Good Practices: Experience in the Market Surveillance of

ISO 9001 Quality Management Systems

UNITED NATIONS
INDUSTRIAL DEVELOPMENT ORGANIZATION

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TABLE OF CONTENTS


UNIDO

UNIDO FOREWORD

The ISO 9000 series of standards on quality management, developed by the International Organization for Standardization (ISO), play an important role in promoting sustainable international trade. In particular, ISO 9001 (Quality Management System – Requirements) is widely used by organizations around the world to demonstrate that they are managing their business processes in order to provide confidence that their products and services will consistently meet customer and applicable statutory and regulatory requirements. The most common way to do this is via the third-party certification process, whereby an independent certification body conducts a programme of audits to ensure that organization meets (and continues to meet) all the applicable requirements of the standard.

The competence of a certification body to carry out such certification can be demonstrated by the process of accreditation. Although there are numerous certification bodies around the world, there is usually only one government-recognized accreditation body in any given country. Such 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 and contributing towards the 2030 development agenda.

It has to be recognized, however, that certification is itself a competitive business, and there are often many competing certification bodies operating in any given economy. It is therefore important to have a mechanism to monitor the effectiveness of the overall accredited certification process and the extent to which it ensures the certified organization's quality management system continues to meet all the requirements of ISO 9001, and is "providing confidence in the organization's ability to consistently provide conforming products and services".

The concept of "market surveillance" is well known in the regulatory context for products and services, but a similar approach can also be applied for management systems. As part of a project that studied the implementation of ISO 9001 in twelve South and South-East Asian countries, UNIDO, ISO and IAF collaborated in the development of such a market surveillance methodology to evaluate the effectiveness of ISO 9001 certification in manufacturing organizations and the performance of the respective certification and accreditation bodies. This project resulted in a comprehensive report entitled "ISO 9001 – Its relevance and Impact in Asian Developing Economies", published in 2012. Based on positive feedback received, the methodology was then then further applied and validated in China and subsequently in Brazil, resulting in two further publications; "ISO 9001 – Relevance and Impact in China" published in 2015 and the other ("ISO 9001 – Relevance and Impact in Brazil"), in 2016.

I very much welcomed the idea to develop this publication in order to share the lessons learned in these joint UNIDO/ISO/IAF projects, and to disseminate good practices on how traditional accreditation oversight of certification schemes in member states can be complemented by appropriate market surveillance in order to ensure their ongoing credibility.

LI Yong

Director General

ACRONYMS

AB	Accreditation Body
BSCI	Business Social Compliance Initiative
CASCO Toolbox	Series of conformity assessment standards issued by ISO/CASCO
CB	Certification Body
EA	European Accreditation Cooperation
EMS	Environmental Management System
EnMS	Energy Management System
IAAC	Inter-American Accreditation Cooperation
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
MSV	Market Surveillance Visit
OHSAS	Occupational Health and Safety Assessment Series
OHSMS	Occupational Health and Safety Management System
PAC	Pacific Accreditation Cooperation
PDCA	The “Plan-Do-Check-Act” cycle (also referred to as the “Deming Cycle”)
QMS	Quality Management System
QuEST Forum	Quality Excellence for Suppliers of Telecommunications Forum
SAAS	Social Accountability Accreditation Service
SDOC	Supplier’s Declaration of Conformity
SME	Small or medium enterprise
UNIDO	United Nations Industrial Development Organization

EXECUTIVE SUMMARY

Although Market Surveillance is a term that is usually applied in a regulatory context for tangible products, a similar approach has been shown to be effective when applied to the voluntary certification of quality management systems, by making short "Market Surveillance" visits to certified organizations. This is consistent with the philosophy that "Output matters" – is the accredited certification process capable of providing confidence in a certified organization's ability to "consistently provide products and services that meet customer and applicable statutory and regulatory requirements"? This is the "expected outcome" for accredited certification to ISO 9001, according to the Joint Communique published by ISO and the IAF[1].

The methodology described in this report was jointly developed by UNIDO, ISO and the IAF, and over 1,600 certified organizations were visited during the course of three UNIDO-led projects covering 14 countries. "Market Surveillance" visits to certified organizations can be used by accreditation bodies or by others (such as customers of certified organizations, regulators and sector scheme owners). They can supplement traditional accreditation methodologies (such as office assessments and witness audits), be used to investigate complaints or be conducted as a result of other trigger mechanisms that indicate cause for concern.

Market surveillance visits can be used to identify trends in the strengths and weaknesses of the implemented quality management systems in particular regions or sectors, thereby providing useful information for certification bodies to be able to focus their attentions during their own surveillance and renewal audits. Results of the various UNIDO-led projects also highlighted variations not only among certification bodies (as determined by the performance of their certified clients) but also among different accreditation bodies. Analysis of the results of such visits could lead to more "targeted" surveillance activities, whereby certification bodies whose clients perform well could benefit from reduced oversight from their accreditation body, whilst certification bodies whose clients indicate cause for concern would be subjected to enhanced oversight.

Whilst the projects on which this report is based were conducted in developing economies, the Case Studies mentioned show that the "Market Surveillance" methodology can be used or adapted as an effective tool in other regions and contexts, and for other management systems.

[1] See bibliography for details.

ISO 9001 (*"Quality management systems – Requirements"*) is widely used by organizations around the world to demonstrate that they have a clearly defined and well managed set of processes that enable them to consistently provide products and services meeting customer and applicable statutory and regulatory requirements.

CHAPTER 1

Objectives of ISO 9001

The International Organization for Standardization (ISO) currently has a portfolio of over 21,000 standards, of which the ISO 9000 series relating to quality management is undoubtedly the best known. Within this series, ISO 9001 (*Quality management systems – Requirements*), is widely used by organizations around the world to demonstrate that they have a clearly defined and well managed set of processes that enable them to consistently provide products and services meeting customer and applicable statutory and regulatory requirements.

Since its first major revision in the year 2000, ISO 9001 has adopted a "process approach" to quality management, with the following key requirements: a clear commitment of the organization's top management to the quality management system; a "customer focus" throughout the organization; a clear quality policy and policy objectives defined by top management; definition of the responsibility and authority of the various personnel involved in the quality management system and communication between them; ensuring the availability of resources (including competent personnel); appropriate levels of documentation; and control of the various operational processes, from sales through design and development of the product or service provided, manufacture (or service provision), process monitoring, inspection and after-sales support.

In order to ensure on-going conformity to ISO 9001 and continual improvement, the standard further requires organizations to carry out their own internal audits and reviews of their system at regular intervals and to undertake corrective actions as needed. The 2015 version of ISO 9001 maintains most of these core concepts, and adds the philosophy of "risk based thinking" (requiring organizations to identify the risks and opportunities that can affect their performance), coupled with the appropriate use of the "Plan-Do-Check-Act" cycle at all levels and new requirements for maintaining "organizational knowledge" and managing change.

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

"The overall aim of certification is to give confidence to all parties that a management system fulfils specified requirements. The value of certification is the degree of public confidence and trust that is established by an impartial and competent assessment by a third-party".

CHAPTER 2

Conformity Assessment of Quality Management Systems

Certification as a confidence-building activity

A common way for organizations to show that they meet all the requirements of ISO 9001 is by using an independent third-party (a certification body) to carry out an audit of the organization, which, if successful, will result in the organization being issued with a certificate of conformity and the initiation of a programme of on-going surveillance by the certification body to ensure that the system is maintained in accordance with that standard.

According to ISO/IEC 17021-1,"The overall aim of certification is to give confidence to all parties that a management system fulfils specified requirements. The value of certification is the degree of public confidence and trust that is established by an impartial and competent assessment by a third-party". The organization's current and potential customers and/or other stakeholders can be confident that the organization has indeed implemented a quality management system that meets the requirements of ISO 9001, and is managing its activities and processes in a way that will consistently achieve the expected outcomes of the system.

In other words, quality management system certification is about providing ***confidence*** - confidence that the certified organization has implemented a system that meets the requirements of ISO 9001, and confidence that the system is effective in achieving its expected outcomes. This means that a certified organization should be achieving the expected outcome of providing "consistent, conforming products and services" to its customers. The IAF and ISO have placed great importance in recent years to emphasize this concept that "output matters", which should be deployed right through the conformity assessment supply chain (from the IAF, to ABs, to CBs to individual auditors). It is not enough for an auditor to simply check that a certified management system includes all the required documentation (standards are in any case becoming more performance-based with less of these prescriptive requirements for documentation) –it really has to be demonstrably ***effective***. According to the definition given in ISO 9000, "effectiveness" means the "extent to which planned activities are realized and planned results achieved". The importance of a certified management system being capable of achieving its "expected outcomes" will be addressed later in this guide.

