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UNITED NATIONS
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ISO 9001

RELEVANCE AND IMPACT
IN CHINA

ISO 9001

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Contents

Acknowledgements	5
Acronyms	7
Summary of the Report	9
Chapter 1: Project Background	11
Chapter 2: Project Activities	13
Chapter 3: Results of the Survey of Chinese Purchasers' Perceptions of ISO 9001-certified Suppliers	17
Chapter 4: Questionnaire Survey of ISO 9001-certified Organizations in China	25
Chapter 5: On-site "Market surveillance" Visits to ISO 9001-certified Chinese Organizations	41
Chapter 6: Conclusions and Recommendations	49
Introduction of CNCA	53
References and Bibliography	57



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, the ISO 9001 requirements standard focuses on 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. The competence of the certification body to carry out such certification can be demonstrated by the process of accreditation. Whilst there are numerous certification bodies around the world, there is usually only one (government-recognized) accreditation body in any given country. These accreditation bodies 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 them with access to international markets and formal tenders where, such certification to ISO 9001 is often a pre-requisite. Furthermore, the proper use of ISO 9001-based quality management systems assists developing countries to promote sustainable trade, thereby pursuing UNIDO's goal of inclusive and sustainable industrial development (ISID).

In recent years, China has overtaken the early implementers of ISO 9001 and now represents approximately 30% of the 1.1 million ISO 9001 certificates issued worldwide. This in turn has attracted a large number of national and international certification bodies to establish a presence in China,

operating under a number of different accreditations from around the globe. The Certification and Accreditation Administration of China was established in 2001 as a regulatory body to oversee the certification and accreditation process.

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 (IAF). 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.

I was very pleased about the cooperation between CNCA and UNIDO to adapt the methodology used in the previous analysis to obtain a first-hand review on the current status of ISO 9001 certification in China. This analysis has provided valuable insights into the ways in which Chinese purchasers view the effectiveness of their ISO 9001-certified suppliers and the perspectives of organizations in China who have implemented a quality management system and opted for certification. We are confident that this analysis will contribute to the overall objective of promoting China's contribution to international trade and ultimately to the promotion of a more inclusive and sustainable development.

LI Yong
Director General



Acknowledgements

This report is based on UNIDO Project TE/CPR/12/002 “Assessment of the economic impact and effectiveness of ISO 9001 quality management system certification in China”, co-funded by the Certification and Accreditation Administration of the People’s Republic of China (CNCA) 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 project received active participation and strong support from UNIDO, local Quality and Technical Supervision Bureaus (QTSBs) and Entry-Exit Inspection and Quarantine Bureaus (CIQs) around China and from the China National Accreditation Service for Conformity Assessment (CNAS) and the China Certification and Accreditation Association (CCAA). Experts from the QTSBs and CIQs carried out the survey and the on-site visits to certified organizations. China Certification and Accreditation Institute (CCAI) undertook the general data analysis and report editing in cooperation with other participating parties.

The project was carried out under the guidance of the following people:

Mr. CHENG Fang, Mr. XU Zengde and Mr. ZHAO Zongbo (CNCA), Mr. XIAO Jianhua (CNAS), Mr. SHENG Fei (CCAA), Mr. QIAO Dong (CCAI), and Mr. Bernardo Calzadilla-Sarmiento, Mr. Otto Loesener, Mr. Ouseph Padickakudi and Mr. Edward Clarence-Smith (UNIDO).

The following individuals contributed their time, energy and professional experience to the planning, organization, implementation, data analysis and editing of this report:

Mr. Nigel H. Croft (UNIDO Consultant), Mr. LIN Feng and Mr. ZHAO Zheng (CNCA), Mr. LIU Ke and Mr. LIU Yan (CCAI), and Ms. DU Juan (CNAS).

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



Acronyms

AB	Accreditation Body
CASCO Toolbox	Series of conformity assessment standards issued by ISO/CASCO
CB	Certification Body
CCAA	China Certification and Accreditation Association
CCAI	China Certification and Accreditation Institute
CIQ	Entry-Exit Inspection and Quarantine Bureau
CNAS	China National Accreditation Service for Conformity Assessment
CNCA	Certification and Accreditation Administration of P. R. China
EMS	Environmental Management System
IAF	International Accreditation Forum
IEC	International Electrotechnical Commission
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
OHSMS	Occupational Health and Safety Management System
PDCA	The "Plan-Do-Check-Act" cycle (also referred to as the "Deming Cycle")
QMS	Quality Management System
QTSB	Quality and Technical Supervision Bureau
SDOC	Self-Declaration of Conformity
SME	Small or medium enterprise
UNIDO	United Nations Industrial Development Organization



Summary of the Report

To have an in-depth understanding of the actual impact of ISO 9001 certification on organizations in China, CNCA and UNIDO jointly conducted a survey of the effectiveness of ISO 9001 quality management system certification in China from September 2012 to September 2013. This survey utilized the methodology and the questionnaires provided by UNIDO, based on a previous similar project in Asian developing economies, and adapted them to the Chinese context. The survey was conducted by Chinese experts, with UNIDO providing technical instruction, training and support to the Chinese surveyors during the whole process. The survey covers the whole of China (except Taiwan, Hong Kong and Macau); over 9000 questionnaires were sent out to ISO 9001-certified organizations and institutional purchasers in China, and 6974 effective completed questionnaires were collected. Physical on-site visits were conducted by trained experts at 958 certified organizations.

According to the survey result, 93% of all the institutional purchasers surveyed expressed that they regarded ISO 9001 certification as an important criterion for evaluation of their suppliers. 75% said their perception of the credibility of ISO 9001 CBs operating in China is “good” or “very good”. Purchasers had a good level of satisfaction with their ISO 9001-certified suppliers. Of the various parameters studied, the highest level of satisfaction is with the product quality of ISO 9001-certified suppliers (98% purchasers stated that they were satisfied, including 7% of all purchasers who were very satisfied). Compared with non-certified suppliers (or comparing the same supplier before and after certification), most purchasers think that the performance of certified suppliers is notably better than that of non-certified suppliers (or the same supplier before certification).

Among all the certified organizations surveyed, 51% said the most important reason for them to implement a QMS was to obtain competitive advantages, for internal improvement or to achieve corporate or top-management objectives, 43 % said the most important reason was to gain market access or to respond to customer pressure or tender requirements, while 6% said it was for marketing and/or public relations. 98% of the organizations surveyed said that regardless of the overall cost, the implementation of ISO 9001 had been a good or a very good investment. Most of the certified organizations said they obtained substantial benefits from the implementation of an ISO 9001-based QMS. 9% of the certified organizations estimated that it brought a benefit of up to RMB 100,000, either in cost savings and/or increased profits. 39% believed it to be between RMB 100,000 to 1,000,000. 37% estimated that it could bring more than RMB 1,000,000 of benefits (either cost savings or increased profits).

The results of the on-site visits to the certified organizations showed that in 93% of the certified organizations visited there was confidence that the QMS was basically sound, with a “good” or “very good” level of confidence in the QMS in 62% of the certified organizations visited. The result of the on-site visits shows that, due to different levels of management involvement and participation in different sized organizations, the overall confidence in the QMS of micro and small-size organizations is lower than that of larger ones.



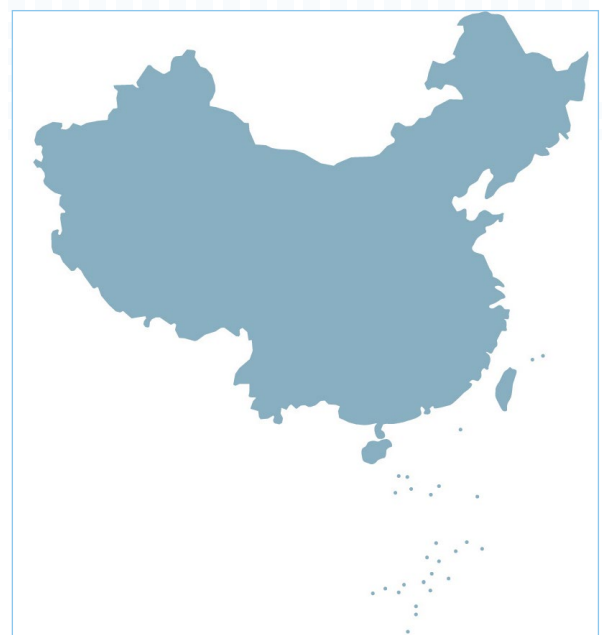
Chapter I

PROJECT BACKGROUND

When ISO 9001 first came into China, it was called “the passport to the international market.” Now it is widely used in most economic and social sectors in China with over 310,000 ISO 9001 certificates issued, remaining number one in the world for years in succession, and making a positive contribution to China’s economic growth and quality upgrade.

CNCA is the regulatory body authorized by the Chinese government to conduct unified administration, supervision and comprehensive coordination of certification and accreditation activities across China. ISO 9001 is one of CNCA’s key focus points. To have an in-depth understanding of the actual effects of the application of the ISO 9001 standard in all types of organizations in China and to have a comprehensive assessment of the impact of ISO 9001 certification, CNCA made a decision in 2012 to initiate a systematic and comprehensive survey of the performance of ISO 9001 certified organizations and of the effectiveness of the certification process carried out by the accredited certification bodies. This will build a good foundation for future policy making, so that ISO 9001 certification will better serve China’s economic transformation and contribute to our “Twelfth Five Year Plan” strategic objectives.

This survey is a China-foreign joint cooperation project, building on advanced international experience and introducing more specificity for the Chinese situation. UNIDO and IAF provided the methodology and sent experts to give guidance. The implementers were the CNCA-line local bodies for quality and technical supervision and entry-exit inspection and quarantine. CNAS, CCAA and CAI participated in the survey and contributed to the analysis of the results.





Chapter II

PROJECT ACTIVITIES

In July 2011, CNCA became aware of the results of a joint UNIDO/ISO/IAF survey on the Impact of ISO 9001 implementation in Asian Developing Economies and communicated by emails and face to face meetings with UNIDO regarding possible collaboration to conduct a similar survey in China,

utilizing similar guiding principles, the working program and the questionnaire papers. In September 2012, a cooperation document was signed, officially launching the project, which lasted for 12 months, ending in September 2013. The project covered the activities below.

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, CNCA and UNIDO experts 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 34 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, and overall opinions about ISO 9001 certification.



The large purchasers surveyed included both ISO 9001-certified large organizations and not-yet-certified ones. In sampling, priority was given to the following industries:

- Aviation
- Automobile
- Construction
- Electronics
- Energy (including power generation and distribution, petroleum and natural gas)
- Health
- Government authorities
- Telecommunications
- Railway
- Retail and Brand
- Information technology
- Mechanical equipment manufacturing
- Chemical industry
- Cement and concrete
- Textiles and apparel
- Civil engineering
- Iron and steel
- Aviation spare parts manufacturing

CNCA selected 1000 large companies in those industries for the survey, geographically covering the whole of China. The questionnaires were distributed to the companies by the local quality and technical supervision bureaus (QTSB) as well as the entry-exit inspection and quarantine departments (CIQ). The organizations surveyed completed the questionnaires of their own free will and interest. Confidentiality agreements were signed by all those who distributed and collected the questionnaires and conducted data analysis. To enlarge the survey scope, CNCA required the local QTSB and CIQ to independently select for the questionnaires some other large purchasers that had not been ISO 9001 certified.

The survey of institutional purchasers started in December 2012 and ended in March 2013, collecting a total of 897 completed and valid questionnaires from 30 provinces, municipalities and autonomous regions (no valid feedback from Qinghai province).

2. INTERVIEW WITH SOME INSTITUTIONAL PURCHASERS

For better information and direct feedback, the Chinese surveyors invited some institutional purchasers for face-to-face conversations to learn about their perceptions

of ISO 9001 certification in China as well as their comments and recommendations on certification and accreditation, and the survey itself.

3. QUESTIONNAIRE SURVEY OF THE ISO 9001-CERTIFIED ORGANIZATIONS

In the context of the circumstances of the certified organizations in China, the survey focused on industrial manufacturing and construction companies. The Chinese surveyors selected 8000 certified organizations for the survey, covering companies of various scales, industries and geographical locations. The certification bodies (CBs) of these certified organizations included all the CBs operating ISO 9001 certification activities in China, both Chinese and international ones, both CNAS-accredited and those accredited by foreign accreditation bodies (ABs), representing quite a

complete picture of the ISO 9001-certified companies in China. The questionnaires were distributed to the companies by the local QTSBs and the CIQs. The companies filled in the questionnaires out of their own free will and interest. Confidentiality agreements were signed by all those who distributed and collected the questionnaires and compiled the data.

The questionnaire survey started in December 2012 and ended in March 2013, collecting a total of 6077 completed questionnaires from all over China.

4. ON-SITE “MARKET SURVEILLANCE VISITS” TO CERTIFIED ORGANIZATIONS

A one-day on-site “market surveillance visit” was conducted by trained personnel at a sample of certified organizations. To ensure the effectiveness of these visits and their relevance to China, CNCA and UNIDO experts worked together to revise the “on-site survey form” used in the previous UNIDO/ISO/IAF project (1) which now forms 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 surveyors were requested to score each item according to their observations about the actual operational situation of the certified organizations and finally gave a score to the overall level of confidence in the system of the certified organizations.

Most of the on-site surveyors were from the local QTSBs and CIQs, with some experts from CNAS, CCAA and CCAI. In April 2013, CNCA convened the on-site surveyors for training on the UNIDO methodology. The training was conducted by UNIDO experts and included participation by the trainees in on-site visits, accompanied by the UNIDO experts, for calibration purposes.

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

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

Guangdong, Jiangsu and Zhejiang, and also northeastern and mid-western areas such as Heilongjiang, Shaanxi, Sichuan and Xinjiang. There were over 260,000 ISO 9001 certificates in these areas, approximately 80% of the national total. The on-site survey was conducted from April to July 2013, visiting 958 certified organizations. For further information, the surveyors asked the organizations to fill in questionnaires while they were on site (see Item 3). Most of the companies filled them in carefully and gave good feedback.

5. DATA ANALYSIS AND REPORT COMPILATION

CCAI undertook the data analysis. In April to September 2013, CCAI compiled and analyzed the survey data feedback, and wrote up the first draft of the report, which was submitted for discussion by all the survey partners. The results were also presented and discussed

in a workshop conducted in Beijing for all interested parties in October 2013, after which comments were noted and incorporated into this final version of the report.



Chapter III

RESULTS OF THE SURVEY OF CHINESE PURCHASERS' PERCEPTIONS OF ISO 9001-CERTIFIED SUPPLIERS

This questionnaire survey was conducted in December 2012 to March 2013. The organizer was CNCA and the local QTSB and CIQ were the questionnaire distributors. 897 purchasers in 30 provinces and municipalities filled in the survey questionnaires.

One point for attention is that some purchasers did not have adequate information and so some of the items in the questionnaire were left blank.

1. DETAILS OF THE PURCHASERS WHO TOOK PART (FIGURE 1 TO 4)

It can be seen from the following figure that the purchasers participating in this survey have a wide geographical distribution.

