

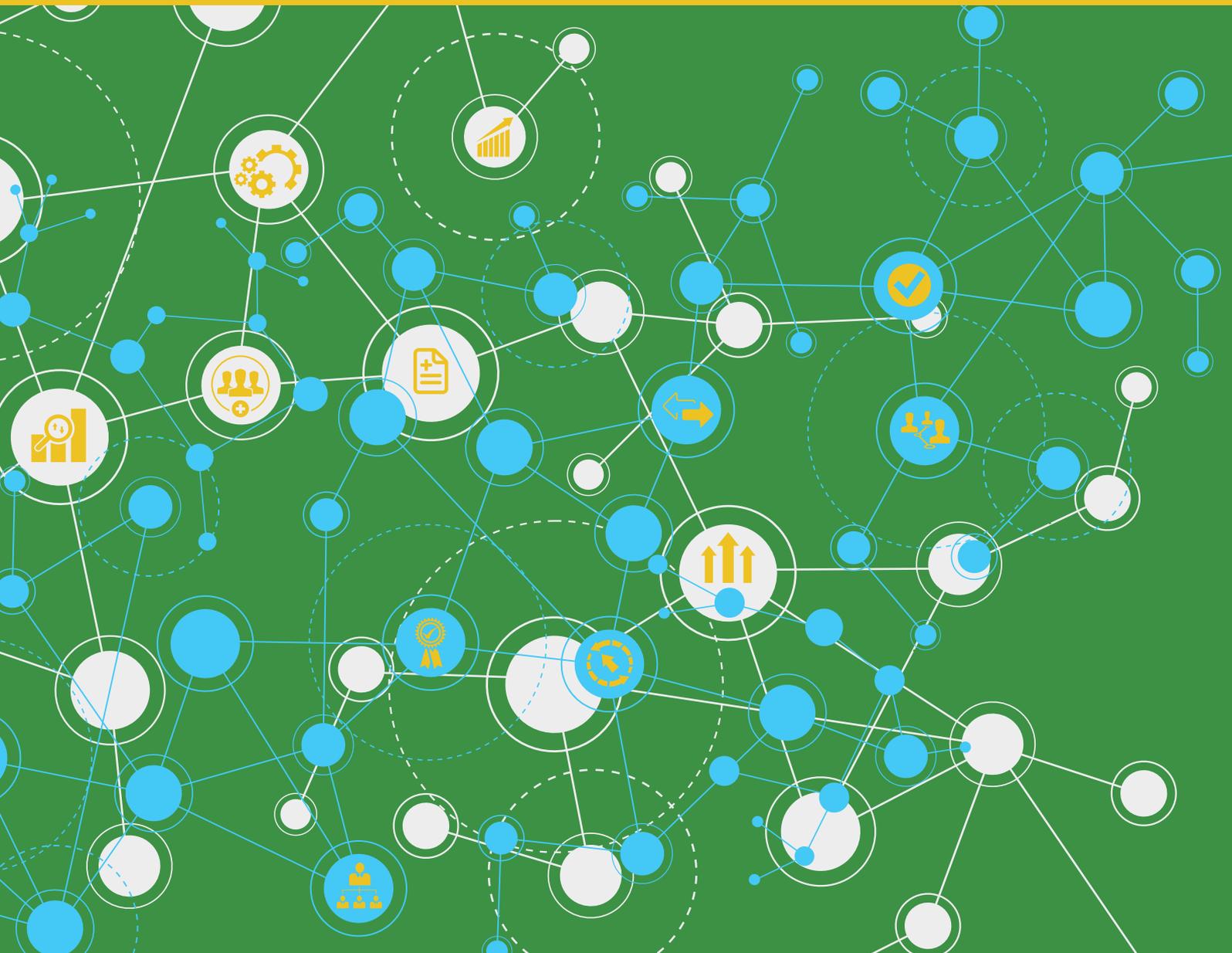


UNITED NATIONS  
INDUSTRIAL DEVELOPMENT ORGANIZATION



# ISO 9001

## Relevance and Impact in Brazil





# ISO 9001

## RELEVANCE AND IMPACT IN BRAZIL





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INDUSTRIAL DEVELOPMENT ORGANIZATION

# Foreword UNIDO



Since their initial publication by the International Organization for Standardization (ISO) in 1987, the ISO 9000 standards have had great impact on international trade and on quality management system implementation by organizations worldwide. In particular, ISO 9001 “Quality management systems – requirements” 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.

Whilst there are numerous certification bodies around the world, there is usually only one government-recognized accreditation body in any given country, such as Cgcre in Brazil, and these bodies work together to 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 providing access to international markets and formal tenders where certification to ISO 9001 is often a pre-requisite. The proper use of ISO 9001-based quality management systems also assists organizations in developing countries to pursue UNIDO’s goal of inclusive and sustainable industrial development (ISID) through the promotion of sustainable international trade.

According to the ISO survey, Brazil has the largest number of ISO 9001 certificates in South America with currently over 18,000 organizations certified by national and international certification bodies from around the world. Around 12,000 of these certificates were issued by certification bodies accredited by Cgcre.

In 2012, UNIDO published the report “ISO 9001 – Its Relevance and Impact in Asian Developing Economies” based on a study of

ISO 9001 implementation in twelve South and South-East Asian countries. This analysis was carried out in close collaboration with ISO and the International Accreditation Forum. As part of the work, a market surveillance methodology was developed and validated in order to evaluate the effectiveness of ISO 9001 certification in manufacturing organizations and the performance of the respective certification and accreditation bodies. This was subsequently applied in China, resulting in the 2015 report “ISO 9001 – Its relevance and Impact in China”.

I very much welcomed the proposal of Inmetro to cooperate with UNIDO in adapting the methodology used in previous projects to obtain a first-hand review on the current status of ISO 9001 certification in Brazil. This has provided valuable insights into how Brazilian purchasers view the effectiveness of their ISO 9001-certified suppliers, and into the perspectives of organizations in Brazil who have implemented a quality management system and opted for certification. We are confident that this analysis will be of use to all interested parties, and will contribute to the overall objective of promoting inclusive and sustainable international trade.

*Li Yong*

Director General



# Foreword INMETRO

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It was with great pleasure that Inmetro has collaborated with UNIDO in this project to assess the impact of ISO 9001 for Quality Management Systems in Brazil. The results of the project have given us a very good picture of the current situation, and have helped to identify various opportunities for management and improvement of the ISO 9001 certification process and the accreditation process for certification bodies.

Inmetro recognizes the importance for Brazil to have ISO 9001-certified organizations with robust and trustworthy quality management systems, in order for them to provide confidence to themselves, their customers, regulatory bodies and consumers that their products and services will meet the requirements of their target markets. ISO 9001 certification is also important from the perspective of facilitating Brazil's role in international trade, which is a key strategic objective for our country.

The global acceptance of certificates only comes as the consequence of a series complex technical activities that not only require the competence of all involved, but the ability to be able to demonstrate that competence. For this reason, accreditation is an essential mechanism in providing global acceptance. Accreditation not only avoids the need to repeat tests, inspections and other assessments of conformity which would otherwise increase costs, but it also provides confidence, national and international recognition with implications for the positive image of certified organizations and their customers' supplier selection processes.

For consumers and end-users, accreditation provides confidence that certified organizations, products and services have undergone a competent and independent assessment of conformity, and can therefore have an influence on their purchasing decisions.

A project of this magnitude helps to strengthen Brazil's image as an important contributor in the identification of best practices for the development of national quality infrastructures, and to leverage the possibilities for "South-South" collaboration among representatives of the Portuguese-speaking developing countries.

*Carlos Augusto de Azevedo*

President



# Foreword ISO

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The International Organization for Standardization (ISO) is an independent, non-governmental, international organization with a membership of 163 national standards bodies. Through its members it brings together experts to share knowledge and develop voluntary, consensus-based, market-relevant International Standards that support innovation and provide solutions to global challenges.

While ISO develops and publishes International Standards, it does not certify to them. Certification is performed by independent, third party certification bodies. However, ISO does play an important role in conformity assessment and certification worldwide, principally by developing standards that set requirements for conducting testing, inspection and auditing in a consistent and competent manner. One of our major standards is ISO/IEC 17021-1 which contains requirements for bodies performing certification to management system standards such as ISO 9001.

The latest ISO Survey shows that over million certificates to ISO 9001 have been issued worldwide, illustrating the global importance of this standard. The growth in certificates in rapidly emerging countries reflects the link between the uptake of standards and economic growth. There is, of course, no obligation to seek certification to an ISO standard, but many companies choose this option to demonstrate to the outside world that they have taken steps to ensure that their products and services consistently meet customers' requirements.

This study provides useful information about the take-up by and benefits for those who have decided to seek an accredited certification of their quality management system based on ISO 9001 in Brazil. We welcome this opportunity to learn more about certification to ISO 9001 in Brazil, specifically how the standard is perceived by certified companies, certification bodies and purchasers using ISO 9001-certified suppliers.

*Kevin McKinley*

Acting Secretary-General



# Foreword IAF



The Chair of IAF at the time this project was initiated was Mr. Randy Dougherty. I participated in a similar project for China some years ago and supported this project in Brazil as Vice Chair of IAF at that time. The IAF Executive Committee studied the results of the project in China and will also make use of the latest results of this project in Brazil. 10 years ago, IAF published a strategic plan with strategic objectives to enhance equivalent accreditation and certification outcomes for stakeholders.

According to the strategic plan, IAF enhanced the communication with industry and end-users for the expectations and outcomes for accredited certifications. IAF and ISO jointly developed concise statements of expected outcomes for accredited certifications to ISO 9001 and ISO 14001, to enhance the value and effectiveness of such certifications.

IAF also developed an informative document for market surveillance visits to certified organizations in 2012. This IAF informative document provides guidance for short market surveillance visits to focus on the output of certifications in order to complement traditional oversight techniques. The methodology for conducting such visits has been developed and validated in UNIDO/ISO/IAF projects for accredited ISO 9001 certification in relevant countries. The project in Brazil provides more results in this respect.

The results of this study in Brazil as well as the project in China 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.

*Xiao Jianhua*

Chair and President

# Acronyms

AB	Accreditation Body
ABENDI	Brazilian Association for Non-destructive Testing and Inspection
ABNT	Brazilian National Standards Body
ABNT/CB-25	ABNT's Quality Committee
ABRAC	Brazilian Association of Conformity Assessment Bodies
CASCO Toolbox	Series of conformity assessment standards issued by ISO/CASCO
CB	Certification Body
Cgcre	Brazilian National Accreditation Body
EGM	Expert Group meeting
EMS	Environmental Management System
EnMS	Energy Management System
IAF	International Accreditation Forum
IEC	International Electrotechnical Commission
Inmetro	Brazilian National Institute for Metrology, Quality and Technology
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
ISO/TC176/SC2	ISO Technical Subcommittee for Quality Systems
MLA	Multi-lateral Recognition Arrangement
MR	Management Representative
NC	Nonconformity
OHSAS	Occupational Health and Safety Assessment Series
OHSMS	Occupational Health and Safety Management System
PBPQ-H	Brazilian Habitational Quality and Productivity Scheme
PDCA	The "Plan-Do-Check-Act" cycle (also referred to as the "Deming Cycle")
QMS	Quality Management System
SBAC	Brazilian System for Conformity Assessment
SDOC	Supplier's Declaration of Conformity
SEBRAE	Brazilian Support Service to Small and Medium Sized Enterprises
SME	Small or medium enterprise
SR	Social Responsibility
TPS	Toyota Production System ("Lean manufacturing")
UNIDO	United Nations Industrial Development Organization

# Acknowledgements

This report is based on UNIDO Project 140107 “Impact assessment of ISO 9001 Quality Management System Certification in Brazil”, co-funded by Inmetro and UNIDO. Funding provided by UNIDO was used to support the technical assistance of the international expert and the adaptation of the previously developed project methodology.

The overall objective of the project was to assess the effectiveness of the ISO 9001 certification process in Brazil from the perspective of certified organizations and their customers, as well as by conducting a number of “market surveillance” visits to a sample of certified organizations. The results will without doubt provide useful information for all interested parties (including certified organizations; their customers; consultants; auditors; auditor training bodies and the national accreditation body) to identify improvement opportunities in the certification process. The project counterparts were:

- Inmetro (National Institute for Metrology, Quality and Technology - Brazil)
- Cgcre (National Accreditation Body - Brazil)
- ABRAC (Association of Brazilian Conformity Assessment Bodies)
- ABNT (National Standards Body - Brazil)
- ABNT/CB-25 (Brazil’s National Quality Committee)
- SEBRAE (Brazilian Support Service to Small and Medium Sized Enterprises).

The project was carried out under the guidance of: Mr. Nigel H. Croft (UNIDO Consultant), Mr. Bernardo Calzadilla- Sarmiento, Mr. Gustavo Aishemberg, Mr. Otto Loesener and Mr. Juan Pablo Diaz-Castillo (UNIDO) and the following experts: Mr. Aldoney Costa Freire, Ms. Sandra Saraiva and Mr. Alexandre S. Cunha (Cgcre), Mr. Jorge Cruz (Inmetro/Caint), Mr. Silvio G Ghelmann and Ms. Raissa V Gomes (Inmetro/Dplan).

A special thank-you must also go to Mr Marco Aurelio Lima, who initially championed the project as the prior Director of Cgcre.

The Steering Committee for the project comprised the following individuals: Mr Aldoney Costa Freire (Cgcre), Mr Gustavo Aishemberg (UNIDO), Mr Masao Ito (ABRAC), Mr Renato Pedroso Lee (ABNT/CB-25), Mr Eugenio Tolstoy de Simone (ABNT), Mr Luiz Fernando C. Ferreira (ABENDI) and Ms Hulda Giesbrecht (SEBRAE).

The Inmetro assessors who conducted the visits to ISO 9001-certified organizations were Veronica Pereira, Felipe Batista, Thomas H. Müller, Eliana Cunha, Wagner Guedes, Ione Videira, Monique Getrouw, Ronald Kirst, Reinaldo Wacha, Bruno Gregório Menita, José Renato Maurício Moreira and Marcia Almeida.

Ms. Cindy Parokkil and Ms Juliana Lima de Regueiro (UNIDO) contributed their time, energy and professional experience to the planning, organization, implementation, data analysis and editing of this report.

We extend our grateful appreciation to all the cooperating parties and experts for participating in and providing support to the project.

# Summary of the report

**KEY FINDINGS:** This project identified many benefits of using ISO 9001 as a basis for the implementation and accredited certification of quality management systems in Brazil, as well as some opportunities for improvements in the implementation and certification processes. It is, however, important to remember that

this was a qualitative study conducted based on the involvement of “willing participants” who responded to the surveys, and in some cases received visits from members of the project team to their organizations, so the data presented and subsequent analysis should be considered in this light.



## Economic benefits of ISO 9001

There are clear empirical economic benefits to the effective implementation and accredited certification of ISO 9001-based quality management systems in Brazil. This was demonstrated by the analysis of a survey conducted among Brazilian purchasers (who use the standard extensively as a basis for their supplier selection), and certified organizations, over 98% of whom considered the investment in their QMS to have been a “good” or a “very good” one.



## Other management systems and supplier selection criteria

ISO 9001 (QMS) continues to be the main focus of Brazilian organizations, both in terms of purchaser requirements and organizations seeking certification. Only 15% of the ISO 9001-certified organizations surveyed also held ISO 14001 (EMS) certification, and only 11% of the purchasers surveyed currently require it. Only 8% of the ISO 9001-certified organizations were also certified to OHSAS 18001 (OHSMS), and only 7% of the purchasers surveyed require it. Very little interest was shown in the other standards mentioned in the survey (ABNT NBR 16001 (Social Responsibility); ISO 27001 (Information Security) and ISO 50001 (Energy Management)), either by purchasers or by the ISO 9001-certified organizations.



## Credibility of ISO 9001

Overall, the perceptions of both the ISO 9001 standard and accredited certification to ISO 9001 in Brazil are good, and there is a very high level of awareness about, and respect for, Inmetro. The National Accreditation Body (Cgcre) is less well known. The roles and responsibilities for accreditation (and particularly those of the IAF in the international context) are not well understood, however, 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. Of those purchasers who continue to conduct their own (2nd-party) audits of suppliers, 7% claimed to have detected significant problems that called into question the validity of the suppliers' certifications. Many purchasers were unaware of the fact that they can complain to a supplier's CB in the case of repetitive problems, or to the AB in more extreme cases.



## 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 10002:2014 “Quality management – Customer satisfaction – Guidelines for complaints handling in organizations”). This is particularly important in light of the relative dissatisfaction of purchasers with the way in which their certified suppliers deal with complaints, an area where certification bodies are recommended to focus more attention in future.



## Perceptions of ISO 9001-certified organizations

The main reasons cited for implementing an ISO 9001-based QMS were for internal improvement, because of corporate objectives, or to achieve competitive advantage. Over 50% of the organizations took between 7 and 12 months to implement their system and achieve certification, but 21% took less than 6 months, with 5% claiming to have done so in less than 3 months.

In terms of CB selection, price does not appear to be the primary consideration. International reputation and national accreditation (by Cgcre) were important, though international accreditation or IAF recognition was less so. The vast majority of the ISO 9001-certified organizations considered both initial and surveillance audits conducted by the CB to be professional impartial, rigorous, and value-adding.

One item of concern, however, was that (according to 6% of the 1206 certified organizations who responded to the survey), some CBs are also conducting internal audits for their certified clients, which is not permitted by the ISO/IEC 17021 standard that is used for accreditation.



### Use of consultants

The vast majority (almost 90%) of the certified organizations surveyed had used the services of a consultant to help with the implementation of their quality management system, and 44% continued to do so after certification, to assist with maintenance of the QMS. This was more pronounced for micro, small and medium organizations. Whilst the overall level of satisfaction with the consultants' performance was reasonable, in some cases significant dissatisfaction was expressed. ABNT, Inmetro, ABRAC, SEBRAE and others need to ensure the timely promotion of standards such as ISO 10019:2005 (*"Guidelines for the selection of quality management system consultants and use of their services"*), and similar documents developed locally in Brazil. In order to be effective, these guidelines need to be made available to organizations **before** they begin implementation of their QMS – one possibility would be to make use of communication channels available through industry associations and federations.



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

There is very little awareness in Brazil about the ISO 9004 guidance standard (ISO 9004:2009 – *"Managing for the sustained success of an organization – A quality management approach"*). Less than a quarter of the certified organizations surveyed had actually read and use this standard. ISO 9004 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.



### Market surveillance of certified organizations

A "market surveillance" methodology involving short (one-day) visits to certified organizations was used. This was based on the document IAF ID4:2012, which in turn had been developed using the results of previous UNIDO/IAF/ISO projects. This was shown to be effective in identifying weak areas of implementation of ISO 9001 among Brazilian organizations, as well as highlighting differences in performance of accredited certification bodies.



### Performance of certified organizations

Overall, the performance of the certified organizations that were visited was good, and demonstrated the effectiveness of the accredited certification process within that sample, particularly in larger organizations (with over 200 employees) and organizations that had been certified for more than 10 years. No "questionable" certificates were detected in either of these categories. However, a small percentage of smaller organizations visited demonstrated unsatisfactory results. Taking into consideration the large number of certificates issued in Brazil, this small percentage represents a significant number of certified organizations, and emphasizes the need to avoid complacency and to drive further improvements in the accredited certification process.



### Weak areas of implementation of ISO 9001

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

- Inadequate internal communication and the need for employees to understand better their roles in the QMS;
- Lack of understanding and effective implementation of the "process approach";
- Poor Cause Analysis and Corrective Actions;
- Lack of focus on preventing nonconformities.



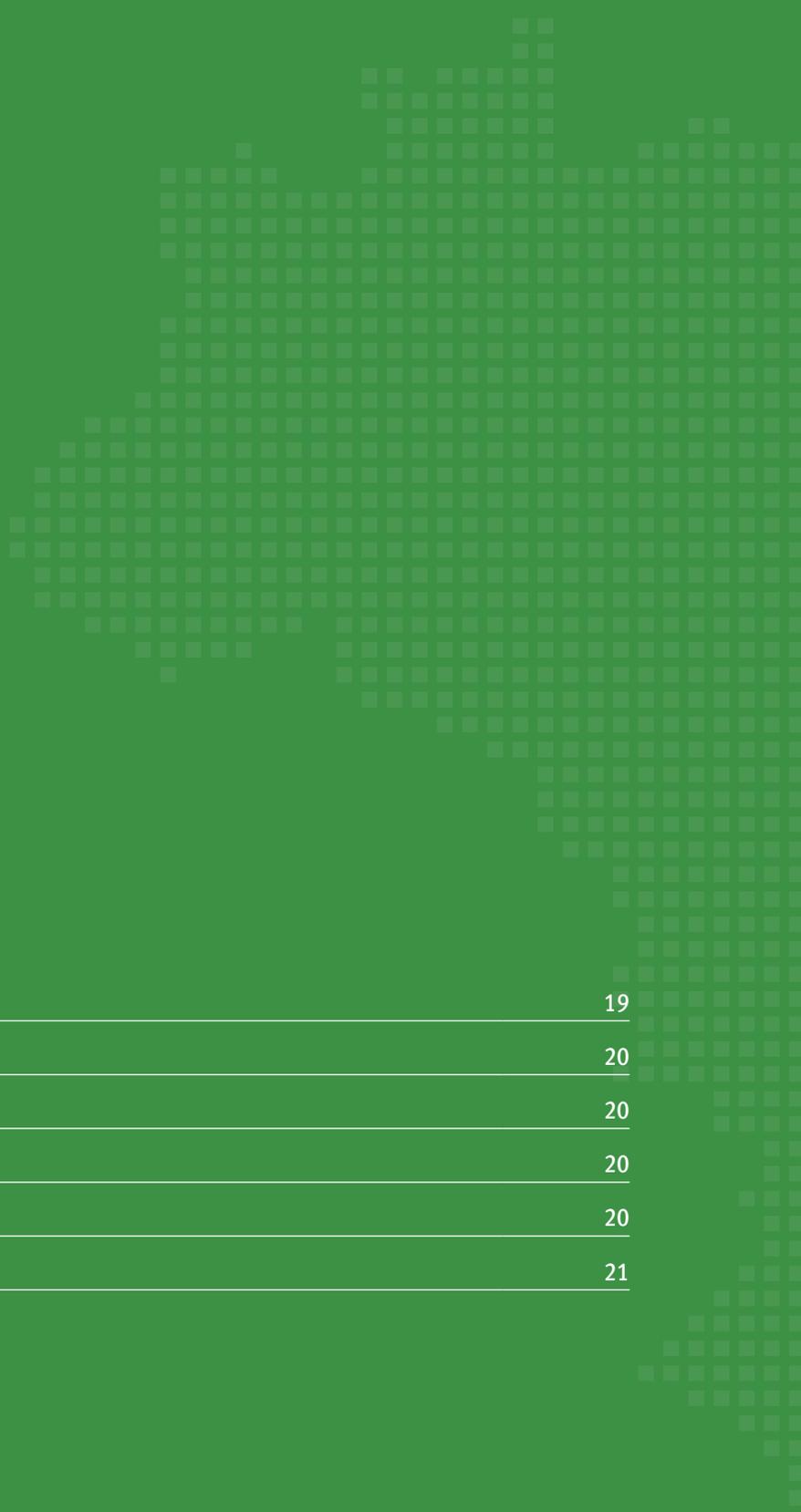
### Differences in performance of certification bodies

It was also found during the one-day "market surveillance" visits to certified organizations that there were notable differences in the performance and level of confidence in organizations certified by different certification bodies. It is to be hoped that this methodology (with some adaptations) can be used more extensively in the future, by means of pro-active collaboration between Cgcre and ABRAC. This could lead to a more results-focused approach to accreditation, rewarding those CBs whose clients perform well by reducing the intensity of traditional surveillance by the AB and conversely by increasing the intensity of surveillance for those CBs whose certified clients perform badly. This would be totally consistent with and embrace the concept that "Output matters!"