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

Evolution of ISO 9001 certification

Over centuries, many forms of conformity assessment have evolved, primarily with the underlying objective of facilitating trade. The most commonly known forms of third party conformity assessment include product inspection and laboratory testing that typically assess the conformity of tangible products against specified characteristics including, for example, weight, strength, concentration, dimension, and many others. Specifications for such characteristics are usually defined in a quantitative manner, including tolerances and clear acceptance criteria. One of the key characteristics of management system certification as a conformity assessment method that makes it different from these "traditional" forms of conformity assessment is the often more abstract and subjective nature of the requirements against which conformity is being assessed. Management system standards often require management or employees to demonstrate "awareness" or "commitment" (that are impossible to quantify into "black or white" Yes/No acceptance criteria). It is common to encounter requirements for activities to be performed "as appropriate" or "where applicable", leading to a need for sound, pragmatic judgement on the part of the management systems certification body and its auditors.

It was not until the early 1980s that management system certification began to emerge, specifically for the field of quality management in the UK. The driver at that time was an initiative by the UK Department of Trade and Industry (DTI) to promote the use of BS 5750 (one of the precursors to ISO 9001) as a tool for effective supplier selection in the defense and other industries. BS 5750 was first published in 1979, and third party certification began soon after. Not surprisingly, many of the first management system certification bodies were offshoots of traditional inspection agencies, mainly in the marine certification arena. The DTI published a "Register" of certified organizations that served as a basis for UK (and other) purchasing organizations to be able identify and have confidence in potential suppliers. Over the years, several attempts have been made to establish a global register of organizations certified to ISO 9001 and/or other management system standards, but these have largely been unsuccessful. As will be seen later, "ISO 9001 certification" has become a very competitive business, and some certification bodies are unwilling to make details of their certified clients publicly available for fear of other certification bodies trying to "poach" those clients. Whilst there is recognition that such a global directory would be desirable, at the time of publication of this guide, for a variety of reasons the infrastructure is not yet in place.

Accredited certification to ISO 9001

Management system certification is one particular form of conformity assessment. ISO/IEC 17000 ("*Conformity assessment — Vocabulary and general principles*") includes the following definitions, which are essential for a proper understanding of management system certification and its accreditation.

CONFORMITY ASSESSMENT	Demonstration that specified requirements relating to a product, process, system, person or body are fulfilled. NOTE 1: The subject field of conformity assessment includes activities such as testing, inspection and certification, as well as the accreditation of conformity assessment bodies.
ATTESTATION	Issue of a statement, based on a decision following review, that fulfilment of specified requirements has been demonstrated. NOTE 1: The resulting statement, referred to as a "statement of conformity", conveys the assurance that the specified requirements have been fulfilled. Such an assurance does not, of itself, afford contractual or other legal guarantees.
CERTIFICATION	Third-party attestation related to products, processes, systems or persons. NOTE 1: Certification of a management system is sometimes also called registration. NOTE 2: Certification is applicable to all objects of conformity assessment except for conformity assessment bodies themselves, to which accreditation is applicable.
ACCREDITATION	Third-party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks.

The various interactions in the "conformity assessment supply chain" for ISO 9001 are shown in Figure 1. The aim is to promote trade by providing confidence throughout this supply chain so that customers (and, ultimately, consumers) can have a reasonable expectation of receiving conforming products and services from suppliers (the certified organizations) wherever in the world these are located. The ultimate objective of accredited certification is to achieve the goal of "Once certified, accepted everywhere".

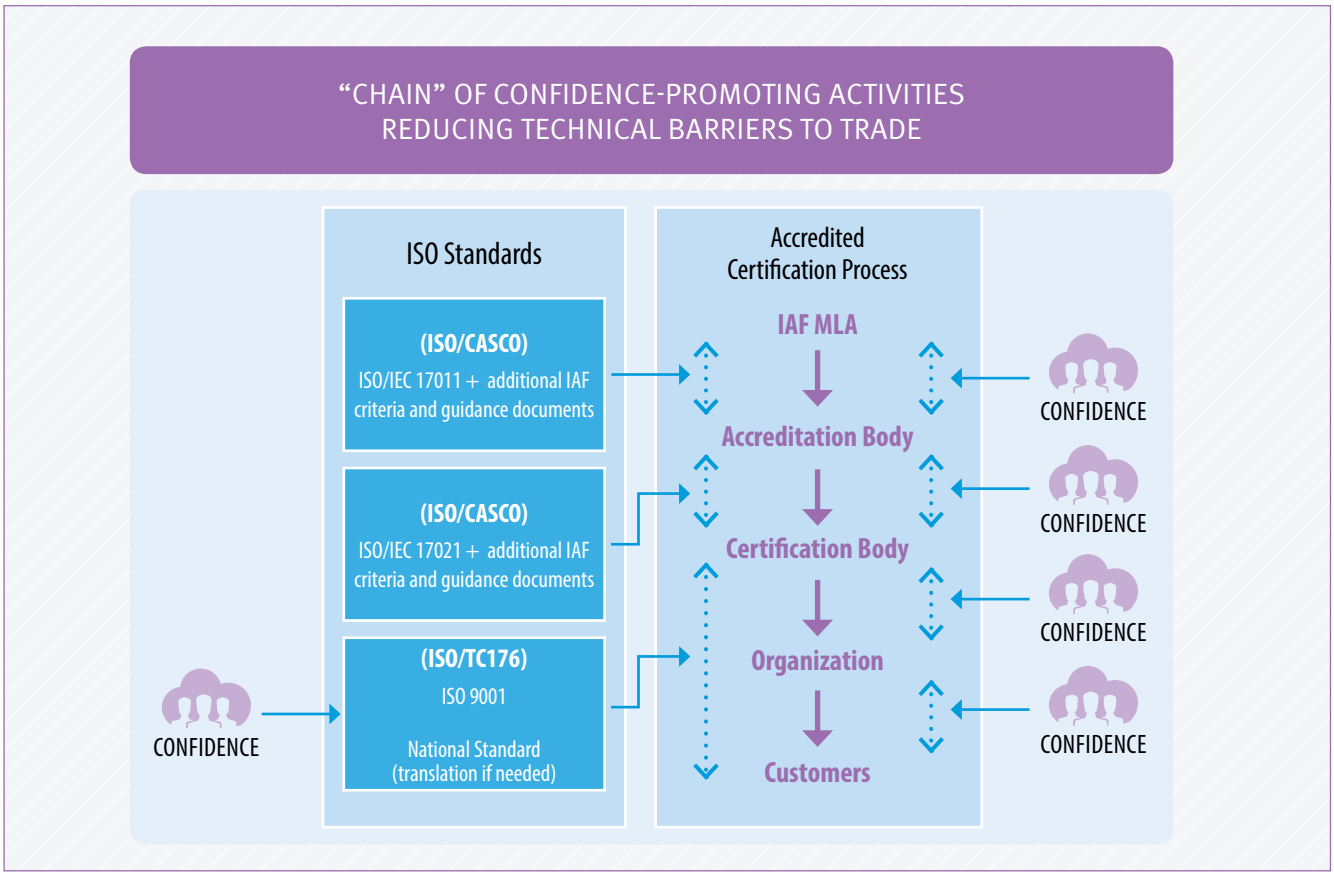

Figure 1 – Interactions within the "conformity assessment supply chain" aimed at providing confidence in ISO 9001 certification

In order to demonstrate its own competence to carry out the management system certification process, a certification body may choose therefore to be accredited by an accreditation body. This accreditation will be based primarily on the requirements defined in ISO/IEC 17021-1, in some cases supplemented by other discipline-specific or sector-specific requirements, as will be discussed later. ISO/IEC 17021-1 is based on the following core principles:

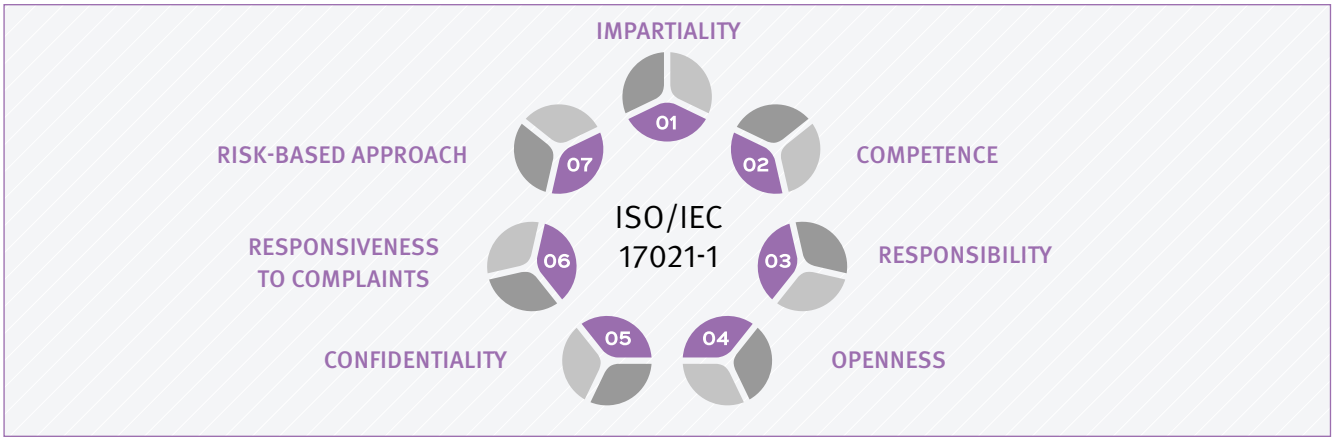

Figure 2 – Core principles of ISO/IEC 17021-1

Whilst these principles do not constitute requirements that a certification body has to meet, they do form the conceptual basis for many of the formal requirements in ISO/IEC 17021-1. The following are extracts taken from ISO/IEC 17021-1, relating to the principles of management system certification, and it is important that accreditation bodies never lose overall sight of these principles when assessing management system certification bodies, in order to put the requirements for accreditation into their proper context.