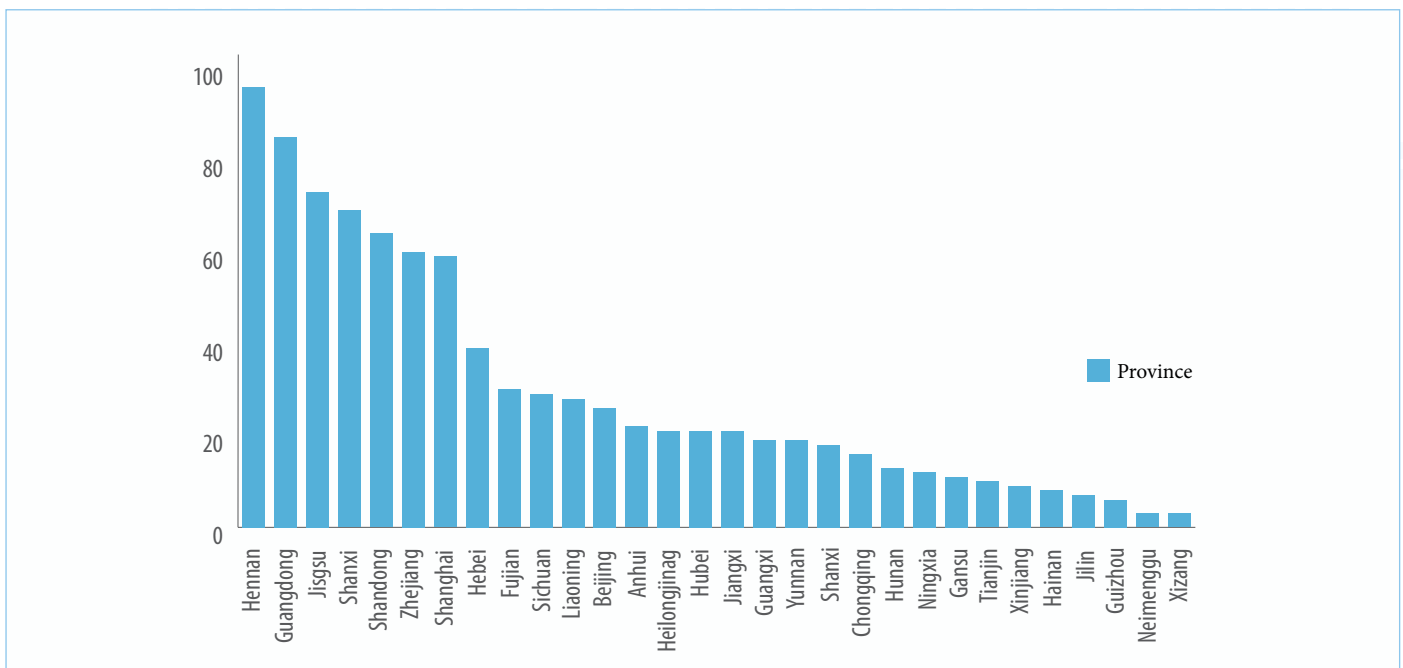


Figure 1. Geographical distribution of the 897 purchasers participating in this survey

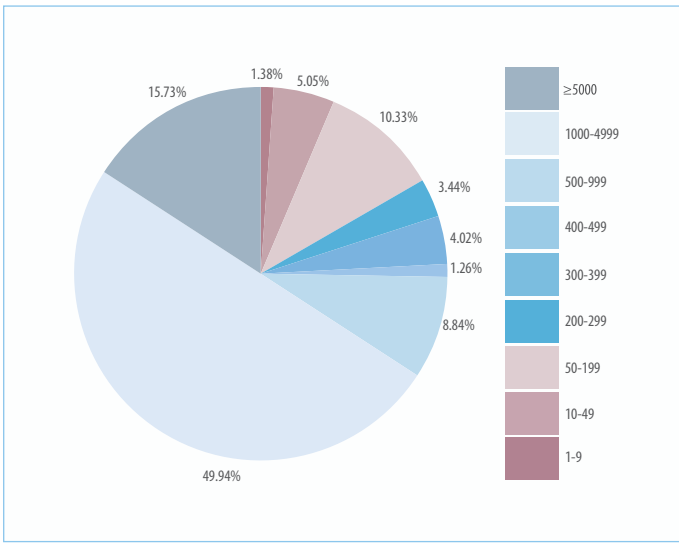


Figure 2. Size distribution of the purchasers surveyed (by number of employees)

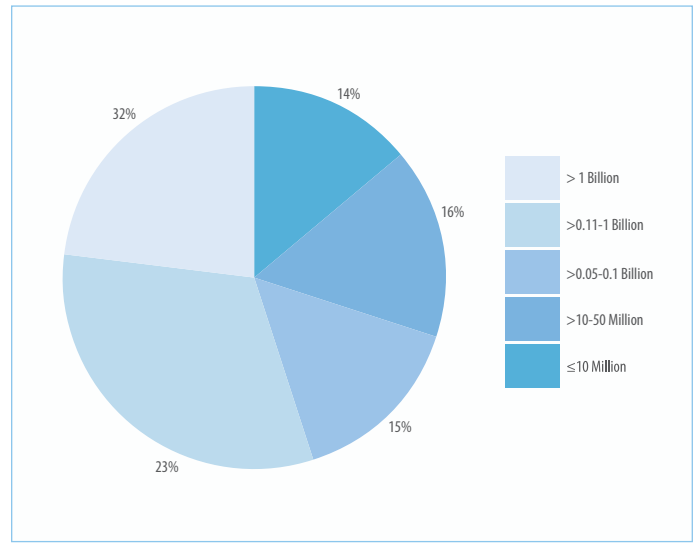


Figure 3. Size distribution of the purchasers surveyed (by annual purchasing budget in RMB)

Figure 2 shows that nearly 50% of the purchasers surveyed had between 1000 and 5000 employees.

In this survey, 8% of the purchasers were branches of a multi-national company, while 92% of the purchasers were local (Chinese) companies

Figure 3 shows that approximately 55% of the surveyed purchasers had an annual purchase budget of more than RMB 100 million, and only 14% had an annual purchasing budget less than RMB 10,000,000.

2. QMS OF THE PURCHASERS

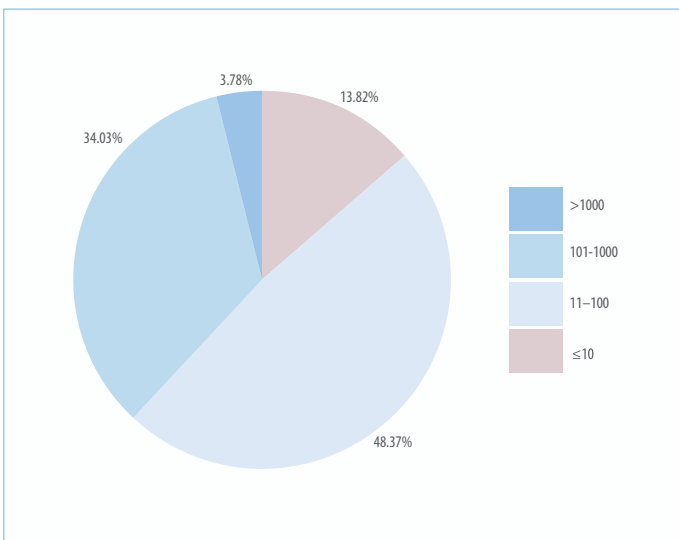


Figure 4. Number of suppliers actively evaluated by each of the purchasers surveyed

Figure 4 shows the number of suppliers actively evaluated and managed in the past year by the purchasers surveyed. 14% of all the purchasers evaluated less than 10 suppliers; 48% of all the purchasers evaluated 11 to 100 suppliers and 38% evaluated over 100 suppliers.

Figure 5 shows that 97% of the purchasers surveyed claimed that their own quality management system met ISO 9001 requirements, and 90% claimed that they had achieved certification.

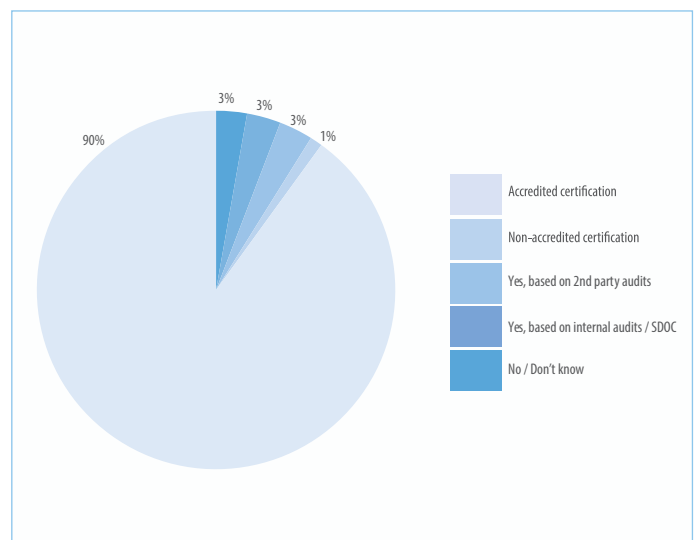


Figure 5. Purchaser self-evaluation of their level of conformity to ISO 9001

3. PURCHASER FAMILIARITY WITH ISO 9001

Of all the purchasers surveyed, 91% believed that they “depended on” or “often used” ISO 9001 (see Figure 6); 5% said that they “had heard of ISO 9001” but had not adopted it. This survey did not find any purchaser who had never heard of ISO 9001.

4. ADOPTION OF ISO 9001 AS A TOOL FOR SUPPLIER EVALUATION

Of the surveyed purchasers, 93% expressed that they regarded ISO 9001 certification as an important criterion for supplier evaluation.

5. PURCHASER FAMILIARITY WITH ISO, AB AND IAF

The survey results shows that 42% of the purchasers knew (correctly) that ISO only plays the role of “standard developer” in the ISO 9001 certification scheme; 3% of them wrongly believed that ISO publishes the ISO 9001 standard and is responsible for conducting the certification thereof; and 55% 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 China, and emphasizes the reputational impact that certification can have on the ISO brand name (positive and negative).

Less than 17% percent of the purchasers was able to name CNAS as their own national AB. An even fewer

6. IN CHINA, PURCHASERS WERE QUITE CLEAR ABOUT THE ROLE OF CNCA

93% of the purchasers that knew that the role of CNCA was to approve and monitor the CBs and that certification activities were conducted by CBs approved by CNCA; only 4% of the purchasers believed that CNCA developed and published the standard (ISO

7. PURCHASER AWARENESS OF CONFORMITY ASSESSMENT METHODOLOGY

According to the survey, most of the purchasers (90%) said that they knew about self-declaration, second-party audits and third-party certification to demonstrate

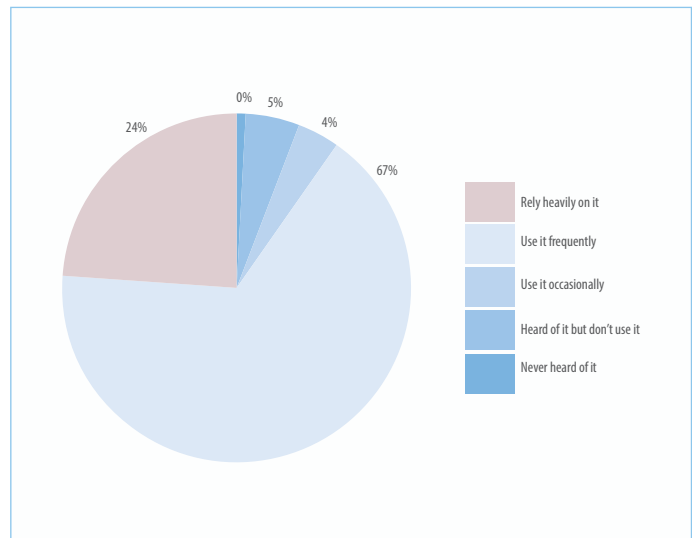


Figure 6. Purchasers' familiarity with ISO 9001

number, (less than 5%) was able to name any of the foreign ABs. About 38% of the large purchasers said that they had heard of IAF and knew its role; 33% said they had heard of the IAF but did not know its role; 29% said they had never heard of IAF.

This is a worrying result, particularly when many purchasers rely on accredited ISO 9001 certification for their supplier selection. It also 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.

9001) but did not directly participate in the certification activities; there were another 3% believed that CNCA developed and published the standard (ISO 9001) and was also responsible for carrying out certification activities.

conformity to standard requirements; only 34% of them knew about and had experience of certificates issued by non-accredited CBs.

8. PURCHASERS' VERIFICATION OF SUPPLIERS' ISO 9001 CERTIFICATION

When supplier selection was based on ISO 9001, 66% of the purchasers required potential suppliers to present a copy of their ISO 9001 certification; 60% said they would verify the validity of the certificates presented by the suppliers; 33% would check for the logo of the AB; 51% would look to make sure that their purchased goods were within the certification scope; 15% would consult the CB or consult the data bank to make sure that the certificate was not withdrawn; 29% would verify it by logging onto the CNCA website (see Figure 7). This verification is to be encouraged, in order to further enhance the credibility of certification in China.

During the past three years, 69% of the purchasers reported that they had 1-100 ISO 9001-certified suppliers; 26% had 100-500 such suppliers; 2% had 500-1,000; 3% had more than 1,000.

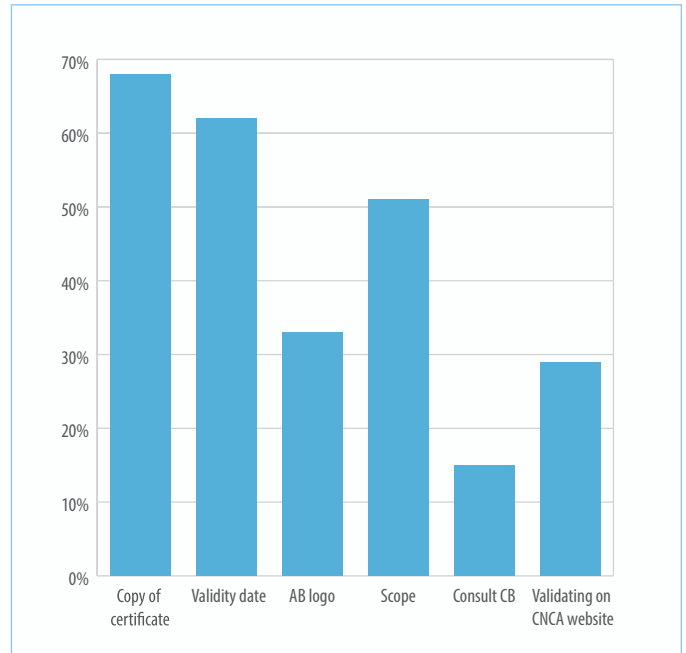


Figure 7. Percentage of the ways that purchasers use to verify the validity of the certificates of suppliers

9. PURCHASER FEEDBACK ON SUPPLIER PERFORMANCE

Figures 8 and 9 show that for the procurement of “high value” and/or “high risk” products, 67% of the purchasers gave regular feedback to their suppliers

about the performance of the products and services; for “low value” and/or “low risk” products, 34% did that.

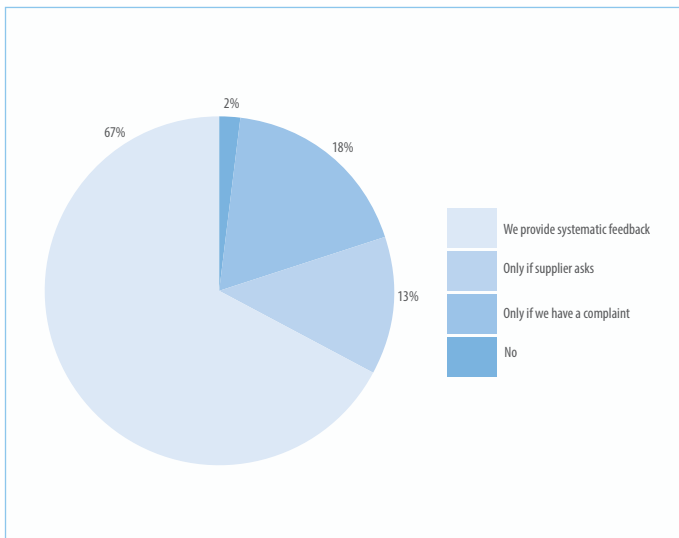


Figure 8. Purchaser feedback to suppliers regarding procurement of “high value” and “high risk” products

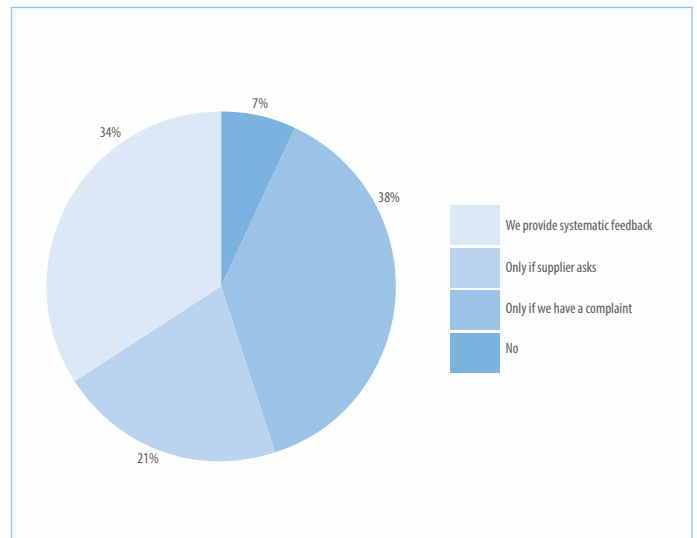


Figure 9. Purchaser feedback to suppliers regarding procurement of “low value” and “low risk” products

10. PURCHASER LEVEL OF CONFIDENCE IN ISO 9001 CERTIFICATION BODIES

Figure 11 shows the level of satisfaction of the purchasers with the performance of their ISO 9001-certified suppliers. The highest level of satisfaction is with the certified suppliers, with 98% of the purchasers saying “satisfied”, of which 7% said “very satisfied”. 88% of the purchasers expressed “satisfaction” with the ability of the certified suppliers to consistently provide conforming products; 9% said “very satisfied”. 90% of

the purchasers surveyed expressed “satisfaction” with communication during the purchase process; 7% were “very satisfied”. 90% were “satisfied” with the accuracy of marketing information from certified suppliers and 5% “very satisfied”. This survey shows that purchasers had a high degree of satisfaction with the ISO 9001-certified suppliers.

