). ISO/IEC 17021 [2] requires certification bodies to carry out surveillance “at least once a year”. Although not frequent, a total of 8 organizations claimed they were audited less than once a year, though it is important not to automatically draw negative conclusions from this fact, which could have been a result of multi-site sampling criteria whereby not every site within a multi-site scope of certification has to be audited every year. This was not verified during the project.

**Figure 40. Graph showing the frequency of surveillance audits reported by the 604 certified organizations surveyed**

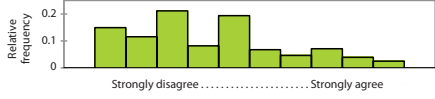
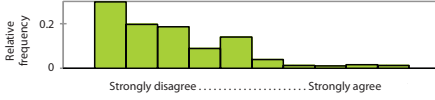
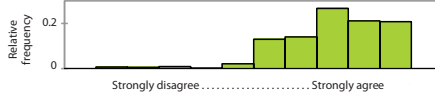
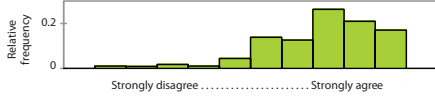


In terms of the surveillance audit process, the certified organizations were again asked to comment on their level of agreement with a series of statements. The results are shown in table 7.

**Table 7. Opinions of 604 certified organizations about their surveillance audit process**

Statement about the surveillance audit process	Level of agreement with the statement (604 responses)	Comments
(1) <i>"The surveillance audits ensure that our system continues to meet the requirements of ISO 9001."</i>		Good levels of confidence were expressed about the effectiveness of the surveillance audit process.
(2) <i>"The surveillance audits encourage us to improve our system."</i>		There was strong agreement that the surveillance audit process encouraged continual improvement.
(3) <i>"The surveillance audits are very useful."</i>		The results show that surveillance audits were considered to be useful.
(4) <i>"The surveillance audits are focused only on documentation."</i>		The majority of certified organizations did not agree that the surveillance audits only focused on documentation, although 15% agreed with this statement.

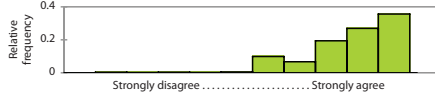


Statement about the surveillance audit process	Level of agreement with the statement (604 responses)	Comments
(5) <i>"The certification body always uses the same auditor(s) for surveillance audits."</i>		There were mixed responses to this statement, as might be expected. Whilst using the same audit team can often make the surveillance audits more efficient, some rotation of the auditors was to be encouraged in order to minimize excessive "familiarity", which can be a potential threat to impartiality (ISO/IEC 17021 Clause 4.2.4).
(6) <i>"The auditor never raises any non-conformities during the surveillance audits."</i>		There was a strong tendency to show that, in the opinion of certified organizations, the certification body auditors were raising nonconformities during surveillance audits.
(7) <i>"We find the surveillance audit report to be very useful."</i>		There was strong agreement among certified organizations that the surveillance audit reports were useful.
(8) <i>"We continue to get value for money with our certification."</i>		Certified organizations were satisfied with their return on investment in the surveillance process.

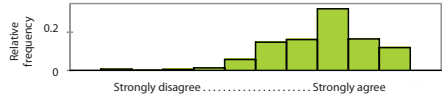
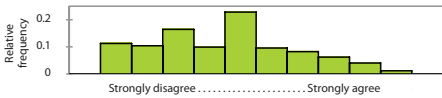
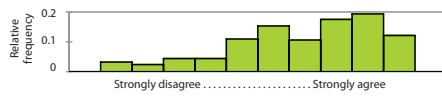
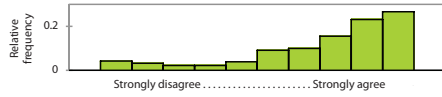
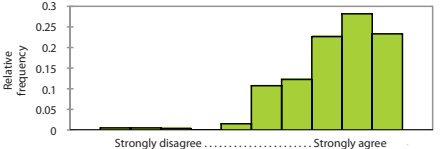
## Overall satisfaction with accredited certification

The results obtained from the 604 certified organizations surveyed about their overall satisfaction with accredited certification are shown in table 8.

**Table 8. Opinions of 604 certified organizations about their overall satisfaction with accredited certification**

Statement about accredited certification	Level of agreement with the statement (604 responses)	Comments
(1) <i>"Our top management has been totally committed to the implementation of ISO 9001."</i>		The respondents considered that top management of their organization had been committed to the implementation of ISO 9001. <i>Note:</i> during the local feedback seminars, many informal comments were received from the certified organizations present to suggest that the responses to this question might be suspect in view of the involvement of top management in providing responses.

Statement about accredited certification	Level of agreement with the statement (604 responses)	Comments
(2) <i>"We have derived significant benefit from implementing ISO 9001 in our organization."</i>		Almost all of the certified organizations that responded to the survey considered the implementation of their quality management system to have been beneficial.
(3) <i>"ISO 9001 certification has helped us to achieve our objectives."</i>		There was a good level of satisfaction that ISO 9001 certification had helped the organization to achieve the objectives that had stimulated it to implement a QMS and to seek certification.
(4) <i>"ISO 9001 certification has helped us improve the way we work."</i>		There was good agreement that ISO 9001 certification had helped organizations to improve their work processes.
(5) <i>"ISO 9001 certification has provided us with more confidence in our ability to produce conforming products."</i>		There was good agreement among the respondents that certification provided more confidence in the certified organization's abilities to provide conforming products.
(6) <i>"Our customers give us credit for our ISO 9001 certification when they choose their suppliers."</i>		In general, the certified organizations surveyed considered that their customers valued the fact that they were ISO 9001-certified.
(7) <i>"ISO 9001 certification has reduced the number of audits we receive from our customers."</i>		There were mixed responses about whether or not ISO 9001 certification had reduced the number of second-party audits that certified organizations received from their customers.
(8) <i>"ISO 9001 has helped us to focus on continually reducing internal re-work and waste."</i>		In general, there was agreement that the implementation of the QMS had helped reduce rework and waste, thereby contributing to overall organizational efficiency as well as effectiveness.
(9) <i>"We have obtained more business because of our ISO 9001 certification."</i>		There was a tendency to agree that ISO 9001 certification had resulted in more business, although 10% of the respondents disagreed.
(10) <i>"We can get a higher price for our products as a result of certification."</i>		Most of the respondents did not agree that ISO 9001 certification allowed them to charge higher prices for their products.

Statement about accredited certification	Level of agreement with the statement (604 responses)	Comments
(11) <i>"We have a much better understanding of our processes as a result of ISO 9001 implementation and certification."</i>		There was general agreement that the implementation of ISO 9001 and certification resulted in a better understanding of the organization's processes.
(12) <i>"ISO 9001 has obliged us to produce too much unnecessary documentation."</i>		There were mixed responses about whether or not ISO 9001 had necessitated too much unnecessary documentation. Of the 604 respondents, 30% considered that they had been obliged to produce too much unnecessary documentation, whilst 70% disagreed.
(13) <i>"We have never seriously considered changing our certification body."</i>		Most of the 604 respondents (75%) had never seriously considered changing their certification body.
(14) <i>"We have never seriously considered cancelling our certification (on our own initiative)."</i>		Although most of the certified organizations had never seriously considered cancelling their certification (on their own initiative), approximately 15% had considered this.
(15) <i>"Overall, the implementation of our quality management system and certification to ISO 9001 has been a good investment."</i>		There was strong agreement among the respondents that ISO 9001 implementation and certification had been a good investment. This is consistent with other responses throughout this survey.

## 6. ASSESSMENT OF CERTIFIED ORGANIZATIONS

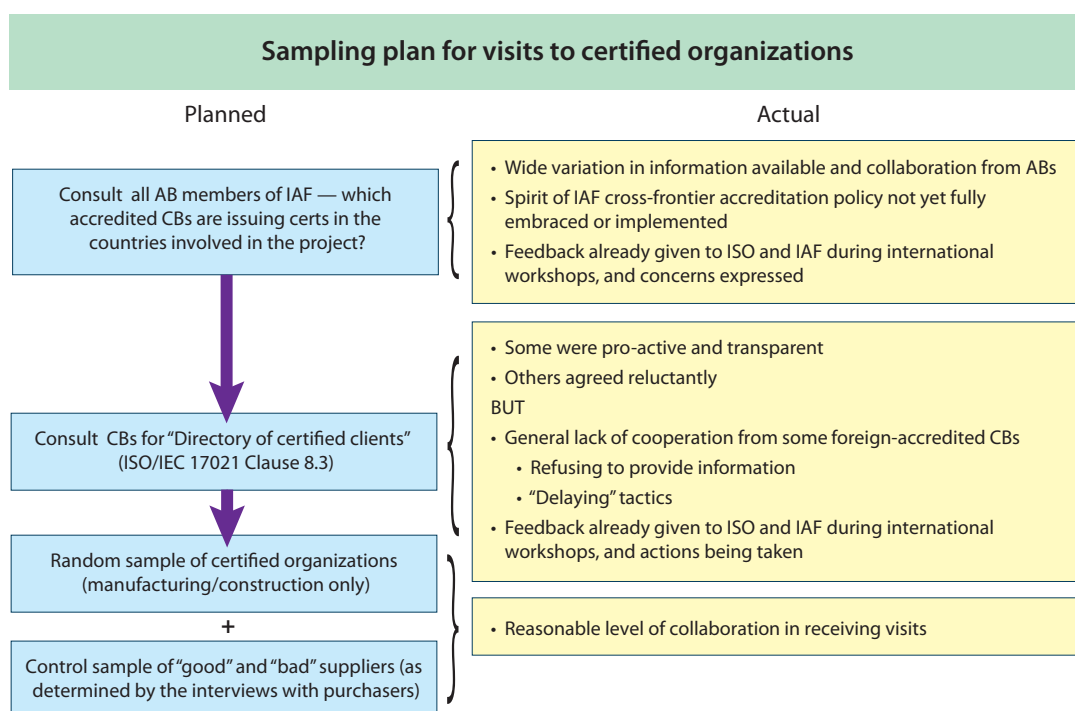
### Overview

A total of 561 certified organizations were visited in the twelve countries, using the sampling criteria shown in table 3. The experiences and observations during both the planning and execution of these visits provided valuable insights into the effectiveness of the accreditation and certification processes, as well as the level of confidence in the certified organization's ability to meet the intent of ISO 9001.