IMPARTIALITY	*"Presence of objectivity"* *NOTE 1: Objectivity means that conflicts of interest do not exist, or are resolved so as not to adversely influence subsequent activities of the certification body.* *NOTE 2: Other terms that are useful in conveying the element of impartiality include "independence", "freedom from conflict of interests", "freedom from bias", "lack of prejudice", "neutrality", "fairness", "open-mindedness", "even-handedness", "detachment", "balance".* *"Being impartial, and being perceived to be impartial, is necessary for a certification body to deliver certification that provides confidence. It is important that all internal and external personnel are aware of the need for impartiality."* *"It is recognized that the source of revenue for a certification body is its client paying for certification, and that this is a potential threat to impartiality."* *"To obtain and maintain confidence, it is essential that a certification body's decisions be based on objective evidence of conformity (or nonconformity) obtained by the certification body, and that its decisions are not influenced by other interests or by other parties."*
COMPETENCE	*("the ability to apply knowledge and skills to achieve intended results").* *"Competence of the personnel of the certification body in all functions involved in certification activities is necessary to deliver certification that provides confidence."* *"The competence also needs to be supported by the management system of the certification body.*
RESPONSIBILITY	*"The certified client, and not the certification body, has the responsibility for consistently achieving the intended results of implementation of the management system standard and conformity with the requirements for certification."* *"The certification body has the responsibility to assess sufficient objective evidence upon which to base a certification decision. Based on audit conclusions, it makes a decision to grant certification if there is sufficient evidence of conformity, or not to grant certification if there is not sufficient evidence of conformity."* *"NOTE Any audit is based on sampling within an organization's management system and therefore is not a guarantee of 100 % conformity with requirements."*
OPENNESS	*"A certification body needs to provide public access to, or disclosure of, appropriate and timely information about its audit process and certification process, and about the certification status (i.e. the granting, maintaining of certification, expanding or reducing the scope of certification, renewing, suspending or restoring, or withdrawing of certification) of any organization, in order to gain confidence in the integrity and credibility of certification. Openness is a principle of access to, or disclosure of, appropriate information."* *"To gain or maintain confidence in certification, a certification body should provide appropriate access to, or disclosure of, non-confidential information about the conclusions of specific audits (e.g. audits in response to complaints) to specific interested parties."*
CONFIDENTIALITY	*"To gain the privileged access to information that is needed for the certification body to assess conformity to requirements for certification adequately, it is essential that a certification body does not disclose any confidential information."*
RESPONSIVENESS TO COMPLAINTS	*"Parties that rely on certification expect to have complaints investigated and, if these are found to be valid, should have confidence that these complaints will be appropriately addressed and that a reasonable effort will be made by the certification body to resolve them. Effective responsiveness to complaints is an important means of protection for the certification body, its clients and other users of certification against errors, omissions or unreasonable behaviour. Confidence in certification activities is safeguarded when complaints are processed appropriately.* *NOTE: An appropriate balance between the principles of openness and confidentiality, including responsiveness to complaints, is necessary in order to demonstrate integrity and credibility to all users of certification."*

RISK-BASED APPROACH

"Certification bodies need to take into account the risks associated with providing competent, consistent and impartial certification. Risks may include, but are not limited to, those associated with:

- *the objectives of the audit;*
- *the sampling used in the audit process;*
- *real and perceived impartiality;*
- *legal, regulatory and liability issues;*
- *the client organization being audited and its operating environment;*
- *impact of the audit on the client and its activities;*
- *health and safety of the audit teams;*
- *perception of interested parties;*
- *misleading statements by the certified client;*
- *use of marks."*

Figure 3 – Extracts taken from ISO/IEC 17021-1 relating to the principles of management system certification

The role of accreditation in facilitating trade

Accreditation bodies in turn may choose to participate in multi-lateral recognition arrangements under the coordination of the International Accreditation Forum (IAF) or its regional groups such as the European Accreditation Cooperation (EA), Inter-American Accreditation Cooperation (IAAC), or Pacific Accreditation Cooperation (PAC), to ensure that the criteria being used for accreditation are comparable around the world. This is intended to facilitate international trade by giving the corresponding accredited certification international validity and recognition, independent of the geographical location of the certified organization.

Accreditation bodies that choose to become signatories of the IAF's Multi-lateral Recognition Arrangement (MLA) are subject to a peer evaluation process based on the requirements of ISO/IEC 17011.

For most management system certification activities, there is typically only one recognized accreditation body per country. In the case of ISO 9001 the accreditation process verifies the certification body's conformity to the ISO/IEC 17021 standard. The requirements of ISO/IEC 17021-1 may be complemented, however, by additional sector- or discipline-specific requirements in the ISO/IEC 17021-x series, and IAF application documents that contains criteria to allow for the consistent application of the IAF MLA.

In both cases (accreditation of certification bodies and peer evaluations of accreditation bodies), those who choose to work under the umbrella of the IAF MLAs are also subject to criteria that ensure the consistent application of ISO/IEC 17021-1 and ISO/IEC 17011 requirements, in the form of IAF mandatory, guidance and informative documents. One of the criteria for acceptance as an IAF MLA signatory is that the accreditation body must formally recognize accreditation granted by other MLA signatories as being equivalent to its own accreditation. In the context of trade capacity building in developing countries, this multi-lateral recognition of certificates issued by accredited certification bodies is of vital importance in providing certified organizations with access to world markets without the need for multiple accreditations.

ISO and the IAF have undertaken a series of initiatives aimed at promoting feedback from users about the performance of their ISO 9001-certified suppliers and the accredited certification process.

CHAPTER 3

Credibility of Management Systems Certification

The latest ISO Survey shows that there are now over a million organizations worldwide that are certified to ISO 9001. The majority of these have dedicated significant efforts and resources (often aided by the sensible use of competent consultants) to implementing robust systems capable of producing the desired outputs – "consistent, conforming products and services". These systems, in turn, have been audited and certified by ethical, impartial certification bodies using competent teams of professional auditors. Croft and Dougherty[2] call all those involved in this process the "good guys". They have done a good job and brought credit to the name of "ISO 9000".

Unfortunately, in the late 1990s, disturbing trends began to emerge of less scrupulous players ("the bad guys") appearing on the scene (probably driven by the commercial factors surrounding the whole "business" of certification) and threatening to undermine the credibility of the ISO 9001 certification process as a whole.

ISO and the IAF have undertaken a series of initiatives aimed at promoting feedback from users about the performance of their ISO 9001-certified suppliers and the accredited certification process. These include:

- The 2006 Joint ISO/IAF Strategic Action Plan "to monitor and improve the effectiveness of Accredited Management System Certification", including the strategic imperative that "Output matters!" (i.e. the focus of auditing and certification should not only be on system documentation, and inward-looking within an organization and its processes. It should focus on whether or not the quality management system is achieving its stated objectives of "providing confidence in an organization's ability to consistently provide confirming products and services");
- Formation of an End-User Advisory Group integrated into the structure of IAF;
- Publication of the joint ISO/IAF Communique "Expected outcomes for accredited certification to ISO 9001"[3], aimed at defining what a quality management system certified to ISO 9001 can realistically be expected to provide, and also what it cannot reasonably be expected to guarantee;
- Publication of the document "ISO 9001 – what does it mean in the supply chain"[2], aimed at educating purchasers about the various forms of conformity assessment for ISO 9001, and how to complain if things go wrong.

[2] See Bibliography.

[3] See Bibliography.