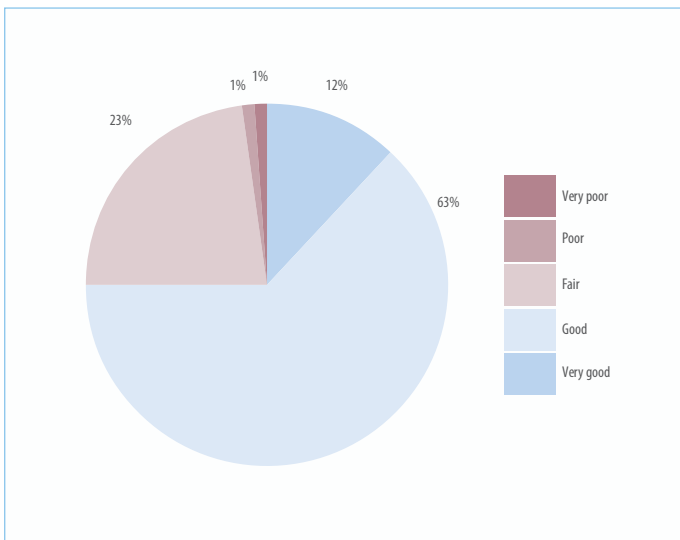


Figure 10. The overall perception of the credibility of ISO 9001 CBs operating in China

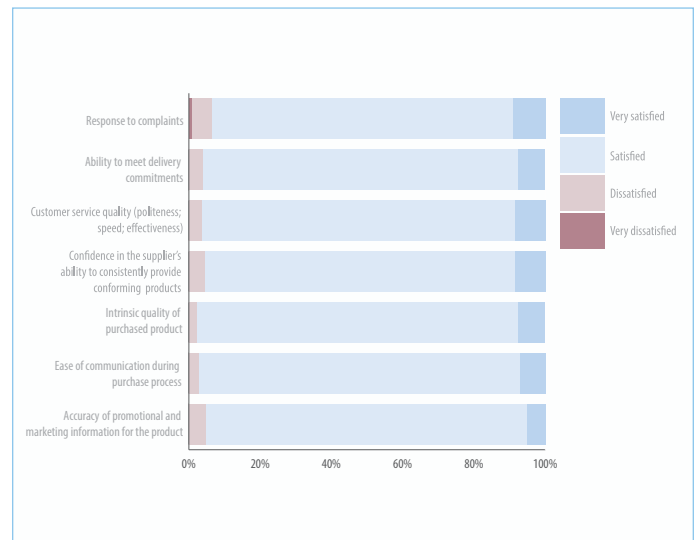


Figure 11. Level of satisfaction of purchasers with certified suppliers

Figure 12 shows the comparison between certified and non-certified suppliers (or comparing the same supplier before and after certification). Comments by purchasers about the ISO 9001-certified suppliers were generally more favourable than those for non-certified suppliers (or for the same supplier before certification). It is important to note that, in line with the results of the previous UNIDO project (1), responsiveness to complaints is also the main cause of dissatisfaction among purchasers in China, and CBs should be encouraged to pay special attention to this when conducting surveillance and reassessment audits of their certified clients. Nevertheless, as will be seen from Figure 12, certified organizations performed better than non-certified organizations in this respect.

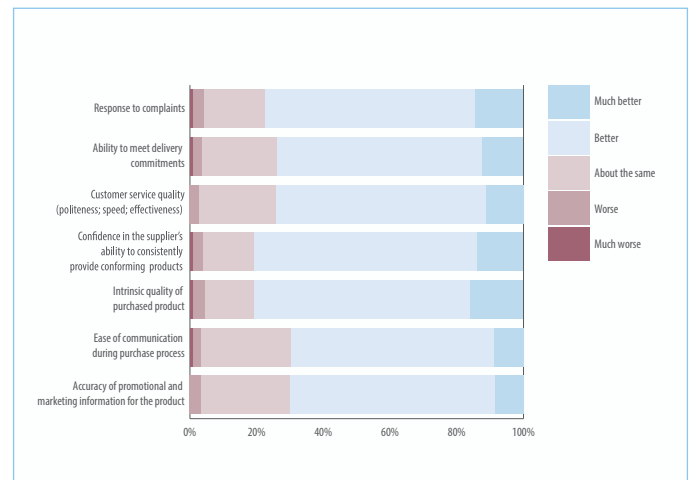


Figure 12. Comments by purchasers on ISO 9001-certified suppliers, compared with the non-certified ones (or on the same supplier before and after certification)

11. COMMENTS BY PURCHASERS ON THE ISO 9001 STANDARD AND CERTIFICATION

Figure 13 illustrates that generally, the purchasers surveyed had quite a high level of satisfaction with the ISO 9001 standard. Of the 897 purchasers, 30% believed it to be “a very good standard”; 54% “a good standard”; 15% “a reasonably good standard”; 1% “an inadequate standard”. The survey did not result in any comment considering ISO 9001 to be “a very poor standard”.

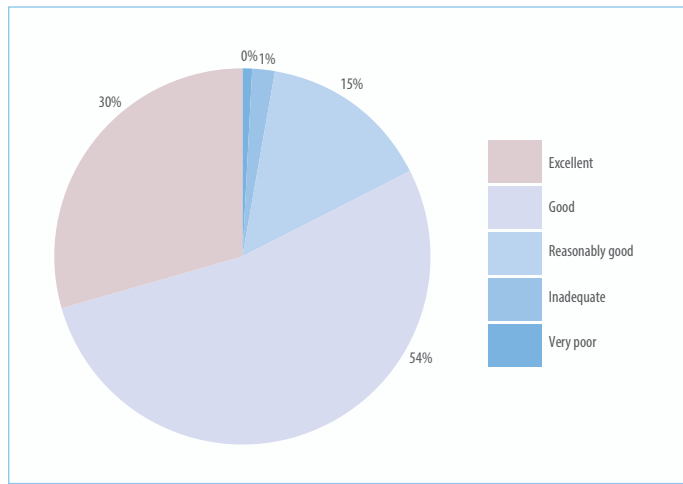


Figure 13. Purchaser opinions on the ISO 9001 Standard

Figure 14.1 shows purchaser confidence in the ability of certified suppliers to provide conforming products. 96% of the purchasers were “satisfied”, of which 9% were “very satisfied”; 4% were “not satisfied”. This survey did not find any purchaser that was “very dissatisfied”.

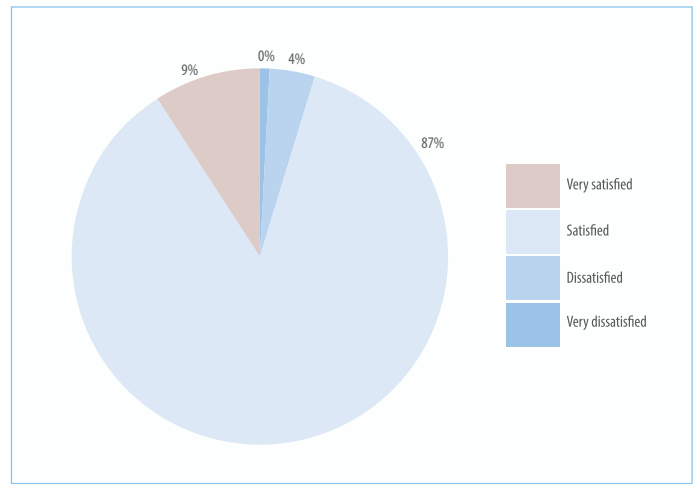


Figure 14.1. Credibility of ISO 9001 certification: Confidence in the provision of conforming products

Figure 14.2 shows the purchasers’ confidence level in their certified suppliers. This reflected whether purchasers had confidence in certification achieving its objective, i.e., demonstrating that suppliers are capable of “constantly supplying purchasers with products conforming to their requirements and applicable regulations”. 60% of purchasers believed it was “good”

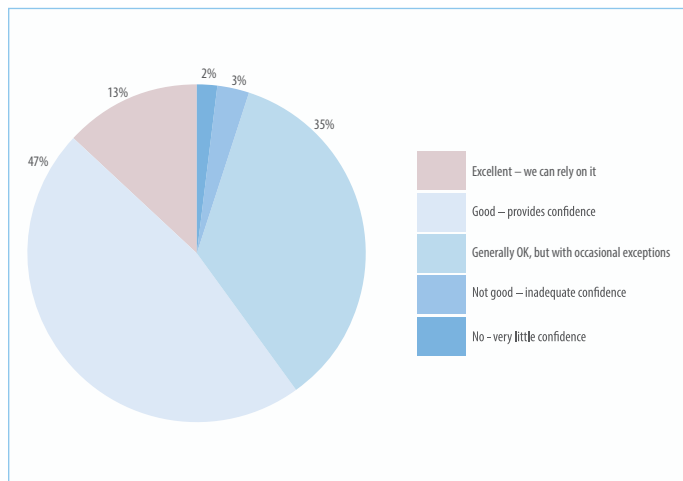


Figure 14.2. Credibility of ISO 9001 certification: Confidence in certification achieving its objective

and “very good”; 35% believed “generally provides confidence but with occasional exceptions”; still another 5% said they did not have adequate confidence, meaning there is still room for improvement of the performance of certified organizations in order to restore purchaser confidence in these cases.

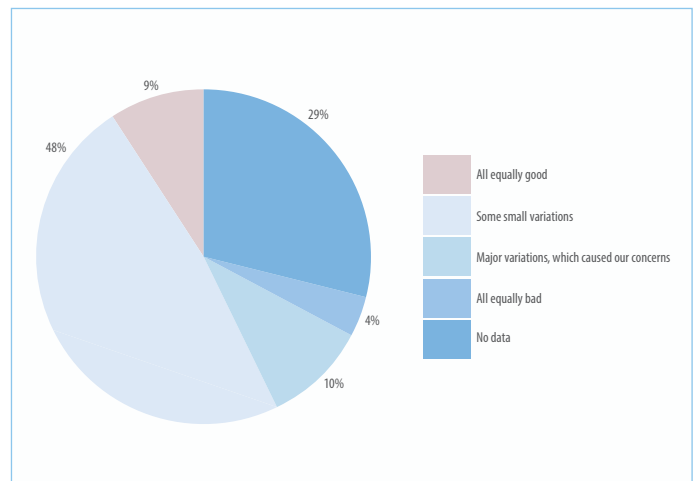


Figure 15. Purchaser perception about systemic differences in the operations of accredited CBs

Figure 15 demonstrates that 48% of the purchasers believed that “there were differences among the CBs operating in China, but the differences were not great”; 10% believed that there was a big difference between CBs, which caused them concerns; 9% believed that the CBs were similar or equally good; 4% believed that the CBs were similar or equally bad; 29% said they did not have any information about this. It can be seen from Figure 16 that 68% of the purchasers had conducted

2nd-party audits of their ISO 9001-certified suppliers, with 47% having obtained satisfactory results; 18% of the purchasers were concerned with the effectiveness of the certification process (a few minor non-conformities were raised during 2nd-party audits); 3% felt “seriously concerned” with the effectiveness of the certification processes (at least one major non conformity was raised during 2nd-party audits).

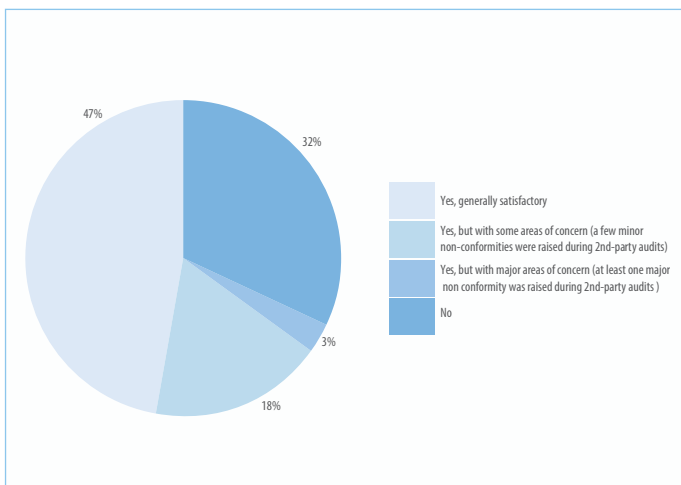


Figure 16. Analysis of the results of purchasers’ 2nd-party audits to evaluate their ISO 9001-certified suppliers

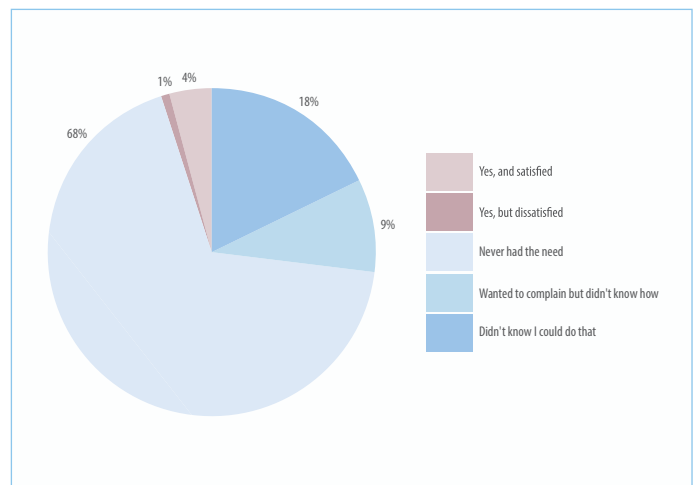


Figure 17. Purchaser complaints to suppliers’ CBs

Figure 17 shows that 5% of the purchasers surveyed had filed complaints to their suppliers’ CBs, with 4% being happy with the results of the CB’s handling of the complaints; 1% were not happy with the results of the CB’s handling of the complaints. 9% of purchasers wanted to complain but did not know how to; 18% did not even know that they could complain to their suppliers’ CBs; 68% did not have any need for making complaints. It is recommended that the ISO Guidance Document “ISO 9001 – What does it mean in the Supply Chain?” should be made available in Chinese, in order to stimulate better feedback from purchasing organizations to their suppliers and, as necessary, to their respective CBs and ABs.

but did not know how to; 18% said they did not know that they could complain; 2% did file complaints, 1% were happy with the results of the investigation and 1% were not happy.

Figure 18 (Purchasers’ complaints to ABs or CNCA against suppliers’ CBs) shows that 73% of the purchasers said they knew that they could complain but did not have any need for that; 7% said they wanted to complain

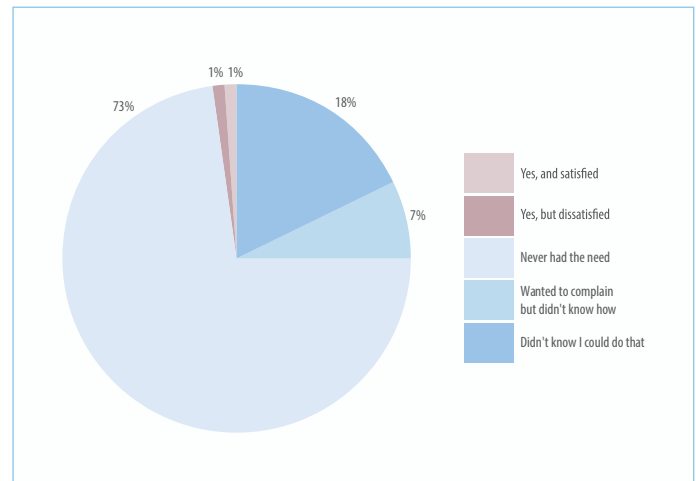


Figure 18. Purchasers’ complaints to ABs or CNCA against suppliers and CBs



Chapter IV

QUESTIONNAIRE SURVEY OF ISO 9001-CERTIFIED ORGANIZATIONS IN CHINA

This survey was open to all the ISO 9001-certified organizations in China. 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). This survey was carried out in December 2012 to March 2013. The

organizer was CNCA and the local QTSB and CIQ helped with distributing the questionnaires, while the certified organizations filled them in out of their own free will and interest.

One point of attention is that some certified organizations did not have adequate information and so some of the items in the questionnaires were left blank.

1. DEMOGRAPHICS OF THE CERTIFIED ORGANIZATIONS

a) Geographical distribution

This time 6077 certified organizations completed the survey. They were located in 31 provinces, municipalities and autonomous regions (see Figure 19).

b) Size distribution

In the 6077 questionnaires, the companies were divided into micro, small, medium, large and “super” ones. In China, this kind of division is usually done according to the number of employees. Those with up to 50 employees belong to the “micro/small” category. There were 1791 such companies in this survey, accounting for 29.5% of the total. Those with more than 50 and less than 500 employees belong to the “medium” companies. This survey covered 2311 medium companies, 38% of the total. So all together there were 4102 small and medium companies covered in this survey, accounting for 67.5% of the total.

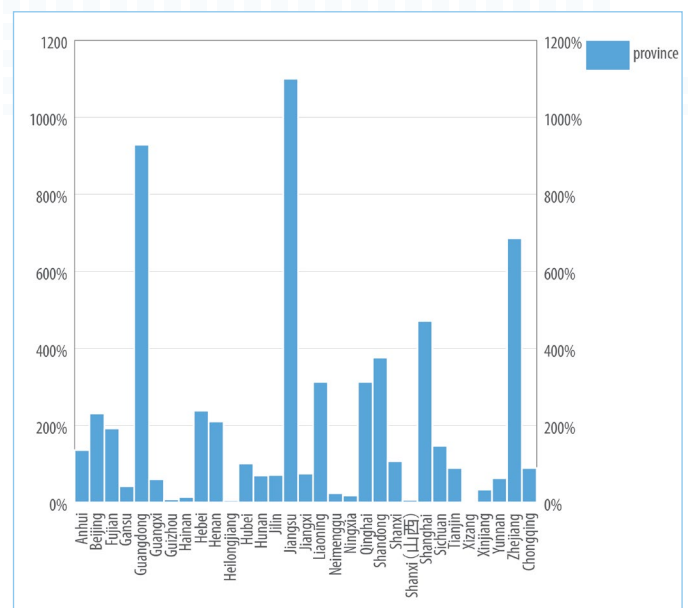


Figure 19. Geographical breakdown of sample organizations

Large companies are those with more than 501 but fewer than 3000 employees and this survey covered 1427 of them, accounting for 23.5% of the total. “Super” companies are those with more than 3000 people and this survey covered 548 of them, 9% of the total. See Figure 20 for the distribution percentage

c) Percentage of certified organizations under multinational companies

Of the 6077 certified organizations surveyed, 342 were branches of multinational companies, representing 5.6% of those surveyed.