A summary of the sampling process for planning the visits to certified organizations and the actual outcomes can be seen in figure 41. This will be discussed in more detail later in this chapter.

In all contacts with certification and accreditation bodies, it was emphasized that this project was being carried out under the overall coordination of UNIDO, with collaboration from ISO and the IAF, and that all the consultants involved had signed strict confidentiality agreements as part of their contracts. This was supported by formal letters of introduction from the President of the IAF and the

**Figure 41. Summary of sampling plan for visits to certified organizations**



Secretary-General of ISO. Even so, we encountered a general reluctance among many certification bodies and accreditation bodies to collaborate in the project by providing the information that was being requested during the planning stages of the visits to certified organizations.

There was a reasonable level of collaboration from the organizations that were eventually selected for visits, when one takes into account the relatively short time frame in which the visits were carried out. Overall, 46% of the organizations contacted agreed to the visit. Although most of the reasons given for not receiving the visit were related to “pressure of work”, “lack of resources” or “other commitments”, it is likely that some of the organizations did not want to be visited due to concerns about the robustness of their quality management system. The reasons for denying the visits could not be determined in all cases, however, and it should not necessarily be implied that those organizations had something to hide. Also worthy of note is that, on many occasions, organizations had agreed in principle to participate and later backed out (after discussion with their certification body and/or consultant). As a consequence, the results of the project once again have to be analysed with caution, with a recognition that the sampling was limited to the “willing certification bodies and their clients” and with no mechanism for making participation mandatory.

## Performance of the certified organizations

### Overall results

The results of the 561 one-day visits to ISO 9001-certified organizations are presented in table 9 for each of the topics covered by the project-specific check-list. Based on these visits, the overall level of confidence in the quality management system of the organizations visited was generally good, with 92% of the results falling into the following UNIDO consultant-assessment categories:

- “We can be proud to use this organization as a benchmark” (6%)
- “Clear evidence that the intent of ISO 9001 is being met” (43%)
- “OK — No reason to doubt that this is being addressed correctly” (43%)

It should also be noted, however, that 8% of the organizations visited fell into the categories:

- “Some evidence presented, but not at all convincing” (7%)
- “Little or no confidence” (1%)

Whilst these percentages reflecting dissatisfaction are small, they do represent a significant number of organizations in absolute terms (over 5,000 in the region as a whole). This number could be higher, when we consider the favourable sampling criteria (only the “willing” certification bodies and certified organizations agreed to be visited), and it would be unwise to use these results as a reason for complacency.

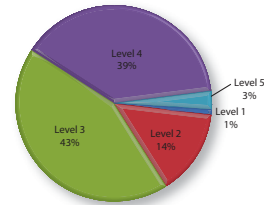
Of equal concern is the finding that in 14% of the visits the UNIDO consultants found little (13%) or no (1%) confidence that the certification process had been conducted effectively by the certification body.

**Table 9. Results of visits to certified organizations**

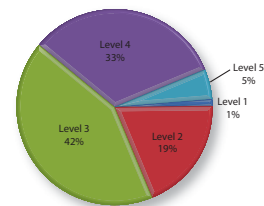
Check-list question	Overall grades (561 organizations)												
(1) The initial (or most recent full recertification) audit duration was appropriate for the size and complexity of the organization (See IAF MD5 [8]).	<p><b>Initial audit duration</b></p> <table border="1"> <thead> <tr> <th>Level</th> <th>Percentage</th> </tr> </thead> <tbody> <tr> <td>Level 1</td> <td>2%</td> </tr> <tr> <td>Level 2</td> <td>18%</td> </tr> <tr> <td>Level 3</td> <td>34%</td> </tr> <tr> <td>Level 4</td> <td>38%</td> </tr> <tr> <td>Level 5</td> <td>8%</td> </tr> </tbody> </table>	Level	Percentage	Level 1	2%	Level 2	18%	Level 3	34%	Level 4	38%	Level 5	8%
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Level 1	2%												
Level 2	18%												
Level 3	34%												
Level 4	38%												
Level 5	8%												
(2) The duration and frequency of surveillance audits are appropriate for the size and complexity of the organization (see Clause 5 of IAF MD5 [8]).	<p><b>Surveillance frequency and duration</b></p> <table border="1"> <thead> <tr> <th>Level</th> <th>Percentage</th> </tr> </thead> <tbody> <tr> <td>Level 1</td> <td>2%</td> </tr> <tr> <td>Level 2</td> <td>9%</td> </tr> <tr> <td>Level 3</td> <td>26%</td> </tr> <tr> <td>Level 4</td> <td>50%</td> </tr> <tr> <td>Level 5</td> <td>13%</td> </tr> </tbody> </table>	Level	Percentage	Level 1	2%	Level 2	9%	Level 3	26%	Level 4	50%	Level 5	13%
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Level 1	2%												
Level 2	9%												
Level 3	26%												
Level 4	50%												
Level 5	13%												
(3) The scope mentioned on the organization's certificate accurately describes its activities and is not misleading.	<p><b>Certification scope</b></p> <table border="1"> <thead> <tr> <th>Level</th> <th>Percentage</th> </tr> </thead> <tbody> <tr> <td>Level 1</td> <td>1%</td> </tr> <tr> <td>Level 2</td> <td>1%</td> </tr> <tr> <td>Level 3</td> <td>22%</td> </tr> <tr> <td>Level 4</td> <td>63%</td> </tr> <tr> <td>Level 5</td> <td>13%</td> </tr> </tbody> </table>	Level	Percentage	Level 1	1%	Level 2	1%	Level 3	22%	Level 4	63%	Level 5	13%
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Level 4	63%												
Level 5	13%												
(4) All exclusions are adequately justified.	<p><b>Exclusions</b></p> <table border="1"> <thead> <tr> <th>Level</th> <th>Percentage</th> </tr> </thead> <tbody> <tr> <td>Level 1</td> <td>2%</td> </tr> <tr> <td>Level 2</td> <td>2%</td> </tr> <tr> <td>Level 3</td> <td>26%</td> </tr> <tr> <td>Level 4</td> <td>59%</td> </tr> <tr> <td>Level 5</td> <td>11%</td> </tr> </tbody> </table>	Level	Percentage	Level 1	2%	Level 2	2%	Level 3	26%	Level 4	59%	Level 5	11%
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Level 4	59%												
Level 5	11%												
(5) There is evidence of top management's involvement with and commitment to the implementation of ISO 9001.	<p><b>Top management commitment</b></p> <table border="1"> <thead> <tr> <th>Level</th> <th>Percentage</th> </tr> </thead> <tbody> <tr> <td>Level 1</td> <td>0%</td> </tr> <tr> <td>Level 2</td> <td>8%</td> </tr> <tr> <td>Level 3</td> <td>31%</td> </tr> <tr> <td>Level 4</td> <td>50%</td> </tr> <tr> <td>Level 5</td> <td>11%</td> </tr> </tbody> </table>	Level	Percentage	Level 1	0%	Level 2	8%	Level 3	31%	Level 4	50%	Level 5	11%
Level	Percentage												
Level 1	0%												
Level 2	8%												
Level 3	31%												
Level 4	50%												
Level 5	11%												
(6) Internal communication is good, and employees are aware of their roles in the QMS.	<p><b>Internal communication</b></p> <table border="1"> <thead> <tr> <th>Level</th> <th>Percentage</th> </tr> </thead> <tbody> <tr> <td>Level 1</td> <td>0%</td> </tr> <tr> <td>Level 2</td> <td>9%</td> </tr> <tr> <td>Level 3</td> <td>42%</td> </tr> <tr> <td>Level 4</td> <td>45%</td> </tr> <tr> <td>Level 5</td> <td>4%</td> </tr> </tbody> </table>	Level	Percentage	Level 1	0%	Level 2	9%	Level 3	42%	Level 4	45%	Level 5	4%
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**Check-list question****Overall grades (561 organizations)**

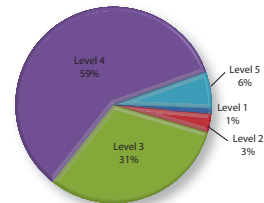
- (7) The “process approach” is clearly understood and implemented throughout the organization.

**Process approach**

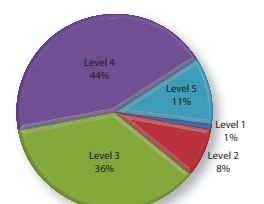
- (8) The organization is managing its QMS processes using a “Plan-Do-Check-Act”-type approach (ISO 9001 Clause 4.1).

**Use of PDCA**

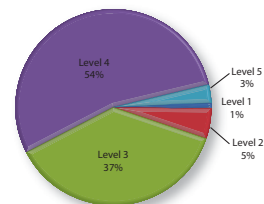
- (9) The quality policy is appropriate for the organization’s situation and culture.

**Quality policy**

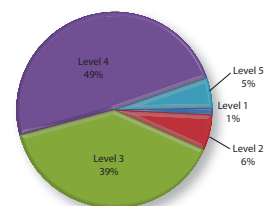
- (10) The organization has established and deployed meaningful objectives at relevant functions and levels.