### Promotion of "South-South" collaboration in other Lusophone countries

The Expert Group Meeting that was held in Rio to present the results of this project and to discuss future South-South collaborations for Quality Infrastructure development was attended by all the African Portuguese-speaking nations, and an MOU was signed with Inmetro to promote future technical assistance.



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# Chapter 1

## PROJECT BACKGROUND

### THE ISO 9000 SERIES OF STANDARDS

The International Organization for Standardization (ISO) currently has a portfolio of over 21,000 standards, of which the ISO 9000 series relating to quality management is undoubtedly the best known. Within this series, ISO 9001 (*“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 and services that meet customer and applicable statutory and regulatory requirements.

The latest version of ISO 9001 was published very recently (at the end of 2015) so this work is based on ISO 9001:2008, but most of the analyses and conclusions are also valid for the 2015 version.

Because ISO 9001 is a requirements standard, it can be subjected to conformity assessment by “first-party” (i.e. an organization itself, via its internal audits), by “second party” (such as a customer auditing a supplier for contractual purposes) or by a “third party”, such as an independent certification body. While third-party certification is not required by the standard or by ISO, well over a million organizations worldwide are estimated to have achieved certification to ISO 9001, and many purchasers place confidence in the fact that a potential supplier is “ISO 9001 certified” as a basis for making their purchasing decisions.

In order to enhance their credibility, certification bodies often choose to have their competence and integrity assessed by an independent accreditation body, which in the case of ISO 9001 is based on the ISO/IEC 17021 standard (*“Conformity assessment - Requirements for bodies providing audit and*

*certification of management systems”*), and its additional personnel competence requirements for quality management systems specified in ISO/IEC 17021-3. ISO/IEC 17021 is produced by ISO’s Conformity Assessment Committee (CASCO).

The 2008 version of ISO 9001 (on which this project was based) 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, 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 9001:2008 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.

## CERTIFICATION TO ISO 9001

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ISO itself is neither directly involved in nor requires third-party certification, but 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. If the audit is successful, this 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. This in turn provides confidence to the organization's current and potential customers 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 and services.

## THE ROLE OF ACCREDITATION

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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 which, in the case of Brazil, is Cgcre. In the case of ISO 9001 certification, the accreditation process verifies the certification body's conformity to the ISO/IEC 17021 standard "*Conformity assessment – Requirements for bodies providing audit and certification of management systems*". This project

was conducted based on the 2011 version of ISO/IEC 17021, which has since been replaced by ISO/IEC 17021-1:2015. ISO/IEC 17021:2008 is based on six core principles: impartiality, competence, responsibility, openness, confidentiality, and responsiveness to complaints. Only those certification bodies that meet all the accreditation requirements are authorized to issue accredited certificates.

## ACCREDITED CERTIFICATION TO FACILITATE TRADE

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Accreditation bodies may choose to participate in multi-lateral 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.

## CREDIBILITY OF ACCREDITED CERTIFICATION

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In recent years there has been some debate in Brazil and elsewhere about 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. This questioning of the credibility of certification has been prompted by a variety of perceptions, often based only on anecdotal evidence. The debate centers on whether:

1. organizations are deriving tangible benefits through ISO 9001 certification (is the money, time, and administrative effort for certification providing enough value?);
2. certification and accreditation bodies are carrying out the certification process effectively and providing overall market confidence in certification; and
3. ISO 9001-certified suppliers can be relied upon to provide "consistent, conforming products and services" to their customers.

## BACKGROUND AND OBJECTIVES FOR THE CURRENT PROJECT

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According to the latest ISO Surveys, there are currently around 18,000 Brazilian organizations that are certified to ISO 9001 (the biggest number of any country in Latin America and the Caribbean region).

Inmetro has in the past conducted a number of surveys of certified organizations and their customers, and these were extensively adapted and used in the UNIDO/ISO/IAF project TE/RAS/09/003 to assess the impact of ISO 9001 in Asian

developing economies in the 2009 – 2012 time-frame. Inmetro also participated in the development of the IAF Informative Document ID4:2012 (“*Market Surveillance Visits to Certified Organizations*”) which was one of the direct outputs of project TE/RAS/09/003.

In order to generate an in-depth fact-based understanding of the application of ISO 9001 in Brazil and to have a comprehensive assessment of the impact of ISO 9001 certification, Inmetro made a decision in 2014 to approach UNIDO with a view to initiating a systematic and comprehensive survey of the performance of ISO 9001 certified organizations and of the effectiveness of the certification process carried out by accredited certification bodies.

The expected outcome was a better understanding of:

- ① Whether an ISO 9001-based quality management system and its subsequent certification can bring significant benefits both to the certified organizations and to their customers;
- ② The perceptions of both the ISO 9001 standard and accredited certification to ISO 9001 in Brazil;
- ③ The performance of ISO 9001-certified suppliers and non-certified suppliers to major purchasers;
- ④ The level of transparency and openness of the certification bodies in Brazil;
- ⑤ The level of confidence to be found in organizations certified by different certification bodies;
- ⑥ Effectiveness of a “market surveillance” methodology involving short (one-day) visits to certified organizations.





## Chapter 2

# STUDY METHODOLOGY

### MAIN ACTIVITIES COVERED IN THE PROJECT

#### 1 Questionnaire survey of institutional purchasers

Institutional purchasers are the major customers and potential customers of ISO 9001-certified organizations (who are their suppliers). A good knowledge of the perception of these institutional purchasers about the performance of their ISO 9001-certified suppliers is of critical importance for an objective evaluation of the effectiveness of ISO 9001 certification and the effects of ISO 9001 management systems in companies.

To achieve the objectives of this current project, Inmetro and UNIDO worked together to adapt the UNIDO “purchaser survey questionnaire” that had been used in the previous project in Asian developing economies (Project TE/RAS/09/003). The questionnaire used in this current survey consisted of 5 parts and 32 questions, covering basic information concerning the purchasing organizations, their opinion on the ISO 9001 standard and certification, criteria for procurement and supplier selection, supplier performance, overall opinions about ISO 9001 certification, and requirements for additional certifications such as ISO 14001 (EMS), OHSAS 18001 (OHSMS) and ISO 50001 (EnMS).

The web-based questionnaires were distributed by e-mail to the companies and the organizations surveyed completed the questionnaires of their own free will and interest. This means that the results were qualitative in nature, and do not purport to represent a truly random sample of all purchasers in Brazil. The data presented and subsequent analysis should therefore be considered in this context.

The survey of institutional purchasers ran from February to October 2015 and resulted in a total of 101 completed and valid questionnaires from throughout Brazil.

#### 2 Additional feedback from some institutional purchasers

For better information and direct feedback, a workshop was held at Inmetro’s headquarters in Rio de Janeiro in October 2015, for face-to-face discussions with purchasers who replied to the questionnaire, in order to learn about their perceptions of ISO 9001 certification in Brazil as well as their comments and recommendations on certification and accreditation, and the survey itself.

#### 3 Questionnaire survey of ISO 9001-certified organizations

In the context of the circumstances of the certified organizations in Brazil, the survey focused on industrial manufacturing and construction companies. Web-based questionnaires were sent out to over 12,000 companies, whose contact information had been provided by members of ABRAC, by ABNT/CB-25 and from Inmetro’s own database, covering companies of various sizes, industries and geographical locations. The certification bodies (CBs) of these certified organizations included most of the Brazilian and international CBs operating ISO 9001 certification activities in Brazil, accredited by Cgcre and by foreign accreditation bodies (ABs). The survey was carried out between January and March 2015, and a total of 1206 companies filled in the questionnaires out of their own free will and interest. Again, this means that the results were qualitative in nature, and do not purport to represent a truly random sample of all certified organizations in Brazil. The data presented and subsequent analysis should therefore be considered in this context.

**4 On-site “market surveillance visits” to certified organizations**

A series of one-day on-site “market surveillance visits” was conducted by Inmetro personnel at a sample of organizations with Cgcre-accredited ISO 9001 certificates. To ensure the effectiveness of these visits and their relevance to Brazil, Inmetro and UNIDO experts worked together to revise the “on-site survey form” used in the previous UNIDO/ISO/IAF projects which now form the basis for the IAF Document ID4:2012 (“Market Surveillance Visits to Certified Organizations”). The on-site survey form and programme finalized for this survey included 26 items, covering all aspects of the QMS. The assessors were requested to score each item according to their observations about the actual operational situation of the certified organizations and finally to give a score to the overall level of confidence in the system of the certified organizations.

All the on-site assessors were full-time employees of Inmetro, to avoid any potential conflicts of interest that might arise by using external resources, and received a four-day training course on the market surveillance methodology, conducted by the UNIDO International expert. This included two “calibration” visits to certified organizations followed by a feedback session in order to ensure consistency of criteria between the various assessors.

For each topic on the “on-site survey form”, a grade was assigned by the assessor to indicate the degree of confidence in that topic, using the following criteria:

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

The on-site visits were conducted from February 2015 to July 2016, including a total of 92 organizations with ISO 9001 certificates accredited by Cgcre. This was less than the number of 100 that was originally planned (100 = √10,000, the number of Cgcre-accredited certificates in Brazil at the time of the project planning phase), primarily because of the severe travel restrictions imposed on Inmetro by the Brazilian government during the crisis year of 2015, but for reasons that will be explained in Chapter 5 of the report, this did not adversely impact the overall results and conclusions.

## 5 Data analysis and report compilation

Inmetro undertook the data analysis, with support from UNIDO. After the initial compilation of results, a series of regional workshops was conducted in May 2016, in order to obtain feedback from the relevant interested parties. Workshops were held in the following Brazilian cities, with a total of over 100 participants:

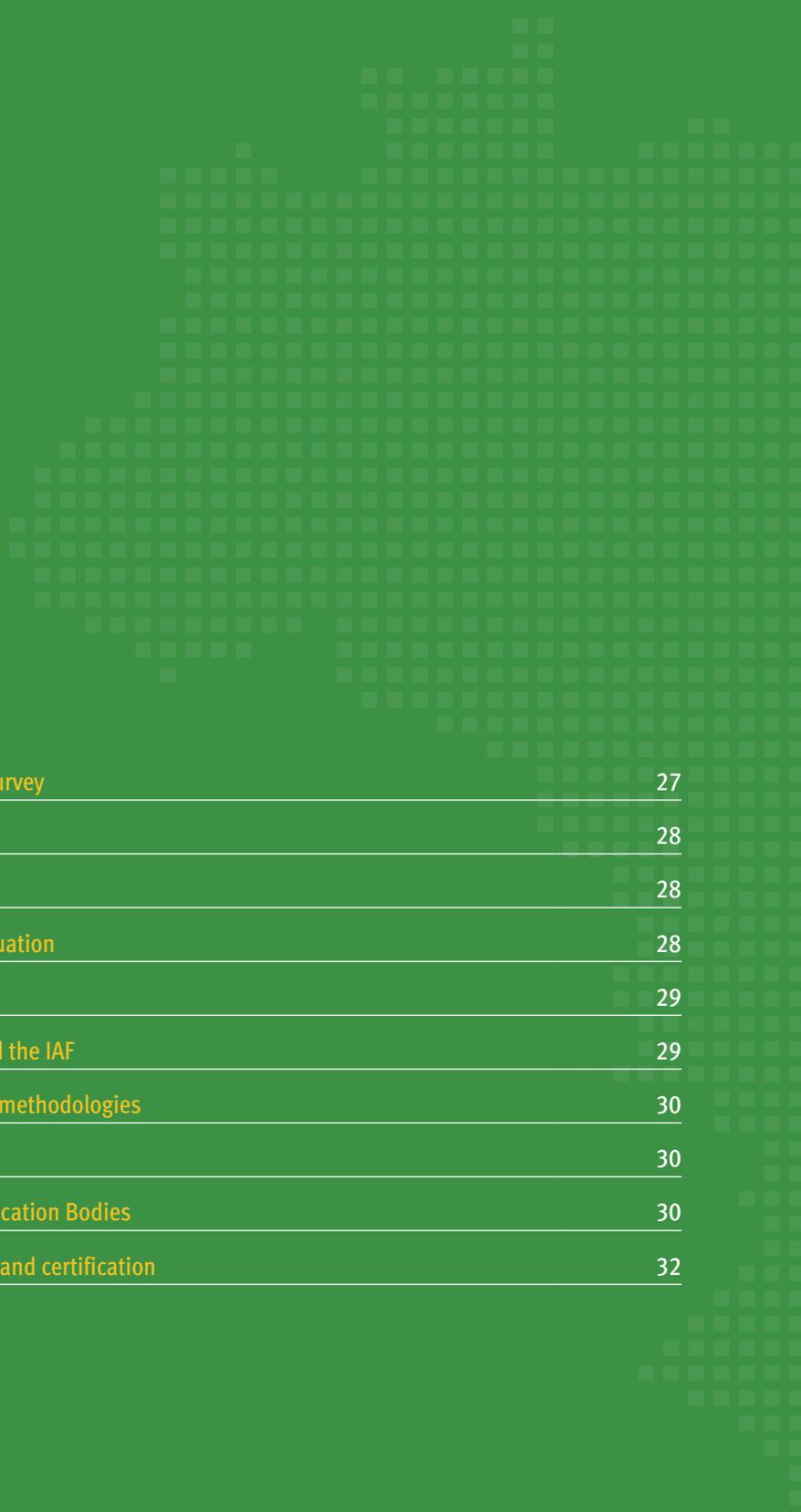
- ① 10th May – Porto Alegre
- ② 11th May – Goiânia
- ③ 12th May – São Paulo
- ④ 13th May – Rio de Janeiro

Participants included representatives of certified organizations, representatives of purchasing organizations, consultants, certification bodies (members of ABRAC), Cgcre, ABNT and SEBRAE, among others.

In all of the workshops, the presentation of the project and the initial results were well received, and followed by lively discussions, mostly relating to the overall perceptions about the credibility of ISO 9001 certification. Some suggestions for additional verification and analysis were made, and have been included in this final report.

In addition, UNIDO organized an Expert Group Meeting for Portuguese-speaking African nations, hosted by Inmetro in May 2016. This was entitled “Promoting south-south collaboration of best practices and policy guidelines for quality infrastructure - improving the functioning of management system certification and accreditation bodies”. It included (in addition to Brazil) representatives from all the Portuguese-speaking African Countries – Angola, Cape Verde, Mozambique, Guinea-Bissau, São Tomé & Príncipe, and Equatorial Guinea. The preliminary results of the current project were presented, and feedback has been incorporated into this report.





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## Chapter 3

# BRAZILIAN PURCHASERS' PERCEPTIONS OF THEIR ISO 9001-CERTIFIED SUPPLIERS

This questionnaire survey was conducted online between February and October 2015. A total of 101 responses

was received, though it should be mentioned that some respondents did not feel able to respond to all of the questions.

### I. DETAILS OF THE PURCHASERS WHO TOOK PART IN THE SURVEY

It can be seen from Figures 1 - 3 that a range of different sized organizations replied to the survey, with annual purchasing budgets ranging from less than USD1m to over USD 100m, and that the respondents generally came from the quality or purchasing areas of their companies. 57% of the respondents were national Brazilian companies and 43% were branches of larger multinational organizations.

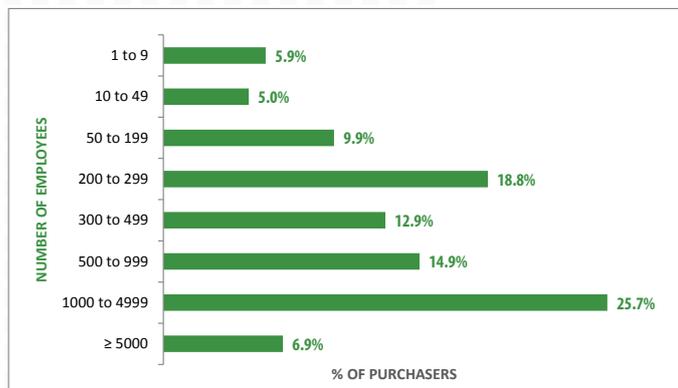


Figure 1. Size distribution of the purchasers surveyed (by number of employees)

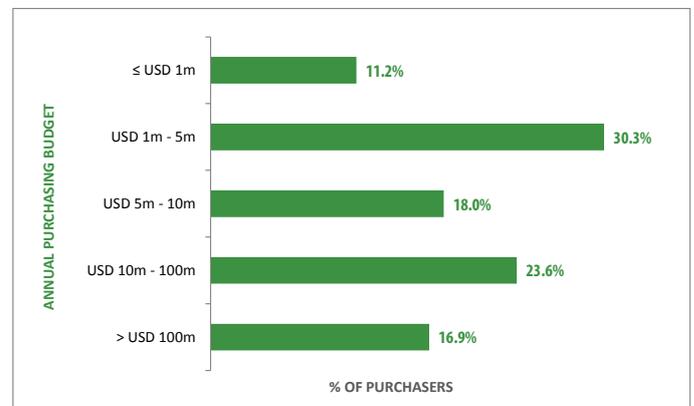


Figure 2. Annual purchasing budget of the organizations surveyed

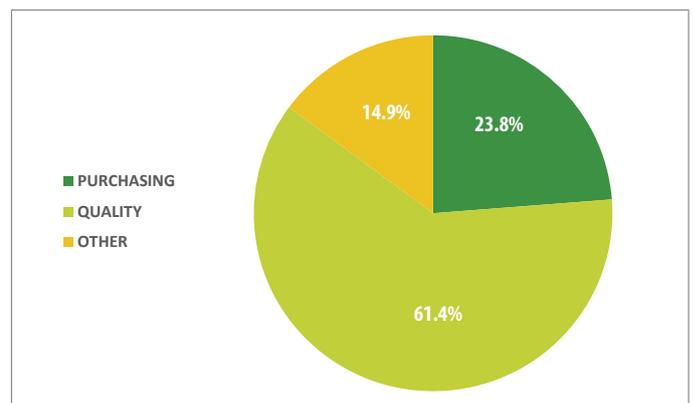


Figure 3. Details of the survey respondents' function within their organization

## II. QMS OF THE PURCHASERS

Of the purchasers who responded the survey, only 4.5% did not have their own quality management system that includes the purchasing function. It can be seen from Figures 4 and 5 that the majority of the purchasers actively evaluated between

11 and 100 suppliers over the last 12 months, with some (6.7% of the respondents) evaluating over 1000, and for most part these were national (Brazilian) suppliers.

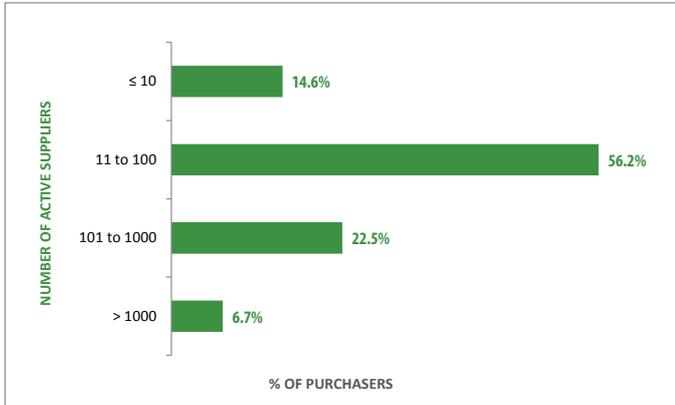


Figure 4. Number of suppliers actively evaluated by the respondents in the last 12 months

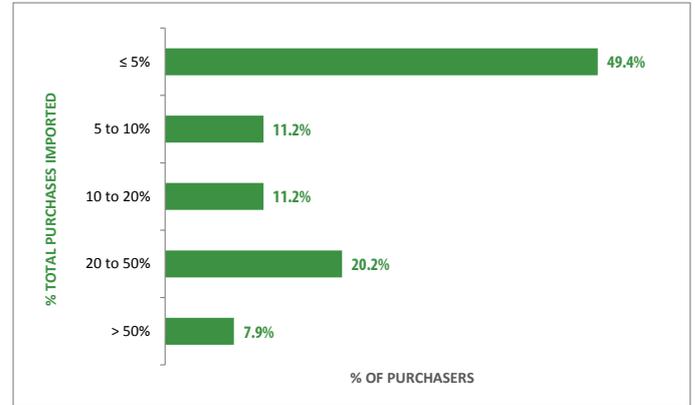


Figure 5. Percentage of imported products and services reported by purchasers

## III. PURCHASER FAMILIARITY WITH ISO 9001

88% of the respondents use ABNT ISO 9001 on a regular basis; 10% said that they “had heard of it” but had not adopted it,

and surprisingly, a small number of respondents (2%) claimed never to have heard about ABNT ISO 9001.