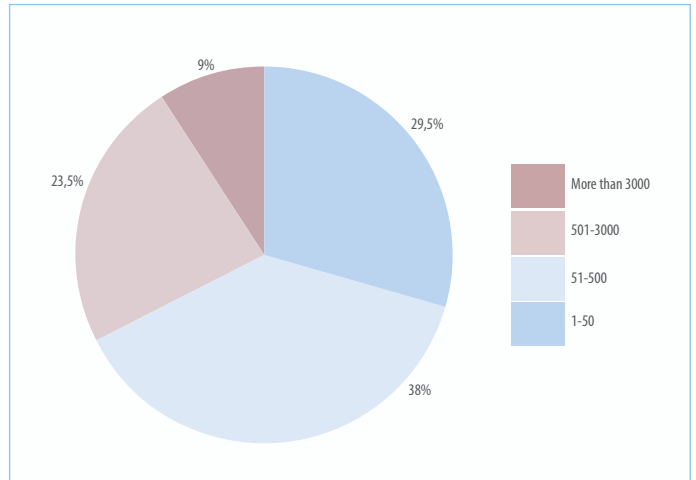


Figure 20. Size distribution of the ISO 9001 organizations surveyed (number of employees)

2. LENGTH OF TIME OF THE ORGANIZATION’S ISO 9001 CERTIFICATION

See Figure 21 for the length of time the organizations had been certified to ISO 9001: 28% had been certified for more than 10 years; 45% for 4 -10 years; 27% for less than three years (meaning that they had not yet completed a recertification audit).

3. REASONS FOR ORGANIZATIONS TO SEEK CERTIFICATION (4884 VALID RESPONSES)

This survey covered the major reasons for organizations to implement an ISO 9001-based QMS and seek certification (see Figure 22). As the figure shows, the most important “Number 1 reason” (25% of the responses) was to “obtain competitive advantage”, with the second one being for “internal improvement” (19% of the responses).

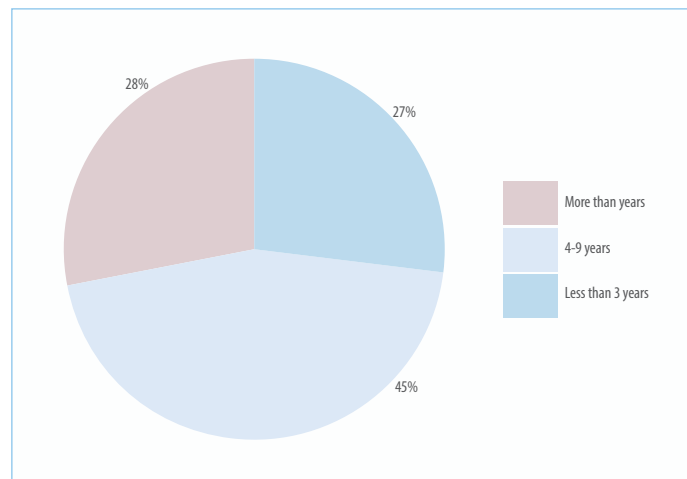


Figure 21. Distribution of length of time of certification

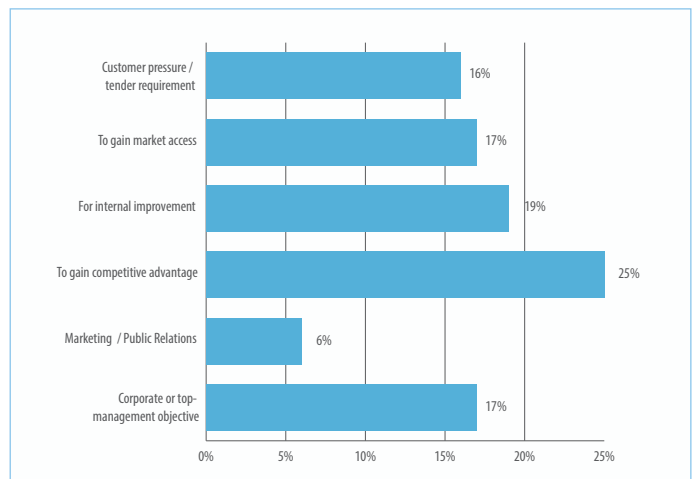


Figure 22. Major reason for implementing a QMS

4. TIME TO IMPLEMENT THE SYSTEM AND ACHIEVE CERTIFICATION

a) Analysis of length of time taken to obtain certification after the decision to implement a QMS

As shown in Figure 23, nearly 34% of the organizations said they took 4-6 months from starting to implement their QMS to becoming certified; 47% of the organizations were certified in 7-12 months; 9% in 13 months to 2 years; 3% in more than 2 years. 7% of the organizations said they obtained certification less than 3 months after their decision to begin implementing the system.

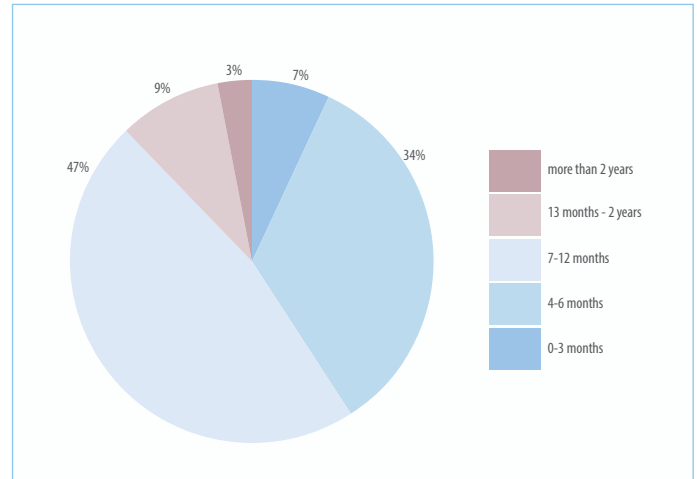


Figure 23. Length of time taken to achieve certification after the decision to implement a QMS

b) Analysis of the length of time taken to achieve certification after the decision to implement a QMS and the length of time certified

5771 organizations completed the survey providing information both of the length of time that they operated their QMS previous to certification and the length of time of their certification. As shown in Figure 24, in recent years the percentage of organizations that took 6 months or less to achieve certification has increased.

From Figure 24, it was observed that of those organizations that had been certified for more than 10 years, only 27% took 6 months or less from launching their QMS to achieving certification, and only 3% took 3 months or less. In contrast, of the organizations that had been certified for 4-10 years, 45% took 6 months or less time to become certified, with 7% taking 3 months or less. Of the organizations that achieved certification during the past three years, 51% took 6 months or less, and 12% took only 3 months or less.

As will be discussed later, there is a clear inverse correlation between the time taken to implement the QMS and the effectiveness of the system, so it is to be recommended that CBs pay special attention to the audit of organizations that claim to have implemented their system in 3 months or less.

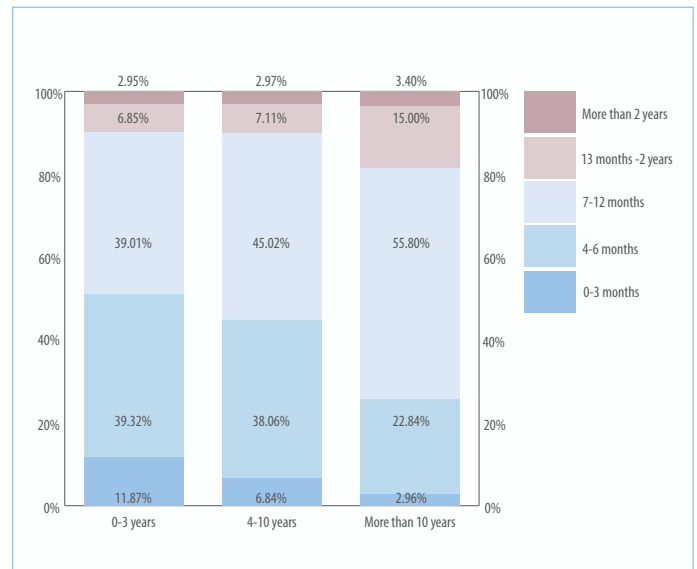


Figure 24. Correlation between duration of certification and the time needed to achieve certification

5. USE OF CONSULTANTS

69% of organizations chose to use consultancy services to help them with the implementation of their QMS; 28% said that continued use of consultancy helps them to maintain their QMS.

a) Analysis of the relationship between consultancy services and the time taken to achieve certification

As shown in Figure 25, there was no obvious difference in statistical terms between the percentage of organizations using consultancy and the time taken to become certified.

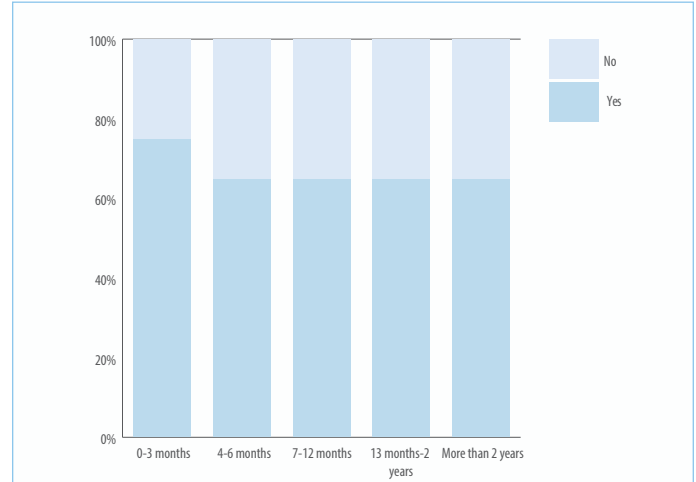


Figure 25. Correlation between using consultancy in implementing a QMS and the time taken to achieve certification

b) Analysis of correlation between consultancy and duration of certification

According to the survey results, there was a slight increase in the percentage of certified organizations using consultancy in recent years (see Figure 26).

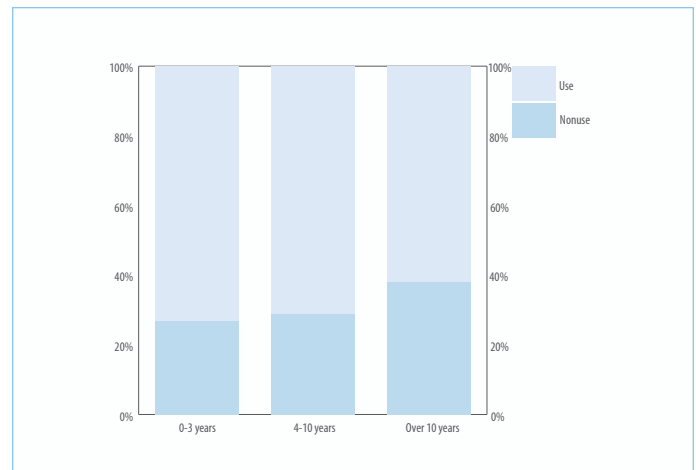


Figure 26. Correlation between consultancy and duration of certification

c) Analysis of correlation between the use of consultancy and the size of the certified organizations

The survey results (see Figure 27) showed that micro, small and medium companies tended to use consultancy services more than the large ones, probably due to limitations of their own resources.

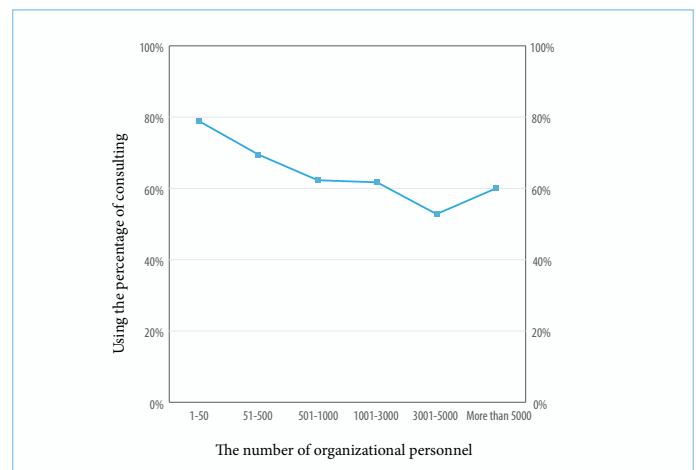


Figure 27. Decreasing correlation between using consultancy and the scale (number of employees) of organizations

d) Analysis of role of consultancy services

Figure 28 shows the various consultancy services provided by consultants to the certified organizations during implementation of the QMS.

At the initial stage of implementation, consultancy services were mostly used to help with development of the quality policy, the quality manual, the documented procedures, work flows and work instructions of the system.

It can be seen that the level of involvement of the consultant varies according to the specific activity. The survey results showed that most of organizations established and implemented their QMS either by themselves or with some help from their consultants. What consultants had done most frequently was the training of “internal auditors”.

The survey showed, however, that 15% of the organizations that used consultancy said that consultants developed their quality manuals for them. The role of a consultant should be giving advice when consulted, guiding the organizations to develop their quality manuals and other system documents in

accordance with their own situation. More worrying was the number of organizations who reported that the consultant selected the certification body, carried out all negotiations with the CB, and was responsible for coordination of audit activities during the CB audit. It is important for CBs to ensure that the consultant does not interfere and/or unduly influence the results of the audit, and to remember that it is the organization that they have to audit, not the consultant.

An interesting result of the survey is that in many cases consultants were also involved in carrying out the organization’s internal audits, rather than training the organizations’ own personnel to carry out this activity.

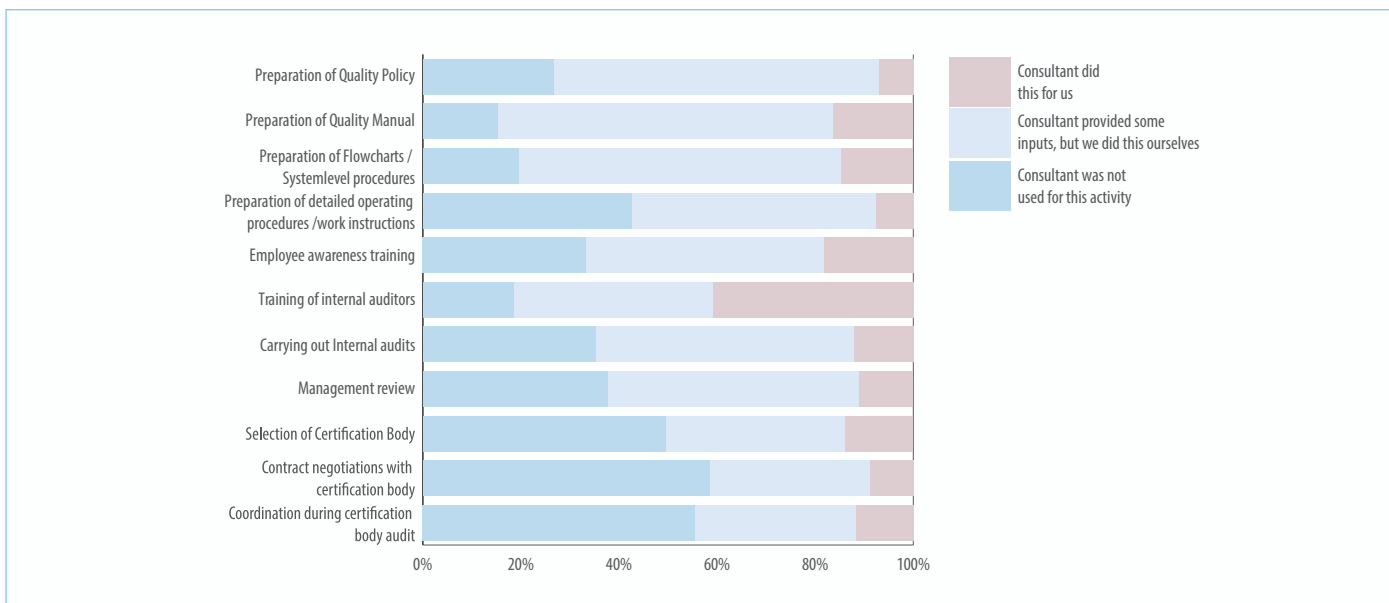


Figure 28. Role of consultancy services

e) Analysis of role of consultancy services

As shown in Figure 29, 97% of the certified organizations demonstrated a high level of satisfaction with consulting bodies (“satisfied” or “very satisfied”). It must be pointed out, however, that this survey was done among organizations that had been successful in achieving certification, which was one of the factors resulting in high levels of satisfaction with the consultants.

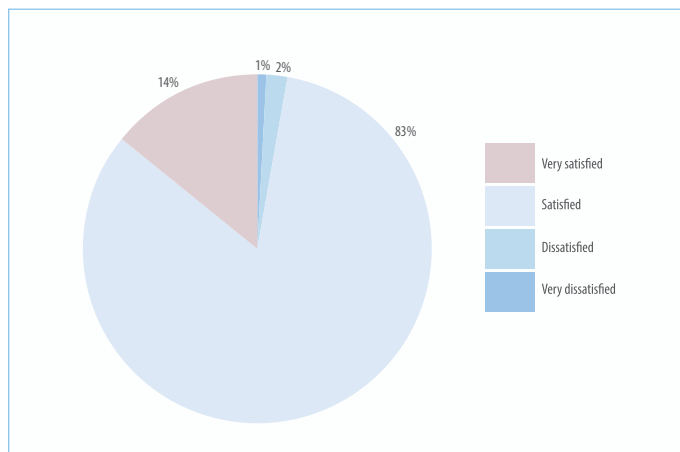


Figure 29. Satisfaction of the surveyed organizations with QMS consultancy

6. ECONOMIC IMPACT AND RETURN ON INVESTMENT

98% of the organizations surveyed said that regardless of the overall cost, ISO 9001 was a worthwhile investment. Only 2% said that ISO 9001 was not a good investment. None of the surveyed organizations said that ISO 9001 was a total waste of money, which reflected the recognition of the value of ISO 9001 certification by the certified organizations (see Figure 30).