**Quality objectives**

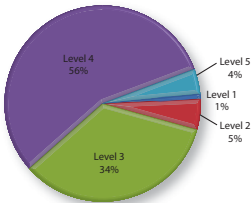
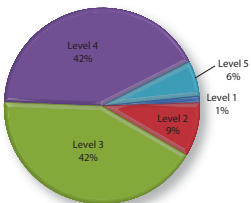
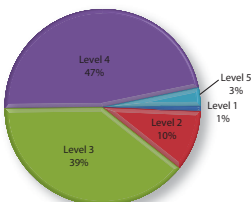
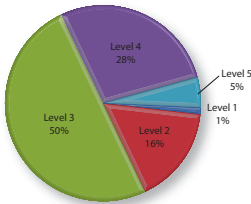
- (11) The quality manual is a good representation of the way the organization actually works.

**Quality manual**

- (12) QMS documentation is being used and is properly controlled.

**Objectives**

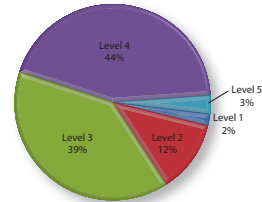
**Key:** 1 “Little or no confidence”; 2 “Some evidence presented, but not at all convincing”; 3 “OK — No reason to doubt that this is being addressed correctly”; 4 “Clear evidence that the intent of ISO 9001 is being met”; 5 “We can be proud to use this organization as a benchmark”.

Check-list question	Overall grades (561 organizations)												
(13) The organization has adequate resources (competent personnel, equipment, etc.) to support its system.	<p><b>Resources</b></p>  <table border="1"> <thead> <tr> <th>Level</th> <th>Percentage</th> </tr> </thead> <tbody> <tr> <td>Level 1</td> <td>1%</td> </tr> <tr> <td>Level 2</td> <td>5%</td> </tr> <tr> <td>Level 3</td> <td>34%</td> </tr> <tr> <td>Level 4</td> <td>56%</td> </tr> <tr> <td>Level 5</td> <td>4%</td> </tr> </tbody> </table>	Level	Percentage	Level 1	1%	Level 2	5%	Level 3	34%	Level 4	56%	Level 5	4%
Level	Percentage												
Level 1	1%												
Level 2	5%												
Level 3	34%												
Level 4	56%												
Level 5	4%												
(14) The work environment is appropriate.	<p><b>Work environment</b></p>  <table border="1"> <thead> <tr> <th>Level</th> <th>Percentage</th> </tr> </thead> <tbody> <tr> <td>Level 1</td> <td>1%</td> </tr> <tr> <td>Level 2</td> <td>9%</td> </tr> <tr> <td>Level 3</td> <td>42%</td> </tr> <tr> <td>Level 4</td> <td>42%</td> </tr> <tr> <td>Level 5</td> <td>6%</td> </tr> </tbody> </table>	Level	Percentage	Level 1	1%	Level 2	9%	Level 3	42%	Level 4	42%	Level 5	6%
Level	Percentage												
Level 1	1%												
Level 2	9%												
Level 3	42%												
Level 4	42%												
Level 5	6%												
(15) Key product realization processes are identified and managed.	<p><b>Product realization processes</b></p>  <table border="1"> <thead> <tr> <th>Level</th> <th>Percentage</th> </tr> </thead> <tbody> <tr> <td>Level 1</td> <td>1%</td> </tr> <tr> <td>Level 2</td> <td>4%</td> </tr> <tr> <td>Level 3</td> <td>37%</td> </tr> <tr> <td>Level 4</td> <td>54%</td> </tr> <tr> <td>Level 5</td> <td>4%</td> </tr> </tbody> </table>	Level	Percentage	Level 1	1%	Level 2	4%	Level 3	37%	Level 4	54%	Level 5	4%
Level	Percentage												
Level 1	1%												
Level 2	4%												
Level 3	37%												
Level 4	54%												
Level 5	4%												
(16) Processes are being adequately monitored and measured.	<p><b>Process monitoring and measurement</b></p>  <table border="1"> <thead> <tr> <th>Level</th> <th>Percentage</th> </tr> </thead> <tbody> <tr> <td>Level 1</td> <td>1%</td> </tr> <tr> <td>Level 2</td> <td>5%</td> </tr> <tr> <td>Level 3</td> <td>36%</td> </tr> <tr> <td>Level 4</td> <td>54%</td> </tr> <tr> <td>Level 5</td> <td>4%</td> </tr> </tbody> </table>	Level	Percentage	Level 1	1%	Level 2	5%	Level 3	36%	Level 4	54%	Level 5	4%
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Level 2	5%												
Level 3	36%												
Level 4	54%												
Level 5	4%												
(17) Product nonconformities are identified and dealt with according to documented procedures.	<p><b>Product nonconformities</b></p>  <table border="1"> <thead> <tr> <th>Level</th> <th>Percentage</th> </tr> </thead> <tbody> <tr> <td>Level 1</td> <td>1%</td> </tr> <tr> <td>Level 2</td> <td>10%</td> </tr> <tr> <td>Level 3</td> <td>39%</td> </tr> <tr> <td>Level 4</td> <td>47%</td> </tr> <tr> <td>Level 5</td> <td>3%</td> </tr> </tbody> </table>	Level	Percentage	Level 1	1%	Level 2	10%	Level 3	39%	Level 4	47%	Level 5	3%
Level	Percentage												
Level 1	1%												
Level 2	10%												
Level 3	39%												
Level 4	47%												
Level 5	3%												
(18) There is a focus on identifying the cause of process, product and system nonconformities, and on implementing effective corrective action.	<p><b>Cause analysis/corrective action</b></p>  <table border="1"> <thead> <tr> <th>Level</th> <th>Percentage</th> </tr> </thead> <tbody> <tr> <td>Level 1</td> <td>1%</td> </tr> <tr> <td>Level 2</td> <td>16%</td> </tr> <tr> <td>Level 3</td> <td>50%</td> </tr> <tr> <td>Level 4</td> <td>28%</td> </tr> <tr> <td>Level 5</td> <td>5%</td> </tr> </tbody> </table>	Level	Percentage	Level 1	1%	Level 2	16%	Level 3	50%	Level 4	28%	Level 5	5%
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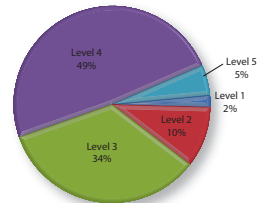


**Check-list question****Overall grades (561 organizations)**

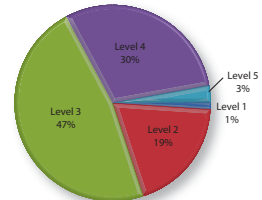
- (19) Internal audits are being carried out according to plan and are effective.

**Internal audits**

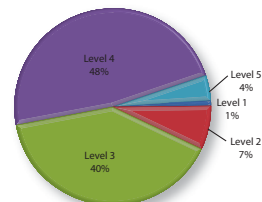
- (20) Management reviews are being carried out according to plan and are effective.

**Management review**

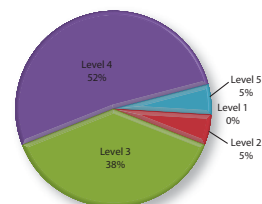
- (21) The organization has a focus on preventing nonconformities.

**Preventive action**

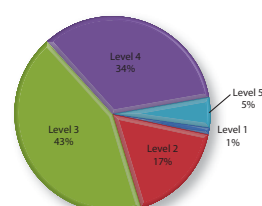
- (22) Customer feedback and customer complaints handling mechanisms are appropriate.

**Customer feedback/complaints**

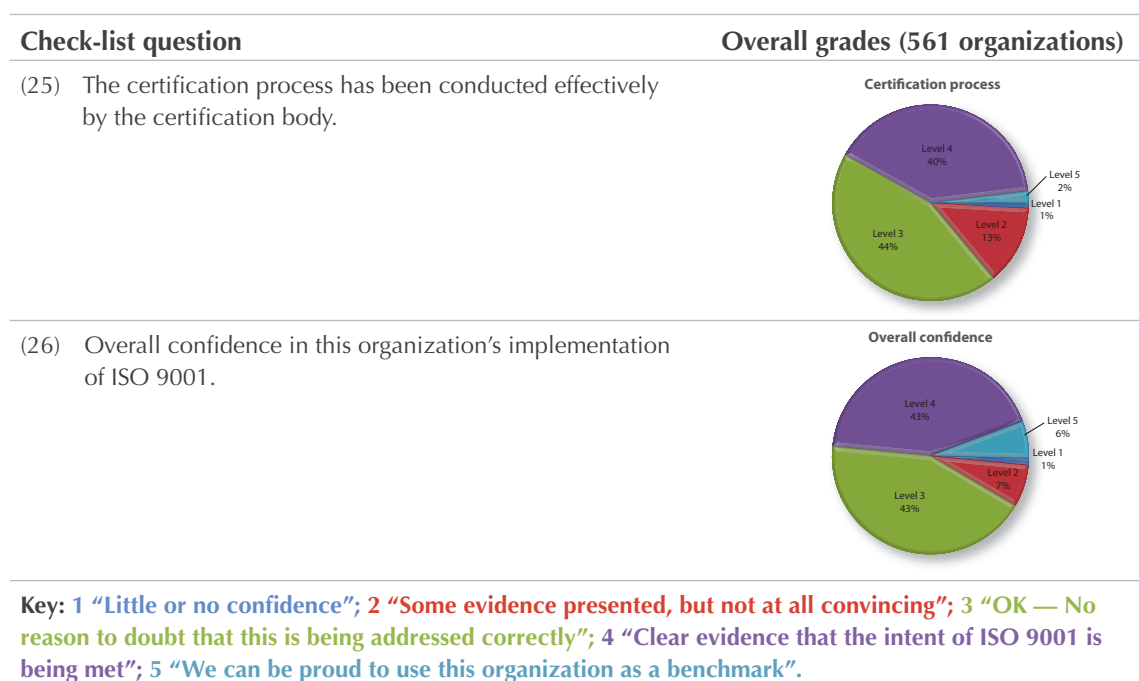
- (23) The QMS is providing confidence in the organization's ability to "consistently provide product that meets customer and applicable statutory and regulatory requirements".