There continues, however, to be an ongoing debate about the effectiveness of accredited certification - whether the focus has shifted from one in which organizations strived to develop an effective quality management system that could subsequently be certified, to one in which the achievement of certification is the only goal. This questioning of the credibility of certification has been prompted by a variety of perceptions, often based only on anecdotal evidence. The debate centers on whether:

(a) Organizations are deriving tangible benefits through ISO 9001 certification (is the money, time, and administrative effort for certification providing enough value?);

(b) Certification and accreditation bodies are carrying out the certification process effectively and providing overall market confidence in certification; and,

(c) ISO 9001-certified suppliers can be relied upon to provide "consistent, conforming products and services" to their customers.

In the period of 2009 – 2015, a series of joint projects involving UNIDO, ISO and the IAF together with local partners in 14 countries[4] obtained systematic feedback from purchasers about their perceptions of their ISO 9001-certified suppliers, and from ISO 9001-certified organizations about the implementation and certification process. A total of over 1400 purchasing organizations was consulted, and more than 7800 ISO 9001-certified companies.

In addition to the questionnaire-based surveys, a "market surveillance" methodology involving short (one-day) visits to certified organizations was developed and more than 1600 organizations were visited. This was shown to be effective in distinguishing between superior and unsatisfactory performances of suppliers (as perceived by their customers), based on the evaluation of a series of parameters related to the implementation of the quality management system.

The methodology for the one-day visits was developed by a process of consultation and consensus, mainly within the IAF Technical Committee Task Force on Market Surveillance. There has been a close interaction with this group throughout the various UNIDO projects, and the methodology has since been adapted and incorporated into the IAF Informative Document IAF ID4:2012. This will be described in greater detail later in this guide.

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

- The visits were not intended to be "repeat audits" and were not focused on generating "conforming/nonconforming" outcomes;
- The results of the visits were strictly confidential and were reported neither to the organization's certification body nor to the respective accreditation body. This was considered essential in order to obtain agreement from the certified organizations to receive the visits;
- The visits were aimed at determining confidence levels related to various aspects of the organization's quality management system and the overall level of confidence in the certification process. The full check-list covered the 26 topics listed in Figure 4 below.

- INITIAL CERTIFICATION BODY AUDIT DURATION
- SURVEILLANCE AUDIT DURATION AND FREQUENCY
- SCOPE STATEMENT ON THE ORGANIZATION'S CERTIFICATE
- JUSTIFICATION FOR ANY EXCLUSIONS (ISO 9001:2008 CLAUSE 1.2)
- TOP MANAGEMENT COMMITMENT
- INTERNAL COMMUNICATION
- UNDERSTANDING AND IMPLEMENTATION OF THE "PROCESS APPROACH"
- USE OF PDCA TO MANAGE PROCESSES (ISO 9001:2008 CLAUSE 4.1)
- QUALITY POLICY
- MEANINGFUL OBJECTIVES
- QUALITY MANUAL AS A TRUE REFLECTION OF THE QUALITY MANAGEMENT SYSTEM
- APPROPRIATE USE OF QUALITY MANAGEMENT SYSTEM DOCUMENTATION
- RESOURCE MANAGEMENT (INCLUDING HUMAN RESOURCES
- WORK ENVIRONMENT

[4] Bangladesh, Bhutan, Brazil, China, India, Indonesia, Maldives, Malaysia, Nepal, Pakistan, Philippines, Sri Lanka, Thailand and Vietnam.

- MANAGEMENT OF PRODUCT REALIZATION PROCESSES
- PROCESS MONITORING AND MEASUREMENT
- TREATMENT OF PRODUCT NONCONFORMITIES
- CAUSE ANALYSIS FOR NONCONFORMITIES AND EFFECTIVE CORRECTIVE ACTION
- INTERNAL AUDITS
- MANAGEMENT REVIEW
- PREVENTION OF NONCONFORMITIES
- CUSTOMER FEEDBACK AND COMPLAINTS HANDLING
- OVERALL CONFIDENCE IN THE ABILITY TO PRODUCE "CONSISTENT, CONFORMING PRODUCTS"
- CONTINUAL IMPROVEMENT OF QUALITY MANAGEMENT
- OVERALL CONFIDENCE IN THE CERTIFICATION BODY'S PROCESSES
- OVERALL CONFIDENCE IN THE ORGANIZATION'S IMPLEMENTATION OF ISO 9001

Figure 4 – Topics covered in the visits to certified organizations

It was found that, after undergoing an appropriate training course and evaluation, assessors were able to discriminate between scores of 1 - 5 within a scale of confidence levels defined for each of the parameters as follows.

GRADE 1	*"Little or no confidence"*	Little or no evidence 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 judgement of the assessor (based on experience), there would probably be evidence to support a nonconformity if a detailed audit trail were to be followed in a full system audit.
GRADE 3	*"OK - No reason to doubt that this is being addressed correctly"*	The "default" grade, where there is no evidence to suggest reasons for concern, based on the assessor's experience and professional judgement.
GRADE 4	*"Clear evidence that this is being done, and meets the intent of the relevant standard"*	Sufficient objective evidence was available to provide a good level of confidence that the organization is meeting the requirements.
GRADE 5	*"We can be proud to use this organization as a benchmark for this topic"*	To be reserved for truly excellent performance.

Figure 5 – Assessment criteria for market surveillance visits

One of the key findings of all the projects, and the main justification for the adoption of a market surveillance methodology, was that there are notable differences in the performance and level of confidence in organizations certified by different certification bodies and under accreditation from different accreditation bodies.

CHAPTER 4

Some Key Findings[5], and the Need for Market Surveillance of ISO 9001 Certification

Economic benefits of ISO 9001

There are clear economic benefits to the effective implementation and accredited certification of quality management systems. Over 95% of the certified organizations surveyed considered this to have been a "good" or "very good" investment.

Credibility of ISO 9001

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

Purchasers' perceptions of their ISO 9001-certified suppliers

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

Lack of transparency in some certification and accreditation bodies

In conducting the various projects, it proved to be almost impossible to obtain reliable information about ISO 9001-certified organizations in each country, because some certification bodies refuse to provide any information about the organizations they certify, and local accreditation bodies are often unaware of the activities of foreign-accredited certification bodies who are active in their region.

[5] It must be emphasized that these findings were based on projects carried out by UNIDO in the 14 developing countries mentioned in Chapter 3, and may not be representative of the global situation.

Performance of certified organizations

Overall, the performance of the certified organizations that were visited was good, and demonstrated the effectiveness of the accredited certification process, but a small percentage of the organizations visited (typically 6 – 8%) gave unsatisfactory results, calling into question the effectiveness of the certification process in these cases, with approximately 1% resulting in serious doubts about the validity of their certification. It should also be pointed out that the sampling was not random, and relied on the goodwill of certification bodies to provide details of their certified clients, and for the certified organizations to agree to receive the market surveillance visit. It can therefore be expected that the results were skewed towards a more favorable outcome than a truly random sample would have generated.

Differences in performance of certification bodies and accreditation bodies

One of the key findings of all the projects, and the main justification for the adoption of a market surveillance methodology, was that there are notable differences in the performance and level of confidence in organizations certified by different certification bodies and under accreditation from different accreditation bodies. In many cases, all the certified clients of some CBs that were visited showed good results, with many of the unsatisfactory results being concentrated in a small number of poorly-performing CBs. This can be seen in Figure 6, based on an analysis of 564 visits carried out in 10 countries as part of UNIDO/ISO/IAF Project TE/RAS/09/003[6]. In a similar fashion, Figure 7 shows variations in the performance of organizations with accredited certification from different accreditation bodies.

It can be seen that organizations certified by some CBs (for example CBs 1, 3, 4, 8, 11, 12 and 18) performed well during the market surveillance visits, suggesting that the accredited certification process had been successful in achieving its intended outcome. On the other hand, visits to organizations that generated doubts about the effectiveness of the certification process were concentrated in organizations certified by a relatively small number of CBs (including, for example, CBs 5, 6, 14, 16 and 17 in Figure 6).

It can also be seen that there is a similar phenomenon for ABs, with figure y showing that organizations with certificates accredited by ABs 2, 7, 8 and 9 performed well overall, whilst those with accreditation from ABs 1, 3, 4 and 5 generated some concerns about the overall effectiveness of the accredited certification process.