This survey also covered the benefits from implementing ISO 9001 certification. 9% of organizations believed that it brought a benefit of up to RMB 100,000, either of monetary savings and/or increased profits. 39% believed it to be between RMB 100,000 to 1,000,000. 37% estimated that it could provide more than RMB 1,000,000 in benefits (either monetary savings or increased profits).

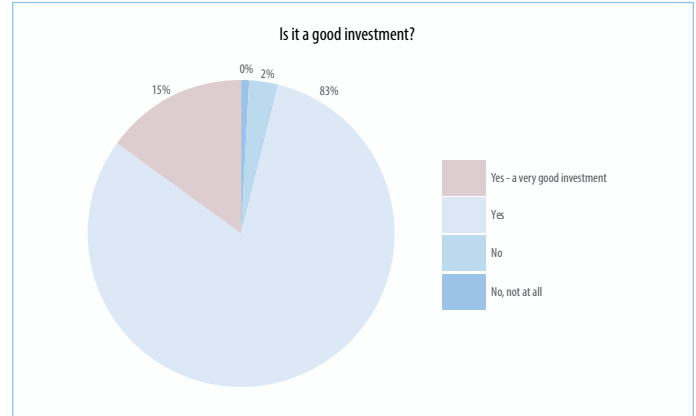


Figure 30. Answers given by certified organizations to the question: "Regardless of the overall cost, do you consider this investment (in the QMS) to have been worthwhile?"

7. COMPATIBILITY OF ISO 9001 AND OTHER MANAGEMENT SYSTEMS STANDARDS

a) Percentage of surveyed organizations holding other certifications

Figure 31. Of the organizations who responded to the survey, 41% were also certified against ISO 14001 (for EMS); 29% against OHSAS 18001 (for occupational health and safety management) and 1% against ISO 27001 (for information security management). The other certifications held by surveyed organizations included various product certifications as well as certifications against particular industry standards such as ISO/TS 16949 (for the automotive industry).

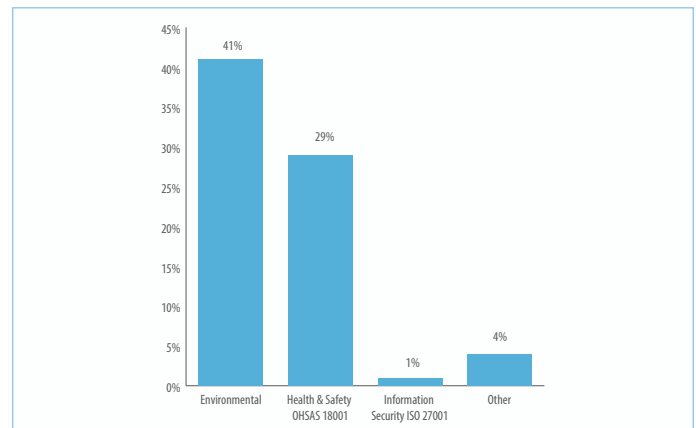


Figure 31. Percentage of surveyed organizations holding other certifications

b) Analysis of surveyed organizations integrating their QMS with other systems

As shown in Figure 32, 45% of the organizations had implemented their management systems in an integrated way; 43% said they had only "partially integrated" their systems; 7% said they had implemented the standards in separate systems.

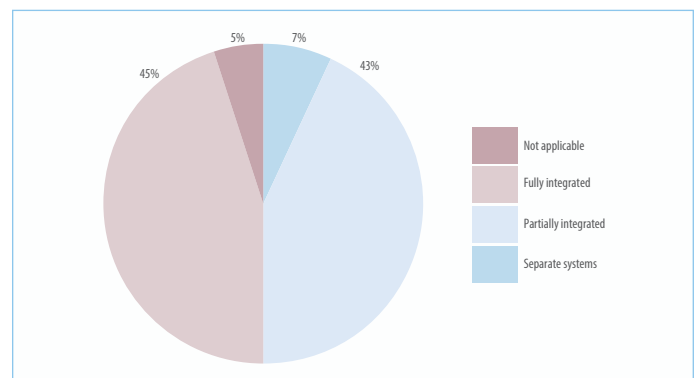


Figure 32. QMS integrated with other systems

c) Perception and application of ISO 9004

It was found in this survey that the ISO 9001-certified organizations were using the ISO 9004 guidance standard (“Managing for the sustained success of an organization — A quality management approach”) only at a low level. 16% of organizations said that they “know and use” the ISO 9004 standard; 52% said they knew of the standard but did not use it. 32% of the respondents said they were not familiar with the standard. 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

Nearly 7% of the respondent organizations believed that it was very easy to understand and use the ISO 9001 language and requirements in their own organizations. Nearly 80% said it was easy or fair.

8. SELECTION OF CBS BY THE ISO 9001-CERTIFIED ORGANIZATIONS

a) Selection of CBs

88% of organizations said that they selected Chinese CBs; 12% said they selected Chinese branches or sub-contractors of foreign CBs. See Figure 33.

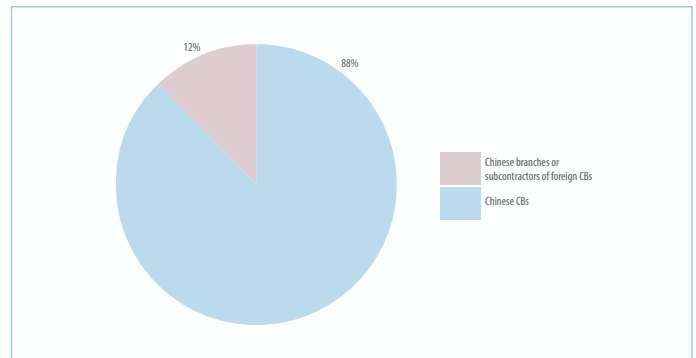


Figure 33. Selection of CBs (percentage)

b) Certified organizations’ transfer to other CBs

Nearly 15% organizations had transferred to another CB some time in the past, of which 69% had only one transfer; 31% more than one transfer. See Figure 34.

c) Knowledge of certified organizations about IAF and ABs

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 and the role of accreditation. About 25% of the certified organizations had heard of IAF and also knew what

it does. About 31% had heard of it but did not know what it does. About 44% had never heard of the IAF. In addition, only 13% was able to name the Chinese accreditation body (CNAS).

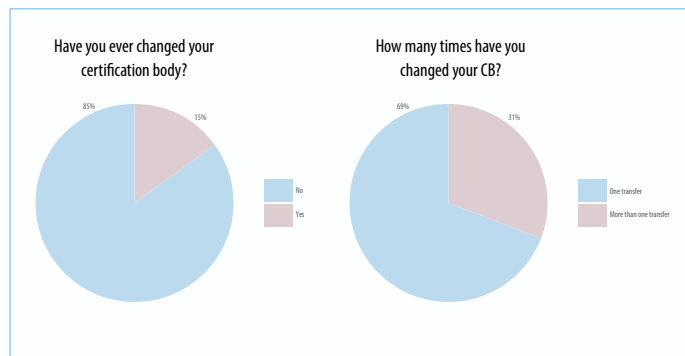


Figure 34. Transfers to other CBs

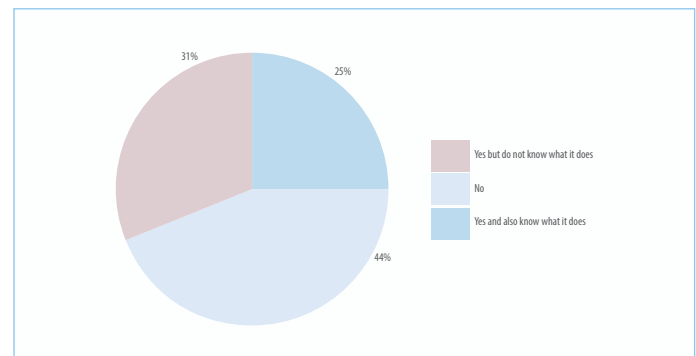


Figure 35. Knowledge of certified organizations about IAF

9. 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 (55% of the total), or at the sites of the organizations (38%) for face-to-face discussions (see Figure 36).

It was disturbing to see that a number of certification bodies were performing in-house training (which, according to ISO/IEC 17021:2011, might be acceptable provided it is limited to the provision of generic information that is freely available in the public domain and does not provide company-specific solutions) or were actually carrying out the organization’s internal audits on their behalf (which is not acceptable, according to ISO/IEC 17021:2011 Clause 5.2.6).

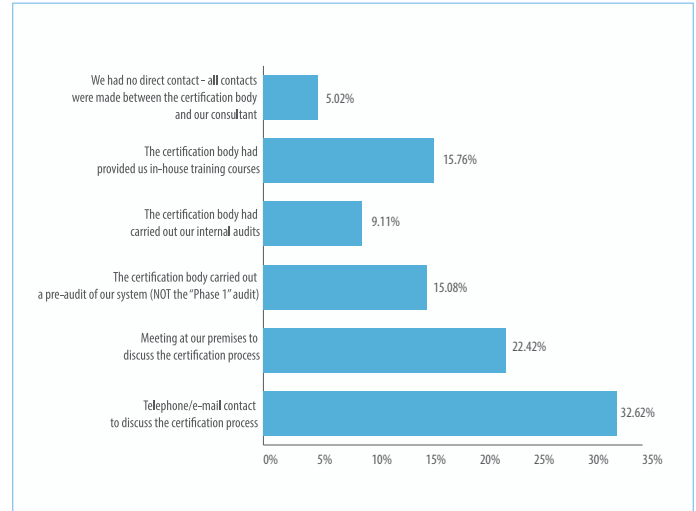


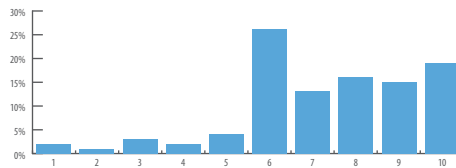
Figure 36. Channels of contact with CBs previous to initial audit

10. CRITERIA FOR CB SELECTION

Analysis of how certified organizations selected their CBs. See Table 1.

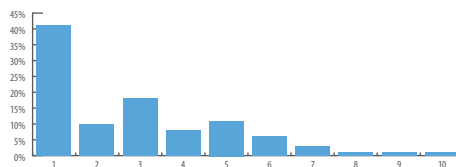
Statements about criteria for selection	Consistency in expression (1=strongly disagree, 10=strongly agree)	Analysis of questionnaire data
(1) Our consultant told us which CB to use.		The contractual negotiations between some organizations and the CBs were done completely by the consultants (See also Figure 28).
(2) We referred to comments by our major clients.		When the major clients did not agree about which CB to use, the organizations would usually make their own independent decision.
(3) Our clients required us to use a specific CB.		A small number of clients would require organizations to use a certain CB.
(4) We did some research about which CB had the best reputation in our industry.		Certified organizations attached importance to the reputation of CBs in their industries.

(5) It was important for the CB to have an international reputation.



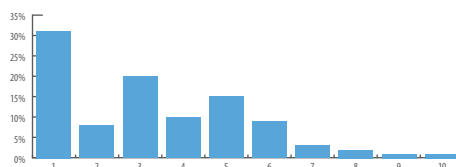
Most certified organizations believed that it was important for their CB to have an international reputation.

(6) We chose this CB because we had heard that it would be easy for us to achieve certification.



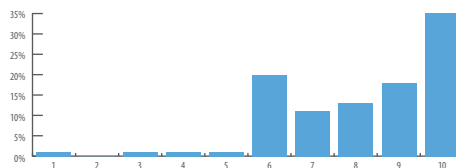
Most certified organizations stated that they would not choose a CB that had a reputation of "easy certification".

(7) We chose the CB because it was the cheapest.



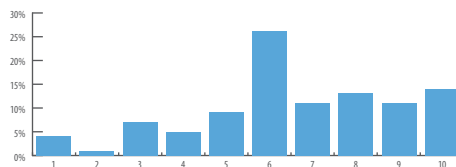
Usually certified organizations would not select a CB for the reason of price alone.

(8) It was important that a CB have accreditation by the Chinese AB.



Most of the respondents believed that it was important for their CB to have accreditation by the Chinese AB.

(9) It was important for the CB to have accreditation by a foreign AB.



There was a tendency for the certified organizations to believe that it is also important that for their CB to have accreditation by a foreign AB.

Table 1. Perception of certified organizations about CB selection process

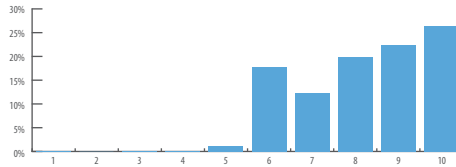
11. PROCESS OF INITIAL AUDITS

Regarding initial audits, the questionnaire requested the respondents to make remarks about the degree

of their agreement or disagreement to the following statements (see Table 2).

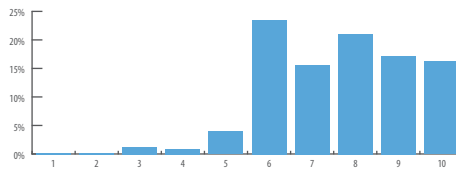
Statements about an initial audit process	Consistency in expression (1=strongly disagree, 10=strongly agree)	Remarks on questionnaire data																						
(1) It was a very rigorous process.	<table border="1"> <thead> <tr> <th>Rating</th> <th>Percentage</th> </tr> </thead> <tbody> <tr><td>1</td><td>1%</td></tr> <tr><td>2</td><td>1%</td></tr> <tr><td>3</td><td>1%</td></tr> <tr><td>4</td><td>1%</td></tr> <tr><td>5</td><td>1%</td></tr> <tr><td>6</td><td>22%</td></tr> <tr><td>7</td><td>13%</td></tr> <tr><td>8</td><td>21%</td></tr> <tr><td>9</td><td>18%</td></tr> <tr><td>10</td><td>23%</td></tr> </tbody> </table>	Rating	Percentage	1	1%	2	1%	3	1%	4	1%	5	1%	6	22%	7	13%	8	21%	9	18%	10	23%	Most of the surveyed organizations considered it as a rigorous audit process.
Rating	Percentage																							
1	1%																							
2	1%																							
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5	1%																							
6	22%																							
7	13%																							
8	21%																							
9	18%																							
10	23%																							
(2) It was an impartial and fair process.	<table border="1"> <thead> <tr> <th>Rating</th> <th>Percentage</th> </tr> </thead> <tbody> <tr><td>1</td><td>1%</td></tr> <tr><td>2</td><td>1%</td></tr> <tr><td>3</td><td>1%</td></tr> <tr><td>4</td><td>1%</td></tr> <tr><td>5</td><td>1%</td></tr> <tr><td>6</td><td>19%</td></tr> <tr><td>7</td><td>13%</td></tr> <tr><td>8</td><td>19%</td></tr> <tr><td>9</td><td>20%</td></tr> <tr><td>10</td><td>28%</td></tr> </tbody> </table>	Rating	Percentage	1	1%	2	1%	3	1%	4	1%	5	1%	6	19%	7	13%	8	19%	9	20%	10	28%	The initial audit process was fair and impartial.
Rating	Percentage																							
1	1%																							
2	1%																							
3	1%																							
4	1%																							
5	1%																							
6	19%																							
7	13%																							
8	19%																							
9	20%																							
10	28%																							

(3) The auditors were professional and competent.



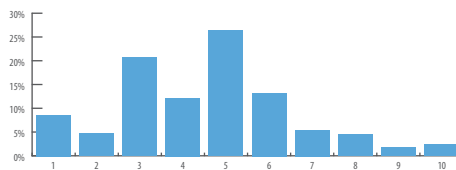
The surveyed organizations thought that the auditors were competent.

(4) The auditors had a good knowledge of our business and processes.



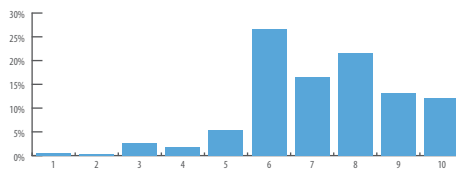
The surveyed organizations agreed that the auditors had a good knowledge of their business and processes.

(5) The auditors spent most of the time looking at our documents.



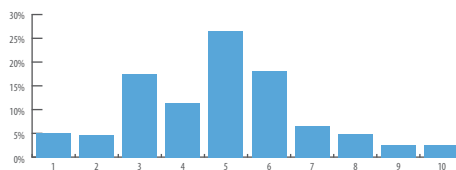
Most of the surveyed organizations considered that auditors did not spend too much time on documents alone.

(6) The auditors were keen to observe the operation of processes and to talk to relevant employees.



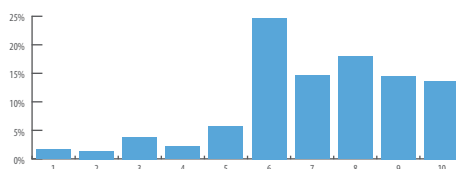
The surveyed organizations confirmed that auditors observed their processes and talked with relevant employees.

(7) During the audit, auditor used a lot of time taking notes.