**Ability to provide conforming product**

- (24) The organization has a culture of continual improvement of the effectiveness of its QMS.

**Continual improvement**

**Key:** 1 "Little or no confidence"; 2 "Some evidence presented, but not at all convincing"; 3 "OK — No reason to doubt that this is being addressed correctly"; 4 "Clear evidence that the intent of ISO 9001 is being met"; 5 "We can be proud to use this organization as a benchmark".



## Weak areas

The weakest areas of implementation that were identified during the visits were:

- Lack of focus on preventive action (Item 21 of the checklist);
- Poor use of the "Plan-Do-Check-Act" approach (ISO 9001 Clause 4.1) to manage the quality management system processes (Item 8 of the checklist);
- Poor culture of continual improvement (Item 24 of the checklist);
- Lack of adequate cause analysis and effective corrective action for process, product and system nonconformities (Item 18 of the checklist);
- Little use of the "process approach" throughout the organization (Item 7 of the checklist).

Interestingly, no major concerns were identified in the customer complaints handling process, considering that this had been identified as one of the main criticisms made by institutional purchasers about their ISO 9001-certified suppliers.

## Correlation between the system performance and the length of time the organization had been certified

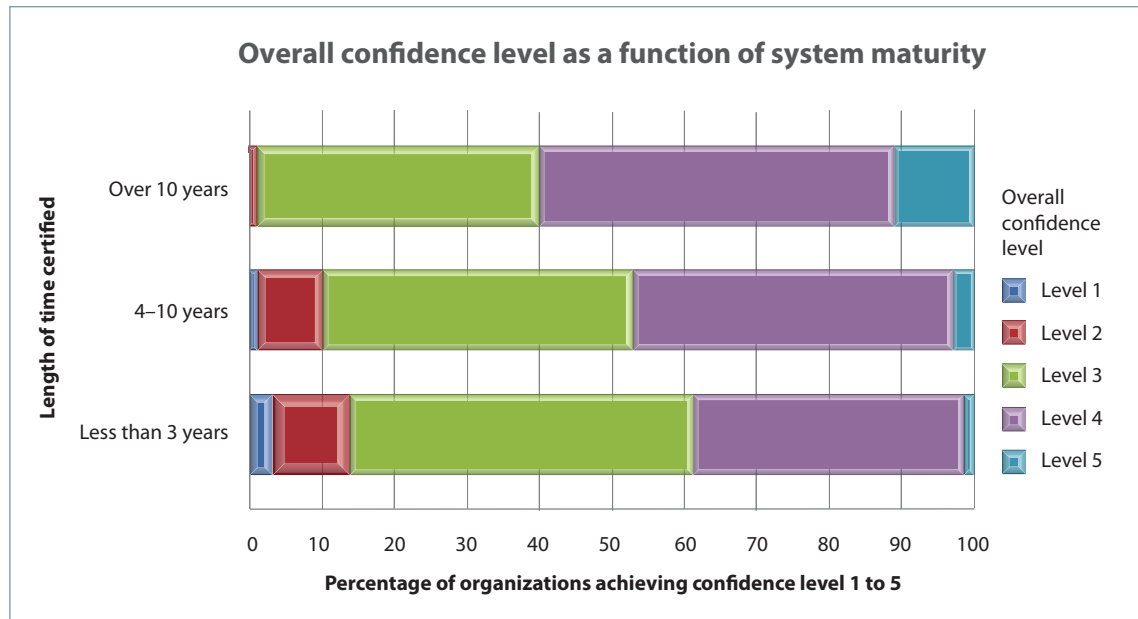
As might be expected, improved levels of confidence in the overall performance of certified organizations were observed as a function of the length of time certified and the maturity of the quality management system. This can be seen in figure 42.

## Correlation between the system performance and the time taken to implement the system

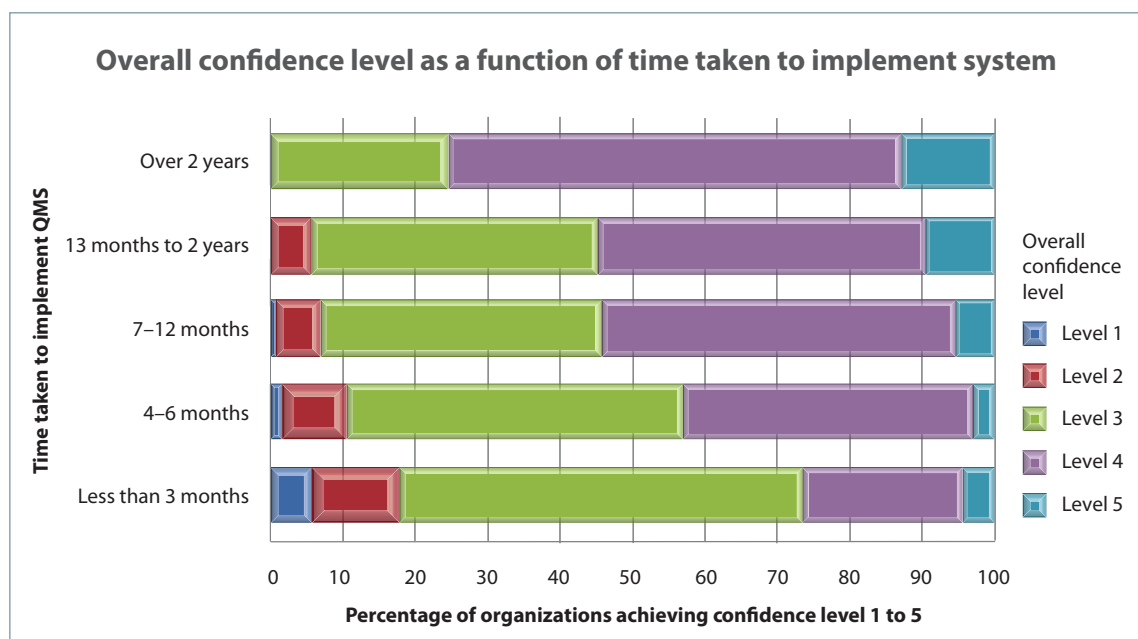
Figure 43 shows that organizations claiming to have implemented their quality management system and achieved certification in less than 6 months had a tendency not to perform as well on the overall

confidence score as organizations that had taken longer to implement the system (regardless of the length of time they had been certified). The latter also achieved a higher percentage of “Grade 5” scores, indicating an excellent (“benchmark”) level of confidence, than did the ones who had achieved certification in a short length of time.

**Figure 42. Overall levels of confidence in the quality management system as a function of the length of time the organization had been certified (based on the visits to 561 certified organizations)**



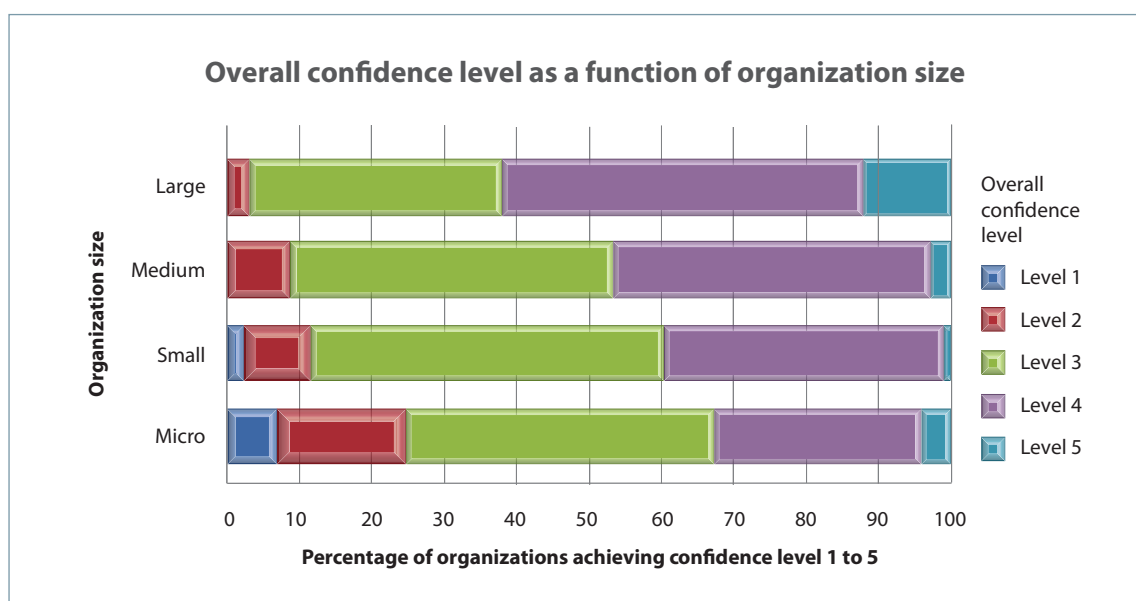
**Figure 43. Overall levels of confidence as a function of the length of time taken by the organization from the decision to implement a QMS until the achievement of certification (based on the visits to 561 certified organizations)**



### Correlation between the system performance and the size of the organization

Figure 44 confirms anecdotal evidence that suggests that small organizations (who also tended to implement their systems quickly) demonstrated a lower overall level of confidence than larger organizations. This can also be explained by the fact that larger organizations usually have more resources available for the implementation of their quality management system.