## IV. ADOPTION OF ISO 9001 AS A TOOL FOR SUPPLIER EVALUATION

Of the purchasers who responded to the survey, 95% expressed that they regarded ISO 9001 certification as an important criterion for supplier evaluation. Figure 6 shows that of those purchasers who require their suppliers to be certified, 69.7% request a copy of the certificate; 65.2% check the validity date on the certificate, and 52.8% make sure that the scope

of the certificate includes the products or services they are purchasing. More worrying is the fact that only 23.6% of the respondents look for the accreditation mark on their suppliers’ certificate, which reinforces the need (highlighted in previous similar surveys) for greater awareness-building about the important role of accreditation to ensure credible certification.



Figure 6. Verification of suppliers’ claims of conformity to ABNT ISO 9001

## V. OTHER REQUIREMENTS PLACED ON SUPPLIERS

The questionnaire asked the purchasing organizations about other certifications they required from their suppliers and/or other supplier selection criteria. Figure 7 shows that ISO 14001 (EMS) is the next most important factor after ISO 9001, but with only 11% of the purchasers currently requiring certification (though a further 46% take it into consideration and 24% intend to do so in the future). Only 7% of the respondents require certification to OHSAS 18001 (OHSMS), with a further 43% “taking it into consideration”, but there is very little

interest in requiring suppliers to be certified to ISO 50001 (EnMS), or the intent to do that in the future. Indeed, according to the latest ISO Survey, there are only eight organizations in Brazil with ISO 50001 certification (2015 Survey, based on Dec 31st 2014 figures). Gender equality and considerations for people with disabilities are also taken into consideration by the purchasers, but there is currently no certification scheme in Brazil for either of these topics.

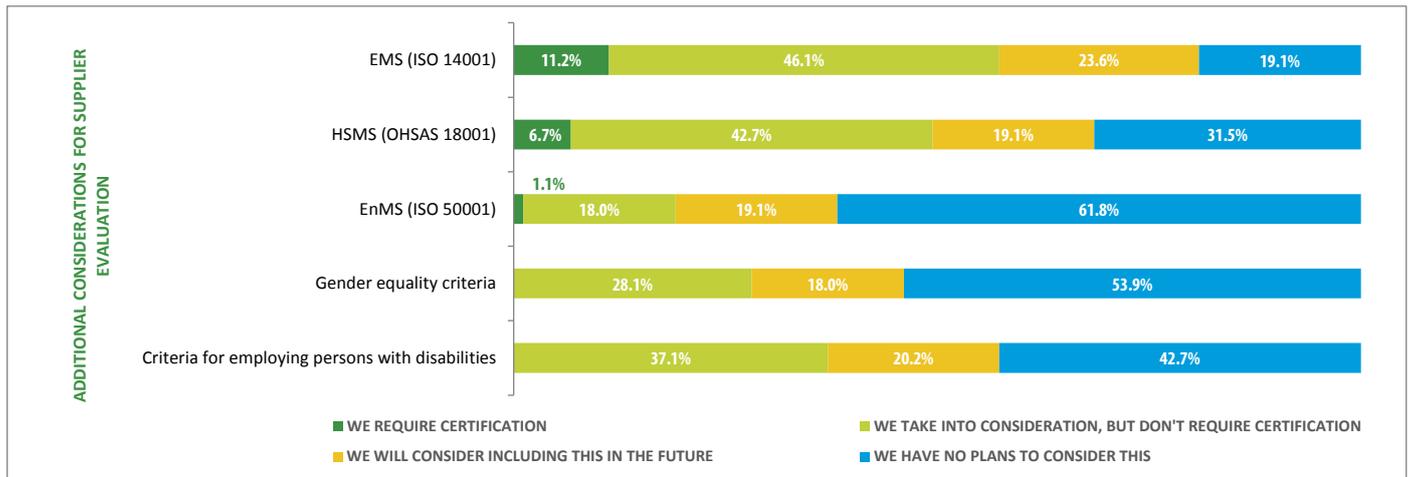


Figure 7. Other factors taken into consideration during supplier evaluation

## VI. PURCHASER FAMILIARITY WITH ISO, ACCREDITATION AND THE IAF

The survey results show that only 35% of the purchasers knew (correctly) that ISO only plays the role of “standard developer” in the ISO 9001 certification scheme; 6% of them wrongly believed that ISO publishes the ISO 9001 standard and is responsible for conducting the certification thereof; and 54% wrongly believed that ISO publishes the ISO 9001 standard and is responsible for accrediting the CBs, with the CBs representing ISO in the certification process. Although this perception is wrong, it is quite common not only in Brazil, but in the other countries where similar surveys have been conducted. This emphasizes the reputational impact that certification can have on the ISO (and the National Standards Body) brand name (both positive and negative).

Interestingly, 71% of the purchasers surveyed were aware of Inmetro’s role in terms of accreditation, though strictly speaking, the national Accreditation Body is no longer “Inmetro”, but Cgcre, established as an independent division of Inmetro to ensure its impartiality from Inmetro’s other activities - a fact that is not well understood. Although 65% of the respondents claimed to be able to name at least one foreign accreditation body, only 30% did so correctly. About 42% of the purchasers said that they had heard of IAF and knew its role; 29% said they had heard of the IAF but did not know its role, and 29% said they had never heard of the IAF.

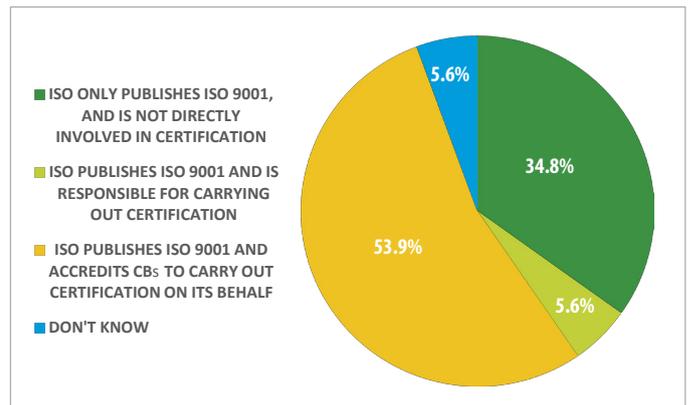


Figure 8. Purchasers' knowledge of ISO's role in certification

This is a worrying result, particularly when many purchasers rely on accredited ISO 9001 certification for their supplier selection, but is very similar to the responses given by purchasers in previous surveys in Asia. Once again, this emphasizes the need for greater promotion and awareness-building of the accreditation concept, and about the mutual recognition agreements that are in place under the IAF, in order to promote international trade.

## VII. PURCHASER AWARENESS OF CONFORMITY ASSESSMENT METHODOLOGIES

According to the survey, most of the purchasers (88%) said that they knew about accredited certification in order for their suppliers to demonstrate conformity to ISO 9001, and 70% stated that this was the method they used. Whilst there was a similar level of awareness of non-accredited certification, only 37% of the respondents had experience with this. By far the most widely known method of conformity assessment, however, continues to be second party auditing, with 98% of the respondents knowing about it, and 79% having experience in these supplier audits.

It can also be seen from Figure 9 that for high value and/or high risk purchases, 60% of the respondents required their suppliers to be ISO 9001 certified, with 46% carrying out their own (2nd-party) audits and 38% also taking into consideration the reputation of and past experience with the supplier (multiple answers were permitted). Requirements for certification and for conducting supplier audits were, as expected, lower for less critical or lower value purchases, where supplier reputation and past performance were the dominant criteria.

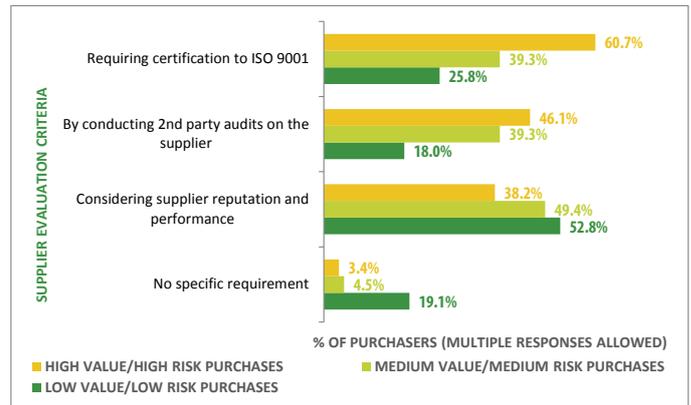


Figure 9. Criteria used for supplier selection

In a similar fashion, the evaluation criteria for products and services provided varied according to the criticality and/or value of the transaction, with most purchasers conducting some kind of incoming inspection of products and services, regardless of the value or criticality. 30% said that for critical and/or high-value purchases, they also conduct monitoring and inspection activities at their suppliers’ premises.

## VIII. PURCHASER FEEDBACK ON SUPPLIER PERFORMANCE

Figure 10 shows that for the procurement of “high value” and/or “high risk” products, 47% of the purchasers gave regular feedback to their suppliers about the performance of their products and services; 30% did so only if they had a complaint,

and 13% only if requested by the supplier. For “low value” and/or “low risk” products, only 25% of the purchasers gave regular feedback; 40% gave feedback only when they had a complaint, and 22% only when requested by the supplier.

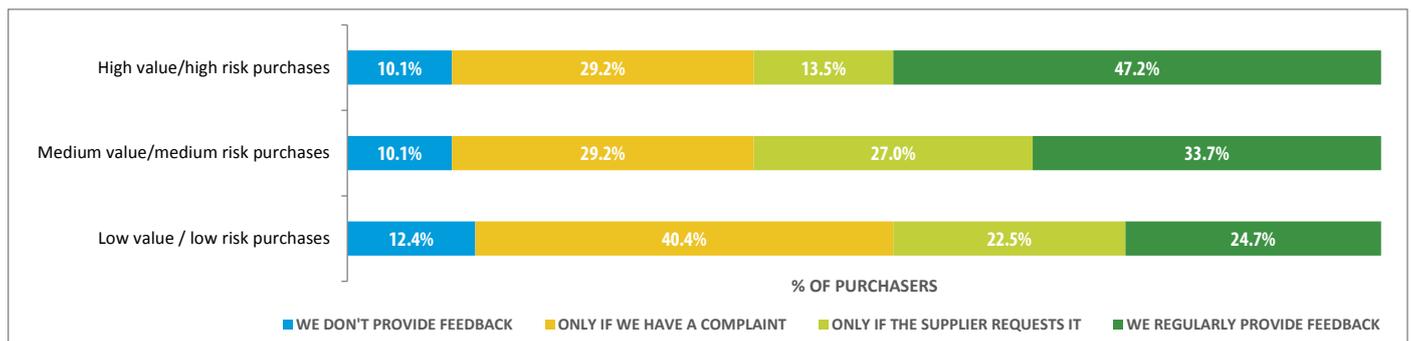


Figure 10. Purchaser feedback to suppliers

## IX. PURCHASER LEVEL OF CONFIDENCE IN ISO 9001 CERTIFICATION BODIES

Figure 11 shows the overall perception of the purchasers regarding the credibility of ISO 9001 CBs operating in Brazil. 81% of the purchasers surveyed considered this to be either “very good”; or “good”; 18% said “fair”; and only 1% (one respondent) said “poor”.

Figure 12 shows the level of satisfaction of the purchasers with respect to various performance aspects of their ISO 9001-certified suppliers. The highest level of satisfaction was with the suppliers’ communication and product marketing processes, followed by the intrinsic quality and consistency

of the products and services provided. In each case, around 90% of the respondents said they were “satisfied”, or “very satisfied”.

Figure 13 shows the comparison between certified and non-certified suppliers (or comparing the same supplier before and after certification). In general, purchasers’ perceptions about their ISO 9001-certified suppliers were more favourable than those for non-certified suppliers (or for the same supplier before certification), with around 50-60% saying that ISO 9001-certified suppliers performed “better” or “much better” across all the categories. As pointed out during the workshops with interested parties, however, Figure 13 also can be interpreted as meaning that somewhere around 40% of the purchasers perceive no difference in the performance of their certified or uncertified suppliers, which is worrying.

It is important to note that, in line with the results of the previous UNIDO projects in Asia, responsiveness to complaints is also the main cause of dissatisfaction among purchasers in Brazil (see Figure 12), and CBs should be encouraged to pay special attention to this when conducting surveillance and reassessment audits of their certified clients. Figure 12 shows that whilst 53% of certified suppliers performed “better” or “much better” in this category, 14% claimed that ISO 9001-certified suppliers were “worse” or “much worse”. The reasons for this are not clear, and should be investigated further.

One possible explanation could be that certified suppliers have a more rigorous complaints handling process, and do not necessarily judge all customer complaints to be

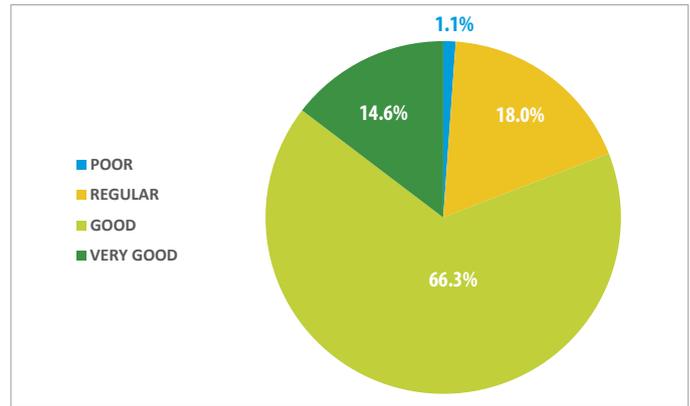


Figure 11. The overall perception of the credibility of ISO 9001 CBs operating in Brazil

valid ones. This could lead to some of the dissatisfaction when compared to uncertified suppliers, who might accept all customer complaints as valid, without making any detailed analysis. 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 10002:2014 “Guidelines for complaints handling in organizations”).

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 ABNT, Inmetro and ABRAC to promote greater awareness of it.

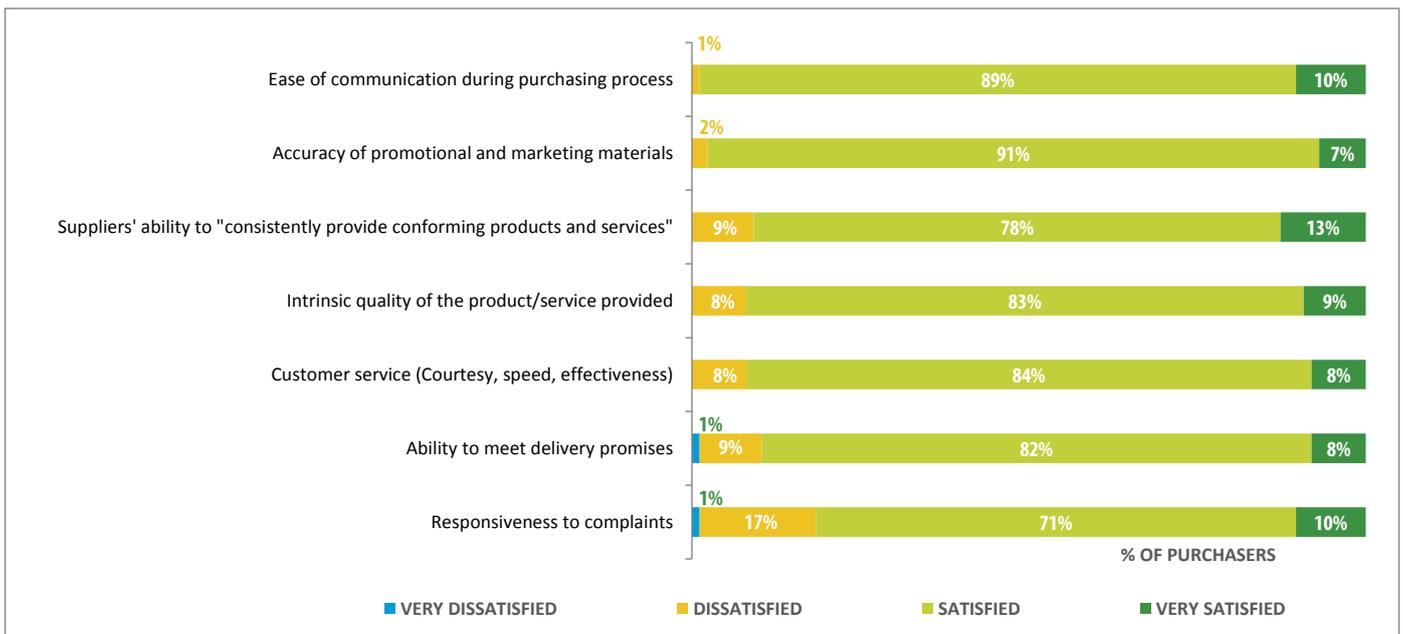


Figure 12. Level of satisfaction of purchasers with certified suppliers

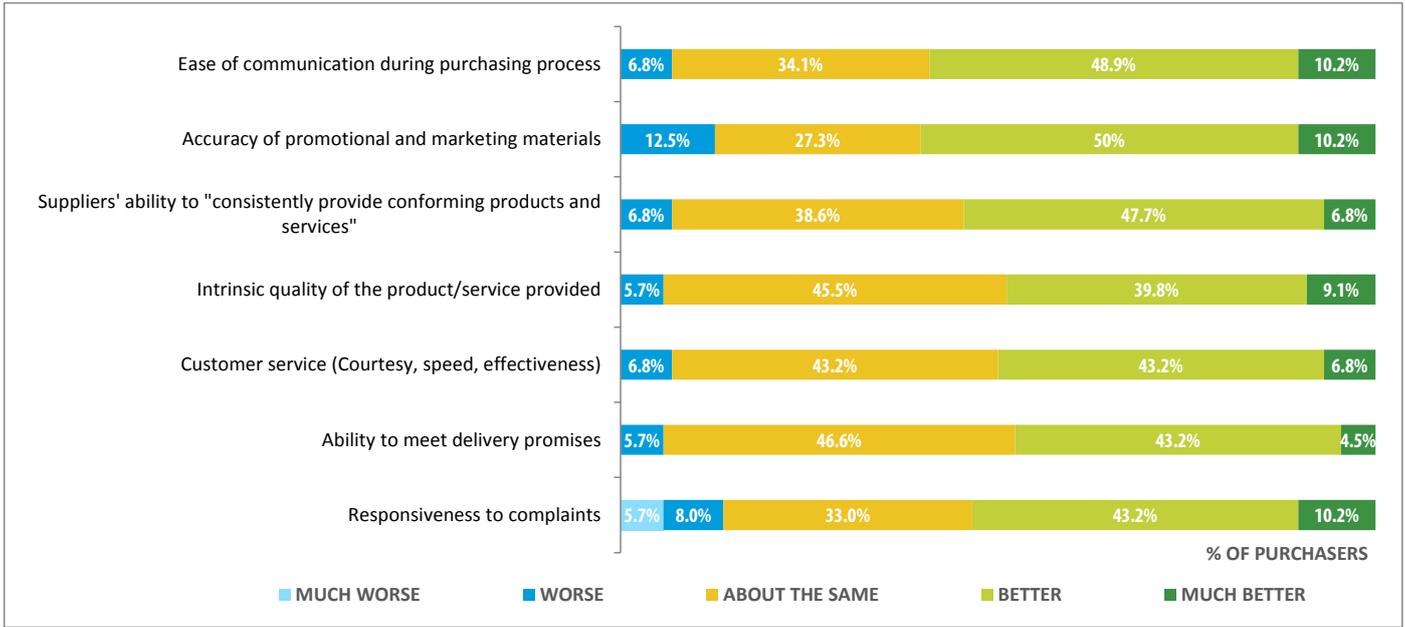


Figure 13. Performance of ISO 9001-certified suppliers, compared with the non-certified ones (or the same supplier before certification)

## X. PURCHASERS' OPINIONS ON THE ISO 9001 STANDARD AND CERTIFICATION

Generally, the purchasers surveyed had a high level of satisfaction with the ISO 9001 standard (without considering conformity assessment aspects). 21% considered it to be an “excellent” standard, 62% “good” and 17% “reasonably good”. No respondent considered ISO 9001 to be either “poor” or “very poor”.

With regard to certification, Figure 14 shows purchaser confidence in the ability of certified suppliers to consistently provide conforming products and services (which is the main stated objective of ISO 9001). 25% of the respondents replied that ISO 9001 certification means that they can always trust their certified suppliers; 18% said that they could “just about always” do so, and the majority (53%) said that they could trust in the products and services provided by certified suppliers “with occasional exceptions”. Only 4.5% of the survey respondents said they had insufficient confidence in their certified suppliers.

Figure 15 shows that 64% of the purchasers stated that in their experience “all accredited CBs operating in Brazil are equally good” or that “there are differences among the CBs, but the differences are not great”; 12% considered that there is a big difference between CBs, which caused them concerns about the performance of suppliers certified by some CBs; whilst 24% of those surveyed had no basis on which to make an evaluation.

It can be seen from Figure 16 that 62% of the purchasers had conducted 2nd-party audits of their ISO 9001-certified suppliers, with 55% having obtained generally satisfactory results (either no nonconformities, or a few minor



Figure 14. Purchaser confidence in ISO 9001-certified suppliers

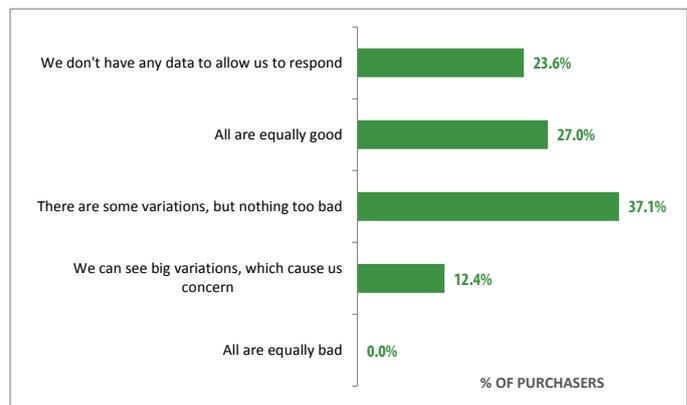


Figure 15. Purchasers' perceptions about differences in performance of accredited CBs

nonconformities that do not call into question the credibility of the certification. However, 7% of respondents had some “serious concerns” with the effectiveness of the certification processes (at least one major non conformity raised during the 2nd-party audits).

Figure 17 shows that 69% of the respondents never felt the need to complain to their suppliers' CB. 20% didn't know that they were able to do that, and 8% would have liked to complain, but didn't know how. Of the 3% (3 purchasers) who did complain, two were happy with the way their complaint was treated, and one was not.