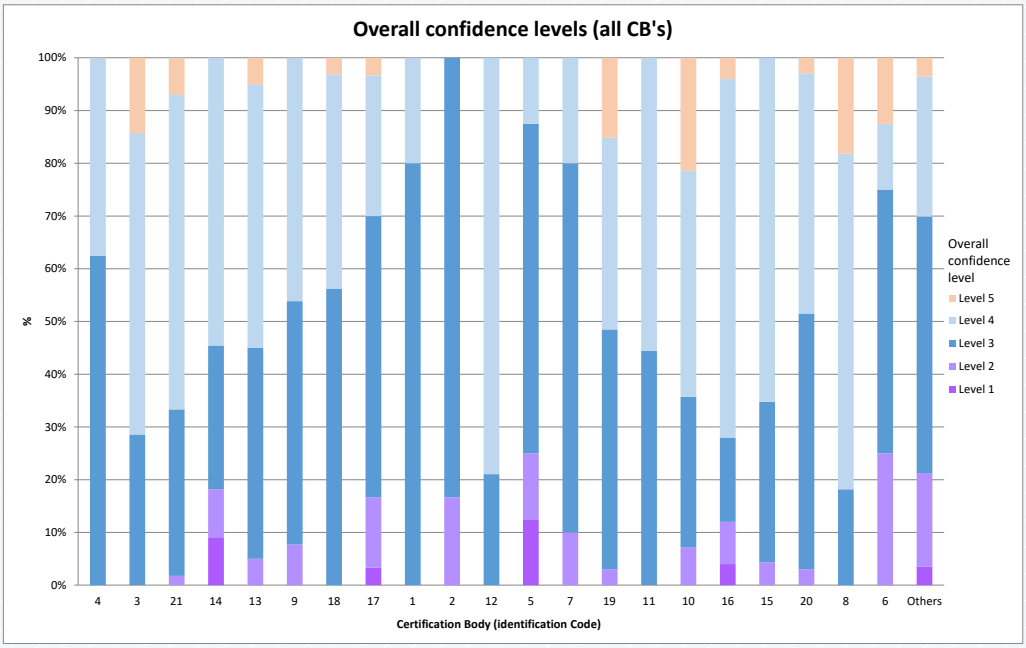

Figure 6 – Overall confidence levels in CBs based on 564 visits carried out in 10 countries

[6] See Bibliography.

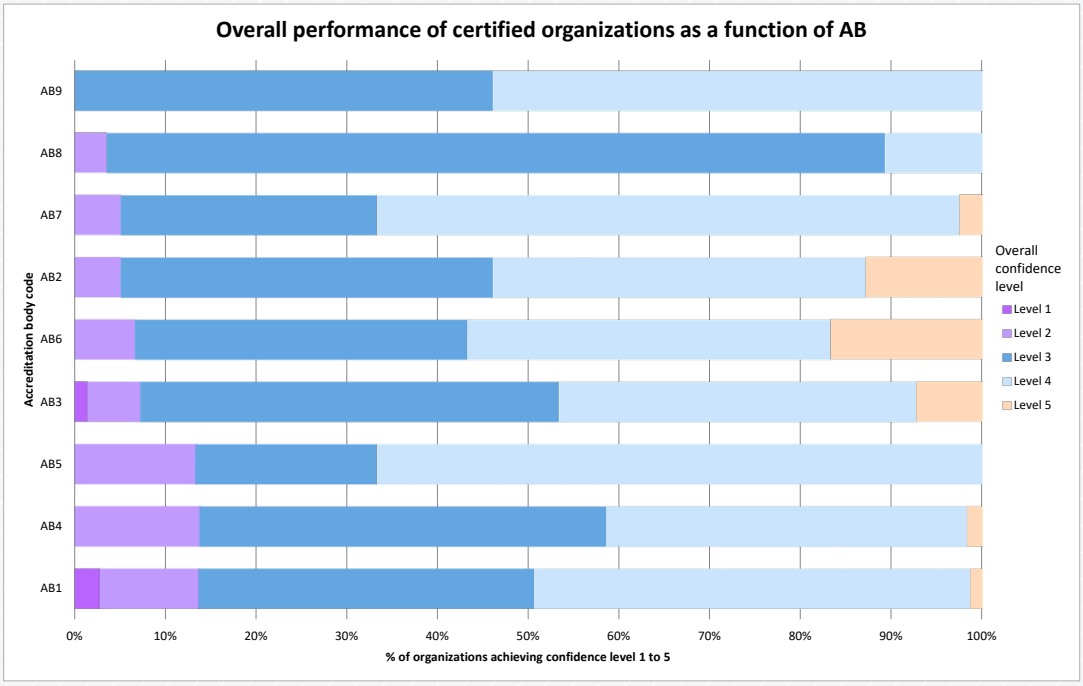

Figure 7 – Variations in the performance of organizations with accredited certification from different accreditation bodies

Performance of local franchisees of foreign certification bodies

The market surveillance visits also highlighted the relatively poor performance of organizations that had been certified by local franchisees of foreign certification bodies, when compared with local certification bodies or branch offices of international certification bodies, and an IAF Task Force is currently studying ways to address this problem.

Weak areas of implementation of ISO 9001

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

- Lack of understanding and effective implementation of the "process approach" throughout the organization
- A general lack of focus on preventing nonconformities
- Poor culture of continual improvement
- Poor use of the "Plan-Do-Check-Act" approach to manage the quality management system (QMS) processes
- Lack of adequate cause analysis and effective corrective action for process, product and system nonconformities
- Inadequate internal communication and employee understanding of their roles in the QMS

Figure 8 – Weakest areas of implementation identified during visits to certified organizations

The traditional methodology used for accreditation of management system certification bodies (CBs) is based on ISO/IEC 17011, and typically involves office assessments of the certification body in conjunction with witnessing a sample of the CB's audits. Office audits necessarily focus on the administrative aspects of a CBs activities, and include extensive review of the CB's documentation, and whilst witness audits are more operational in nature, they have in the past been shown to alter CB auditor behaviour in the presence of the AB assessor, resulting in a process that does not necessarily represent the reality of audits under normal operating conditions.

CHAPTER 5

Methodology for Market Surveillance of ISO 9001 Certification[7]

Background

The traditional methodology used for accreditation of management system certification bodies (CBs) is based on ISO/IEC 17011, and typically involves office assessments of the certification body in conjunction with witnessing a sample of the CB's audits. Office audits necessarily focus on the administrative aspects of a CBs activities, and include extensive review of the CB's documentation, and whilst witness audits are more operational in nature, they have in the past been shown to alter CB auditor behaviour in the presence of the AB assessor, resulting in a process that does not necessarily represent the reality of audits under normal operating conditions. Nevertheless, in spite of these inevitable limitations, this methodology works well when dealing with the accreditation of CBs who are well-intentioned. There have, however, been growing concerns in recent years about the effectiveness of this methodology in ensuring that expected outcomes from management system certification are being achieved consistently among all accredited CBs around the globe.

Consistent with the philosophy that "Output Matters!" one of the specific actions in the 2006 Joint ISO/IAF Strategic Action Plan (subsequently revised) was "Development of criteria for the performance of "validation audits" by the ABs at the certified organizations to check the effectiveness of the management system". These have since been re-designated as "Market Surveillance visits", and the methodology for conducting such visits was based on experiences from the 2012 report on ISO 9001 implementation in Asian Developing Economies (UNIDO/ISO/IAF Project TE/RAS/09/003). Whilst the term "market surveillance" has traditionally been used to address methodologies adopted by regulatory bodies or others related to products covered by technical regulations[8], the concept can also be applied to the certification of management systems.

IAF informative document ID4:2012 provides suggestions about how short market surveillance visits might be used by accreditation bodies or others in order to complement traditional oversight techniques. In the context of accreditation, this is consistent with Clause 7.11.2 of ISO/IEC 17011:2004 which states "The accreditation body shall establish procedures and plans for carrying out periodic surveillance onsite assessments, other surveillance activities and reassessments at sufficiently close intervals to monitor the continued fulfilment by the accredited CAB of the requirements for accreditation". It is recognized that some accreditation bodies (and others) already conduct such visits to certified organizations, and whilst the objective of IAF ID4 is not to make such visits mandatory, it is intended to provide a common platform and methodology for such visits if and when they are deemed to be appropriate.

[7] The following draws extensively on the IAF Informative Document IAF ID4:2012 ("Market Surveillance Visits to Certified Organizations") which in turn was developed based on the joint UNIDO/ISO/IAF projects mentioned earlier in this Guide.

[8] See ISO Brochure "Principles and practices in product regulation and market surveillance."

It is important to emphasize that the adoption of the methodology described in IAF ID4 should not necessarily increase the cost of the accreditation process. On the contrary – the objective is to make the accreditation process more effective and efficient, by the intelligent use of a "Plan-Do-Check-Act" approach. This means that the output of market surveillance visits could be used to provide input into the planning of subsequent oversight activities by the AB (including the frequency and duration of office assessments and witness audits), based on the "proven stability that the services of the CB have achieved" (ISO 17011:2004 Clause 7.11.3). This could mean, for example, that CBs whose certified clients demonstrate a high level of confidence in the effectiveness of their management systems during market surveillance visits might subsequently benefit from a less onerous programme of office assessments and witness audits by the AB. Conversely, CBs whose certified clients do not provide an acceptable level of confidence during market surveillance visits could be subjected to a more intense (and targeted) programme of traditional oversight.