**Figure 44.** Overall levels of confidence as a function of the organization size (based on the visits to 561 certified organizations). “Micro” is less than 10 employees; “small” is 11 to 50 employees; “medium” is 51 to 250 employees, and “large” is over 250 employees (See, for example, European Commission Recommendation 2003/361/EC[18])



## Performance of the accreditation bodies

### Requirements for IAF membership

In order to be recognized under the IAF MLA, accreditation body members of the IAF are required to comply with the requirements of ISO/IEC 17011:2004 “Conformity assessment — General requirements for accreditation bodies accrediting conformity assessment bodies”[10] as well as a series of IAF mandatory documents for the consistent application of that standard. The objective is to ensure that all accredited certification bodies are meeting the requirements defined in ISO/IEC 17021, and that the levels of confidence in organizations holding ISO 9001 certificates issued by certification bodies accredited by different IAF accreditation body members are comparable, thereby facilitating world trade.

There are, however, situations where certification bodies will seek more than one accreditation, or a “foreign” accreditation, and it is the certification body’s right to do so. Nevertheless, IAF strongly encourages certification bodies to have local country accreditation whenever it is available. In many of the Asian developing economies, there is a strong presence of certification bodies accredited by

“foreign” accreditation bodies, due in some cases to the non-existence or relatively recent establishment of the local accreditation body, the perception that “foreign accreditation is more prestigious”, or the fact that some multinational certification bodies (quite legitimately) operate all their branches globally under a single accreditation, normally issued in their home country.

The IAF Guidance Document GD3 [24] (“Guidance on Cross-Frontier Accreditation”), which, in spite of its title, was deemed a mandatory document at the time of publication, is aimed at ensuring transparency and collaboration between accreditation bodies operating in any given country.

Clause 2.1.1 of IAF GD3 states that:

“IAF MLA signatory ABs should record the countries in which each CB accredited by them issues certificates under their accreditation. This includes:

- Countries into which accredited certificates are issued directly from the CB’s head or other office; and
- Countries in which the CB operates from local offices, whatever the legal relationship of such offices with the parent CB.”

### Availability of information from accreditation bodies

During the planning stages of the project, all the IAF accreditation body members were contacted and requested to provide details of their accredited certification bodies who operated in the Asian economies within the project scope. Of the 56 accreditation body members of the IAF, only 24 responded formally. Whilst some members who did not respond were unlikely to have accredited certification bodies operating in this region (for example, South American accreditation bodies), that was not the case for some European accreditation bodies who failed to respond, even after follow-up requests.

The level of detail provided by the accreditation bodies also varied significantly:

- Some accreditation bodies maintained on-line databases of all certificates (with details of the respective certification bodies) that are under their accreditation. This transparency is to be applauded and goes beyond what is required by IAF GD3.
- Some accreditation bodies were able to provide details of the countries in which their accredited certification bodies are operating (within the spirit of IAF GD3).
- One large accreditation body responded that they did not have data readily available.
- One accreditation body with a significant presence in Asia referred us to its website to collate these data ourselves but with the warning that “it’s probably out of date”.

There was also a considerable variation in the willingness of certification bodies accredited by different accreditation bodies to provide the information required by ISO 17021 Clause 8.3 (see later), and in the level of support from their respective accreditation bodies to require or encourage them to do so. This is reflected in the following data for three of the international accreditation bodies (ABs) with a major presence in the Asian developing economies.

- AB1 — Provided all the data required by Clause 8.3 on its publicly-accessible website.

- AB2 — Prompted all its accredited certification bodies to provide the data requested, and after much follow-up by the AB over a period of 6 weeks, 100% of its certification bodies provided the information.
- AB3 — Less than half of the accredited certification bodies provided the information within two months of the request, despite numerous contacts and follow-ups.

These variations confirm the anecdotal evidence that the requirements of IAF GD3 are still not fully embraced or implemented by the IAF's accreditation body members; this needs to be addressed by the IAF.

### Overall performance of organizations certified under different accreditations

Figures 45 and 46 show the overall confidence levels of the quality management system ranked according to the different accreditation bodies that had accredited the organizations' certification bodies. In cases where the certification body in question held two or more accreditations, both (or all) those accreditation bodies were included in the analysis.

Figure 45 sorts the accreditation bodies in order of the percentage of the organizations exhibiting "poor" performance (confidence levels 1 + 2), ranging from best to worst, whilst Figure 46 provides the same data, sorted in order of the percentage of organizations exhibiting "good" performance (confidence levels 4 + 5), again ranging from the best to worst.

*Note:* Only accreditation bodies (ABs) with 15 or more certified organizations visited were included in this analysis.

**Figure 45. Overall confidence levels as a function of AB in order of the percentage of the organizations exhibiting "poor" performance (confidence levels 1 + 2), ranging from best to worst (based on the visits to 561 certified organizations)**

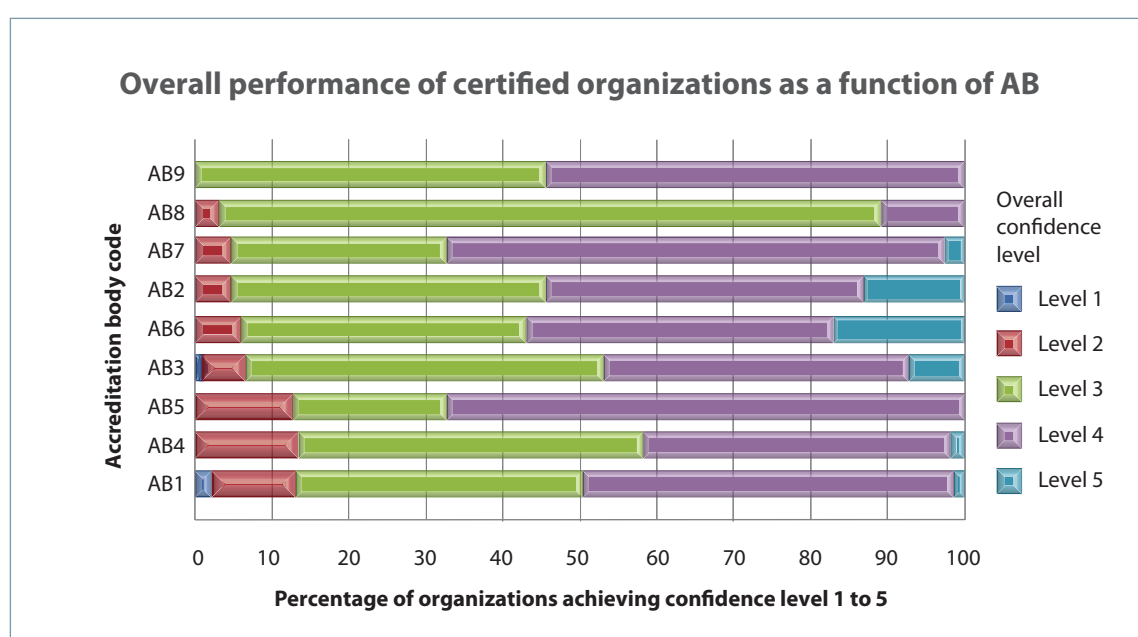
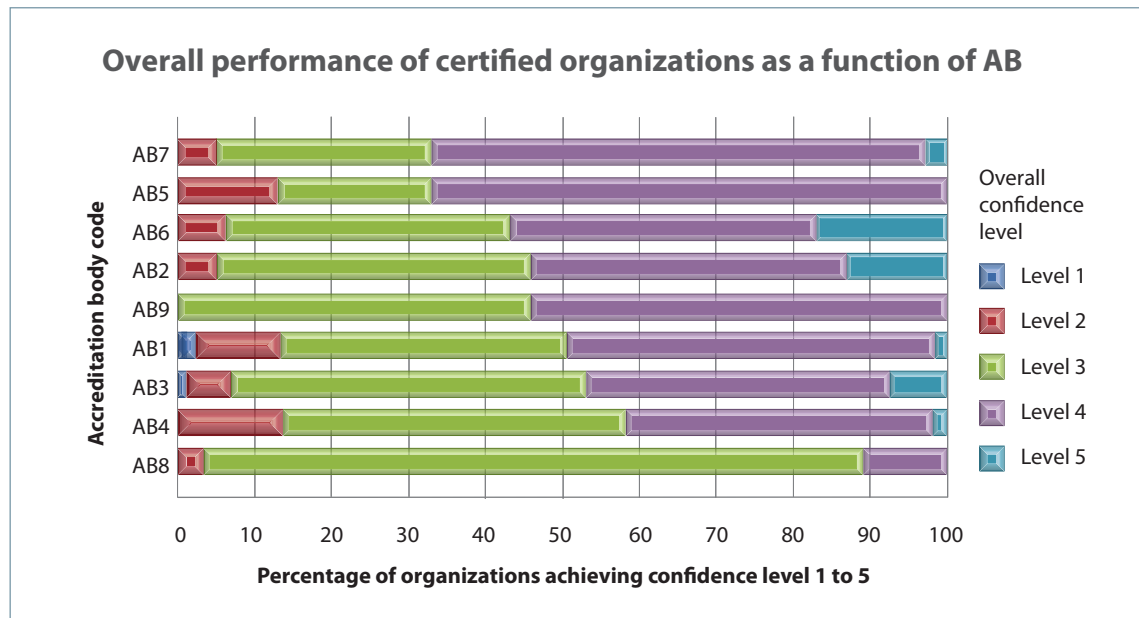


Figure 46. Overall confidence levels as a function of AB in order of the percentage of the organizations exhibiting “good” performance (confidence levels 4 + 5), again ranging from the best to worst (based on the visits to 561 certified organizations)



It is clear that there are variations in performance of organizations that have been certified by certification bodies operating under different accreditations. Codes have been used to preserve the anonymity of the accreditation bodies, but all the accreditation bodies mentioned have been informed of their individual codes, and it is expected that each analyse their own performance and take the appropriate actions.