In a similar fashion, Figure 18 shows that 74% of the purchasers said they knew that they could complain to the AB about the performance of a CB and/or its certified clients, but did not have any need to do that. 18% didn't know that they were able to do that, and 6% would have liked to complain, but didn't know how. Of the 2% (2 purchasers) who did complain, one was happy with the way their complaint was treated, and one was not.



Figure 16. Purchaser experiences from their 2nd-party audits of ISO 9001-certified suppliers

It is therefore recommended that the ISO Guidance Document “ISO 9001 – What does it mean in the Supply Chain?” and the Portuguese translation (available on the ABNT/CB-25 website) should be more widely promoted, in order to stimulate better feedback from purchasing organizations to their suppliers and, as necessary, to their respective CBs and ABs.

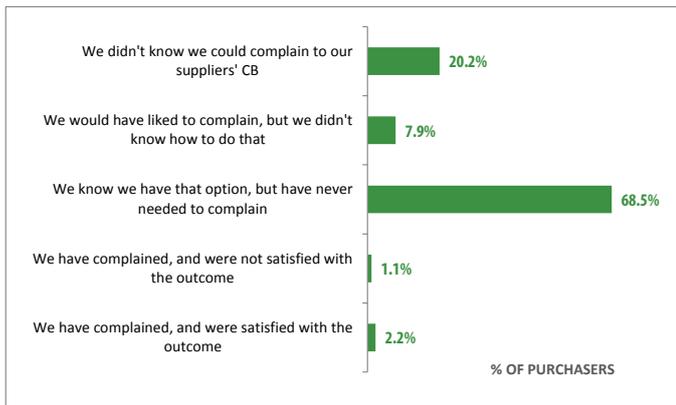


Figure 17. Purchaser complaints to suppliers' CBs

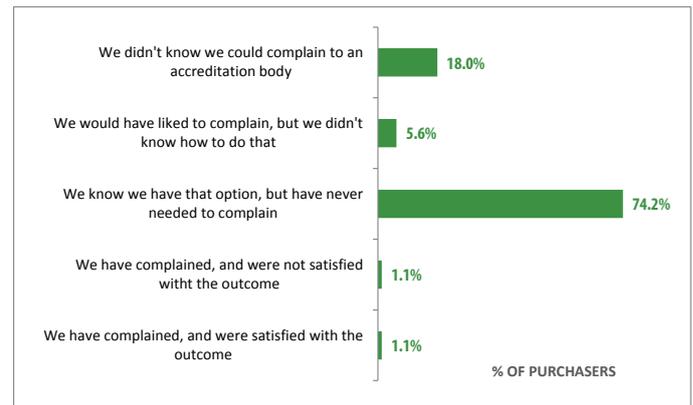
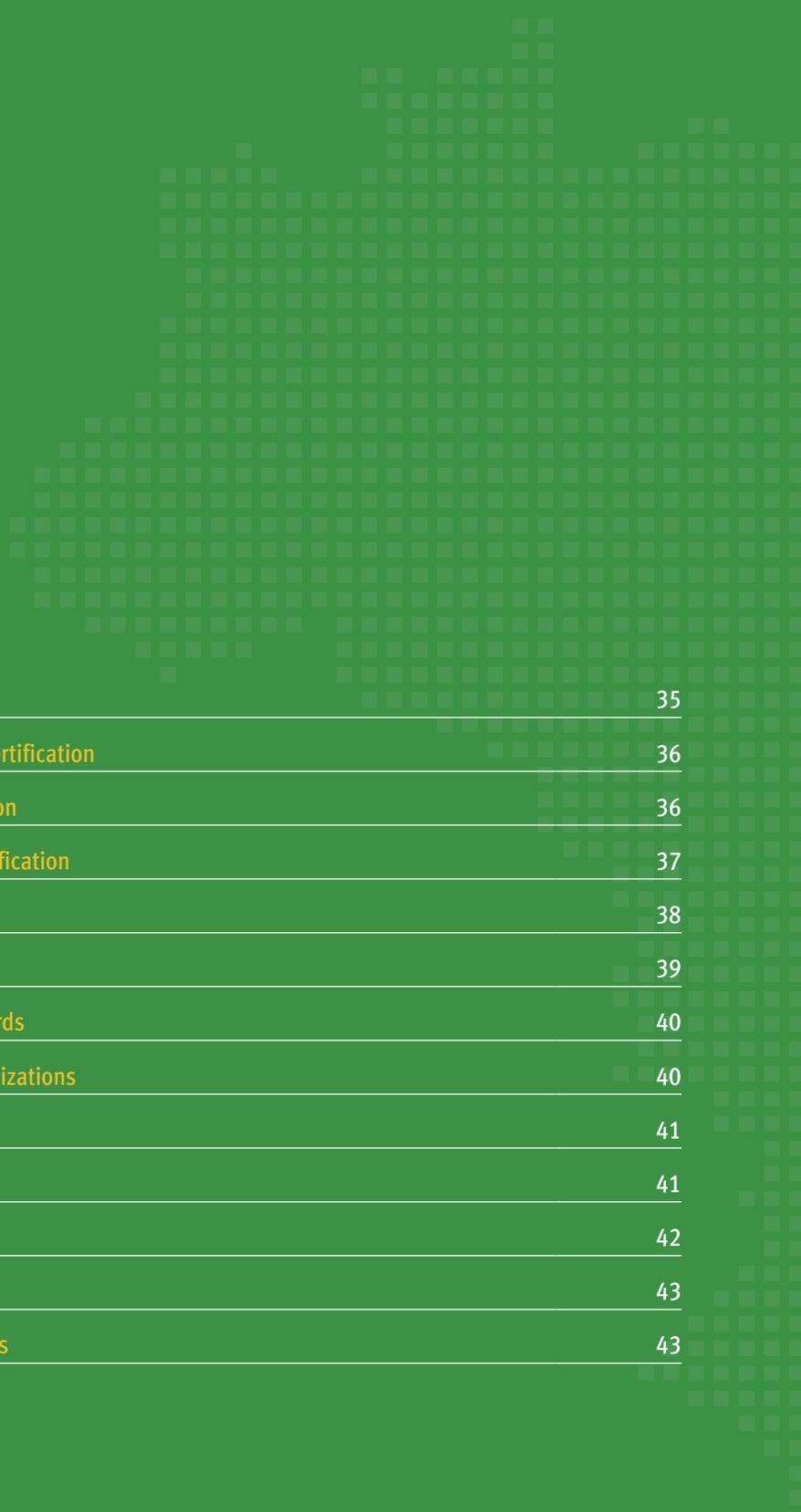


Figure 18. Purchasers' complaints to ABs about ISO 9001-certified suppliers and/or CBs



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## Chapter 4

# RESULTS OF SURVEY OF ISO 9001-CERTIFIED ORGANIZATIONS

This web-based survey was open to all ISO 9001-certified organizations in Brazil. Questionnaires were used to survey the certified organizations about their motives for seeking certification, experience in the implementation of ISO 9001 and satisfaction with the actual results of having implemented their QMS (including the certification process), among other things.

This survey was carried out between January and March 2015. The certified organizations provided information of their own free will and interest, and there was a good response rate (1206 participants), though several organizations left some items in the questionnaires blank.

### I. DEMOGRAPHICS OF THE CERTIFIED ORGANIZATIONS

Figures 19 and 20 show that the survey respondents came from a good distribution of business sectors, and organizations of all sizes. 81% of the respondents were national Brazilian

companies and 19% were branches of larger multinational organizations.

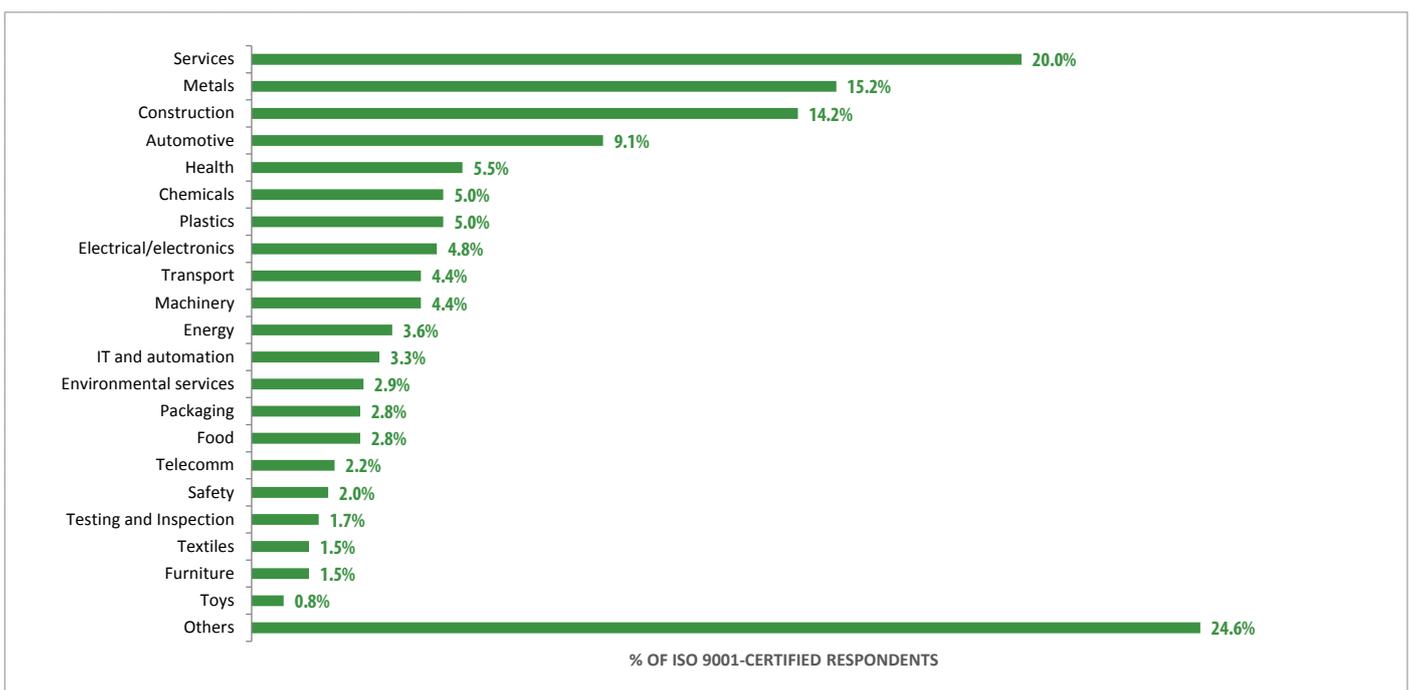


Figure 19. Main areas of economic activity of the ISO 9001-certified survey respondents

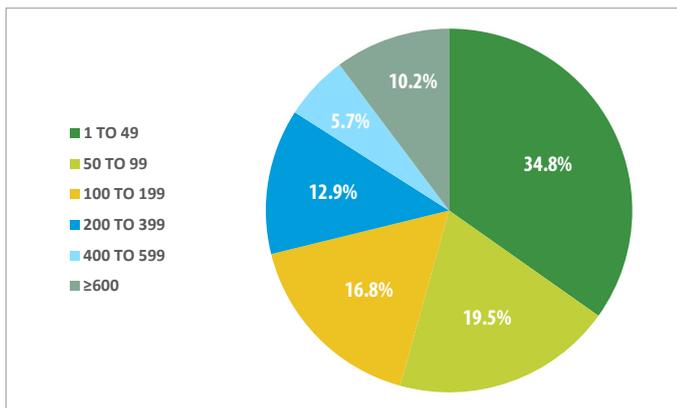


Figure 20. Size distribution of the ISO 9001-certified survey respondents (number of employees)

It can be seen from Figures 21 and 22 that overall, approximately 30% of all employees in the responding organizations are female, for all organizations sizes, with a slightly higher percentage occupying management positions. This is encouraging, because it demonstrates that there are no apparent obstacles to female employees being promoted within the organizations.

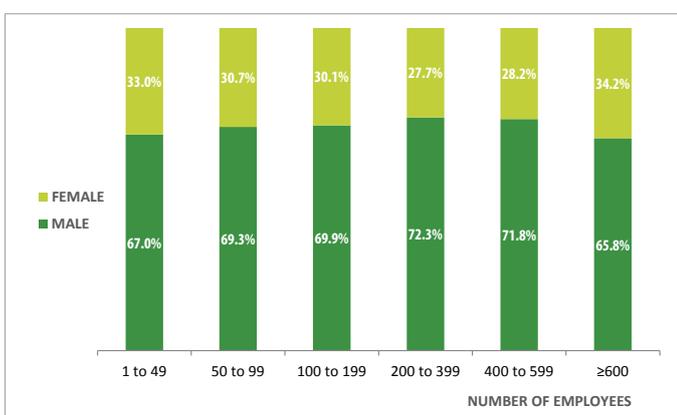


Figure 21. Gender distribution (based on total number of employees)

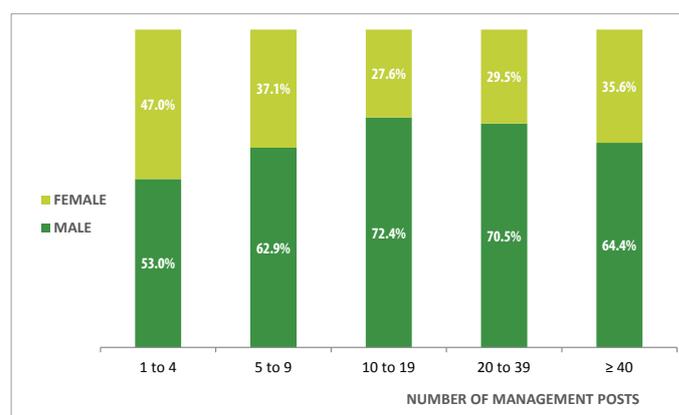


Figure 22. Gender distribution (based on participation in management positions)

## II. LENGTH OF TIME OF THE ORGANIZATIONS' ISO 9001 CERTIFICATION

Figure 23 shows the length of time the responding organizations had been certified to ISO 9001. The distribution was even between organizations that had been certified for more than 10 years (28%); organizations certified between 4 and 10 years (39%) and those certified for less than three years (33%), meaning that they had not yet completed a full certification cycle or a recertification audit.

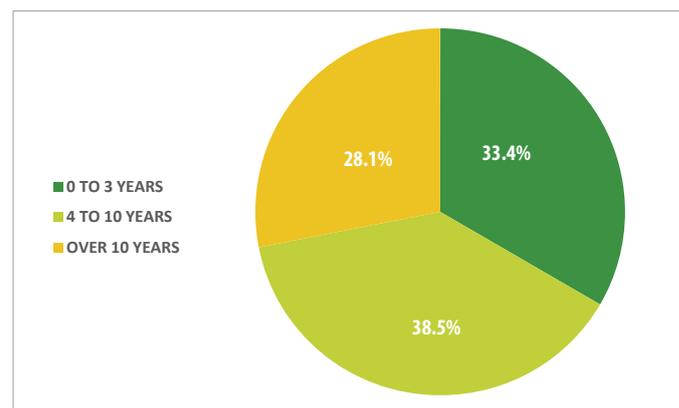


Figure 23. Distribution of length of time of certification

## III. REASONS FOR THE ORGANIZATIONS TO SEEK CERTIFICATION

This survey covered the major reasons for organizations to implement an ISO 9001-based QMS and to seek certification (see figure 24). As the figure shows, the most important reason given was for “internal improvement”, followed by “corporate or top management objective”, and

this has not changed over the years. Customer pressure, the ability to participate in tenders, and competitive advantage were also considered to be important, though the survey respondents did not give great importance to the ability to participate in international markets.

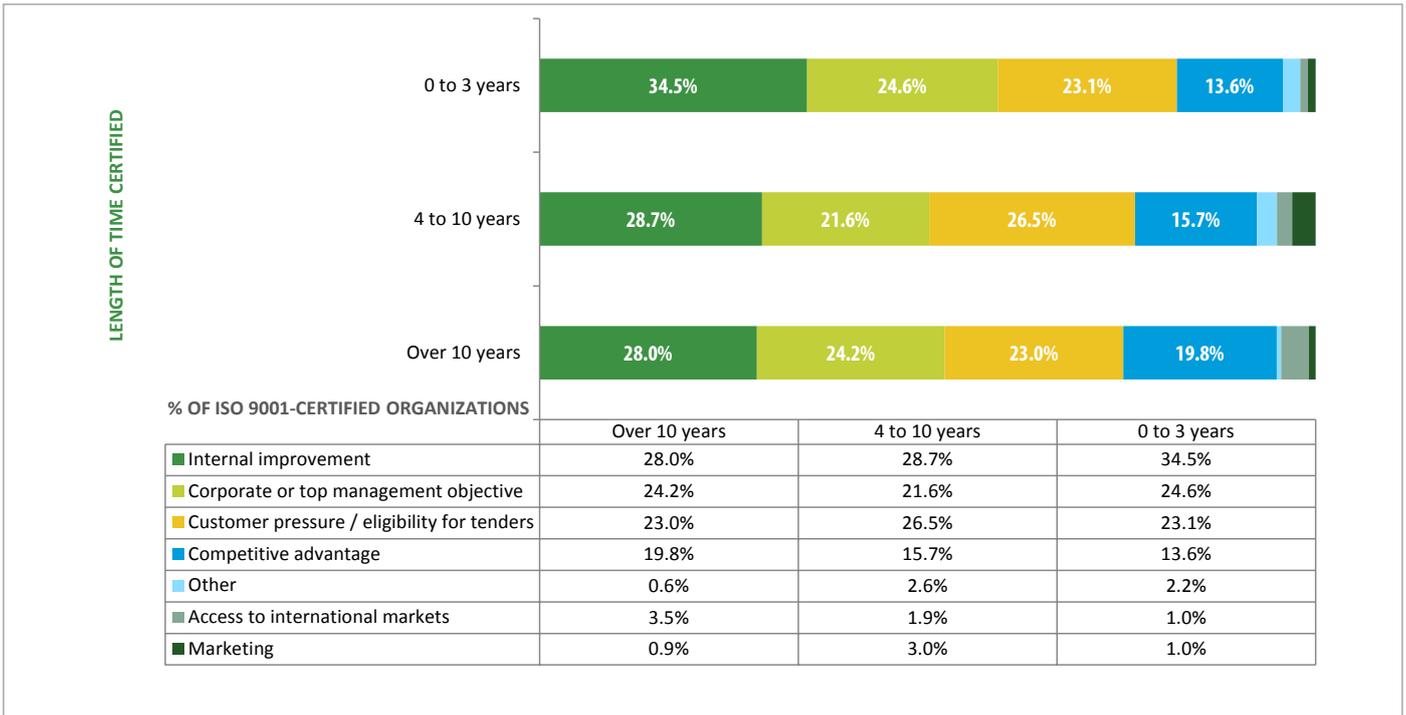


Figure 24. Major reasons mentioned for implementing a QMS

#### IV. TIME TO IMPLEMENT THE SYSTEM AND ACHIEVE CERTIFICATION

As shown in Figure 25, the majority of organizations (52%) took between 7 months and one year to implement their QMS and obtain certification to ISO 9001, and 27% took more than a year. More disturbing, though, is that over 20% claimed to have obtained certification within 6 months of starting implementation, including 5% who claimed to have done so in 3 months or less. The results from previous surveys have shown that in these cases, the degree of confidence that can be placed in such certification is much lower, regardless of the length of time the organization has been certified.

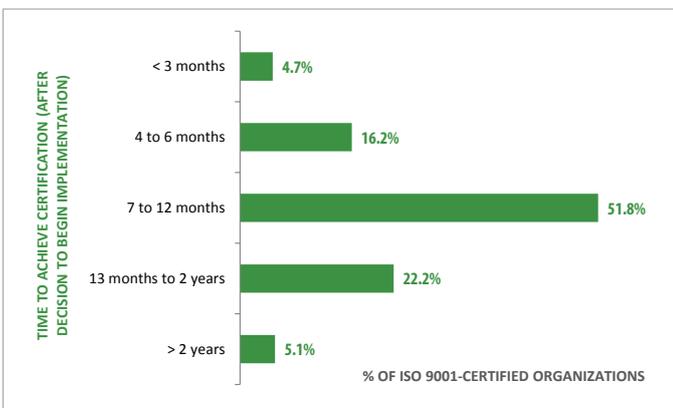


Figure 25. Time taken to achieve certification after the decision to start implementing a QMS

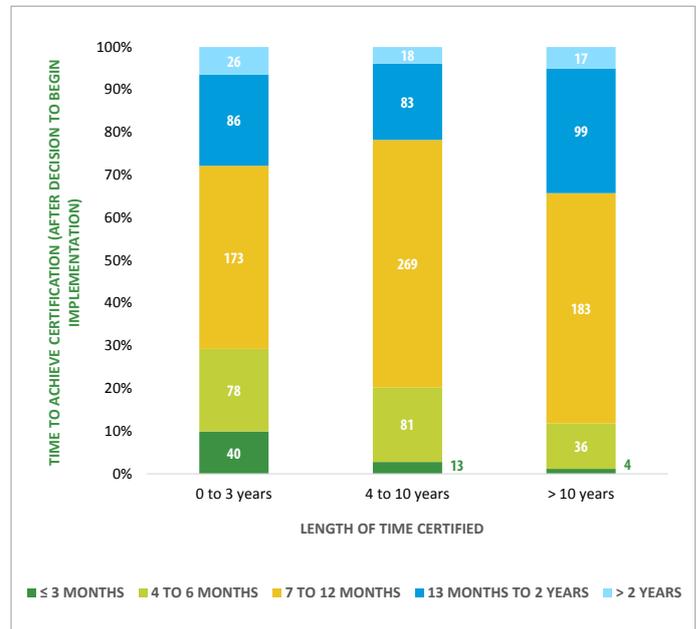


Figure 26. Correlation between time taken to achieve certification and the length of time certified

As shown in Figure 26, in recent years the percentage of organizations that took 6 months or less to achieve certification has increased. There may be many legitimate reasons for that

(for example, a subsidiary company of a larger organization that is already certified, or an organization with a mature quality philosophy), but it is nevertheless of concern, and it is recommended that CBs pay special attention to the initial audit of organizations that claim to have implemented their system in 3 months or less. This information could be requested as part of the CB's contract review process.

## V. USE OF CONSULTANTS

Overall, 88% of the survey respondents chose to use consultancy services to help them with the initial implementation of their QMS and 44% said that continued use of consultancy helps them to maintain it in accordance with ISO 9001. As shown in Figures 27 and 28, the use of consultants for the implementation of the QMS is more pronounced in SMEs, and likewise for the maintenance of the system after initial certification.