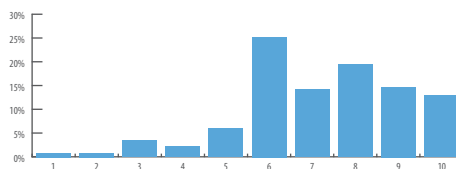
Most of the surveyed organizations did not agree that the auditors used too much time taking notes.

(8) The auditors gave us advice, told us how to do things.



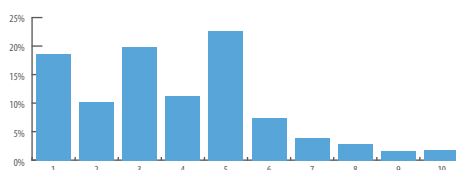
Most surveyed organizations agreed that auditors gave them advice. According to ISO/IEC 17021 clause 5.2.5, the certification body and any part of the same legal entity shall not offer or provide management system consultancy. It could be that the question was misunderstood, but this is worthy of further investigation when the opportunity arises.

(9) The auditors took adequate time talking with top management.



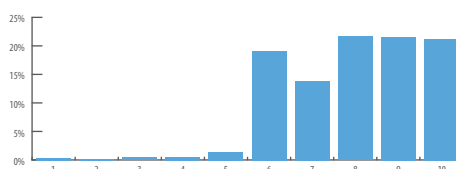
The surveyed organizations considered that auditors took adequate time talking with top management.

(10) The auditors seldom left the management representative's office.



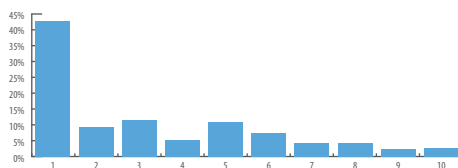
The surveyed organizations did not think that auditors spent too much time talking only with the management representative.

(11) The auditors were able to identify problem areas in the system and raise appropriate non-conformities.



The surveyed organizations thought that auditors were able to identify problem areas in the system and raise appropriate non-conformities.

(12) The consultant answered most of the questions asked by the auditors.



In general, the surveyed organizations did not believe that their consultants answered most of the questions asked by auditors.

Table 2. Certified organizations' perception of an initial audit

12. SURVEILLANCE AUDITS

According to the survey (see Figure 37), 89% of the organizations said that surveillance audits were an annual event. 3% said the surveillance frequency was once every 6 months. 4% said it was 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, there were according to the survey 3% of the organizations that said that their surveillance audits were carried out less than once a year. According to the analysis by the Chinese surveyors, this might be a result of the multi-site sampling standard, which does not require an annual surveillance audit at each and every site in the scope of a multi-site certification. This point was not verified in this project.

Regarding the surveillance audit process, the certified organizations were required to make remarks about the degree of agreement to the following statements. The results are in Table 6.

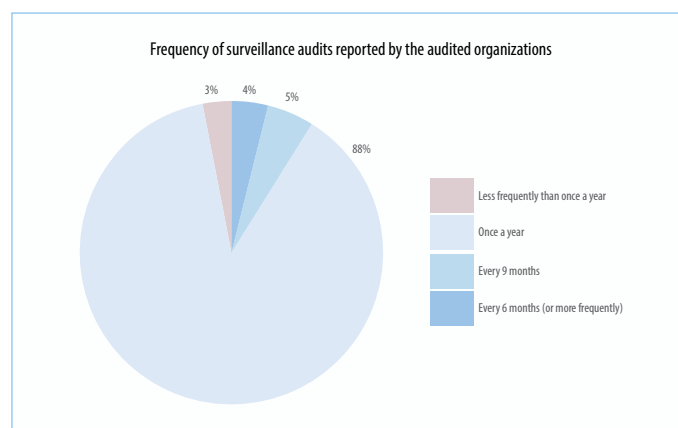
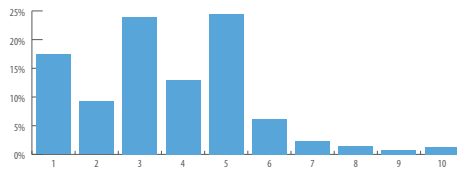


Figure 37. Frequency of surveillance audits reported by the certified organizations

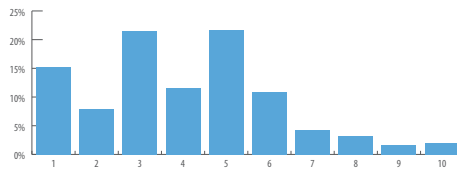
Statements on surveillance audit process	Consistency in expression (1=strongly disagree, 10=strongly agree)	Remarks on questionnaire data																						
(1) Each surveillance audit followed up on the NCs of the previous audit.	<table border="1"> <caption>Data for Statement (1): Consistency in expression</caption> <thead> <tr><th>Rating</th><th>Percentage</th></tr> </thead> <tbody> <tr><td>1</td><td>0%</td></tr> <tr><td>2</td><td>0%</td></tr> <tr><td>3</td><td>1%</td></tr> <tr><td>4</td><td>1%</td></tr> <tr><td>5</td><td>2%</td></tr> <tr><td>6</td><td>21%</td></tr> <tr><td>7</td><td>13%</td></tr> <tr><td>8</td><td>16%</td></tr> <tr><td>9</td><td>17%</td></tr> <tr><td>10</td><td>28%</td></tr> </tbody> </table>	Rating	Percentage	1	0%	2	0%	3	1%	4	1%	5	2%	6	21%	7	13%	8	16%	9	17%	10	28%	The surveyed organizations said that each surveillance audit followed up on the NCs of the previous audit.
Rating	Percentage																							
1	0%																							
2	0%																							
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5	2%																							
6	21%																							
7	13%																							
8	16%																							
9	17%																							
10	28%																							
(2) Surveillance audits encourage us to improve our system.	<table border="1"> <caption>Data for Statement (2): Consistency in expression</caption> <thead> <tr><th>Rating</th><th>Percentage</th></tr> </thead> <tbody> <tr><td>1</td><td>0%</td></tr> <tr><td>2</td><td>0%</td></tr> <tr><td>3</td><td>1%</td></tr> <tr><td>4</td><td>1%</td></tr> <tr><td>5</td><td>2%</td></tr> <tr><td>6</td><td>18%</td></tr> <tr><td>7</td><td>14%</td></tr> <tr><td>8</td><td>17%</td></tr> <tr><td>9</td><td>22%</td></tr> <tr><td>10</td><td>27%</td></tr> </tbody> </table>	Rating	Percentage	1	0%	2	0%	3	1%	4	1%	5	2%	6	18%	7	14%	8	17%	9	22%	10	27%	The surveyed organizations said that surveillance audit processes facilitated their continual improvement.
Rating	Percentage																							
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4	1%																							
5	2%																							
6	18%																							
7	14%																							
8	17%																							
9	22%																							
10	27%																							
(3) Surveillance audits were very useful.	<table border="1"> <caption>Data for Statement (3): Consistency in expression</caption> <thead> <tr><th>Rating</th><th>Percentage</th></tr> </thead> <tbody> <tr><td>1</td><td>0%</td></tr> <tr><td>2</td><td>0%</td></tr> <tr><td>3</td><td>1%</td></tr> <tr><td>4</td><td>1%</td></tr> <tr><td>5</td><td>2%</td></tr> <tr><td>6</td><td>21%</td></tr> <tr><td>7</td><td>14%</td></tr> <tr><td>8</td><td>18%</td></tr> <tr><td>9</td><td>20%</td></tr> <tr><td>10</td><td>25%</td></tr> </tbody> </table>	Rating	Percentage	1	0%	2	0%	3	1%	4	1%	5	2%	6	21%	7	14%	8	18%	9	20%	10	25%	The surveyed organizations believed that surveillance audits were useful.
Rating	Percentage																							
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4	1%																							
5	2%																							
6	21%																							
7	14%																							
8	18%																							
9	20%																							
10	25%																							

(4) Surveillance audits focused only on documents.



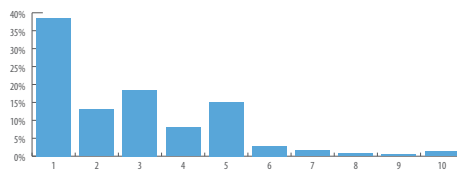
Most of the surveyed organizations disagreed that the surveillance audits were "focusing only on documents".

(5) CBs always sent the same auditors for surveillance audits.



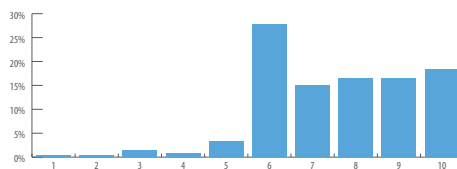
The surveyed organizations consider that the CBs do use different auditors for surveillance audits.

(6) In surveillance audits, auditors never raised any NCs.



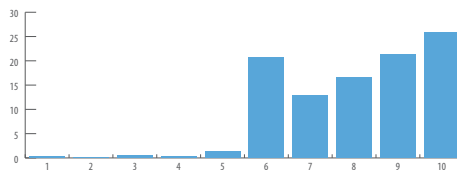
Most of the surveyed organizations consider that the auditors ARE raising NCs during surveillance audits.

(7) We found that surveillance audit reports were very useful.



The surveyed organizations believed that surveillance audit reports were useful.

(8) We continue to get value out of our certification.



The surveyed organizations were satisfied with the return on their investment in the surveillance audit process.

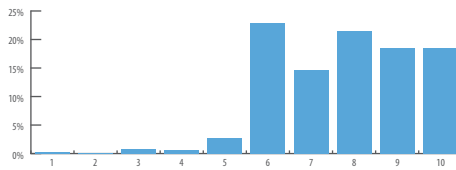
Table 3. Perception of certified organizations about the surveillance audit process

13. OVERALL COMMENTS ABOUT THE CERTIFICATION PROCESS

Overall comments from certified organizations about the certification process - see Table 4.

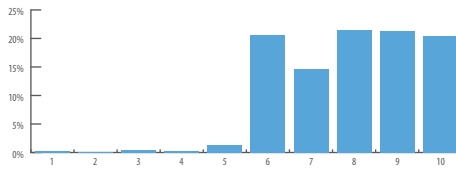
Statements about CBs	Consistency in expression (1=strongly disagree, 10=strongly agree)	Remarks on questionnaire data																						
(1) Our top management is fully committed to implementing ISO 9001.	<table border="1"> <thead> <tr> <th>Agreement Level</th> <th>Percentage</th> </tr> </thead> <tbody> <tr><td>1</td><td>1%</td></tr> <tr><td>2</td><td>1%</td></tr> <tr><td>3</td><td>1%</td></tr> <tr><td>4</td><td>1%</td></tr> <tr><td>5</td><td>2%</td></tr> <tr><td>6</td><td>20%</td></tr> <tr><td>7</td><td>12%</td></tr> <tr><td>8</td><td>16%</td></tr> <tr><td>9</td><td>20%</td></tr> <tr><td>10</td><td>32%</td></tr> </tbody> </table>	Agreement Level	Percentage	1	1%	2	1%	3	1%	4	1%	5	2%	6	20%	7	12%	8	16%	9	20%	10	32%	The surveyed organizations said that their top management was fully committed to implementing ISO 9001.
Agreement Level	Percentage																							
1	1%																							
2	1%																							
3	1%																							
4	1%																							
5	2%																							
6	20%																							
7	12%																							
8	16%																							
9	20%																							
10	32%																							
(2) The organization has achieved marked benefits from implementing ISO 9001.	<table border="1"> <thead> <tr> <th>Agreement Level</th> <th>Percentage</th> </tr> </thead> <tbody> <tr><td>1</td><td>1%</td></tr> <tr><td>2</td><td>1%</td></tr> <tr><td>3</td><td>1%</td></tr> <tr><td>4</td><td>1%</td></tr> <tr><td>5</td><td>2%</td></tr> <tr><td>6</td><td>20%</td></tr> <tr><td>7</td><td>13%</td></tr> <tr><td>8</td><td>19%</td></tr> <tr><td>9</td><td>19%</td></tr> <tr><td>10</td><td>27%</td></tr> </tbody> </table>	Agreement Level	Percentage	1	1%	2	1%	3	1%	4	1%	5	2%	6	20%	7	13%	8	19%	9	19%	10	27%	The surveyed organizations believed that it was beneficial to implement their QMS.
Agreement Level	Percentage																							
1	1%																							
2	1%																							
3	1%																							
4	1%																							
5	2%																							
6	20%																							
7	13%																							
8	19%																							
9	19%																							
10	27%																							

(3) Certification has helped us achieve our objectives.



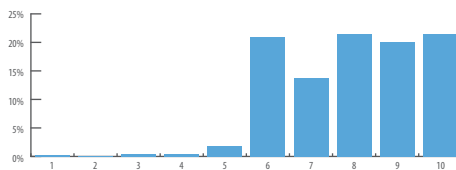
The surveyed organizations said that ISO 9001 certification helped them to achieve their organizational objectives.

(4) ISO 9001 certification has helped us improve our work.



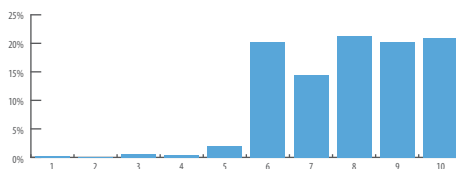
The surveyed organizations said that ISO 9001 certification had helped them improve the way they work.

(5) ISO 9001 certification helps us improve product quality.



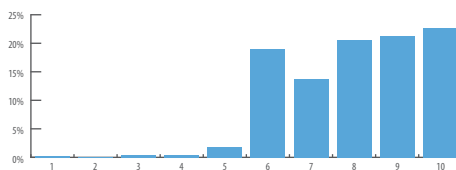
The surveyed organizations said that ISO 9001 certification helped improve product quality.

(6) ISO 9001 documents truly reflect our work procedures and methods.



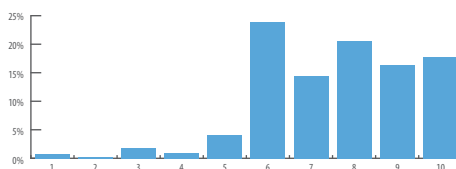
Most of the surveyed organizations said that ISO 9001 documents truly reflected their work procedures and methods.

(7) ISO 9001 certification provides more self-confidence in our capability to produce conforming products.



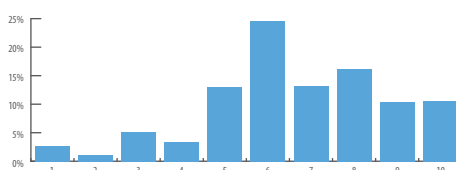
The surveyed organizations said that certification provided more self-confidence in their capability to produce conforming products.

(8) In selecting suppliers, credibility is given to ISO 9001 certification.



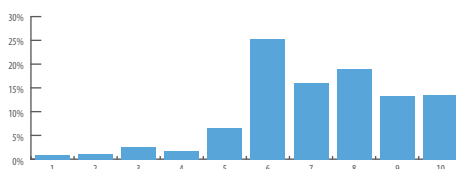
The surveyed organizations said that when selecting suppliers, their customers attached importance to the fact that their supplier is ISO 9001-certified.

(9) ISO 9001 has reduced the number of client audits.



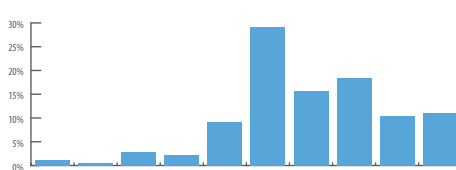
The majority of organizations considered that ISO 9001 certification has reduced the number of client audits, but a significant minority disagreed.

(10) ISO 9001 has helped us to reduce waste and duplication of internal work.



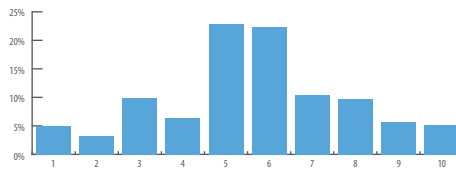
Most of the surveyed organizations said that the implementation of QMS had helped reducing work duplication and waste.

(11) Being certified against ISO 9001 has helped us to obtain more business.



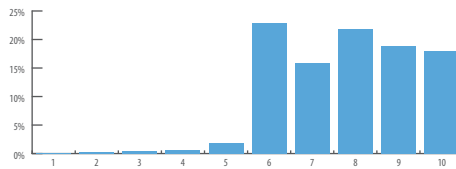
Most of the surveyed organizations said that ISO 9001 certification had brought them more business.

(12) Certification has enabled us to achieve higher prices for our products.



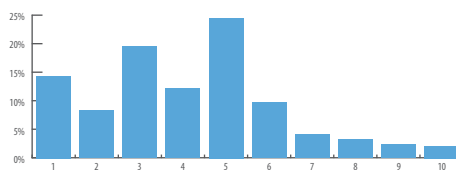
The surveyed organizations gave different ideas as to whether certification against ISO 9001 brings higher prices to their products due to industry and product differentiations.

(13) As a result of the implementation of ISO 9001 and certification, we have a better understanding of our work flows and processes.



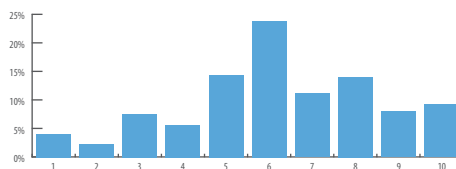
Most of the surveyed organizations said that the implementation of the QMS and certification to ISO 9001 helped them to understand better their work flows and processes.