## Performance of the certification bodies

### Requirements for accreditation

In order to be accredited, certification bodies have to meet the requirements of ISO/IEC 17021:2006[2] (“Conformity assessment — Requirements for bodies providing audit and certification of management systems”), which is based on six core principles — impartiality, competence, responsibility, openness, confidentiality, and responsiveness to complaints — as well as a series of IAF mandatory documents for the consistent application of that standard. The objective is to ensure that the organizations being certified by accredited certification bodies are meeting the requirements of ISO 9001 and achieving the expected outcomes of that standard. These expected outcomes are explained in detail in the Joint ISO/IAF Communiqué “Expected outcomes for accredited certification to ISO 9001”[11] and essentially focus on the certified organization’s ability to “consistently provide product that meets customer and applicable statutory and regulatory requirements”.

It is worth quoting verbatim from ISO/IEC 17021:2006 on the principles on which the credibility of certification depends, and particularly that of “openness”, which was found to be lacking in many cases during this project. (*Note: **bold** has been added for emphasis.*)

#### *“4 Principles*

##### *4.1 General*

*4.1.1 These principles are the basis for the subsequent specific performance and descriptive requirements in this International Standard. This International Standard does not give specific requirements for all situations that can occur. These principles should be applied as guidance for the decisions that may need to be made for unanticipated situations. Principles are not requirements.*

*4.1.2 The overall aim of certification is to give confidence to all parties that a management system fulfils specified requirements. **The value of certification is the degree of public confidence and trust** that is established by an impartial and competent assessment by a third-party. Parties that have an interest in certification include, but are not limited to*

- (a) the clients of the certification bodies,*
- (b) the customers of the organizations whose management systems are certified,*
- (c) governmental authorities,*
- (d) non-governmental organizations, and*
- (e) consumers and other members of the public.*

##### *4.1.3 Principles for inspiring confidence include*

- impartiality,*
- competence,*
- responsibility,*
- openness,*
- confidentiality, and*
- responsiveness to complaints ...*

##### *4.5 Openness*

*4.5.1 A certification body needs to provide public access to, or disclosure of, appropriate and timely information about its audit process and certification process, and about the certification status (i.e. the granting, extending, maintaining, renewing, suspending, reducing the scope of, or withdrawing of certification) of any organization, in order to gain confidence in the integrity and credibility of certification. Openness is a principle of access to, or disclosure of, appropriate information...”*

Clause 8.3 of ISO/IEC 17021:2006 specifically requires certification bodies to maintain a directory of valid certifications, as shown below.

##### *“8.3 Directory of certified clients*

***The certification body shall maintain and make publicly accessible, or provide upon request,** by any means it chooses, **a directory of valid certifications** that as a minimum shall show the name, relevant normative document, scope and geographical location (e.g. city and country) for each certified client (or the geographic location of the headquarters and any sites within the scope of a multi-site certification).*

*Note: The directory remains the sole property of the certification body”*



### Availability of information from certification bodies

Overall, out of a total of 153 certification bodies contacted, 57 (37%) either would not or could not provide information about their certified clients (the information requested was no more than that mentioned in ISO/IEC 17021:2006 Clause 8.3). A variety of reasons were given by certification bodies for not providing the information requested in a timely manner, and a number of very disappointing and disturbing incidents occurred:

- Some local branches and franchisees of overseas certification bodies alleged that this information is strictly confidential and aggressively declined to provide any details of their certified clients.
- Some local branches and franchisees of overseas certification bodies responded by saying, “the information is only available in hard copy at our overseas corporate headquarters”.
- Three international certification bodies agreed to provide the information requested but subject to a confidentiality agreement. It is important to note, however, that according to ISO/IEC 17021 Clause 8.3, this is information that is supposed to be “publicly-accessible, or available on request”.
- One certification body agreed to show their database of certified clients in the relevant countries but would only provide the information requested for a sample of these, which were selected during a visit to their corporate headquarters.
- Several certification bodies simply refused to provide the information, alleging that ISO/IEC 17021 does not require them to provide this information, and their accreditation body (“AB3”) was not willing or able to enforce this.

It is vital to the credibility of the accredited certification process that these inconsistencies be analysed by both the IAF and ISO/CASCO and a common interpretation and application of the requirements of ISO/IEC 17021:2006 Clause 8.3 be agreed upon and effectively implemented by all.

It is also important to recognize that the main concerns expressed by certification bodies about providing the requested information were related to commercial sensitivities, and that, by making information available, other certification bodies might try to “poach” their clients. Regardless of the implications in terms of ISO/IEC 17021 Clause 8.3, this reaction was disappointing and serves to highlight the fact that certification has become a very competitive business.

These concerns were subsequently discussed within the IAF, and a formal decision was made during the March 2011 IAF Technical Committee meeting that “Accreditation Bodies members must ensure that their accredited Certification Bodies comply with the requirements of ISO/IEC 17021:2006/2011 Clause 8.3. Accredited Certification Bodies must be able to demonstrate to their Accreditation Body(s) how they have chosen to make this information accessible or available on request, keeping in mind the IAF Technical Committee decision 08/03/03 that providing only a means to confirm the validity of a given certification does not conform to the requirement of clause 8.3.”

This lack of willingness of some overseas certification bodies to provide the information requested is the main reason why the results of this project have to be interpreted with caution, since it was not possible to include clients of these certification bodies within the sample of certified organizations that were chosen to be visited. Overall, a total of 57 certification bodies (including 25 foreign

certification bodies accredited by AB3) did not provide the information requested. Since the total number of certificates issued by these certification bodies in the region is not documented, the effects of excluding them from the survey are unknown and unknowable, but undoubtedly will have skewed the results to some extent towards a more favourable conclusion than a truly “random” sample. It may also reinforce the perceptions that were expressed by some participants during the initial workshops that the operation of a number of franchisees and branches of foreign certification bodies is not as transparent as it should be and is inconsistent with the overall principle of “openness” on which the credibility of certification is based. This is unfortunate because otherwise the results of the survey have shown the outcomes of accredited certification in a very positive light.

Despite the lack of cooperation from these certification bodies, alternative methods to collect information about ISO 9001-certified organizations were explored, including information from industry associations, chambers of commerce and general marketing materials. This meant that some organizations certified by “non-collaborative certification bodies” were still selected for visits, though not all agreed to be visited.

At the time of preparation of this report, one proposal that is currently being discussed within ISO and the IAF envisages the development of a single, international database of certified organizations, and the experiences of the current project would certainly endorse the need for such a database. During the local feedback workshops, it also became apparent that such a database would serve as a strong deterrent to those issuing fraudulent certificates since it would provide an easy, transparent mechanism to verify the authenticity of any certificates presented.

### Overall performance of organizations certified by different certification bodies

Figures 47 and 48 show the variations in the overall confidence levels in the quality management system for organizations certified by different certification bodies.

Figure 47 shows the results for certification bodies where the number of certified clients visited ranged from 5 to 20, and figure 48 the results for certification bodies where the number visited was over 20. Certification bodies with less than 5 clients that were included in the survey were not considered in this analysis but were grouped together under the category “others”.

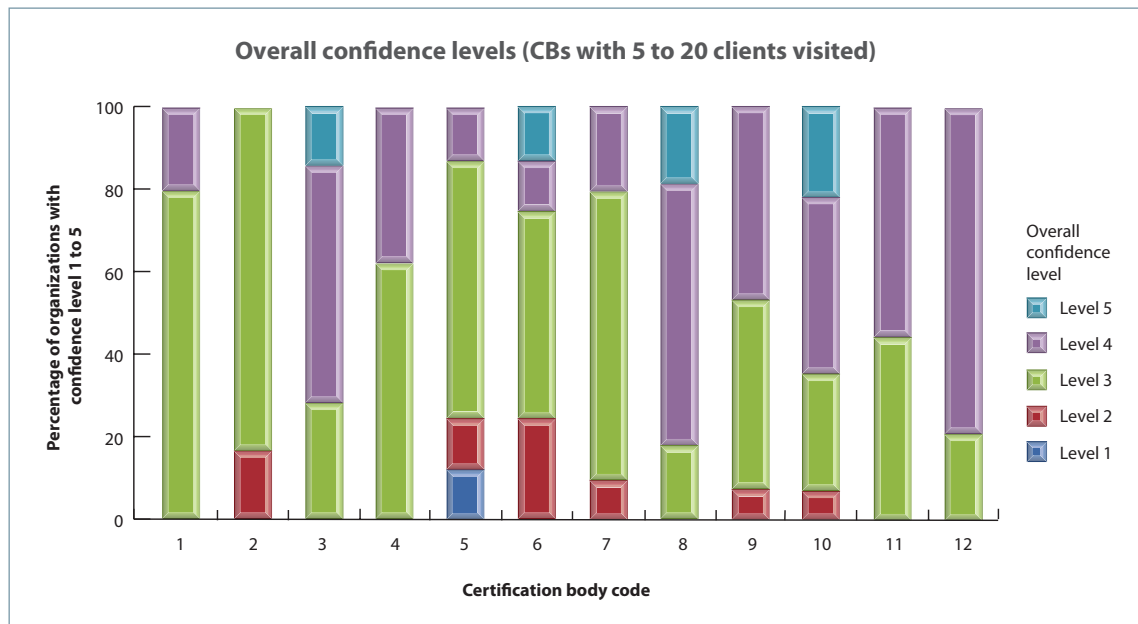
*Note:* Codes have been used to preserve the anonymity of the certification bodies, but individual codes can be provided to certification bodies on request.