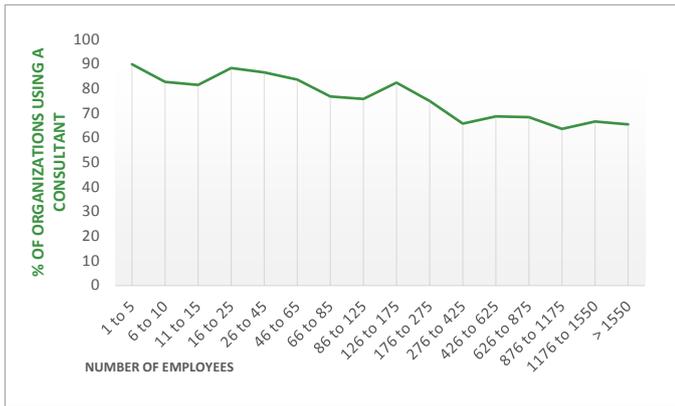


Figure 27. % of organizations using a consultant as a function of organization size

Figure 29 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 18% of the organizations who

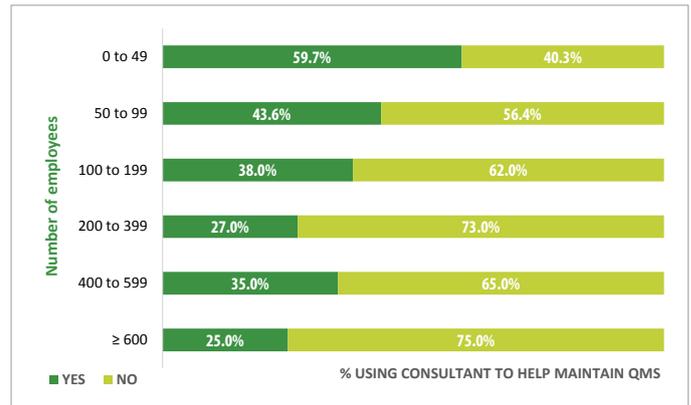


Figure 28. % of organizations using consultants to maintain their QMS after initial certification as a function of organization size

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 43% of the organizations responding used the consultants to carry out internal audits on their behalf.

Although 20% of the respondents carried out their management review without any involvement of their consultant, and a further 71% used the consultant to provide inputs, it is worrying to see that 7% 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

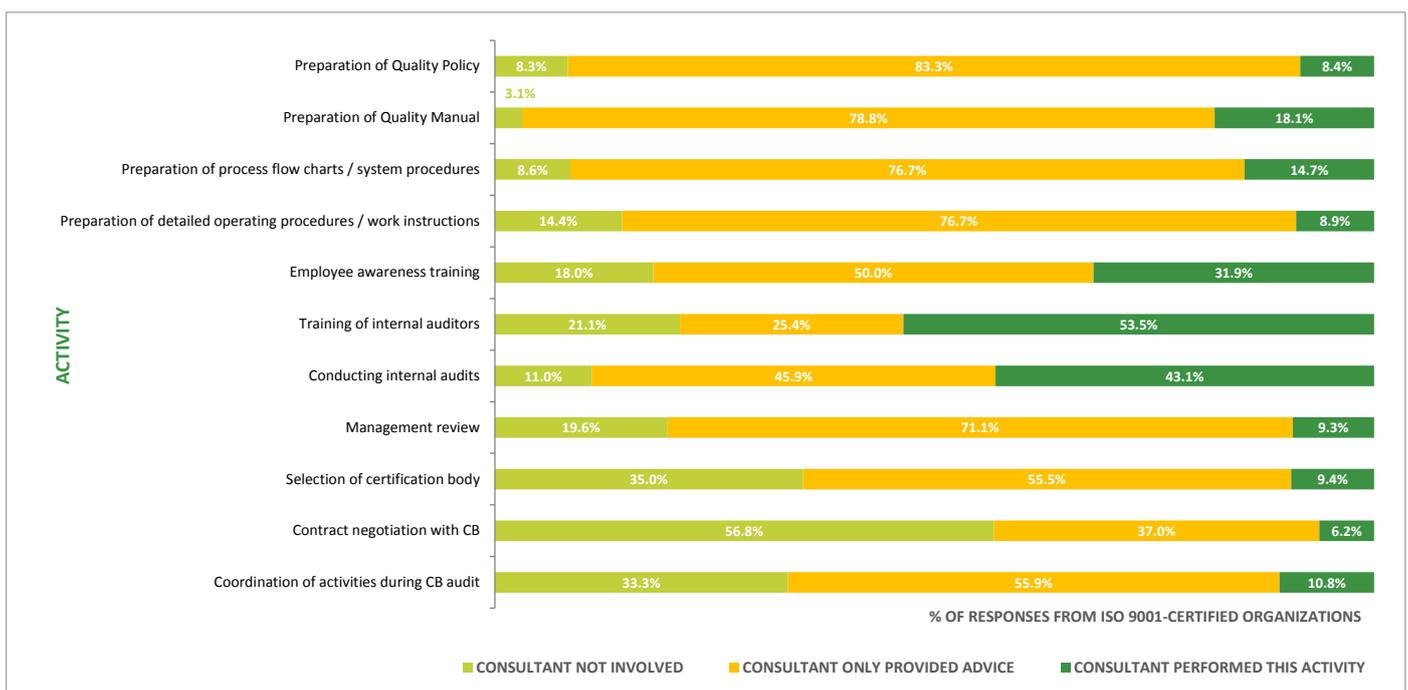


Figure 29. Involvement of consultants during implementation of the QMS

continuing suitability, adequacy and effectiveness” – and this is not something that should be delegated to a consultant. Also of concern are the approximately 10% of organizations who responded that the consultant had selected the certification body on their behalf, and coordinated activities during the CB’s initial audit.

Figure 30 shows that 34% of the respondents were “very satisfied” with the services provided by their consultant, and a further 61% were “satisfied”. However, 5% of the respondents were dissatisfied, with 1% being “very dissatisfied”.

Some of the reasons given by those who were dissatisfied included the following:

- “Our system was implemented by “copying” that of another organization, which did not reflect our own reality. This created a lot of problems when we tried to adapt it to our real situation.”
- “Consultant was working with a lot of different clients, and did not give us enough attention.”
- “The consultants implemented a system that meant we were dependent on them for absolutely everything.”
- “Inability to explain clearly and objectively the requirements of ISO 9001.”
- “The consultants used a pro-forma set of documents for all the companies where they were providing services.”
- “The consultant provided the necessary explanations, but the system did not fit the context and culture of our company. We had to hire another consultant to help us with our internal audits and to customize the system according to our own needs.”
- “The consultant created a culture where the procedures were the responsibility of the quality department, and not the organization as a whole.”

“The consultant used a very complicated methodology, with pre-prepared documents that in most cases were not appropriate for our needs. He was very knowledgeable, but used language that was impossible to understand for our employees, which generated a lot of dissatisfaction.”

“Left us with a very bureaucratic, unwieldy system.”

... and many similar complaints.

It is to be hoped that consultants who read this report take good note of these concerns. They also reinforce the need for ABNT, Inmetro, ABRAC, SEBRAE and others to ensure the timely promotion of standards such as ISO 10019 “Guidelines for the selection of quality management system consultants and use of their services” (and similar documents developed locally in Brazil). In order to be effective, these guidelines need to be made available to organizations **before** they begin implementation of their QMS – one possibility would be to make use of communication channels available through industry associations and federations. 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.

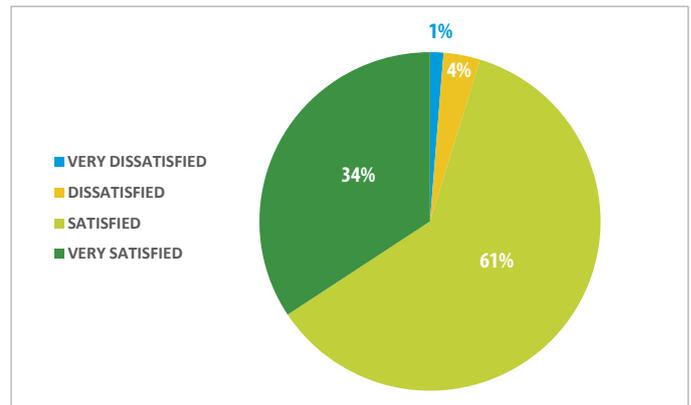


Figure 30. Satisfaction of the surveyed organizations with QMS consultancy

## VI. 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 varying inflation rate over the years, 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 1206 respondents, Figure 31 shows that over 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” (26%). Less than 2% considered the implementation of ISO 9001 not to have been a good investment.

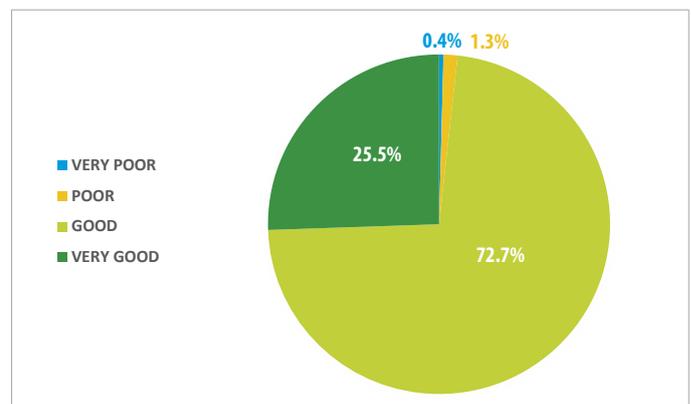


Figure 31. Perceptions about the return on total investment for ISO 9001 implementation and certification

## VII. UTILIZATION OF OTHER MANAGEMENT SYSTEM STANDARDS

As shown in Figure 32, 15% of the organizations who responded to the survey were also certified to ISO 14001 (for EMS); and 8% to OHSAS 18001 (OHSMS), with a further 41% and 32% respectively either implementing or intending to implement these systems. Very little interest was shown in the other standards mentioned in the survey (ABNT NBR 16001 (Social Responsibility); ISO 27001 (Information Security) and ISO 50001 (Energy Management)). The other certifications mentioned by the respondents included various product certifications as well as certifications against particular industry standards such as ISO/TS 16949 (for the automotive industry), ISO 22000 (food industry) and ISO 13485 (Medical devices) as well as the Brazilian PBPQ-H certification scheme for the construction sector.

The current survey confirmed the results of previous surveys in Asia, that even among ISO 9001-certified organizations little use is made of the ISO 9004 guidance standard (“Managing for the sustained success of an organization — A quality management approach”). It can be seen from Figure 33 that only 23% of the respondents said that they “know and use”

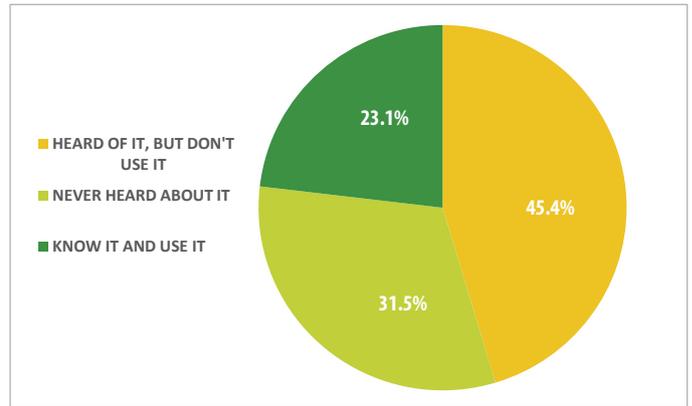


Figure 33. Awareness and use of ISO 9004 among ISO 9001-certified organizations

ISO 9004; 45% said they knew of the standard but did not use it, and 32% of the respondents were unaware of the standard’s existence. Greater promotion of the use of ISO 9004 is to be recommended as a means to improve organizational efficiency and achieve long term sustained success.

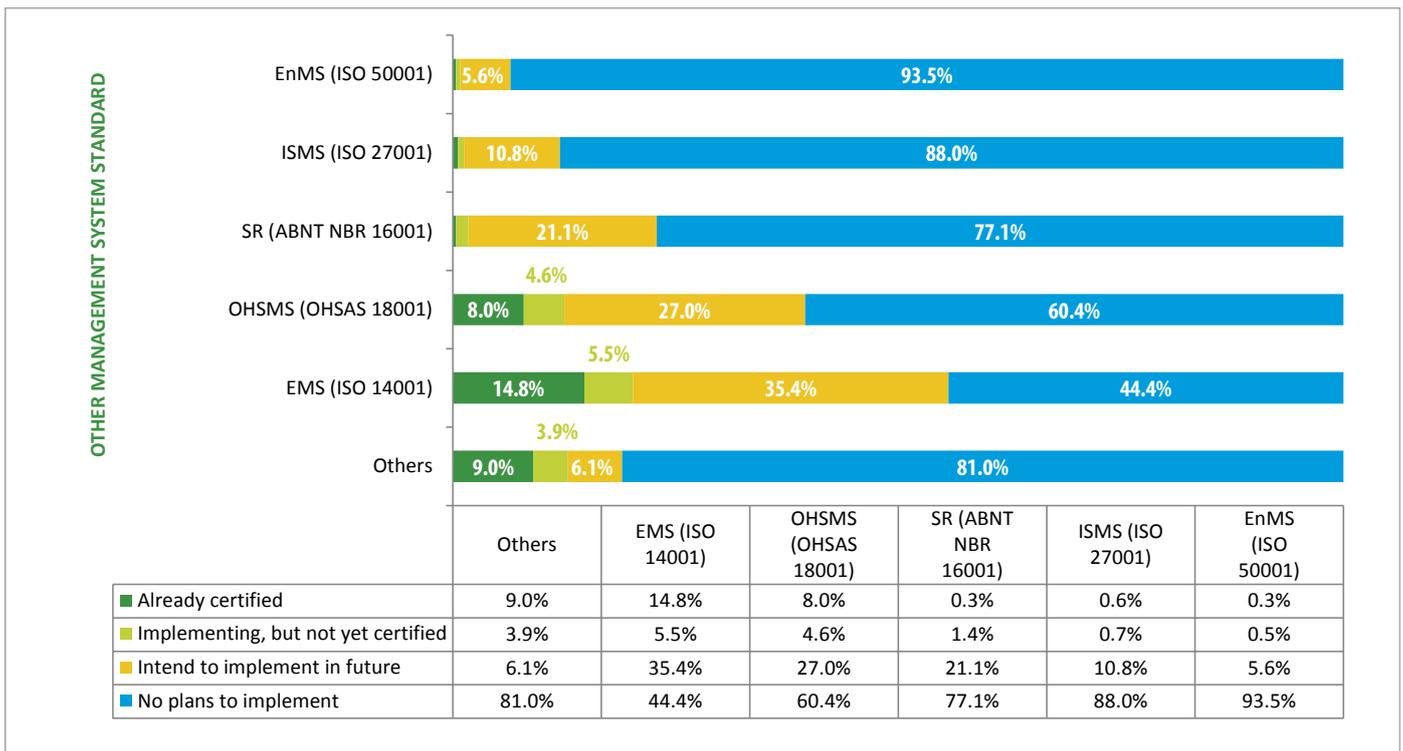


Figure 32. Percentage of surveyed organizations holding or seeking other certifications

## VIII. SELECTION OF CBS BY THE ISO 9001-CERTIFIED ORGANIZATIONS

As shown in Figure 34, over 50% of the respondents are certified by a local branch of foreign certification body; 37% by a local (Brazilian) CB, and 5% by a local franchise of an

overseas CB. Nearly 18% of the respondents also stated that they had transferred to another CB at some point during their certification history.

In line with the results of the survey of purchasing organizations, the ISO 9001-certified organizations did not have a high level of knowledge about the IAF or the role of accreditation. Only 44% could correctly name the AB under whose accreditation their own certificate was issued. 29% did not know, and the remaining 27% confused the AB with the CB, or with a CB Association. 52% were however able to name Inmetro (strictly speaking, now Cgcre) as the national AB for Brazil. About 25% of the certified organizations had heard of IAF and claimed to know what it does. 27% had heard of it but did not know what it does, and 48% had never heard of the IAF.

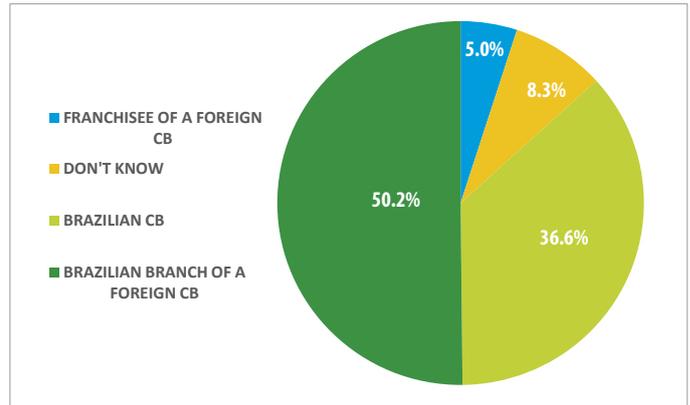


Figure 34. Categories of CBs used by the ISO 9001-certified survey respondents

### IX. COMMUNICATION WITH CBS PRIOR TO AN INITIAL AUDIT

According to the survey, contact with the CBs prior to the initial audit was usually done through telephone or e-mail (82% of the total), and/or at the sites of the organizations (30%) for face-to-face discussions (see Figure 35). A relatively high percentage of organizations (45%) had undergone a pre-audit before formally engaging the CB.

It was disturbing to see that 8% of the correspondents had no direct contact with the CB at all (all contacts having been made by the consultant), and 6% of the respondents mentioned that their CB had conducted internal audits on their behalf (which is not acceptable, according to ISO/IEC 17021:2011 Clause 5.2.6).

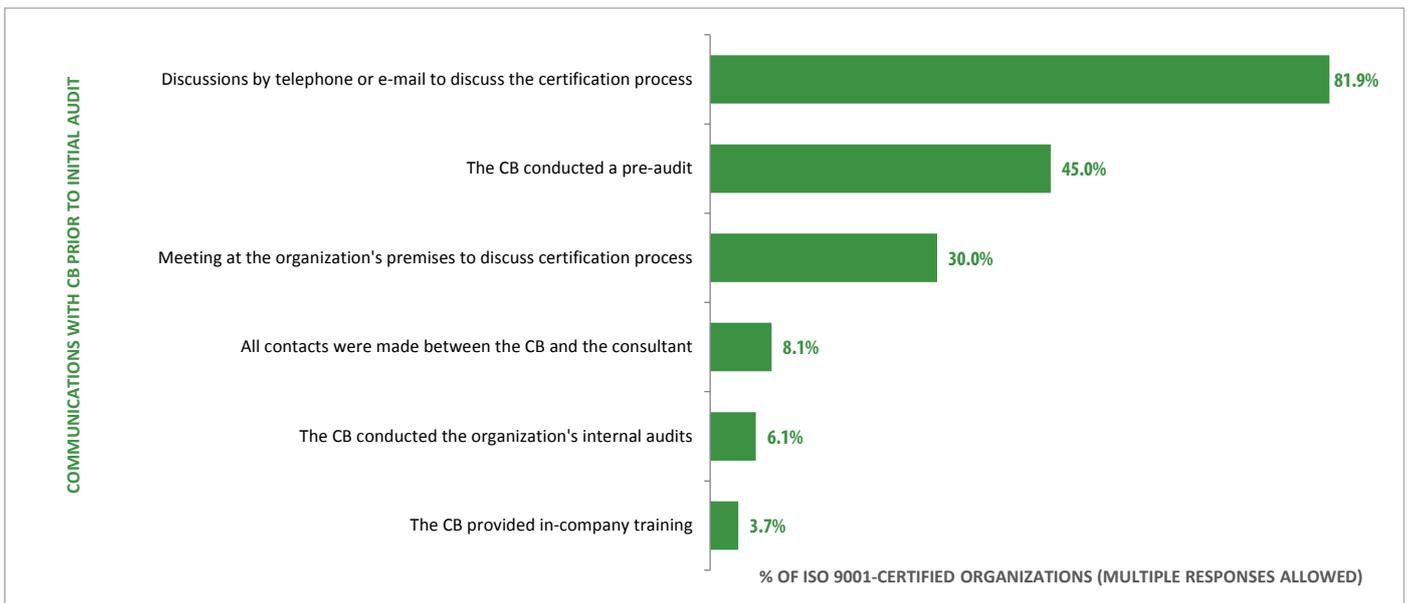


Figure 35. Communications with CBs prior to initial audit

### X. CRITERIA FOR CB SELECTION

Figure 36 shows the level of agreement of the certified organizations with a series of statements regarding the criteria they used when selecting their CB. It can be seen that high importance is given to accreditation, and specifically national accreditation (by Cgcre), and also to CBs with an international

reputation. Of lesser importance is accreditation by a foreign AB or by an IAF MLA Signatory member. The respondents disagree that price is the main factor in their CB selection, or that they choose CBs based on a reputation for leniency.