Although the methodology described in IAF ID4 is for information only (and not mandatory), some CB's and their respective AB's, as well as regulators, sector schemes and management system accreditation bodies in the Social Auditing arena have already seen the advantages of adopting such market surveillance visits, to complement traditional accreditation techniques. See Case Studies later in this Guide from:

- Accredia (Italian National Accreditation Body);
- QuEST Forum (TL 9000 for the telecom sector);
- CNCA (Chinese regulator);
- SAAS (SA 8000 Accreditation Body).

Definitions

A Market Surveillance visit is typically a short (one-day) visit to a certified organization, to determine the level of confidence in the conformity of the management system to specified requirements and the effectiveness of the accredited certification process.

NOTE: A market surveillance visit is not a "repeat audit", and is not intended to identify or document specific nonconformities; the visit is intended only to provide confidence in the effectiveness of the accredited certification process.

Objective

The objective of a market surveillance visit is to establish the level of confidence in the CB's certification process by direct observations carried out during visits to a sample of its certified organizations, to use the results to define appropriate levels of surveillance of the CB's activities, and to improve the overall credibility of accredited certification.

The methodology for market surveillance visits described in IAF ID4 could be used not only by ABs, but also by any duly authorized interested party including (but not limited to):

- CB's (e.g. CB head office market surveillance of branch activities, or franchisor market surveillance of franchisee activities);
- Regulators (e.g. to investigate specific concerns that call into question the validity of accredited certification);
- Customers of certified organizations (e.g. when there are indications that their certified supplier is not fulfilling the requirements of the relevant accredited certification);
- Sector schemes / scheme owners (e.g. to provide additional confidence in the scheme).

Criteria for initiating a Market Surveillance visit

The use of market surveillance visits by ABs and CBs may be on a voluntary basis, by mutual agreement, or may be initiated by the AB (or other interested parties) to investigate specific situations triggered by adverse trends (including the indicators that are required to be identified by the CB and informed on a regular basis to the AB) or market feedback, such as:

- A sudden change in the number of certificates issued by a CB;
- A CB that raises few or no NC's in long period of time;
- Crises that call into question the credibility of accredited certification (for example product recalls, or safety incidents;

- Complaints from customers of certified organizations or other interested parties indicating concerns about the effectiveness of a CB's certification process;
- Negative publicity:
  - Issues raised by media organizations regarding a particular product, organisation or accredited CB, with relation to specific technical areas including, but not limited to EMS, OHS, FSMS;
  - Problems identified through social networking sites;
  - Specific negative feedback from NGOs regarding the performance of accredited certification;
- Unilateral intervention from regulators, or negative feedback from regulators.

NOTE: ABs may need to establish feedback mechanisms with regulators to ensure that they are made aware of trends in non-compliances with legislation.

Market surveillance visits may be applied on an individual basis, or as part of a program including a larger sample (client-specific, regional, or CB-specific).

Planning of market surveillance visits

Before initiating a programme of market surveillance visits, it is important to define:

The contractual basis under which the visits will be carried out:

- *ABs are recommended to include legally enforceable requirements in their contracts with accredited CBs (and require accredited CBs to do the same with their clients) to allow the AB to conduct market surveillance visits if and when the need arises;*
- *Confidentiality criteria.*

The objectives of the visit or programme of visits. These may be:

- *Part of a routine surveillance mechanism agreed with the CB;*
- *Triggered as a result of negative market feedback.*

The sampling criteria to be used.

Who will participate? For example:

- *The AB assessor (in case of foreign accreditation this may be carried out by or in collaboration with the local AB);*
- *A CB representative (as an invited observer);*
- *Other relevant interested parties, as agreed.*

The competence needed by the assessment team:

- *The assessors should be competent with respect to the management system under consideration, and in the methodology of conducting short market-surveillance visits.*

NOTE: Competence in conducting assessments to ISO/IEC 17021-1 may be advantageous but is not mandatory.

Who will be covering the costs of the visit(s)?

- *This will vary depending on the objective and trigger mechanism for the market surveillance visit, but should be clearly defined before the visit is conducted.*

Methodology of a market surveillance visit

The UNIDO/ISO/IAF Projects mentioned earlier in this Guide used a check-list comprising 26 topics to be covered during a one-day visit (see Chapter 3). For each item on the check-list, and in particular for overall perceptions about the validity of a specific organization's certification, it has been shown that competent assessors can distinguish between five distinct "confidence levels" during a short, one-day visit, and it is recommended that these be utilized to provide a consistent basis for market surveillance visits, regardless of who carries them out or the reasons for initiating them. These five levels follow the criteria already mentioned in Chapter 3, and are expressed in simple terms as follows:

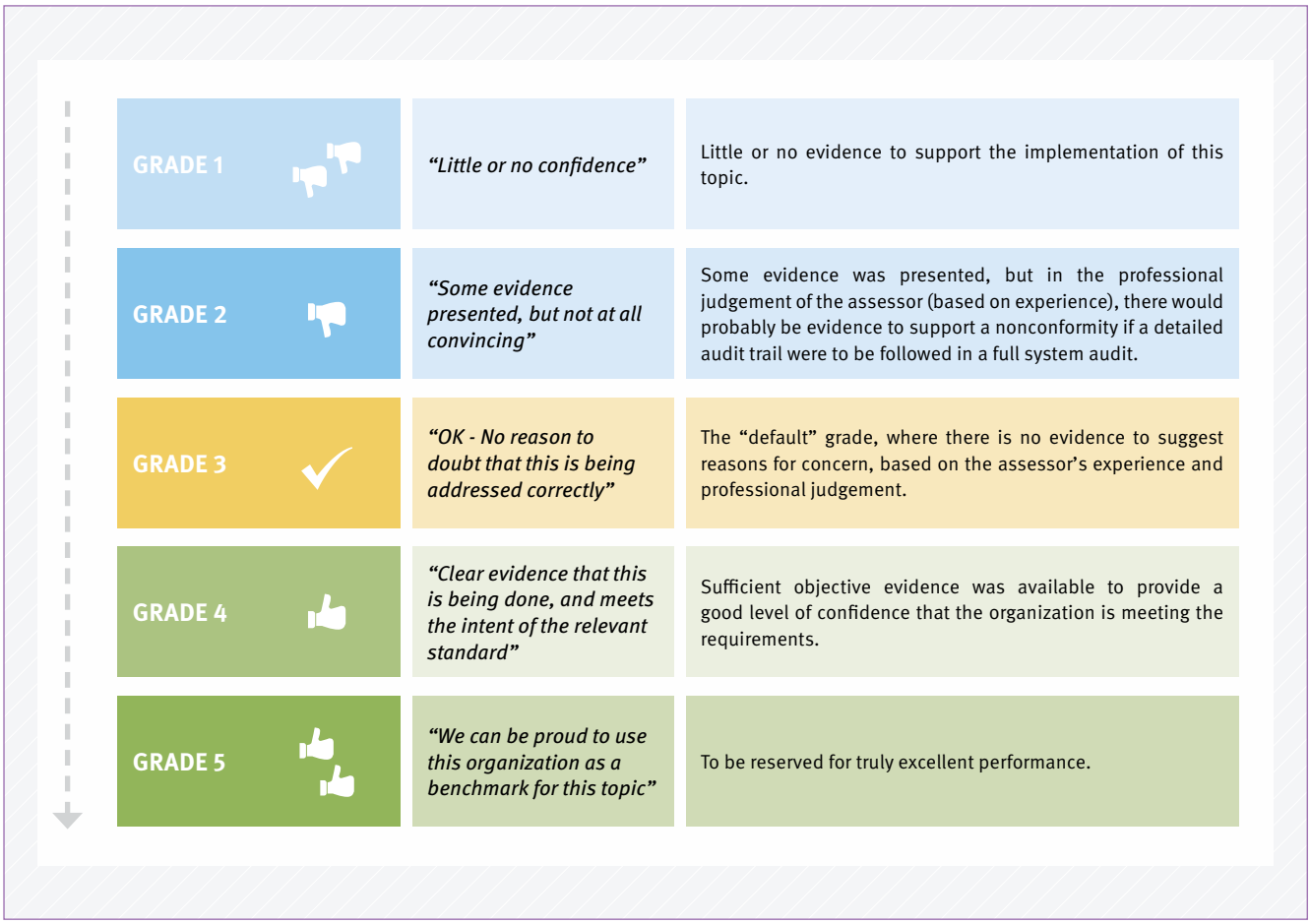

Figure 9 – Simplified Assessment criteria for market surveillance visits

Analysis of results

Grades 3 to 5 are considered to be acceptable results that confirm the validity of the accredited certification. CBs whose clients are consistently assessed to be Grade 4 or Grade 5 should be considered as having robust certification process and ABs should consider reducing the traditional oversight of surveillance assessment and witnessing.