It can be seen that there are some variations in performance, but the following comments should be taken into consideration:

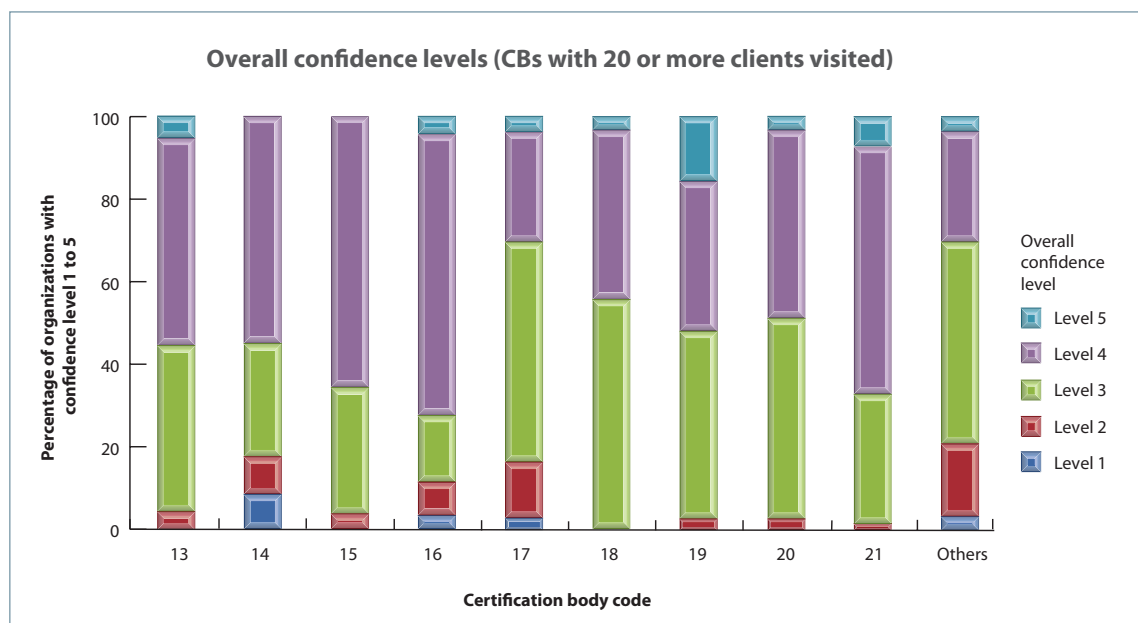
- No attempt has been made to provide a “ranking” of the certification bodies, in view of the fact that there are many variables that affect the overall performance. This analysis, for example, includes certification bodies operating throughout the region, as well as some certification bodies operating in only one specific country.
- It is important to remember that many certification bodies did not provide information about their directory of certified clients in the region, and so were not included in this analysis.
- The number of organizations visited was not necessarily proportional to the overall number of certificates issued by each certification body in the region.

- It is interesting to note that the certification bodies in the category of “others”, representing a total of 56 certification bodies, each with less than 5 certified clients visited during this project (with a total of 113 certified clients visited between them), had among the lowest levels of confidence in the performance of their certified clients. This can be seen in figure 48, where 21.5% of these organizations exhibited an overall confidence level of 1 or 2.

**Figure 47. Variations in the overall confidence levels in the QMS for organizations certified by different certification bodies where the number of certified clients visited was from 5 to 20**



**Figure 48. Variations in the overall confidence levels in the QMS for organizations certified by different certification bodies where the number of certified clients visited was over 20**

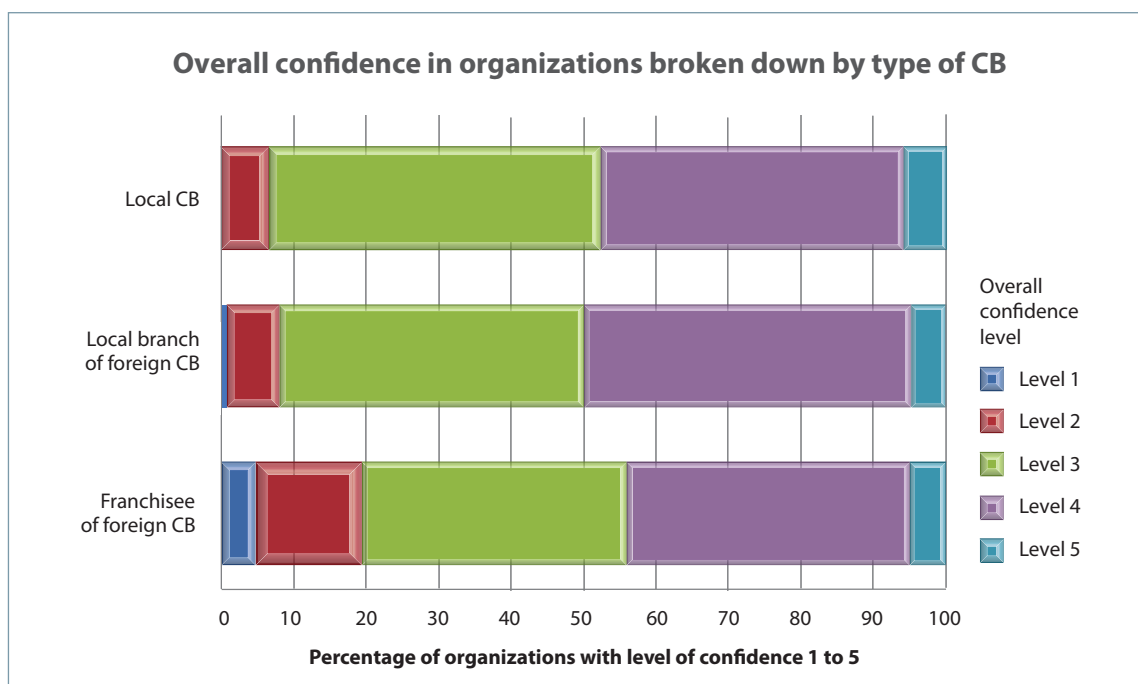


During the March 2011 meeting of the IAF Technical Committee, comments (based on anecdotal evidence) were made to suggest that one key area of concern about the credibility of ISO 9001 certification relates to the operation of “franchisees” (subcontracted bodies who perform audits on behalf of foreign certification bodies). These are usually not considered to be “Foreign Critical Locations” (as defined in IAF GD3 [24]) and are rarely subject to visits by the franchisor’s accreditation body.

By using the data obtained during the present project, it was possible to confirm this tendency. As shown in figure 49, it is clear that, whilst the performance of organizations certified by local certification bodies or by branch offices of foreign certification bodies are similar, the percentage of organizations with low levels of confidence (scores of “1” or “2”) is much higher for organizations certified under “franchising” arrangements.

The IAF is currently initiating a project to investigate these trends further and to take the appropriate actions to address these concerns.

**Figure 49. Performance of organizations certified by “franchised” certification bodies, compared with those certified by local certification bodies or by branch offices of foreign certification bodies (based on the visits to 561 certified organizations)**



## Effectiveness of one-day “market surveillance” visits

One very important outcome of this project was the excellent correlation demonstrated between the results of the one-day visits to certified organizations and the performance of these organizations as perceived by their customers.

The 28 local consultants employed to carry out these visits were unanimous in their conclusion that a one-day visit is more than sufficient to be able to make a judgment about the validity of an

organization's ISO 9001 certification. This could form the basis for a new market surveillance approach to monitoring the effectiveness of accredited certification, in line with the ISO/IAF Strategic Imperative that "Output matters!"[11].

The following considerations are important when analysing the results:

- All the UNIDO consultants had been subjected to intensive (5-day) training courses, which included visits to certified organizations for the purpose of calibration and to ensure that consistent criteria were applied during the subsequent project visits.

After each of the "calibration" visits (carried out in three separate groups of approximately nine participants per group), feedback was provided to the consultants on their own results compared to those of their peers.

It was found that there was an excellent degree of consistency among the consultants' independent marking of the organizations' performance in most of the 26 topics that were included in the check-list.

Any individual tendencies to be excessively rigid or excessively lenient (compared to the instructors' and peers' evaluations) were discussed among the group in order to ensure homogeneous performance during the subsequent one-day visits.

- With reference to the results that are presented in figures 50 and 51, the following observations may be made:

Intuitively, the control sample of "good suppliers" that had been identified by the "knowledgeable purchasing organizations" during the face-to-face interviews can be seen to demonstrate consistently better scores on a wide range of parameters during the one-day visits.

Likewise, the control sample of "bad suppliers" that had been identified by the purchasing organizations had consistently lower scores on a wide range of parameters during the one-day visits.

Statistical analysis on the visit results was carried out by the Institute of Applied Statistics and Quality Management in Lucknow, India, in order to verify the statistical significance of the differences observed between the "good" and "bad" suppliers. Because the visit results are based on attribute (rather than variable) data, parametric inference analysis such as Student's "t-test" was not possible. Non-parametric inference (Mood's Median Test) was considered to be the most appropriate for this kind of study. Although the level of confidence in the results is not as high as for parametric inference analysis, a number of the items of the check-list were found to have statistically significant differences between the "good" and "bad" suppliers. These items are highlighted in boxes in figures 50 and 51.

It is important to note, however, that out of the control sample of "good" and "bad" suppliers selected for the one-day visits, the sample size of "bad suppliers" who agreed to receive a visit was very small (8 organizations) compared to the sample of "good suppliers" (33 organizations). Although the Mood's Median test indicated statistically significant results, the small sample size did not facilitate an extremely robust analysis.

The topics that showed a statistically significant difference should therefore be prioritised in any future applications of this “market surveillance” methodology. These include the following items of the check-list:

*Item 10* — The organization has established and deployed meaningful objectives at relevant functions and levels.

*Item 12* — QMS documentation is being used and is properly controlled.

*Item 13* — The organization has adequate resources (competent personnel, equipment, etc.) to support its system.

*Item 14* — The work environment is appropriate.

*Item 15* — Key product realization processes are identified and managed.

*Item 17* — Product nonconformities are identified and dealt with according to documented procedures.

*Item 19* — Internal audits are being carried out according to plan and are effective.

*Item 21* — The organization has a focus on preventing nonconformities.

*Item 22* — Customer feedback and customer complaints-handling mechanisms are appropriate.

*Item 23* — The QMS is providing confidence in the organization’s ability to “consistently provide product that meets customer and applicable statutory and regulatory requirements”.

*Item 25* — The certification process has been conducted effectively by the certification body.