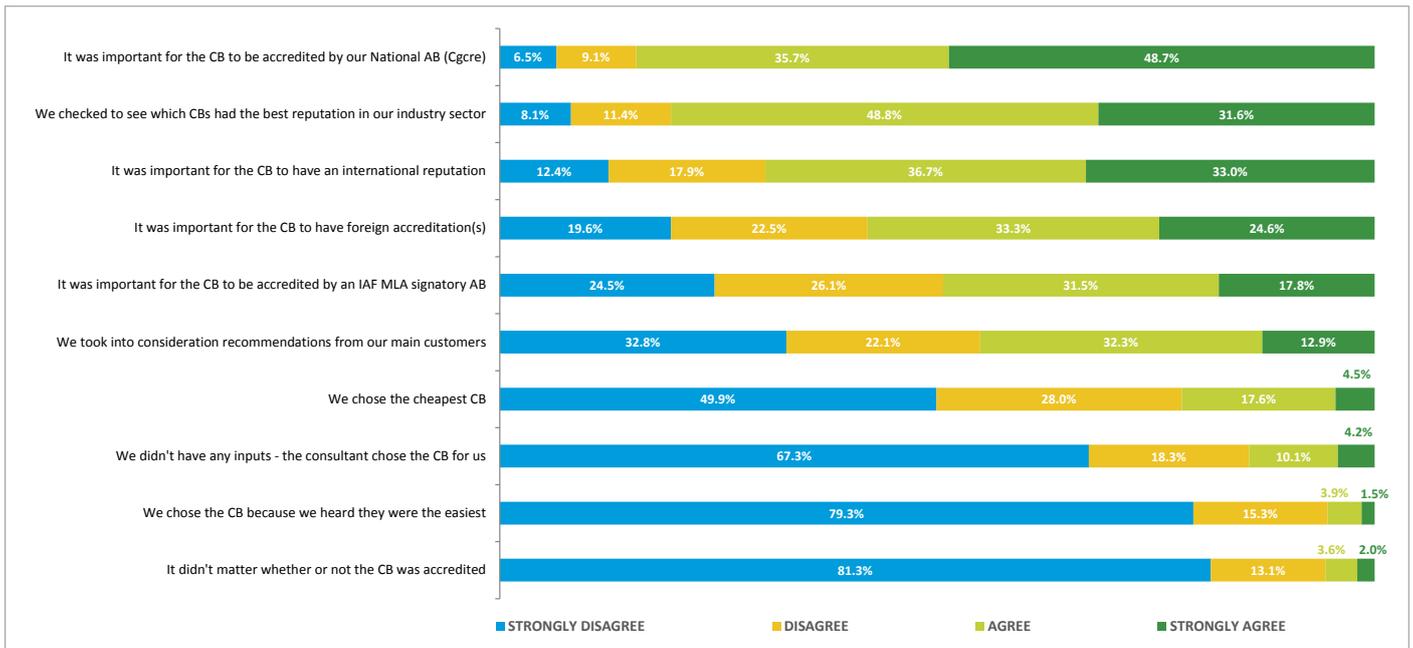


Figure 36. Criteria used by ISO 9001- certified organizations for the CB selection process

## XI. PROCESS OF INITIAL AUDITS

Regarding initial audits, respondents were requested to quantify their degree of agreement or disagreement to the following statements (see Figure 37). The results show that in general, opinions about the professionalism and impartiality of the auditors were good, as was the knowledge of the particular economic sector of the auditees. Again, in general terms, the respondents said that the auditors were keen to observe the

organization’s processes and were able to identify weaknesses in the QMS. The audits were found to be challenging, and not too easy. There was some disagreement about whether or not the auditors spent sufficient time auditing top management, but overall the organizations did not consider that the auditors had spent too much time in the Management Representative’s office, or only looking at documentation.

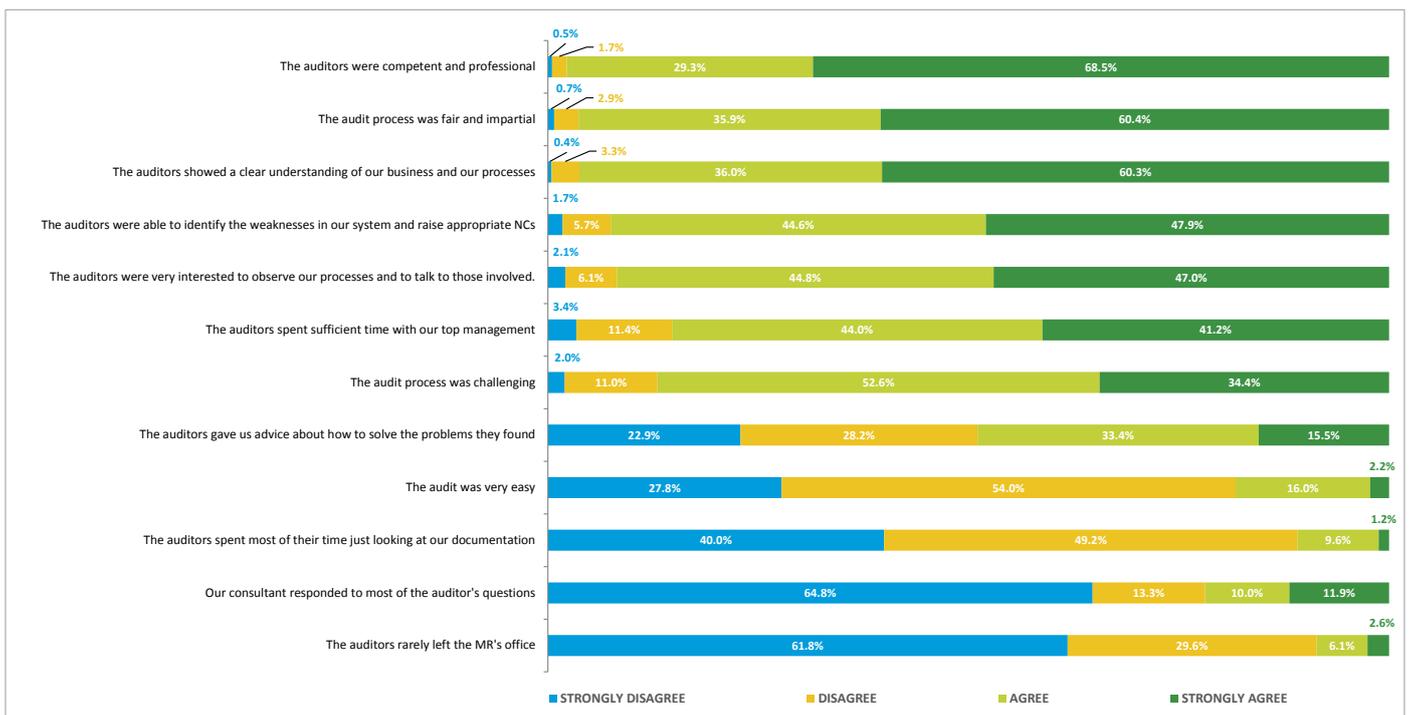


Figure 37. Certified organizations’ perceptions of the initial audit

## XII. SURVEILLANCE AUDITS

According to the survey responses, 83% of the organizations said that surveillance audits were conducted annually, 15% said every 6 months, and a small percentage (1%) said every 9 months, i.e. within the three-year certification cycle, there would be one initial audit or recertification audit and three surveillance audits.

ISO/IEC 17021:2011 requires the CB to conduct at least one surveillance audit a year. Though not frequent, just under 1% of the organizations said their surveillance audits were carried out less than once a year. This might be a result of multi-site sampling, which does not require an annual surveillance audit at each and every site in the scope of a multi-site certification, but this point was not verified.

Regarding the surveillance audit process, the certified organizations provided their level of agreement or disagreement to a series of statements. The results are shown in Figure 38. There was strong consensus that the surveillance audits are useful, ensure ongoing conformity to ISO 9001, encourage continual improvement of the QMS and continue to add value in terms of the investment made. The respondents disagreed that the surveillance audits only focus on documentation, or that the auditors never raise nonconformities.

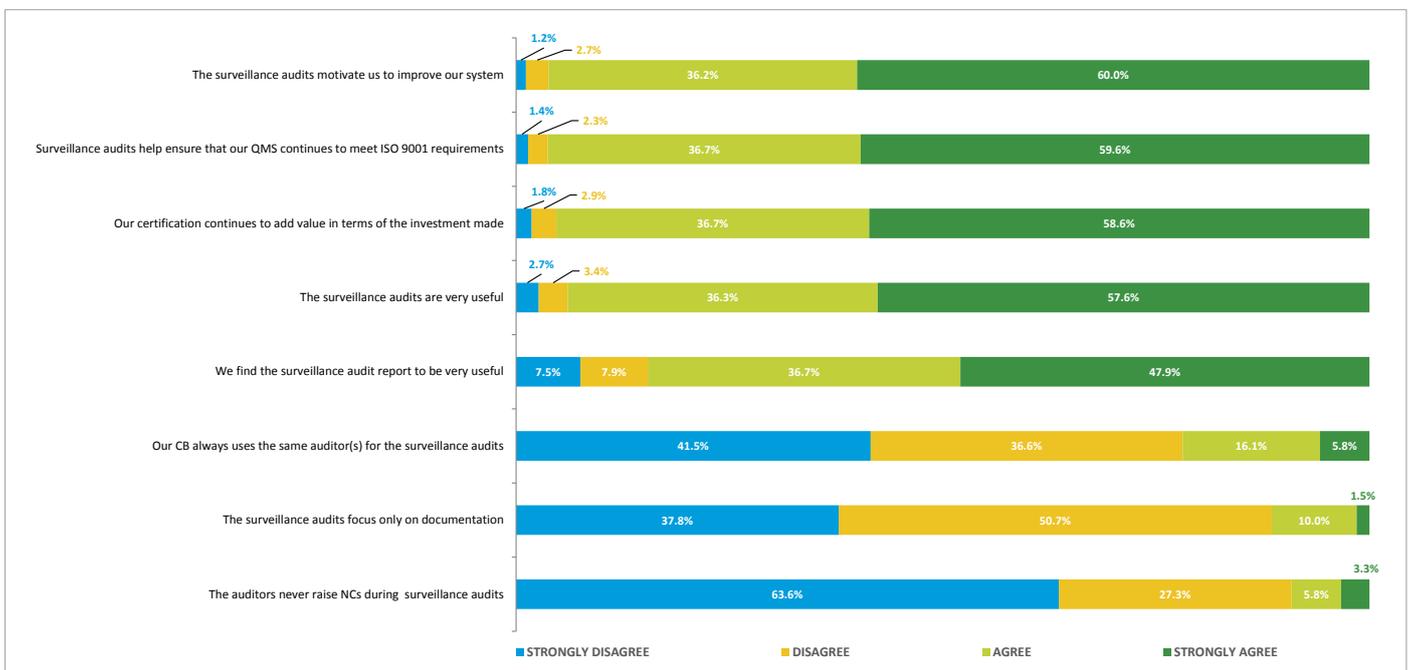


Figure 38. Certified organizations' perceptions of the surveillance audit process

## XIII. OVERALL COMMENTS ABOUT THE CERTIFICATION PROCESS

Figure 39 shows that, in general terms, the certified organizations confirmed that ISO 9001 certification has been a good investment, has helped to improve the way they work, meet their organizational objectives, and given them more confidence in their ability to consistently provide conforming products and services to their customers. Implementation and certification has also promoted a better understanding of the organization's processes, and to reduce rework and waste. The respondents do not consider that ISO 9001 has introduced too much bureaucracy into their organization, but whilst 83% agreed that when evaluating potential suppliers, their customers give them credit for being certified, and 72% agreed that they can obtain more business, this does not necessarily translate into higher prices.

The following is a selection of some of the specific comments received:

“ISO 9001 implementation has had a welcome effect on our organization, and improved our product quality. We are able to transmit more confidence to our customers.”

“In general terms the system has added value for us, and therefore it has been worth every cent we invested in it.”

“ISO 9001 certification has shown us how to monitor and improve our processes, but our customers still question the value of certification. We are not chosen as a supplier because we are certified, but based on price. Certification can open doors for us, but we still see a lack of loyalty from our customers who, in the current market conditions, will still buy cheaper products from suppliers with no certification or qualification at all.”

- “We really have to thank (our CB), because every audit provides us with learning opportunities, and stimulates us to improve.”
- “The implementation of ISO 9001 together with other initiatives like ISO14001, and TPS helps us to maintain our competitiveness and continually improve our processes.”
- “ISO 9001 can bring many benefits, so long as it is properly implemented throughout the organization. Companies that seek certification by hiring consultants to do things for them, without top management commitment, don’t get any result, except a “certificate on the wall” and just lead to ISO 9001 losing credibility.”
- “We started the process in a very heavy, bureaucratic and restrictive way, using a consultant who only had experience with large corporations or foreign companies. We then started contacting other SMEs who had been certified and eventually we chose (our current CB). We realized that it doesn’t have to be bureaucratic and the cost can be quite low. We lost a lot of time at the beginning!”
- “It’s important to clarify that we are a government organization, subject to the Law No 8666<sup>1</sup>, so we have to choose the CB based on open tenders. We have to make sure the tender documents provide us with all the criteria needed to give confidence in the CB; after that it goes to the CB with the lowest price.”
- “Unfortunately, certification is often not perceived by the customer to add value. This is one of the main obstacles that needs to be overcome. Also, because they don’t understand the technical aspects of the system, Top Management regard it as a “necessary evil”, and not as an investment. This can be very demotivating for quality professionals.”
- “ISO 9001 certification should become an integral part of the commercial relationship between companies, customers and other interested parties, so that we can promote continual improvement together.”
- “One of the most important factors is auditor competence. Some add value, and others don’t – previously we had an auditor who never raised any nonconformities, and our system deteriorated. Now we have a different auditor, and we are much more satisfied, even though we are given more nonconformities!”

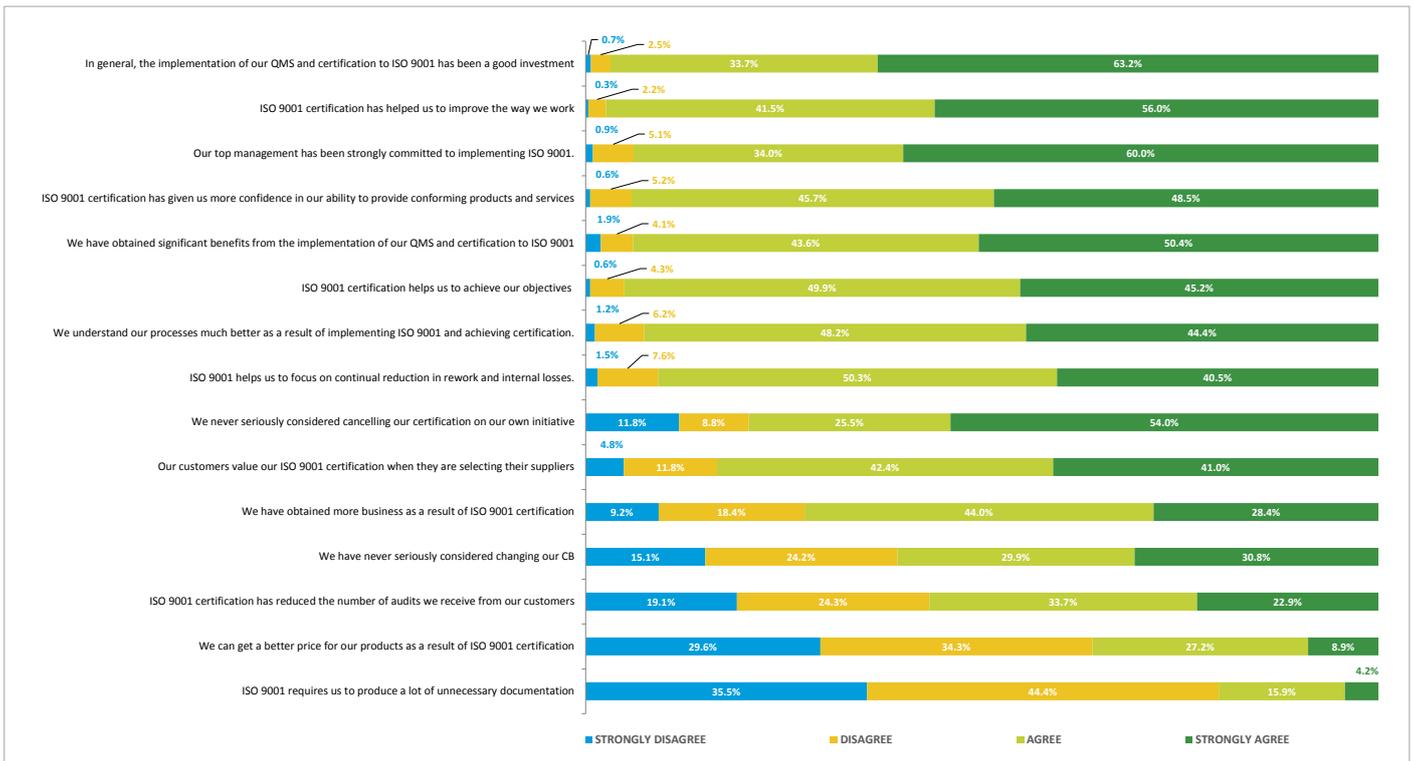


Figure 39. Overall perception of certified organizations about the certification process

<sup>1</sup>Brazilian Law No. 8666/93 sets out the general rules for bidding procedures and government contracts





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## Chapter 5

# ON-SITE “MARKET SURVEILLANCE” VISITS TO ISO 9001-CERTIFIED ORGANIZATIONS

## I. VISIT PLANNING

During the planning stages, the following factors affected the way in which the project evolved, and the sampling criteria used:

- There is a significant difference in the number of ISO 9001 certificates in Brazil reported by the ISO Survey 2015 (<http://www.iso.org/iso/iso-survey>) and those by Inmetro ([www.certifiq.inmetro.gov.br/](http://www.certifiq.inmetro.gov.br/)). The ISO Survey reports that Brazil had 18,201 certificates at the end of 2014 (down from 22,128 the previous year, due to some sources of the data not contributing to the latest survey). This compares to a total of 11,459 certificates reported by Inmetro, relating to certificates recognized under the SBAC (Brazilian System for Conformity Assessment). We attribute these differences to two factors:
  - Certificates issued by CBs who are not part of the SBAC (i.e. under foreign accreditations) that are reported to ISO, but not to Inmetro;
  - Overall inconsistencies in the two counting methodologies.
- There was great difficulty in obtaining accurate information about the organizations that had been certified to ISO 9001 in Brazil, particularly in the case of certificates issued by CBs under the accreditation of foreign accreditation bodies. At the time the survey was conducted, ISO/IEC 17021:2011 was the applicable version of the standard that CBs are supposed to meet in order to be accredited, but the requirement in that standard for all CBs to “*maintain and make publicly accessible, or provide upon request... a directory of valid certifications...*” was being ignored by many CBs, and not being enforced by their ABs. The new 2015 revision of the standard has now removed that requirement, which will certainly reduce the transparency of accredited certification and make future surveys of this kind even more difficult.
- A decision was therefore made to limit the sampling to those organizations holding ISO 9001 certificates issued by Cgcre-accredited CBs under the SBAC, in order to validate the “market surveillance methodology”. Even so, there was still considerable difficulty in obtaining information from some of the accredited CBs, despite encouragement from ABRAC and Inmetro to provide this.
- This overall lack of credible information about the number and details of certified organizations in Brazil is a topic that merits further discussion between the various parties involved, since it undermines public confidence in certification. According to ISO/IEC 17021-1:2015, “The overall aim of certification is to give confidence to all parties that a management system fulfills 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.” The initiative by Inmetro and ABNT to develop a searchable directory of valid certifications in Brazil ([www.certifiq.inmetro.gov.br/](http://www.certifiq.inmetro.gov.br/)) is to be applauded, but the database is still far from being fully populated and there are a number of inconsistencies that need to be resolved before it can be considered reliable.
- During the course of the project, Brazil entered a period of financial crisis, and Inmetro’s travel budget was frozen. This meant that most of the visits were carried out in the Rio de Janeiro region (obviating the need for air travel by the Inmetro assessors), with some visits being conducted in São Paulo and other regions as a result of additional funding provided by UNIDO, and/or the physical presence of some of the trained assessors in these regions.
- It has to be emphasized that the organizations visited by the assessors agreed to receive the visit voluntarily. This means that when analyzing the results, due consideration must be given to the fact that the sampling was skewed towards those organizations that were confident enough about their QMS to open their doors to a visit from the Inmetro/UNIDO project assessors. This would be the case regardless of the number of visits undertaken, unless there were to be contractual agreements in place between Cgcre and the CBs, and the CBs and their certified clients, to make the acceptance of such visits compulsory.

By the end of the project, the Inmetro assessors had visited a total of 92 organizations certified to ISO 9001 under the SBAC. Although this number was not sufficient to be of statistical significance to draw absolute conclusions, there were a number

of lessons learned that can provide useful information if the “Market Surveillance” methodology is to be implemented on a more routine basis to complement traditional accreditation methodologies (Office visits and witness audits).

## II. RESULTS AND DISCUSSION

52% of the organizations visited had been certified for between 4 and 10 years; 23% had been certified of over 10 years and 25% for 3 years or less (meaning they had not yet completed a full certification cycle or a recertification audit). The size distribution of the organizations is shown in Figure 40.