Grade 2 raises doubts regarding the way in which the accredited certification process has been conducted, but requires a more in-depth analysis before reaching conclusions. Decisions should not be made based on a single "Grade 2" result at a certified organization.

Grade 1 calls into question the validity of the CB's accreditation, and should lead to further investigation and action.


ISO 9001

Annexes

ANNEX 1

Typical Visit Plan for One-day Visits to ISO 9001-certified Organizations

NOTE: Timings are approximate, and may be adapted to suit local or cultural needs.
CB invited to participate as *observer*.

TIMING	ACTIVITY	COMMENTS
09:00 – 09:30h	Opening briefing	Explain context and objectives of the visit. (This may vary depending on what triggered the visit). Emphasize that the visit is NOT intended to be an audit, and that the results will be CONFIDENTIAL. It is not intended to determine conformity or non-conformity of the system. The results of the visit will not necessarily affect the organization's certification status. Objective is to look at effectiveness of the **CB's processes** for ISO 9001 certification on a sample basis. Aim is to ***improve the accredited certification process.*** Record attendance and sign confidentiality agreements as appropriate. Agree schedule for rest of day. Allow time for short presentation by organization (15 min max).
09:30 – 10:00h	Management representative	Discuss "self-assessment questionnaire" with MR (Annex 2). Use time to establish empathy with MR.
10:00 – 12:30h	"Site" Tour	Things to look for... Do employee numbers tie in with those used for audit duration calculations? General housekeeping and work environment / infrastructure. Communications? Notice boards up-to-date? (or electronic communications / intranet etc). Talk to sample of employees: ▪ Concept of process; ▪ Ability to describe responsibilities, activities undertaken etc; ▪ Awareness of Quality Policy, objectives etc; ▪ Link to competence/ effectiveness. Availability of work instructions as needed? User-friendliness? Look at Monitoring & Measurement / Inspection & Testing facilities as applicable: ▪ Availability of equipment; ▪ Sample of calibrations OK?

12:30h – 14:00h	Lunch and discussions with top management (Sequentially or together)	What are their perceptions? Is certification adding value? Find out about how they arrived at the quality policy – how does it relate to overall organizational policy and culture? What about the Quality Objectives? ▪ Do these help them to manage the organization? ▪ Are they realistic, achievable, measurable, challenging? ▪ Relate to company's immediate concerns. Talk about customers – who are they? What do they want? Involvement and ability to discuss latest Management Reviews; actions arising etc. Strengths & weaknesses of their system.
14:00 – 16:30h	Management Representative[9] and others, as needed	Review certificate: ▪ Does scope of certification clearly define what products and services are covered? Review of Quality Manual, including justification for any exclusions (emphasis on Design & Development and Process Validation). Internal audits: ▪ Are they being done? - Look at audit plan and recent reports; ▪ Are NC's being identified... closed out? ▪ Root causes being investigated? ▪ Corrective actions (not just correction) implemented and effective? ▪ Linkage with management review & analysis of data. Corrective and preventive actions – are causes being identified? Is effectiveness verified? Customer feedback (including customer complaints). Review recent certification body audit reports.
16:30 – 17:00h	Time to prepare visit summary	Includes time to tie up any loose ends.
17:00 – 17:30h	Closing briefing	Summary* Praise if appropriate; if there are problems, make it clear that it's between them and their CB. Avoid negative comments about CB. * Take care not to make conclusions about the conformity (or otherwise) of the management system. NOTE: It is NOT expected that the visit summary (Annex 3) will be made available to the organization.

[9] This methodology was developed prior to the publication of ISO 9001:2015, which no longer formally requires an organization to have a "Management Representative"; if that is the case, these discussions should involve the relevant personnel with responsibility for coordinating the QMS.

ANNEX 2

"Self-assessment" by the Certified Organization

Date _____

(To be filled out together with the assessor, if clarifications are necessary)

The following questionnaire is designed to address several key components regarding your experiences, ***as an ISO 9001-certified organization***, regarding the certification process.

IMPORTANT NOTE:
We request that this questionnaire be filled out by the MANAGEMENT REPRESENTATIVE[9] of your organization, without discussing with any consultant who may have helped in the implementation of your system, or with your certification body. This is not because we don't trust them – it's because we want YOUR opinions!

1. Name and address of organization:

2. Management representative:

Name:

Function:

E-mail:

Telephone:

3. Top Management name(s) ("Person or group of people who directs and controls the organization at the highest level"):

4. Certification Body (Please attach a copy of the certificate):

5. Scope of certification:

6. Number of employees in your organization **(Please mark with an "X" in the appropriate box)**:

1 to 5	6 to 10	11 to 15	16 to 25	26 to 45	46 to 65	66 to 85	86 to 125	126 to 175	176 to 275	276 to 425	426 to 625	626 to 875	876 to 1175	1176 to 1550	Over 1550 (please state number)

7. How long have you been certified to ISO 9001? **(Please mark with an "X" in the appropriate box)**:

0-3 years	4-10 years	Over 10 years

8. How many auditor-days did the certification body use during your initial (or most recent full re-certification) audit? (for example, 2 auditors full-time for a total of 3 days = 6 auditor-days) **(total number of auditor-days)**:

9. How often does your certification body visit you to carry out surveillance audits, to ensure your system continues to meet the ISO 9001 requirements?

Every 6 months	Every 9 months	Once a year	Less frequently than once a year

10. How many auditor-days does your certification body spend each year on surveillance audits? (for example, 2 auditors full-time for a total of 2 days = 4 auditor-days) **(number of auditor days per year)**:

11. What was the name of the auditor who visited you last time?

12. Are you happy with the way in which your CB has conducted your audits?

13. What is your own opinion about the status of your management system?

ANNEX 3

Example of Visit Summary (QMS Effectiveness)

NOTE: This is NOT a "Conformity assessment" exercise. Results are to be expressed in terms of confidence levels, based on observations and discussions during the visit.

1 = Little or no confidence
2 = Some evidence presented, but not at all convincing
3 = OK - No reason to doubt that this is being addressed correctly
4 = Clear evidence that this is being done, and meets the intent of ISO 9001
5 = We can be proud to use this organization as a benchmark for this topic

STATEMENT	CONFIDENCE LEVEL*					COMMENTS AND/OR JUSTIFICATIONS (REQUIRED IN CASE OF LEVEL 1 OR 5)
	1	2	3	4	5	
1) The initial (or most recent full recertification) audit duration was appropriate for the size and complexity of the organization (See IAF MD5).						IAF Table (adjusted for complexity etc): Actual: Comments:
2) The duration and frequency of surveillance audits are appropriate for the size and complexity of the organization (see Clause 5 of IAF MD5).						IAF Table (adjusted for complexity etc): Actual: Comments:
3) The scope mentioned on the organization's certificate accurately describes its activities, and is not misleading.						
4) All exclusions are adequately justified (if there are no exclusions, give Grade "4" and make a note in comments).						
5) There is evidence of top management's involvement with and commitment to the implementation of ISO 9001.						
6) Internal communication is good, and employees are aware of their roles in the QMS.						
7) The "process approach" is clearly understood and implemented throughout the organization.						
8) The organization is managing its QMS processes using a "Plan-Do-Check-Act" –type approach.						
9) The quality policy is appropriate for the organization's situation and culture.						
10) The organization has established and deployed meaningful objectives at relevant functions and levels.						

STATEMENT	CONFIDENCE LEVEL*					COMMENTS AND/OR JUSTIFICATIONS (REQUIRED IN CASE OF LEVEL 1 OR 5)
	1	2	3	4	5	
11) The Quality Manual is a good representation of the way the organization actually works.						
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) Processes are being adequately monitored and measured.						
17) Product nonconformities are identified and dealt with according to documented procedures.						
18) There is a focus on identifying the CAUSE of process, product and system nonconformities, and on implementing effective corrective action.						
19) Internal audits are being carried out according to plan, and are effective.						
20) Management reviews are being carried out according to plan, and are effective.						
21) The organization has a focus on PREVENTING nonconformities.						
22) Customer feedback and customer complaints handling mechanisms are appropriate.						
23) The QMS is providing confidence in the organization's ability to "consistently provide product that meets customer and applicable statutory and regulatory requirements".						
24) The organization has a culture of continual improvement of the effectiveness of its QMS.						
25) The certification process has been conducted effectively by the certification body.						
26) ***OVERALL confidence in this organization's implementation of ISO 9001.***						
Space for Additional Comments						

Assessor: Date:

Case Studies

- Accredia
- SAAS
- QuEST Forum
- CNCA

Accredia

ACCREDIA is the Italian National Accreditation Body appointed by the State to perform accreditation activities.