(14) ISO 9001 compels us to formulate too many unnecessary documents.



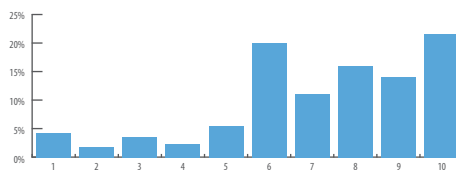
Most of the surveyed organizations said that they did not feel they had been compelled to establish too many unnecessary documents.

(15) We've never seriously considered changing our CB.



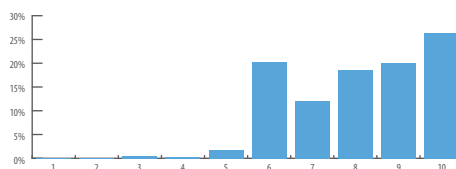
There was a normal distribution of opinions; some said that never seriously considered changing their CBs, but different ideas were given by other respondents.

(16) We've never considered giving up certification (on our own initiative).



Most of the surveyed organizations said that they did not have any thoughts of giving up certification.

(17) In general, implementing QMS and achieving ISO 9001 certification is a good investment.



The surveyed organizations said that the implementation and certification of ISO 9001 was a good investment.

Table 4. Overall comments from certified organizations about the certification process



Chapter V

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

1. GENERAL

This project sampled 958 certified organizations for an on-site survey. In the stage of planning the visits to the certified organizations, the project enjoyed great support at the national level from CNAS, and from the QTSB and CIQ at the local levels.

2. PERFORMANCE OF THE CERTIFIED ORGANIZATIONS

a) Overall results

Table 5 shows the results from the visits to 958 organizations certified to ISO 9001. The results are presented here according to the items in the visit checklist. The survey shows that in general the QMS of certified organizations achieved a high confidence level. 93% of the organizations visited provided at least “adequate” confidence in their QMS (Grade 3 or better). Details are as follows.

Grade 5	“We can be proud to use this organization as a benchmark for this topic”	6%
Grade 4	“Clear evidence that this is being done and meets the intent of ISO 9001”	56%
Grade 3	“OK - No reason to doubt that this is being addressed correctly”	31%

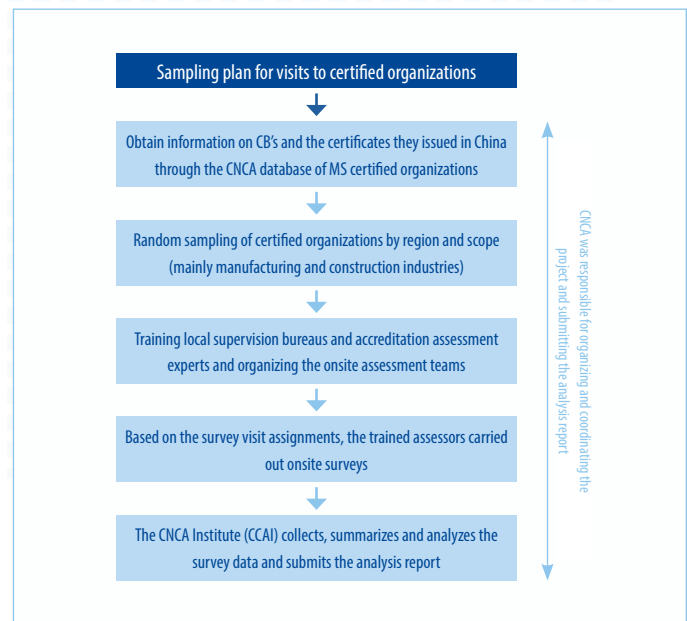


Figure 38. Sampling plan for the visits to the certified organizations

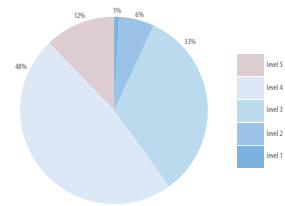
It should also be pointed out, however, that 7% of the visited organizations were listed in the “low confidence” category. Details are as follows:

Grade 2	“Some evidence presented, but not at all convincing”	6%
Grade 1	“Little or no confidence”	1%

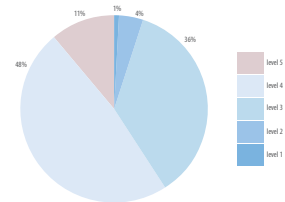
Items in the check list

Overall situation (958 organizations)

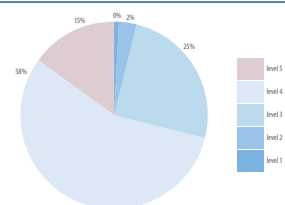
(1) The number of auditor days in initial certification (or the latest re-certification audit) were appropriate to the scale and complexity of the organization as well as the actual number of employees (see IAF MD 5).



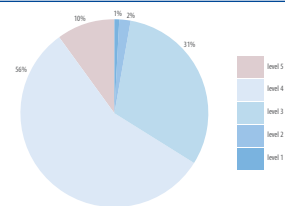
(2) The number of auditor days and frequency for surveillance audits are appropriate to the scale and complexity of the organization as well as the actual number of employees (see IAF MD 5 Chapter 5).



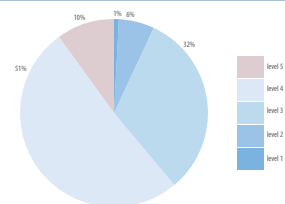
(3) The certification scope on the certificate correctly describes the organization's activities and is not misleading.



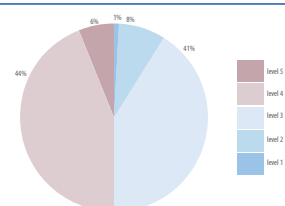
(4) All exclusions are adequately justified.



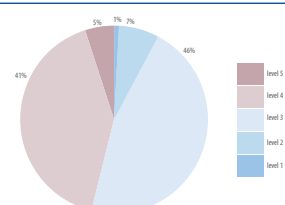
(5) There is evidence that top management participates in and is committed to the implementation of ISO 9001.



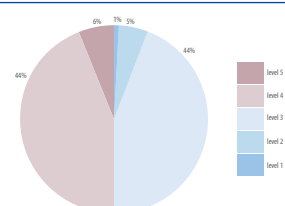
(6) There is good internal communication and employees know of their role in the QMS.



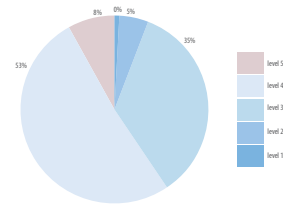
(7) The whole organization has a clear understanding of and implements the "process-approach".



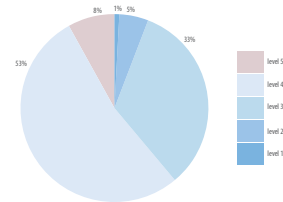
(8) The organizations uses the "Plan, Do, Check, Act (PDCA)" methodology (Clause 4.1 in ISO 9001).



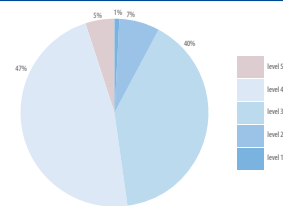
(9) The quality policy suits the organization's actual situation and culture.



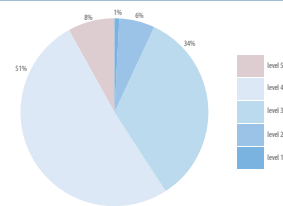
(10) The organization has established and deployed meaningful quality objectives at relevant functions and levels.



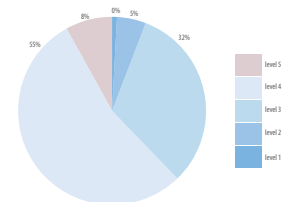
(11) The way the organization actually works is consistent with its Quality Manual.



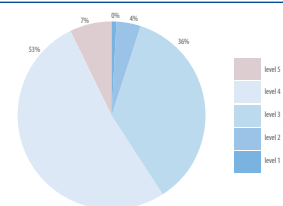
(12) QMS documentation is being used and is properly controlled.



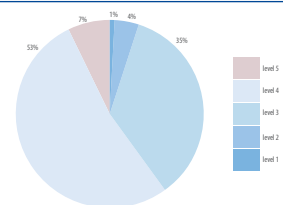
(13) The organization has adequate resources (competent personnel, equipment etc) to support its system.



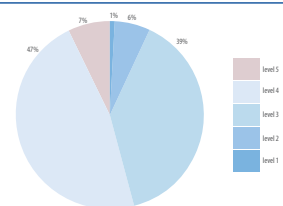
(14) The work environment is appropriate.



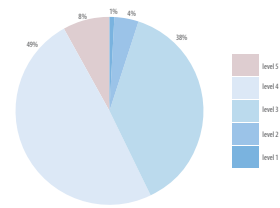
(15) Key product realization processes are identified and managed.



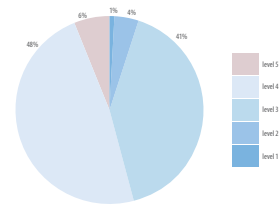
(16) All processes are adequately monitored and measured.



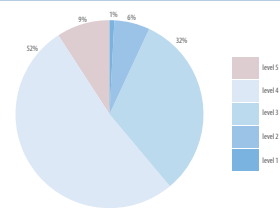
(17) Non-conformities in the products are identified and handled according to documented procedures.



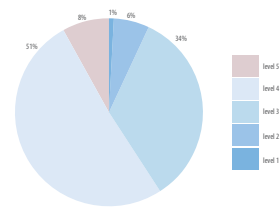
(18) The organization is committed to identifying and taking effective corrective actions against the causes of non-conformities in its processes, products and systems.



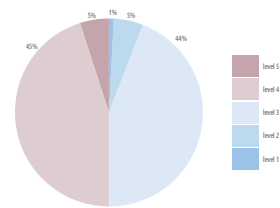
(19) Internal audits are conducted as planned and are effective.



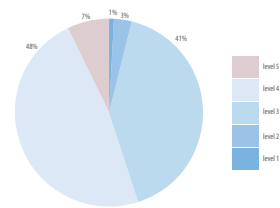
(20) The management review is conducted as planned and is effective.



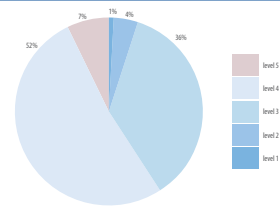
(21) The organization places a focus on preventing the occurrence of non-conformities.



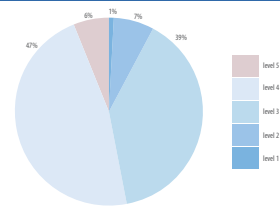
(22) Customer feedback and customer complaint handling mechanisms are appropriate.



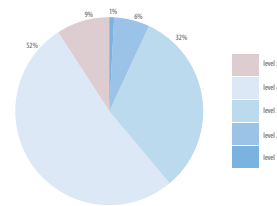
(23) The QMS provides confidence in the ability of the organization to “consistently provide products that conform to customer and applicable regulatory requirements”.



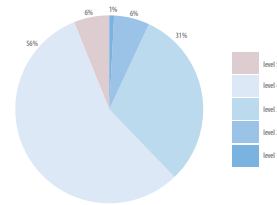
(24) The organization has a corporate culture for continual improvement of the effectiveness of its QMS.



(25) The CB has conducted an effective audit process.



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



Note: Grade 1: "Little or no confidence at all"; Grade 2: "There is some evidence, but not convincing"; Grade 3: "It's OK, no reason to doubt"; Grade 4: "Clear evidence shows that this is being done"; Grade 5: "We can proudly set this organization as an example".

Table 5. Results from the on-site visits to the certified organization

b) Weaknesses as demonstrated by the results of the market surveillance visits

The weakest areas in the system operation of the certified organizations were as follows:

1. Inadequate internal communication and the need for employees to understand better their roles in the QMS (Item 6 in the checklist);
2. Inconsistencies between the Quality Manual and the way the organization actually works (Item 11 in the checklist);
3. Lack of understanding and effective implementation of the process approach (Item 7 in the checklist);
4. Poor corporate culture for continual improvement of the effectiveness of its QMS (Item 24 in the checklist).

c) Relation between QMS credibility and certification duration

Figure 39 shows the relationship between QMS certification duration and system maturity. For organizations that have been certified for a longer time, the quality management system maturity and its overall credibility can be seen to improve.

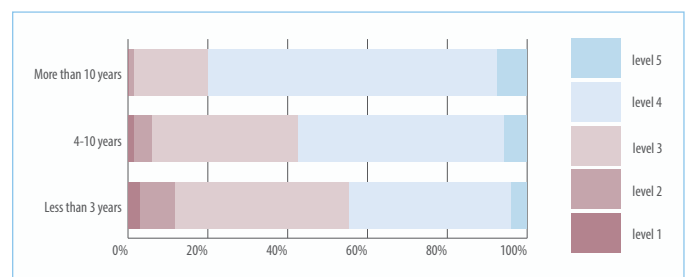


Figure 39. Relation between overall QMS credibility and length of time certified

d) Relation between system performance and implementation time prior to certification

Figure 40 shows that the certified organizations that took a short time (particularly less than 6 months) to implement their QMS before seeking certification have a lower level of overall credibility than those that took a longer time. With the increase in the time taken to implement the QMS, the percentage of organizations obtaining Level 4 and Level 5 for overall credibility also increases.

In China, most of the organizations that establish a QMS will seek certification to ISO 9001. It usually takes 7-12 months for them to become certified subject to good enthusiasm and attention on the part of the organization and a smooth certification process. Figure 40 shows that these organizations have a higher level of overall credibility. The highest percentage of organizations getting a 5-mark for overall certification

credibility was with those that operated their QMS for longer than 12 months before seeking certification. This shows that certification effects will be better with adequate operation and greater maturity of the QMS. There were, however, some organizations that took a very long time to achieve certification, presumably because of their poor management practices, inadequate attention or inadequate resources. In this survey, these organizations had operated their QMS for longer than 12 months before they finally became certified, and yet they still achieved only low overall scores.

e) Relation between QMS performance and size of organization

Figure 41 shows that the overall QMS credibility of small-size organizations is lower than that of the large-size ones.

Figure 41. Functional correlation between overall QMS credibility and organization size. "Micro" = fewer than 10 employees; "Small" = 11-50 employees; "Medium" = 51-250 employees; "Large" = more than 250 employees (see EU Proposal 2003 / 361 / EC)

f) Correlation between time spent auditing top management and effectiveness of audit

Figure 42 shows the relationship between the time that the CB audit team spent with top management and the effectiveness of the audit.

A comparison of the organizations that gave good marks (4 and 5 marks) to audit effectiveness with those that gave poor marks (1 and 2 marks) shows that when the CB audit team arranged more audit time with the organization's top management, it is of benefit to the overall audit effectiveness. That is, better in-depth communication with the top management will enable

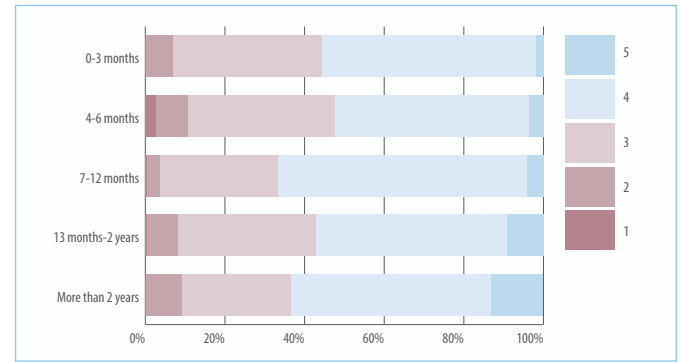
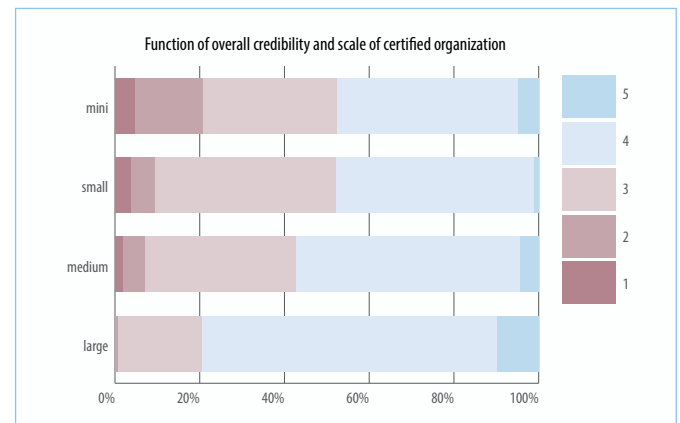


Figure 40. Relation between overall credibility and the time taken from decision to implement QMS to achieving certification



the audit team to have a better understanding of the organization's policy and strategic plans, which in turn will enable the audit team to harmonize its audit activities with the actual operations of the organization. In addition, the audit team will have clearer audit trails and the effectiveness of the audit will be better. Meanwhile, the top management will also obtain more valuable management information from the audit team feedback and give more attention to the QMS. Such audits will be "win-win" audits.