The results of the visits are presented in Table 1 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 (see Checklist Item 26), with 94% of the results falling into assessment categories 3, 4 or 5. It should also be pointed, however, out that 6% of the visited organizations were listed in the “low confidence” category (Grades 1 and 2). Details are as follows:

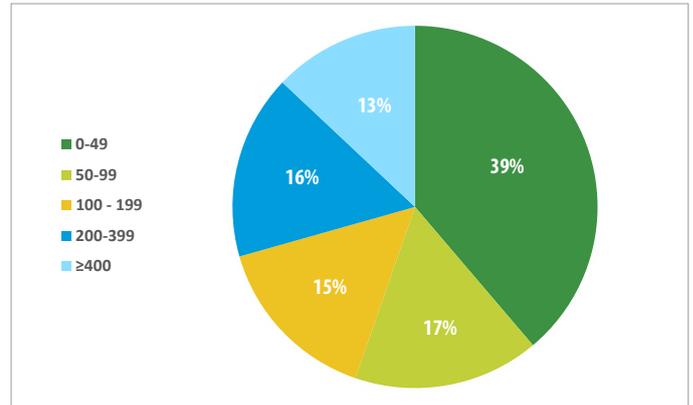
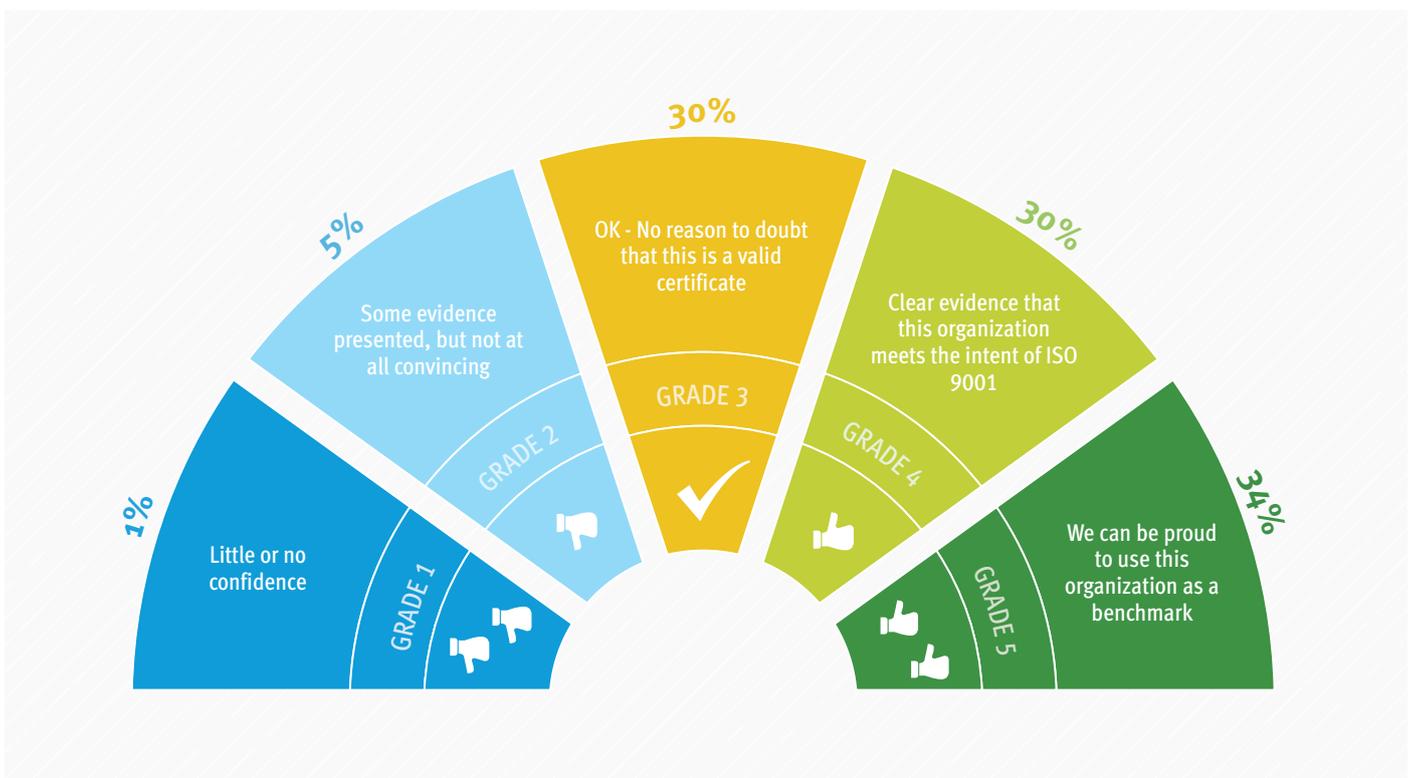


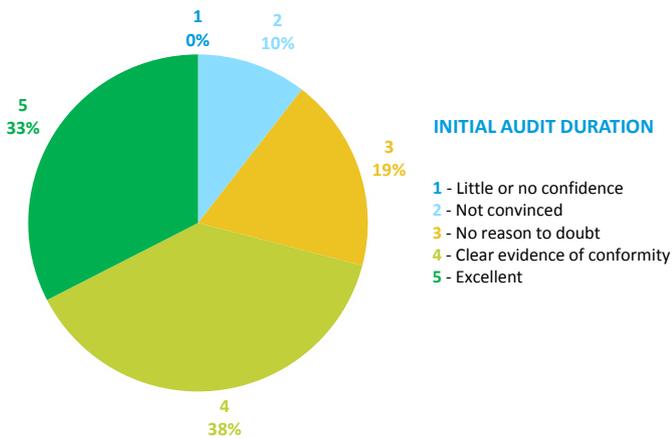
Figure 40. Size range (by number of employees) of the organizations visited



Whilst these percentages reflecting dissatisfaction are small, they do represent a significant number of organizations in absolute terms, particularly when we consider the favorable 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.

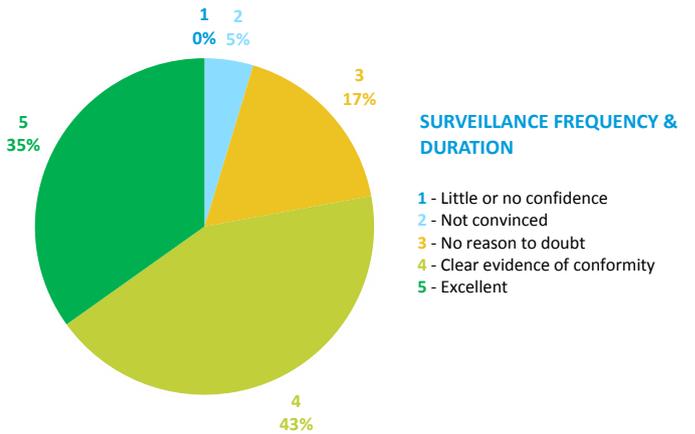
Of equal concern is the finding that in 9% of the visits the Inmetro assessors found little (7%) or no (2%) confidence that the certification process had been conducted effectively by the certification body.

Results



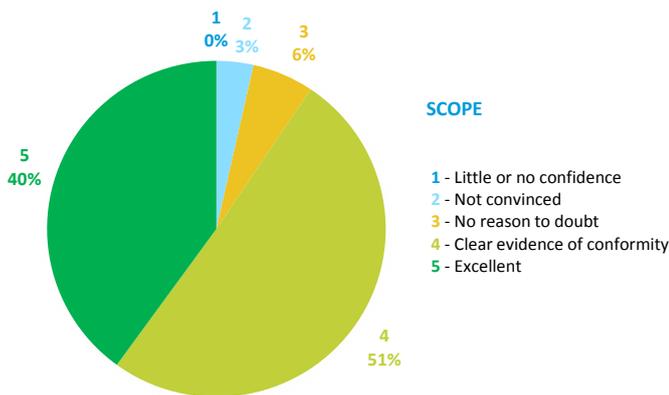
**Check list item**

**1.** The number of auditor days in initial certification (or the latest re-certification audit) were appropriate to the scale and complexity of the organization as well as the actual number of employees (see IAF MD 5).



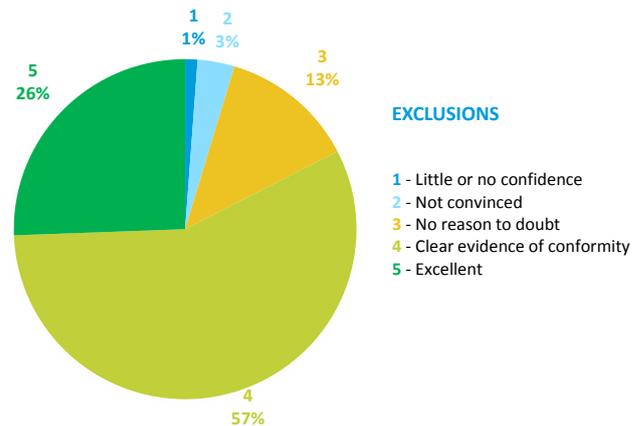
**Check list item**

**2.** The number of auditor days and frequency for surveillance audits are appropriate to the scale and complexity of the organization as well as the actual number of employees (see IAF MD 5 Chapter 5).



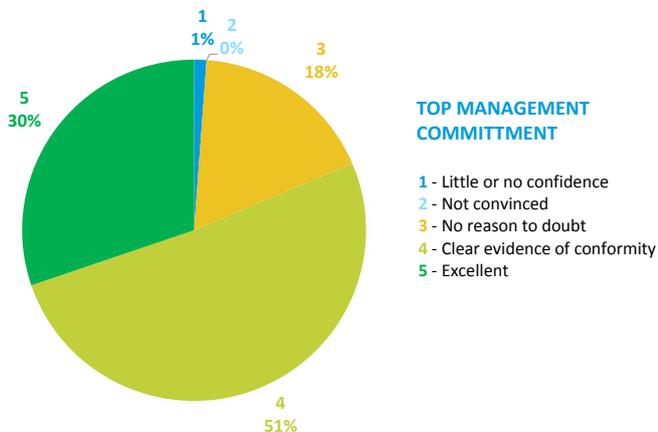
**Check list item**

**3.** The certification scope on the certificate correctly describes the organization's activities and is not misleading.



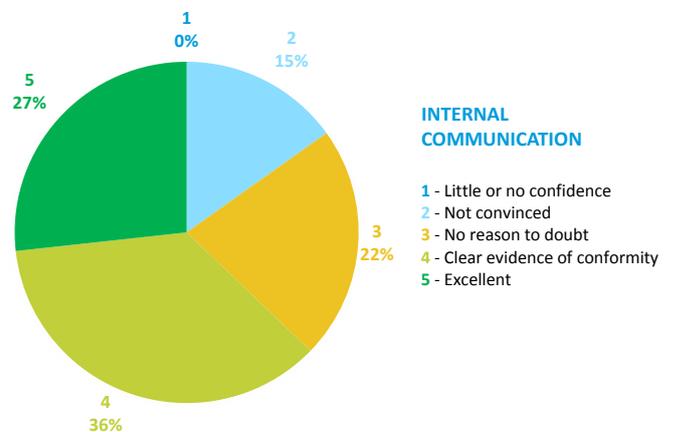
**Check list item**

**4.** All exclusions are adequately justified.



**Check list item**

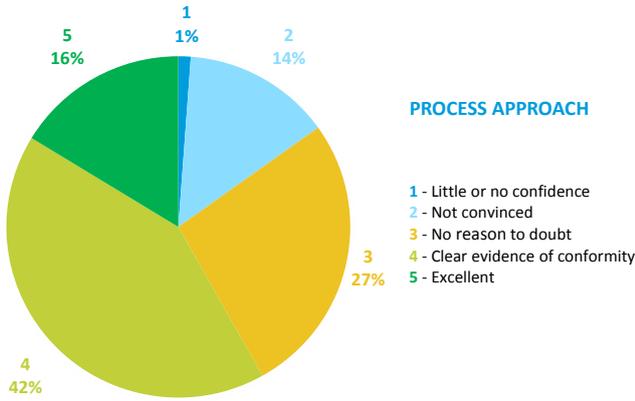
**5.** There is evidence that top management participates in and is committed to the implementation of ISO 9001.



**Check list item**

**6.** There is good internal communication and employees know of their role in the QMS.

Results

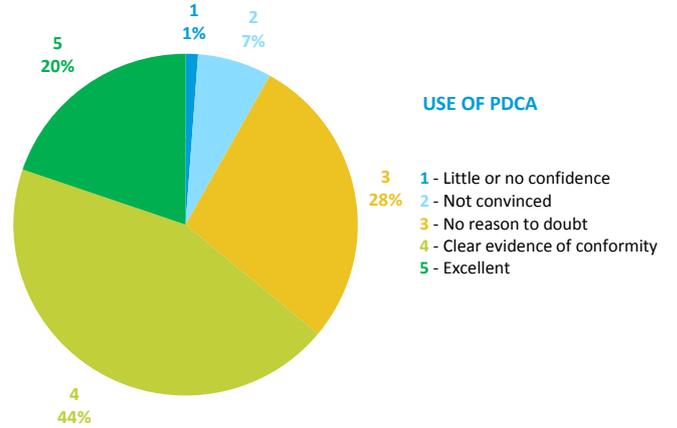


PROCESS APPROACH

- 1 - Little or no confidence
- 2 - Not convinced
- 3 - No reason to doubt
- 4 - Clear evidence of conformity
- 5 - Excellent

Check list item

7. The whole organization has a clear understanding of and implements the “process-approach”.

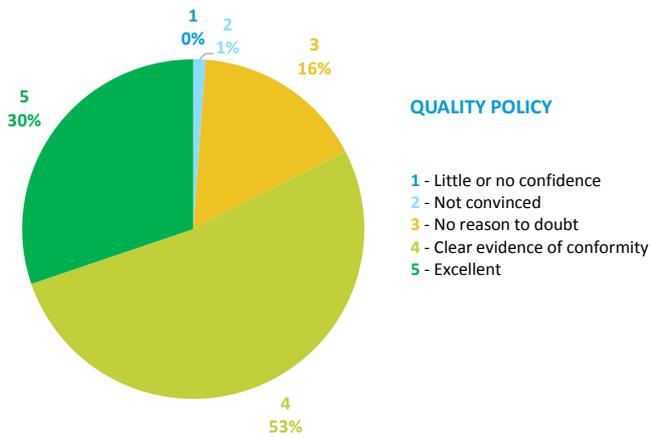


USE OF PDCA

- 1 - Little or no confidence
- 2 - Not convinced
- 3 - No reason to doubt
- 4 - Clear evidence of conformity
- 5 - Excellent

Check list item

8. The organizations uses the “Plan, Do, Check, Act (PDCA)” methodology (Clause 4.1 in ISO 9001).

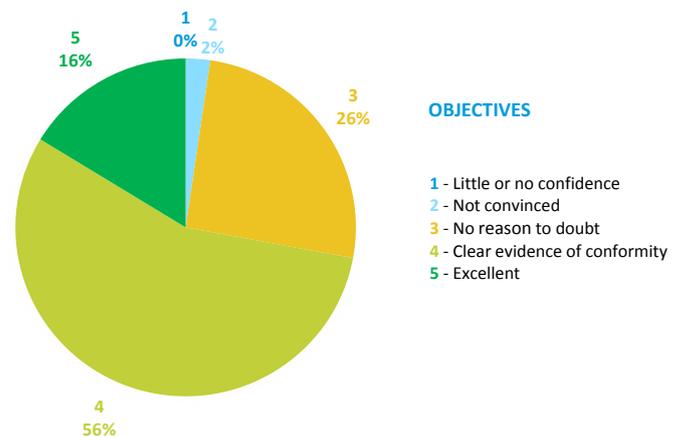


QUALITY POLICY

- 1 - Little or no confidence
- 2 - Not convinced
- 3 - No reason to doubt
- 4 - Clear evidence of conformity
- 5 - Excellent

Check list item

9. The quality policy suits the organization’s actual situation and culture.

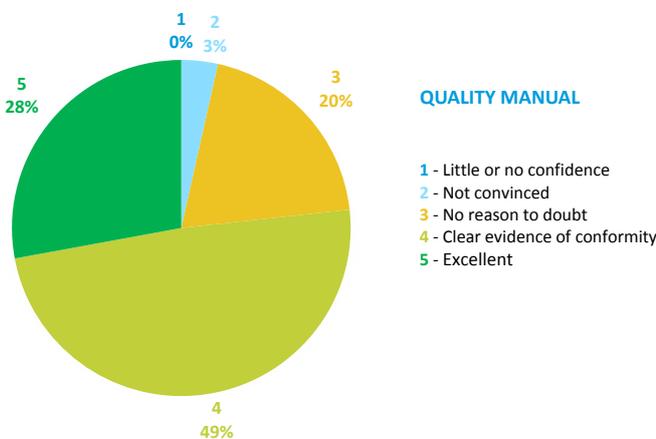


OBJECTIVES

- 1 - Little or no confidence
- 2 - Not convinced
- 3 - No reason to doubt
- 4 - Clear evidence of conformity
- 5 - Excellent

Check list item

10. The organization has established and deployed meaningful quality objectives at relevant functions and levels.

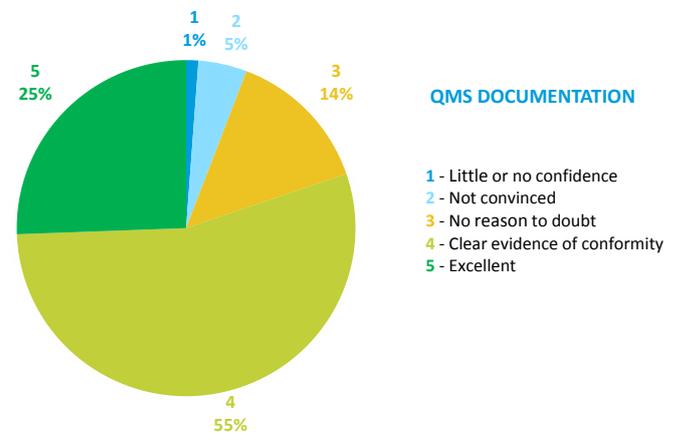


QUALITY MANUAL

- 1 - Little or no confidence
- 2 - Not convinced
- 3 - No reason to doubt
- 4 - Clear evidence of conformity
- 5 - Excellent

Check list item

11. The way the organization actually works is consistent with its Quality Manual.



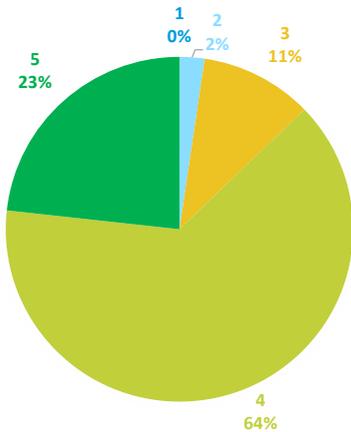
QMS DOCUMENTATION

- 1 - Little or no confidence
- 2 - Not convinced
- 3 - No reason to doubt
- 4 - Clear evidence of conformity
- 5 - Excellent

Check list item

12. QMS documentation is being used and is properly controlled.

Results

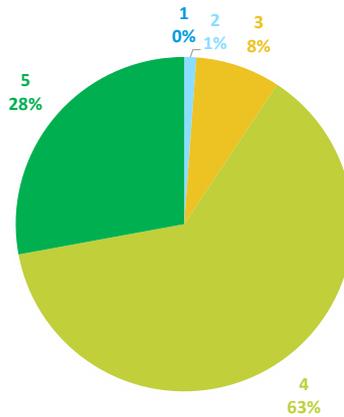


RESOURCES

- 1 - Little or no confidence
- 2 - Not convinced
- 3 - No reason to doubt
- 4 - Clear evidence of conformity
- 5 - Excellent

Check list item

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

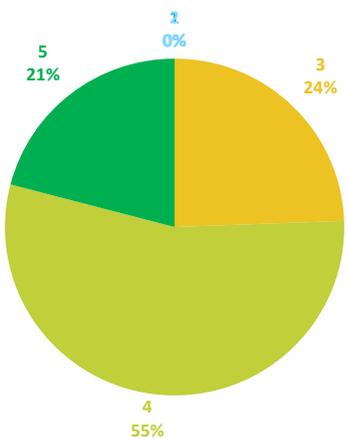


WORK ENVIRONMENT

- 1 - Little or no confidence
- 2 - Not convinced
- 3 - No reason to doubt
- 4 - Clear evidence of conformity
- 5 - Excellent

Check list item

14. The work environment is appropriate.

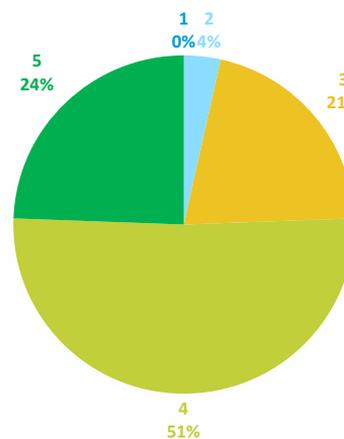


PRODUCT REALIZATION  
PROCESS IDENTIFICATION

- 1 - Little or no confidence
- 2 - Not convinced
- 3 - No reason to doubt
- 4 - Clear evidence of conformity
- 5 - Excellent

Check list item

15. Key product realization processes are identified and managed.

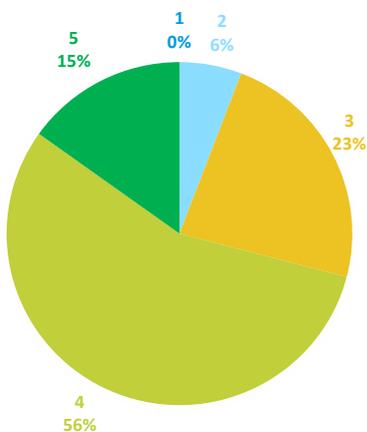


PRODUCT REALIZATION  
MONITORING & MEASUREMENT

- 1 - Little or no confidence
- 2 - Not convinced
- 3 - No reason to doubt
- 4 - Clear evidence of conformity
- 5 - Excellent

Check list item

16. All processes are adequately monitored and measured.

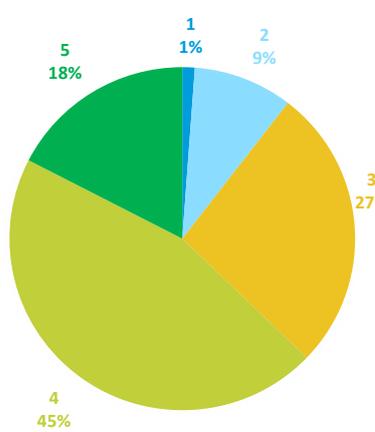


PRODUCT  
NONCONFORMITIES

- 1 - Little or no confidence
- 2 - Not convinced
- 3 - No reason to doubt
- 4 - Clear evidence of conformity
- 5 - Excellent

Check list item

17. Non-conformities in the products are identified and handled according to documented procedures



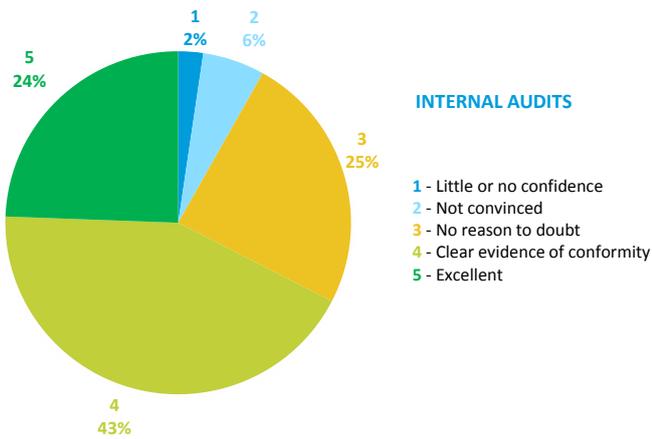
CAUSE ANALYSIS &  
CORRECTIVE ACTION

- 1 - Little or no confidence
- 2 - Not convinced
- 3 - No reason to doubt
- 4 - Clear evidence of conformity
- 5 - Excellent

Check list item

18. The organization is committed to identifying and taking effective corrective actions against the causes of non-conformities in its processes, products and systems.