In Italy, ISO 9001 certification is used by the Italian Government as a basis to qualify organizations that can participate in public tenders in the construction sector, so great importance is given to the reliability of such certification. In order to guarantee to regulators and to the market the ongoing validity of these ISO 9001 certifications, Accredia decided to implement a market surveillance campaign in this particular field.

How does it work? During the traditional office assessment, performed in the premises of the certification body, one Accredia assessor chooses one or more client files as a sample. The sampling is made based on the scope of application, the complexity, and the auditors that performed the audit.

The assessors make a full copy of the report, and all the relevant documentation (e.g. audit program for the three-year certification cycle, check list, notes, audit plans).

After that, in few days (usually within one week) the market surveillance visit is performed.

The aim of this visit is mainly focused to understand if the audit has been performed, with the right competence and time allocation. It is also very useful to investigate if the report is sufficiently detailed, since the audit report is the only document that allows the certification body's decision maker to take a proper decision on the certification. In order to verify if the audit has been properly conducted, the assessors check all the evidence contained in the report, to see if they really reflect the reality of the certified organization. We have also found it to be very useful to check the auditors' receipts for travel and accommodation, to make sure the auditor really visited that organization for the full period mentioned in the audit report. The consistency of the scope of the certification and the competence of the auditors is also evaluated.

After the first period of application of this methodology, our experience is that it is much more effective that a witness audit, because it is more focused on the expected outcomes of accredited certification, especially when the visit is planned to investigate a complaint or targeted based on market information.

Accredia utilizes this market surveillance methodology mainly in three situations; to evaluate complaints, to maintain accreditation for ISO 9001 certification in the construction sector and when it is difficult to perform a witness audit. This can happen when a certification body has only a few certified organizations and it is necessary to perform an on-site evaluation to extend the scope of the accreditation certificate, or to maintain the scope during the accreditation cycle.

In order to further increase the effectiveness of accreditation oversight, we plan to combine the market surveillance methodology with a "mystery shopping" activity, in which an organization, acting as a "mystery shopper" on behalf of Accredia, will make an application to one or more certification bodies for ISO 9001 certification. In this way, we will obtain insights into the approach of the certification body, for example to check if they are offering consultancy services, or to ensure they are giving the right importance to the evaluation of the information provided, in order to make a correct determination of the audit duration.

SAAS (Social Accountability Accreditation Services)

SAAS is the accreditation body responsible for oversight of certification to the SA 8000 (Social Responsibility) standard, and for audits to the BSCI (Business Social Compliance Initiative) criteria. SAAS has used market surveillance visits MSVs, as well as other related methodologies in addition to their standard surveillance activities of office and witnessed audits for both SA 8000 and BSCI audits. According to SAAS, "We have used MSVs as a tool towards moving to performance based approaches for accreditation and certification. The goal of a Market Surveillance Visit at the certified client is to check the effectiveness of the management system implemented by the client and confirm the results of the audits conducted by the CB." The MSV provides SAAS with validation, verification and confirmation of the results of CB certification audits in the field. The MSV program was initiated to provide SAAS with a survey of the quality of certificates in specific high-risk countries where the effectiveness of SA 8000 certification was being called into question.

Triggers for SAAS MSVs (or issue based audits) may include:

- Ongoing unresolved complaints (complaints investigation or issue-based audit);
- Endemic complex issues requiring interpretation or intervention (issue-focused audit);
- Concerns about the market/quality of certificates in a region or country (validation audit);
- Receipt of a complaint by SAAS;
- Feedback from Stakeholders or other sources to SAAS;
- SA8000 Witness Audit Performance;
- 'Whistle blowing' by CB staff, auditors or contractors.

According to SAAS, "The main objectives of our MSVs are as follows:

- Investigate an ongoing persistent complaint to make a conclusive determination based on interpretation and implementation;
- Investigate an ongoing persistent complaint to identify fresh objective evidence that will assist in achieving a conclusive determination;
- Address questions and provide interpretations of SA8000 elements and/or policy requirements".

SAAS has conducted a series of MSVs in specific countries where market concerns were raised about effective implementation and/or audit practices in that region. They have also used MSVs to investigate complaints about a specific CB or their clients in specific countries. MSVs have assisted in both confirming concerns/complaints that were raised as well as supporting effective systems by both SAAS-accredited CBs and their clients.

QuEST Forum

The QuEST Forum is a sector scheme for the Information and Communications Technology (ICT) industry that uses ISO 9001 as the basis for the quality management systems component of its TL 9000 requirements, with a number of industry and product/service-specific additional requirements ("adders"). Certification to TL 9000 is carried out by CBs accredited by several IAF accreditation body members who are recognized by the QuEST Forum. Certification to TL 9000 also requires certified organizations to submit performance data according to criteria defined in the TL 9000 "Measurements Handbook". In addition to assessing the Organization's QMS, CBs are required to audit and validate the counting rules for measurements submitted by certified organizations.

In recent years, some concerns have been expressed by interested parties about the consistency of worldwide TL 9000 assessments and therefore the effectiveness of the accredited certification process. After conducting a validation audit pilot project, it was clear an additional data-based evaluation of the TL 9000 certification scheme was needed.

QuEST Forum has now launched their new third party evaluation program ("3PEVP") that looks into specific CB and AB performance using a predefined set of criteria.

Based on statistical analysis of CB audit results, if either of 2 conservative trigger values are surpassed (see below),

QuEST Forum will require the relevant Accreditation Body to conduct an evaluation of that specific Certification Body. That evaluation will be either an internal investigation of the specific CB's performance ("Trigger 1") or a market surveillance audit based on the methodology presented in this Guide ("Trigger 2"). QuEST Forum's high-level "3PEVP" process is as follows:

- QuEST Forum's OSWG (Oversight Work Group) collects quarterly data from each CB indicating the number of findings detected during their TL 9000 audits. The combined total of Major and Minor Nonconformities per Audit day over the most recent 12-month period for each CB are compared against worldwide performance. If the CB's results are below pre-determined triggers, action is required:
  - When Trigger 1 is reached the AB is required to perform an evaluation (this may be an office visit or other evaluation);
  - When Trigger 2 is reached, the AB is required to perform a market surveillance visit in order to check the effectiveness of the certified organization's QMS, utilizing IAF ID-4 as a guideline. The purpose is to assess whether the CB's most recent audit was thorough and effective;
- The Accreditation Body then reports to QuEST Forum their findings and details of any Corrective Actions required by the Certification Body.

CNCA

The Certification and Accreditation Administration of the People's Republic of China (CNCA) is the regulatory body that was established and 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. CNCA considers the methodology described in this Guide to be useful for the following reasons:

- The Market Surveillance Visit methodology covers the most important elements of the certified QMS, and make it possible to reveal a true picture of the implementation of and ISO 9001 QMS in the certified organizations within the constraints of available human resources and a realistic timeframe;
- Based on the methodology, we have developed a full set of working documents that can give both the assessor and the people in the certified organizations a clear idea of the activities that will be carried out for the investigation and a clear explanation of the nature of the visit. This is very helpful to ensure the visits run smoothly;
- The way the assessors conduct this on-site investigation and its duration are very practical and can ensure that the objective of the investigation is achieved without over-burdening the certified organization;
- The 5 grades used in this methodology are simple and easy to understand, and can be used to communicate the different levels of confidence observed in the QMS of the visited organization. It enables the relevant parties to understand the implementation level of the QMS easily and clearly so they can analyze the results of the visits and take appropriate action;
- We give clear instructions to our assessors that the people being interviewed should answer the questions independently - that means without the assistance of the consultant and certification bodies. This ensures the credibility of the results of the on- site visits;
- Together with the methodology for the on-site visit, training of the assessors has been of vital importance. The training course contained structured lessons as well as a pilot on-site visit led by the tutor to calibrate the assessors' perceptions under real conditions. This is very important to ensure all the assessors fully understand the method of the Market Surveillance Visits - that they are not intended to be "repeat audits" - and to keep good consistency between different assessors;
- We consider that the Market Surveillance Visit methodology described in this guide to be both scientific and practical. These Market Surveillance Visits to certified organizations can provide very useful information about the real implementation level of the certified QMS for regulators, standardization bodies, accreditation bodies, CBs and other interested parties.

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INDUSTRIAL DEVELOPMENT ORGANIZATION

For further details contact:

United Nations Industrial Development Organization
Department of Trade, Investment and Innovation
Vienna International Centre
P.O. Box 300, 1400 Vienna, Austria
http://www.unido.org