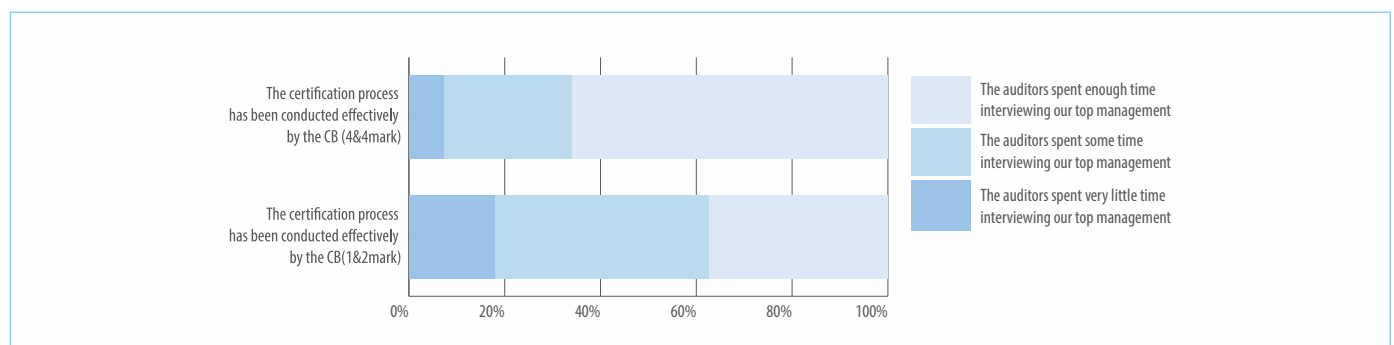


Figure 42. Relation between audit time spent with organization's top management and effectiveness of the CB audit

3. CORRELATION BETWEEN SYSTEM PERFORMANCE AND THE CBS

Figures 43-44 shows the overall credibility of the QMS in organizations that were certified by different CBs.

In this survey 7 certification bodies that had more than 20 certified organizations were visited. The credibility of the QMS of these certified organizations is in Figure 43. There are 27 CBs that had 5-20 certified organizations visited in this survey and the credibility of the QMS of these certified organizations is in Figure 44. CBs with less than 5 certified organizations visited in this survey were not considered in the analysis but were grouped together under the category "others" in Figure 44.

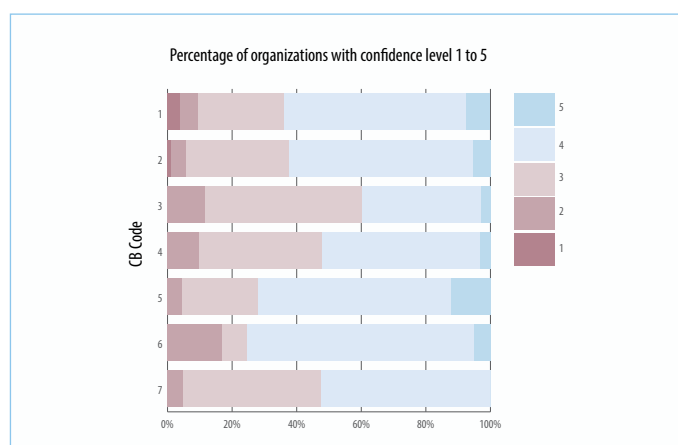


Figure 43. Overall credibility of QMS certification conducted by CBs that had more than 20 of their certified organizations visited for the survey

Due to the limited sample size of this survey, it was not possible to reflect the audit effectiveness of all the CBs operating in China. Therefore, this survey analysis did not rank the CBs by means of this information. It can be seen, however, that some CBs had up to (or in one case more than) 20% of their certified clients with a poor overall credibility (Score of 1 or 2), and it is to be recommended that greater emphasis be given to those CBs in any future oversight activities.

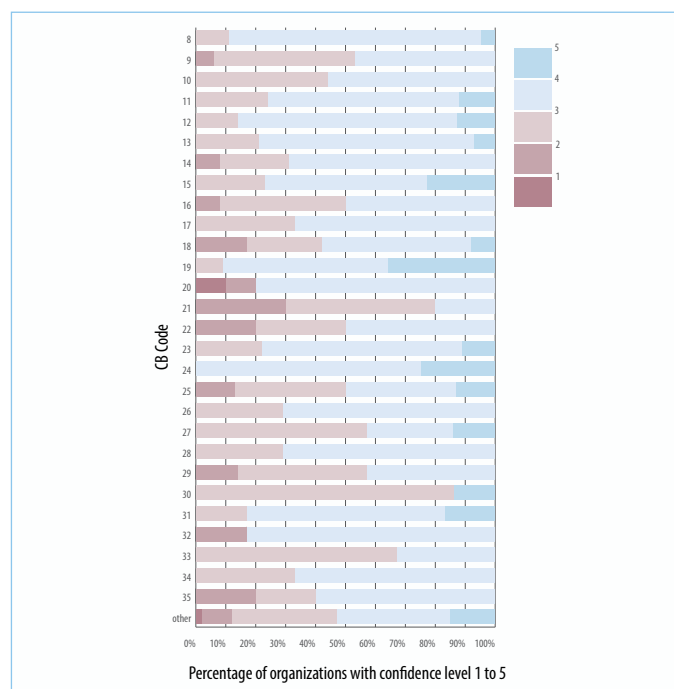


Figure 44. Overall credibility of QMS certification conducted by CBs that had 5-20 of their certified organizations visited for the survey

4. RELATION BETWEEN QMS PERFORMANCE OF THE CERTIFIED ORGANIZATIONS AND THE ABS

Figure 45 shows the difference in certification results of CBs accredited by various different accreditation bodies (ABs).

Note: Only ABs with 50 or more certified organizations visited were included in this analysis.

As with the performance of the CBs, it can be seen that there are differences in the performance of organizations certified under the accreditation of different ABs. Whilst the names of the individual ABs have not been included in this report for reasons of confidentiality, it can clearly be seen that AB3 is linked with the majority of organizations that achieved a score of "1" during the market surveillance visits (little or no confidence in the certified organization). It is recommended that this be communicated to the AB involved, and the causes investigated further.

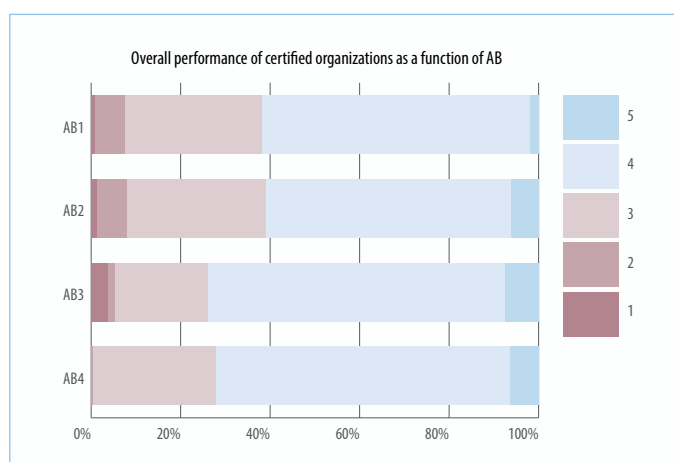


Figure 45. Relation between overall QMS credibility of the certified organizations and accreditation



Chapter VI

CONCLUSIONS AND RECOMMENDATIONS

The result of this survey shows that purchasers in China are generally satisfied with the overall performance of their ISO 9001-certified suppliers. Most purchasers think that the performance of certified suppliers is notably better than that of non-certified suppliers (or the same supplier before certification). 98% of the purchasers are satisfied with the product quality provided by ISO 9001-certified suppliers, including 7% of all purchasers who are very satisfied. The result of the survey proves once again that ISO 9001 QMS is useful to provide confidence in the quality of products.

In this survey, Chinese certified organizations also gave positive remarks regarding their experiences with ISO 9001-based quality management systems. Among the surveyed organizations, most of them said they obtained substantial benefits from the implementation of an ISO 9001-based QMS; 98% of the organizations surveyed said that regardless of the overall cost, ISO 9001 was a good or a very good investment. Although the size of organization differs, 39% of the organizations surveyed believe that the benefits from implementing ISO 9001 certification are between RMB 100,000 to 1,000,000 and 37% estimated that it could bring more than RMB 1,000,000 of benefits.

According to the survey result, purchasers have a positive attitude toward ISO 9001 certification in China. 93% expressed that they regarded ISO 9001 certification as an important criterion for supplier evaluation, and 73% said that their perception of the credibility of ISO 9001 CBs operating in China was “very good” or “good”.

In general, the result of this project shows that the effect of ISO 9001 certification is widely recognized by purchasers and certified organizations in China.



The “market surveillance” methodology developed in a previous UNIDO project in Asian developing countries (now adopted by the IAF in its document ID4:2012 “Market Surveillance Visits to Certified Organizations”) was used in this project. A similar methodology has been practiced by CNCA and CNAS in the certification market supervision and accreditation surveillance in China for over 10 years. The experiences of those practices also provide a good base for the implementation of this project. The implementation of this project will effectively promote the continual improvement of certification market surveillance activities in China.

This project has also been very useful in generating information that allows for a clearer understanding of the motivation of Chinese companies to implement a quality management system and to seek ISO 9001 certification. 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. Organizations (and in particular purchasers) should be encouraged to make more use of the CNCA or accreditation bodies’ website in order to verify claims of conformity to ISO 9001 made by their suppliers.
3. Survey result shows that some purchasers are not satisfied with the complaint handling of certified suppliers and their CBs; certified organizations and their CBs should improve their customer complaints handling process.
4. 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.

5. Accreditation bodies should be made aware that, in this survey, some certified organizations said the certification bodies carried out internal audits on behalf of the certified organizations (which is not acceptable, according to ISO/IEC 17021:2011 Clause 5.2.6).
6. The on-site market surveillance visits to certified organizations shows that some organizations and CBs should improve the following aspects:
 - i. Ensure that the QMS documentation and the Quality Manual reflect the way the organization actually works;
 - ii. Improve internal communication to enable employees understand better their roles within the QMS;
 - iii. Improve the use of the process approach and “PDCA” method to manage the QMS processes;
 - iv. Implement more effective management review processes;
 - v. Establish and maintain a corporate culture for continual improvement of the QMS effectiveness;
7. CBs should pay close attention to the QMS effectiveness of small organizations, and organizations claiming to have implemented their QMS in less than three months
8. For future oversight activities, CNCA and the relevant accreditation bodies should focus their attention on the CBs and their respective ABs whose certified clients performed badly during the market surveillance visits, and enhance the supervision over those CBs and ABs.



Introduction to CNCA

The Certification and Accreditation Administration of the People's Republic of China (CNCA) was established by the State Council and is authorized by the State Council to exercise administrative responsibilities of undertaking unified management, supervision and overall coordination of certification and accreditation activities across the country.

The responsibilities of CNCA are:

1. To draft and implement laws, regulations and rules related to certification and accreditation, safety license, hygiene registration and conformity assessment; To work out, promulgate and organize to implement policies, regulations and stipulations related to supervision and administration over certification and accreditation;
2. To propose and organize to implement national policies, regulations and working rules related to certification, accreditation and conformity assessment; To coordinate and guide certification and accreditation activities across the country; To supervise and administer relevant accreditation bodies and personnel registration bodies;
3. To draft the catalogue of products subject to China Compulsory Certification and Safety License System; To formulate and promulgate certification marks, conformity assessment procedures and technical requirements; To organize the implementation of China Compulsory certification and Safety License System;
4. To be responsible for hygiene assessment of manufacturing and processing establishments of import-export food and cosmetics, and the actual registration thereof; To be responsible for notification of their registration and recommendation to foreign countries;
5. To supervise and regulate certification market according to relevant laws; To supervise and administer voluntary certification as well as intermediary services and technical evaluation activities including certification-related consultancy and training; To be responsible for the qualification screening of, and supervision over certification bodies, certification consultancy bodies, certification training bodies, and inspection bodies that have businesses related to certification

- (including joint ventures, cooperative entities and wholly foreign-owned entities) according to relevant regulations; To supervise and administer operations of relevant bodies from other countries (regions) within China in accordance with relevant laws; To accept, investigate complaints and appeals related to certification and accreditation and make prosecutions; To regulate and supervise certification activities, and to guide and promote the reform of providers of intermediary services related to certification;
6. To administer the assessment and qualification approval of the technical competence of relevant calibration, testing and inspection laboratories; To organize the implementation of the assessment, metrological auditing, registration and qualification approval of laboratories responsible for entry-exit inspection and quarantine, and laboratories responsible for product quality supervision; To be responsible for the designation of certification bodies, testing laboratories and inspection bodies undertaking China Compulsory Certification and Safety License System; To be responsible for the qualification screening of the technical competence of calibration bodies, testing bodies, verification bodies, inspection bodies as well as quarantine bodies (including joint ventures, cooperative entities and wholly foreign-owned entities);
 7. To administer and coordinate international cooperation activities in the field of certification, accreditation and conformity assessment which are participated in the name of the government; to represent China in the conformity assessment field in international and regional organizations such as ISO and IEC, and be in charge of signing relevant agreements and protocols; to coordinate and supervise activities of international or regional conformity assessment organizations which are attended at the capacity of NGOs such as IAF, ILAC, IPC, PAC and APLAC; to be responsible for conformity assessment-related work within ISO and IEC China National Committees; to be responsible for approval for foreign activities related to certification, accreditation and conformity assessment;
 8. To be responsible for the research, transposition, promotion and implementation of international guidelines, recommendations and standards related to certification and accreditation; To collect and analyze information related to conformity assessment, certification and accreditation; To undertake WTO/TBT and WTO/SPS notifications where certification and accreditation is concerned and to deal with relevant enquiries;
 9. To be responsible for research and standardization related to accreditation and conformity assessment, including certification, to set up and organize to implement relevant programs; To undertake routine work of the Technical committee of Standardization related to Certification and Accreditation; To manage the work of making and revising test standards used in import and export inspection; To organize to make standardization plans, to review and recommend new standards and revisions, and to be responsible for relevant statistics;
 10. To draft fee charts for certification and accreditation activities, and exercise supervision over the implementation jointly with other relevant governmental authorities.



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List of Figures

Figure 1	Geographical distribution of the 897 purchasers participating in this survey	17
Figure 2	Size distribution of the purchasers surveyed (by number of employees)	18
Figure 3	Size distribution of the purchasers surveyed (by annual purchasing budget in RMB)	18
Figure 4	Number of suppliers actively evaluated by each of the purchasers surveyed	18
Figure 5	Purchaser self-evaluation of their level of conformity to ISO 9001	18
Figure 6	Purchasers' familiarity with ISO 9001	19
Figure 7	Percentage of the ways that purchasers use to verify the validity of the certificates of suppliers	20
Figure 8	Purchaser feedback to suppliers regarding procurement of "high value" and "high risk" products	20
Figure 9	Purchaser feedback to suppliers regarding procurement of "low value" and "low risk" products	20
Figure 10	The overall perception of the credibility of ISO 9001 CBs operating in China	21
Figure 11	Level of satisfaction of purchasers with certified suppliers	21
Figure 12	Comments by purchasers on ISO 9001-certified suppliers, compared with the non-certified ones	21
Figure 13	Purchaser opinions on the ISO 9001 Standard	22
Figure 14.1	Credibility of ISO 9001 certification: Confidence in the provision of conforming products	22
Figure 14.2	Credibility of ISO 9001 certification: Confidence in certification achieving its objective	22
Figure 15	Purchaser perception about systemic differences in the operations of accredited CBs	22
Figure 16	Analysis of the results of purchasers' 2nd-party audits to evaluate their ISO 9001-certified suppliers	23
Figure 17	Purchaser complaints to suppliers' CBs	23
Figure 18	Purchasers' complaints to ABs or CNCA against suppliers and CBs	23
Figure 19	Geographical breakdown of sample organizations	25
Figure 20	Size distribution of the ISO 9001 organizations surveyed	26
Figure 21	Distribution of length of time of certification	26
Figure 22	Major reason for implementing a QMS	26
Figure 23	Length of time taken to achieve certification after the decision to implement a QMS	27
Figure 24	Correlation between duration of certification and the time needed to achieve certification	27
Figure 25	Correlation between using consultancy in implementing a QMS and the time taken to achieve certification	28
Figure 26	Correlation between consultancy and duration of certification	28
Figure 27	Decreasing correlation between using consultancy and the scale (number of employees) of organizations	28
Figure 28	Role of consultancy services	29
Figure 29	Satisfaction of the surveyed organizations with QMS consultancy	29
Figure 30	Answers given by certified organizations to the question: "Regardless of the overall cost, do you consider this investment worthwhile?"	30
Figure 31	Percentage of surveyed organizations holding other certifications	30
Figure 32	QMS integrated with other systems	30
Figure 33	Selection of CBs	31
Figure 34	Transfers to other CBs	31
Figure 35	Knowledge of certified organizations about IAF	31
Figure 36	Channels of contact with CBs previous to initial audit	32
Figure 37	Frequency of surveillance audits reported by the certified organizations	35
Figure 38	Sampling plan for the visits to the certified organizations	41
Figure 39	Relation between overall QMS credibility and length of time certified	45
Figure 40	Relation between overall credibility and the time taken from decision to implement QMS to achieving certification	46
Figure 41	Functional correlation between overall QMS credibility and organization size	46
Figure 42	Relation between audit time spent with organization's top management and effectiveness of the CB audit	46
Figure 43	Overall credibility of QMS certification conducted by CBs that had more than 20 of their certified organizations visited for the survey	47
Figure 44	Overall credibility of QMS certification conducted by CBs that had 5-20 of their certified organizations visited for the survey	47
Figure 45	Relation between overall QMS credibility of the certified organizations and accreditation	47



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