Results

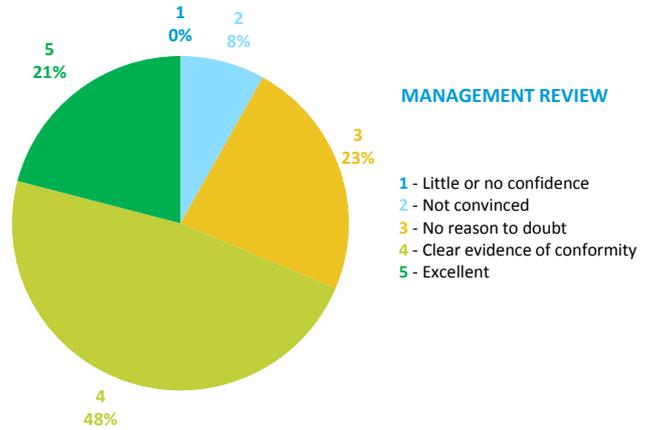


INTERNAL AUDITS

- 1 - Little or no confidence
- 2 - Not convinced
- 3 - No reason to doubt
- 4 - Clear evidence of conformity
- 5 - Excellent

Check list item

19. Internal audits are conducted as planned and are effective.

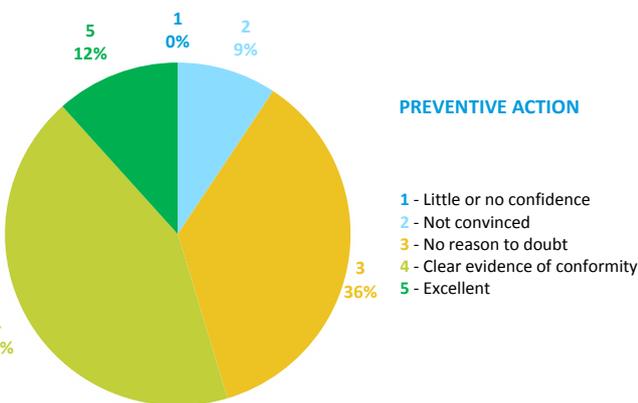


MANAGEMENT REVIEW

- 1 - Little or no confidence
- 2 - Not convinced
- 3 - No reason to doubt
- 4 - Clear evidence of conformity
- 5 - Excellent

Check list item

20. The management review is conducted as planned and is effective.

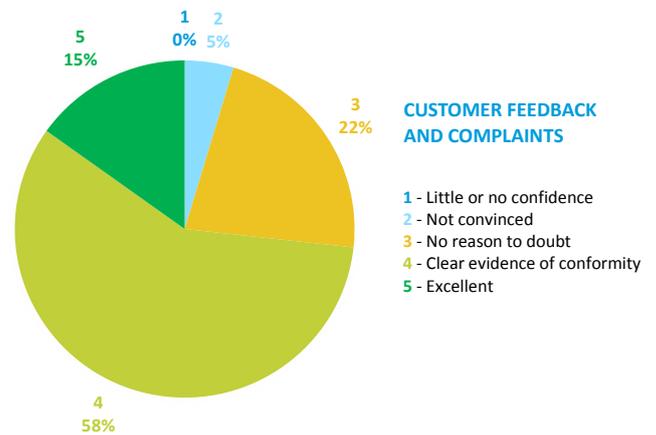


PREVENTIVE ACTION

- 1 - Little or no confidence
- 2 - Not convinced
- 3 - No reason to doubt
- 4 - Clear evidence of conformity
- 5 - Excellent

Check list item

21. The organization places a focus on preventing the occurrence of non-conformities.

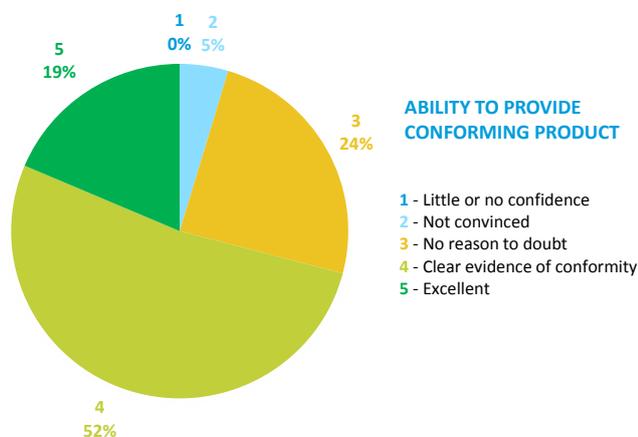


CUSTOMER FEEDBACK AND COMPLAINTS

- 1 - Little or no confidence
- 2 - Not convinced
- 3 - No reason to doubt
- 4 - Clear evidence of conformity
- 5 - Excellent

Check list item

22. Customer feedback and customer complaint handling mechanisms are appropriate.

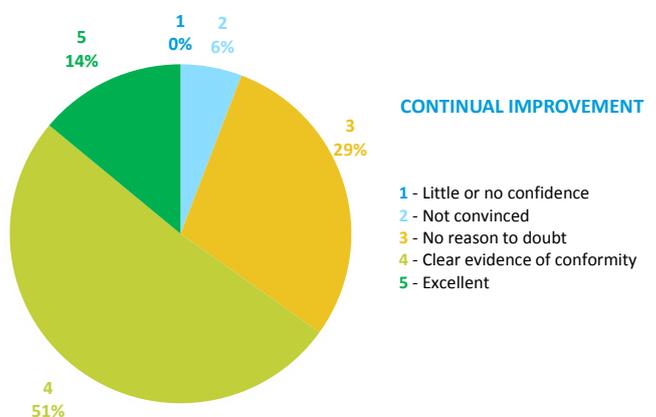


ABILITY TO PROVIDE CONFORMING PRODUCT

- 1 - Little or no confidence
- 2 - Not convinced
- 3 - No reason to doubt
- 4 - Clear evidence of conformity
- 5 - Excellent

Check list item

23. The QMS provides confidence in the ability of the organization to “consistently provide products that conform to customer and applicable regulatory requirements”.



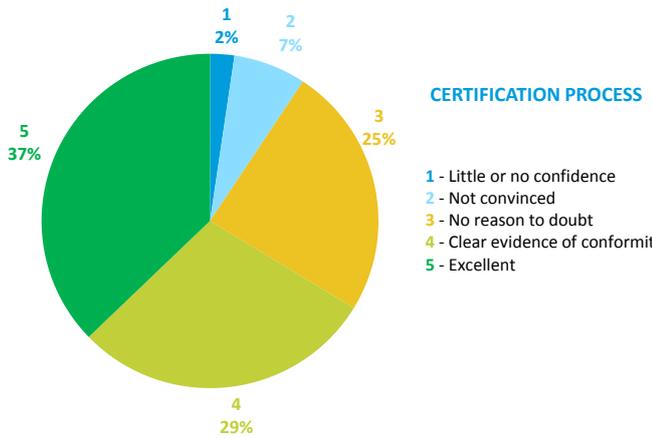
CONTINUAL IMPROVEMENT

- 1 - Little or no confidence
- 2 - Not convinced
- 3 - No reason to doubt
- 4 - Clear evidence of conformity
- 5 - Excellent

Check list item

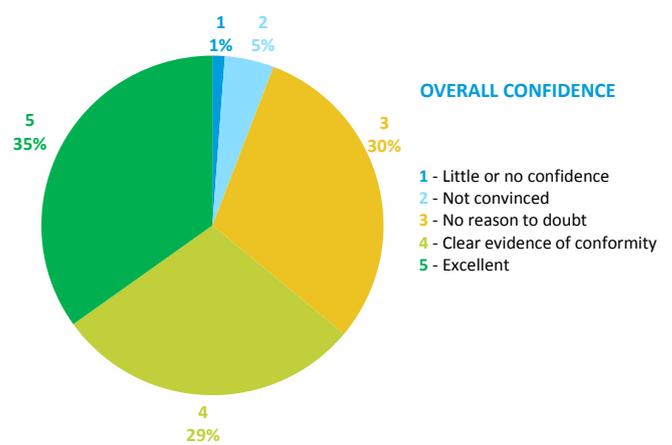
24. The organization has a corporate culture for continual improvement of the effectiveness of its QMS.

Results



Check list item

25. The CB has conducted an effective audit process.



26. Overall level of confidence in the ISO 9001 system of the organizations.

Table 1. Results from the on-site visits to the certified organizations

III. DISCUSSION OF THE RESULTS OF THE MARKET SURVEILLANCE VISITS

The weakest areas in the QMS of the certified organizations were as follows (based on % (Grade 1 + Grade 2) scores):

1. Inadequate internal communication and the need for employees to understand better their roles in the QMS (Item 6 of checklist);
2. Lack of understanding and effective implementation of the process approach (Item 7 of checklist);
3. Poor Cause Analysis and Corrective Actions (Item 18 of checklist);
4. Lack of focus on preventing nonconformities (Item 21 of checklist).

This is very much in line with anecdotal evidence, and comments made during the workshops with interested parties by some of the purchasing organizations who had conducted their own 2nd-party audits (but not necessarily of the organizations included in the current sample). Interestingly, however, customer complaints handling was not identified as a problem area, although this was a major cause of dissatisfaction among purchasers. This “mismatch” also occurred in previous surveys conducted by UNIDO, and CBs are encouraged to place more emphasis on this topic.

Figure 41 shows the relationship between QMS certification duration and system maturity. For organizations that have been certified for over 10 years, the quality management system maturity and its overall credibility can be seen to be good, with no organizations visited receiving a “Grade 1” “Grade 2” overall assessment. Interestingly, however, the organizations that have been certified for three years or less performed better than those certified between 4 and 10 years. This may

be due to the fact that the recently-certified organizations were still “fresh” from their initial certification audits, and had not slipped into bad habits. This is a topic that could be subjected to further analysis by ABRAC and Cgcre, as appropriate.

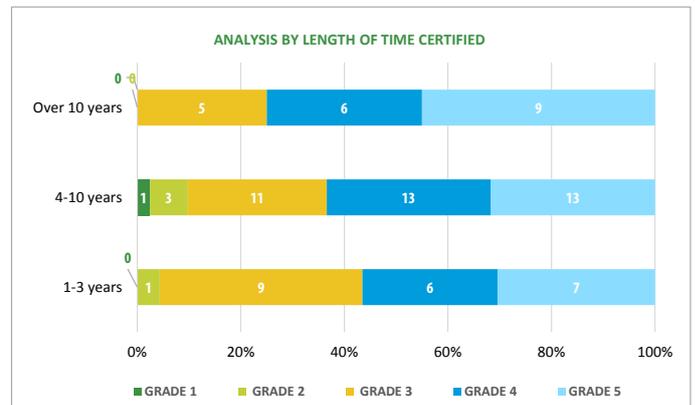


Figure 41. Relation between overall QMS credibility and length of time certified

Figure 42 shows that in general, the organizations with over 200 employees that were visited performed well, with no organizations scoring “Grade 1” or “Grade 2” in their overall assessment. For smaller organizations, some doubts were raised about the effectiveness of the QMS with less than 200 employees (9% of the organizations with a score of “Grade 1” or “Grade 2” overall), though organizations in the 50 – 99 size range seemed to perform better (probably due to sampling error rather than any systematic tendency).

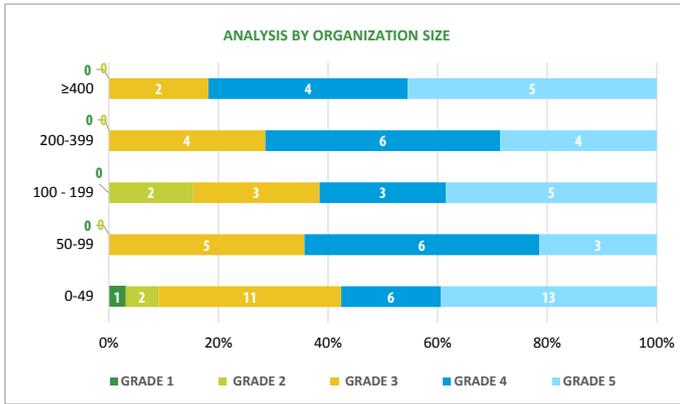


Figure 42. Correlation between overall QMS credibility and organization size.

Figures 43 and 44 show the effectiveness of the certification process and the overall confidence in the certified organizations’ ISO 9001 QMS respectively, broken down by CB. Results are shown only for CBs for whom 5 or more certified clients had been visited. Although the sample size and sampling criteria were insufficient to make statistically significant conclusions, it can be seen that if this “Market Surveillance” methodology were to be implemented on a more routine and disciplined basis, it is capable of distinguishing between CBs whose certified clients performed well, and those that did not. For example, doubts could be raised about the performance of CBs 2 and 6, and result in a more targeted approach from the accreditation body, whilst CBs 3 and 5 provided more confidence (in both the perceived effectiveness of their certification processes and the overall confidence observed in their certified clients) and could benefit from a “lighter” approach from the accreditation body (less frequent audits; less auditor days, for example).

This is considered to be one of the most important results of the project, which 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!”

Although there has been some reluctance at the international level to implement such an approach, the methodology is gaining traction among sector-specific QMS certification schemes (for example for TL 9000 in the Telecom industry) and in Social Auditing (for example for SA 8000).

During the regional workshops with the interested parties where the preliminary results of this project were presented, there was significant interest shown by the CBs present to try out this methodology (at least on a pilot basis), and it is recommended that this be discussed within ABRAC and between ABRAC and Cgcre, based on this project report. Factors that would need to be taken into consideration for such a methodology to be successful would include:

- How could such an initiative be financed, and how would the costs be distributed? Although there may be some initial investments to be made, if the approach is successful, then the ongoing costs could be similar to the overall cost of conducting office assessments and witness audits;
- The contractual basis under which accreditation body assessors could ensure access to a CB’s certified clients if these were selected for such market surveillance visits, in order to ensure a random sample;
- 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.

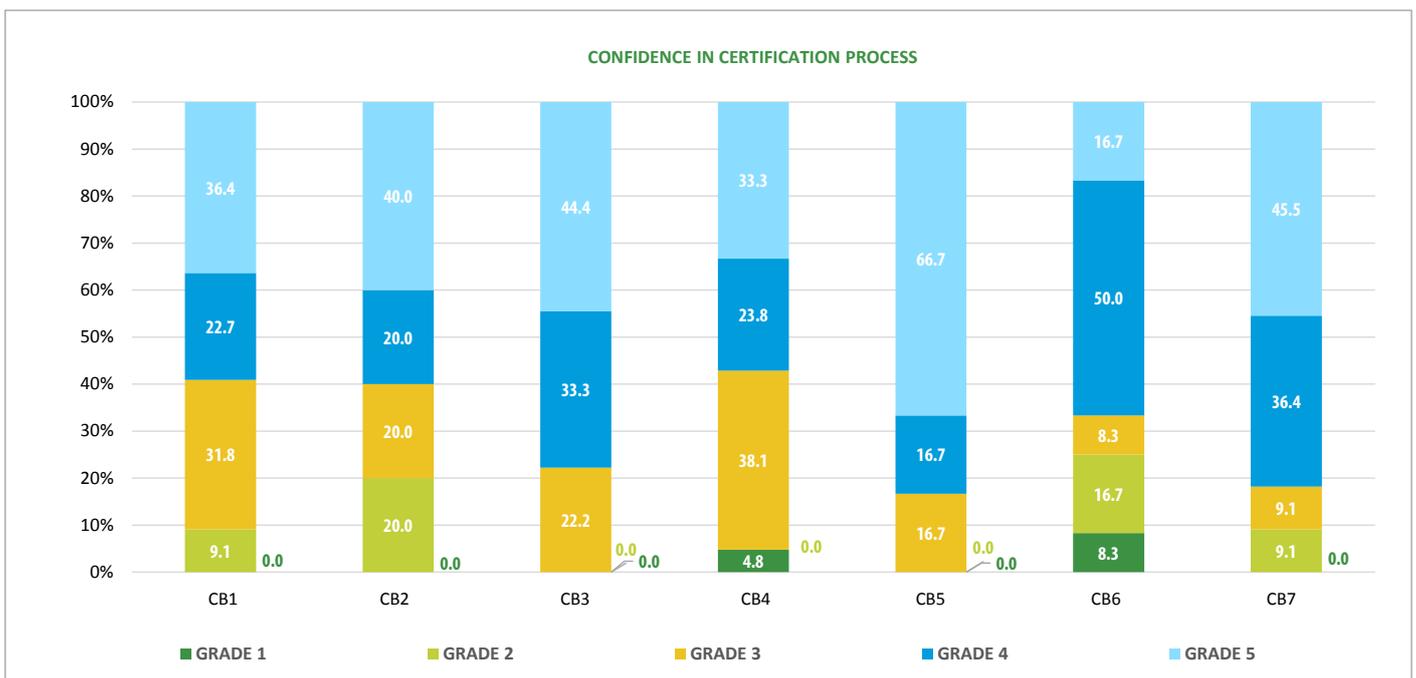


Figure 43. Overall perceived effectiveness of the certification process, broken down by CB

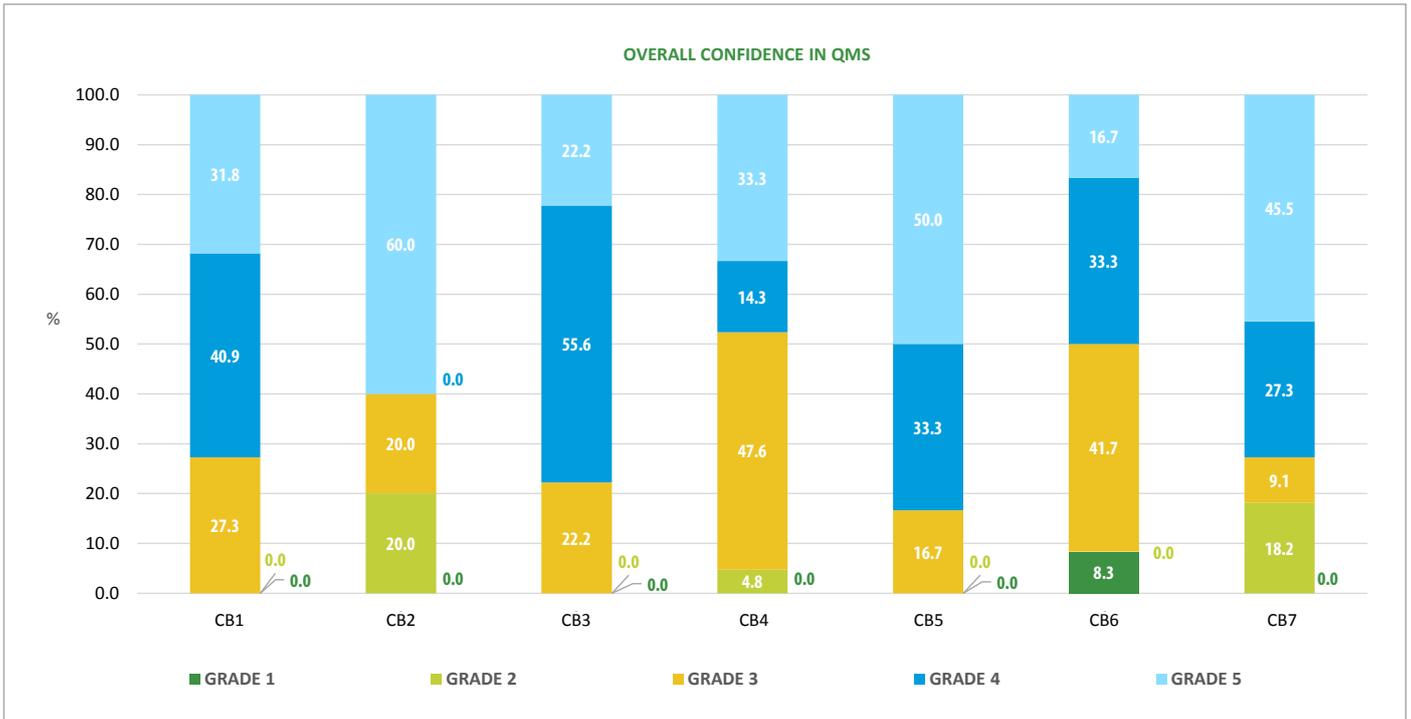


Figure 44. Overall confidence in the certified organizations' ISO 9001 QMS



## Chapter 6

# CONCLUSIONS AND RECOMMENDATIONS

This report has provided an in-depth look at the Brazilian market for ISO 9001 and its accredited certification, and is expected to be of use for all the relevant interested parties, including government agencies, regulatory bodies, certified organizations and their customers; consultants; auditors; auditor training bodies, the national standards body (ABNT) and its quality committee (ABNT/CB-25) and the national accreditation body (Cgcre).

The results of the project show that ISO 9001 is well respected in Brazil, and is considered by certified organizations to be a good investment. Purchasers are generally satisfied with the overall performance of their ISO 9001-certified suppliers.

There is little interest at the moment in other management systems standards, with the exception of ISO 14001 (EMS) and OHSAS 18001 (OHSMS).

The overall credibility of accredited certification in Brazil is good, but there are some areas that need to be improved. Based on the results of a series of short “market surveillance” visits, differences can be seen in the performance of ISO 9001 certified organizations and their certification bodies. This could form the basis for more focused accreditation surveillance activities in future.

There are a number of recommendations resulting from this report, which can be summarized as follows:

- 1 There is a need for greater promotion and awareness-building among both purchasers and certified organizations regarding the concept of accreditation. This is particularly important when considering the mutual recognition agreements that are in place under the IAF, in order to promote international trade.
- 2 The directory of certifications issued under the SBAC in Brazil needs to be finalized and maintained. Inmetro and ABNT need to work together with ABRAC to identify ISO 9001 certificates issued by foreign-accredited CBs in order to provide an accurate picture of the total number of ISO 9001-certified organizations in Brazil.
- 3 ABNT, Inmetro, ABRAC, SENAE and others need to ensure the timely promotion of standards such as ISO 10019:2005 “*Guidelines for the selection of quality management system consultants and use of their services*” in order to address some of the concerns expressed by ISO 9001-certified organizations about the performance of their consultants.
- 4 The survey results show that some purchasers are not satisfied with the complaint handling process – this needs to be addressed proactively by CBs, ABRAC and Cgcre.
- 5 Greater promotion of the use of ISO 9004 is to be recommended as a means to improve organizational efficiency and to help organizations achieve long term sustained success, using their quality management system as a base.
- 6 ABRAC and Cgcre need to address the fact that some certified organizations claimed that their CBs had carried out their internal audits (which contravenes the impartiality requirements of ISO/IEC 17021).
- 7 The on-site market surveillance visits to certified organizations show that some organizations and CBs should improve the following aspects:
  - a) Internal communication and the need for employees to understand better their roles in the QMS;
  - b) Understanding and effective implementation of a “process approach” to quality management;
  - c) Cause Analysis and implementation of effective Corrective Actions;
  - d) Greater focus on **preventing** nonconformities.<sup>2</sup>

<sup>2</sup> The new ISO 9001:2015 standard reinforces this by requiring organizations to identify and address the risks involved in their activities, that might lead to product or service nonconformities



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<sup>3</sup> Version that was used throughout this project – since superseded by a new version in 2015

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