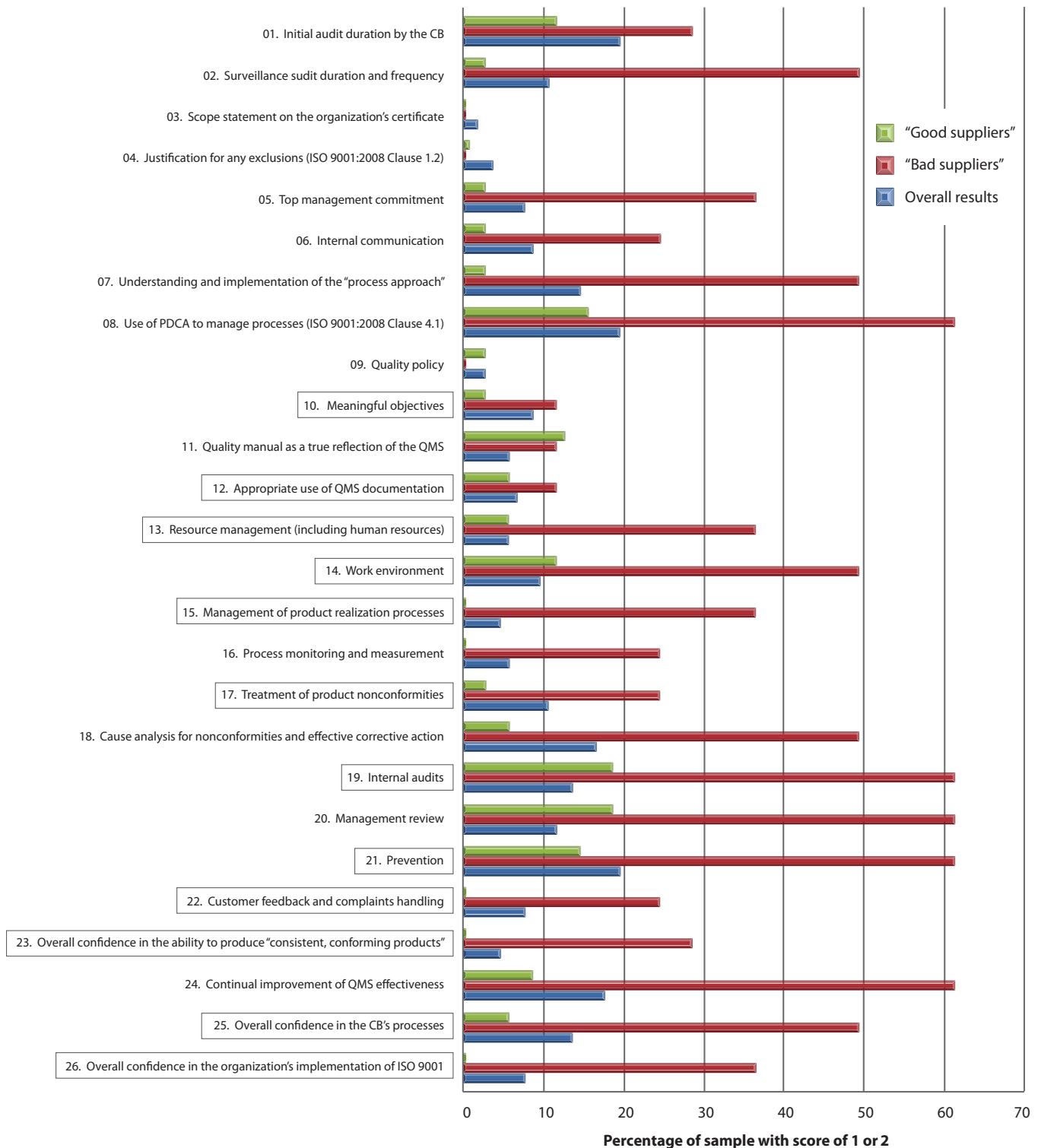
*Item 26* — Overall confidence in this organization’s implementation of ISO 9001.

This result has far-reaching implications and strongly supports the validity of using short “market-surveillance” type visits of this kind to monitor the effective implementation of ISO 9001 in certified organizations and the performance of accredited certification bodies. Although the phrase “market surveillance” is traditionally associated with compulsory product certification, the concept can equally be applied to (voluntary) management system certification by verifying the effectiveness of the accredited certification process through a sampling of the certification body’s “product” (in this case, the level of confidence in a certified organization’s quality management system).

This in turn could lead to a more results-focused approach to accreditation, rewarding those certification bodies whose clients perform well by reducing the intensity of accreditation surveillance (office visits and witness audits), and conversely by increasing the intensity of accreditation surveillance for those certification bodies whose certified clients perform badly. This would be totally consistent with and embrace the concept that “Output matters!”

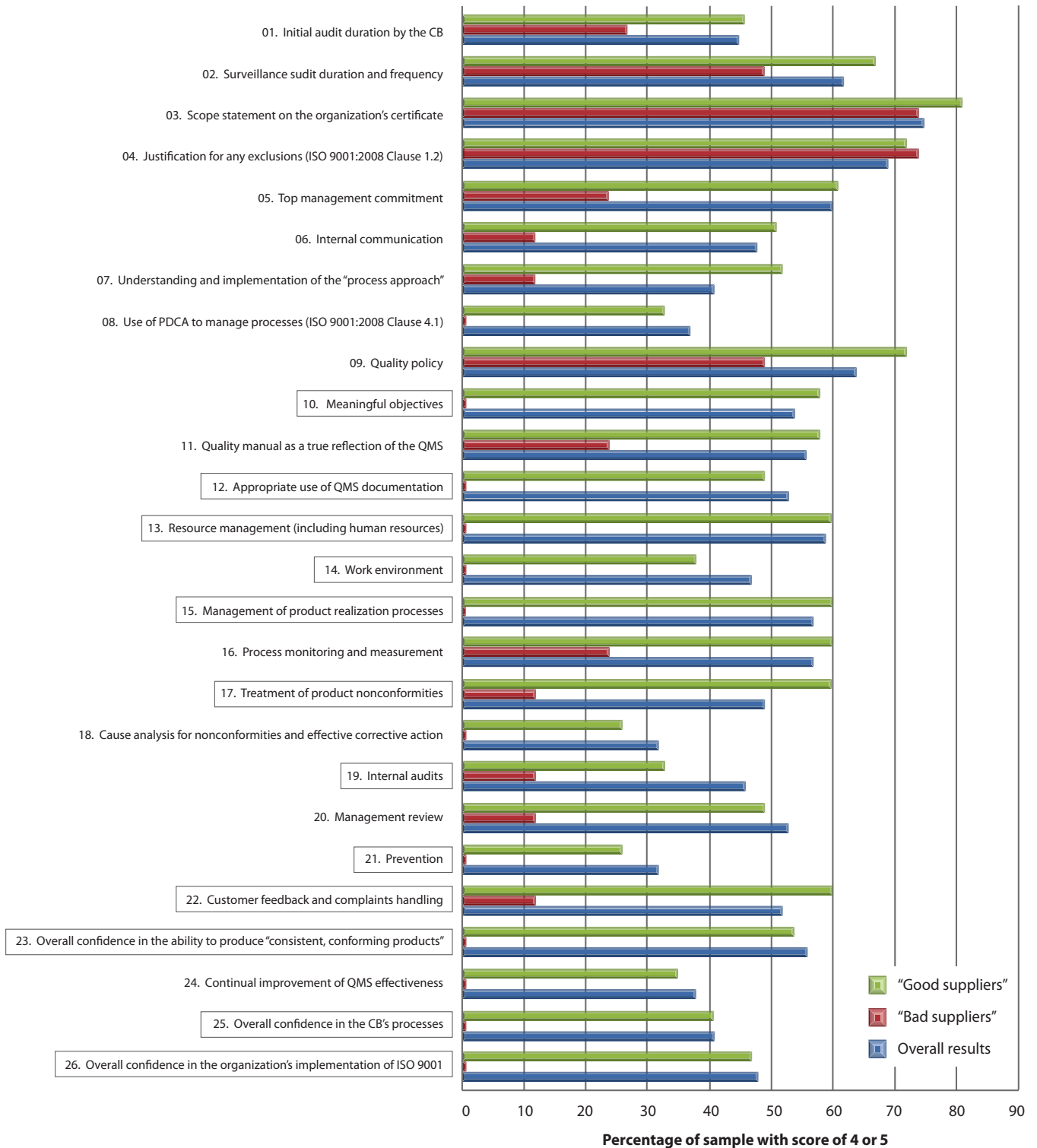
**Figure 50. Comparison between “good” and “bad” suppliers for the 561 one-day visits (low scores)**

**Percentage of “good” and “bad” suppliers with a score of 1 or 2 compared to overall sample**



**Figure 51. Comparison between “good” and “bad” suppliers for the 561 one-day visits (high scores)**

**Percentage of “good” and “bad” suppliers with a score of 4 or 5 compared to overall sample**





It is strongly recommended that ISO, the IAF and other stakeholders define how to implement such a market surveillance programme, in order to further enhance the effectiveness and credibility of accredited certification. It is recognized that this performance-based approach is likely to meet with significant resistance from some of those involved, but this project has clearly demonstrated the validity of such a methodology in identifying sub-standard performance of certified organizations and their certification bodies. Factors that would need to be taken into consideration include:

- Who would be responsible? (ISO and/or the IAF, or some other independent entity (to be defined)?)
- How could such an initiative be financed?
- The contractual implications for accreditation bodies and certification bodies to ensure access to certified clients if these were selected for such market surveillance visits.
- The benefits that certification bodies might derive from such an approach if their certified clients demonstrate good levels of confidence during the market surveillance visits.
- The sanctions (increased accreditation surveillance?) that might be imposed for certification bodies whose certified clients perform badly.

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\* Although the title refers to "Guidance", at the time this document was published (2003) it was mandatory in nature for all IAF MLA members.

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