



ISO 9001

Good Practices: Experience in the Market Surveillance of ISO 9001 Quality Management Systems



UNITED NATIONS
INDUSTRIAL DEVELOPMENT ORGANIZATION

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VIENNA, AUSTRIA
OCTOBER 2016



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Acknowledgements

UNIDO gratefully acknowledges the dedicated work of Mr Nigel H Croft (UNIDO Consultant), who prepared the document. Overall guidance was provided by Mr Bernardo Calzadilla-Sarmiento, Mr Otto Loesener and Mr Juan Pablo Diaz-Castillo and of UNIDO. Ms Cindy Parokkil (UNIDO Consultant) contributed to the planning, organization and implementation of this report.

Special thanks must go to Mr. Randy Dougherty and other experts who contributed their time and energy to peer-reviewing the draft.

It is based on experiences gained during visits to certified organizations in a number of countries, conducted as part of several projects conducted with the support of the following organizations:

- **PROJECT TE/RAS/09/003 (BANGLADESH, INDIA, INDONESIA, MALAYSIA, NEPAL, PAKISTAN, SRI LANKA, THAILAND, PHILIPPINES AND VIETNAM)** – funded by NORAD (Norwegian Agency for Development Cooperation) and conducted by UNIDO, in collaboration with ISO and IAF, with support from the relevant national standards bodies, local accreditation bodies, and UNIDO offices. A full list of those involved is mentioned in the report “ISO 9001 – Its relevance and impact in Asian Developing Economies”, UNIDO, Vienna, 2012;
- **PROJECT TE/CPR/12/002 (CHINA)** – co-funded by UNIDO and CNCA (Certification and Accreditation Administration of the People’s Republic of China), and conducted as a collaboration between UNIDO and CNCA, with support from CCAA (China Certification and Accreditation Association), CNAS (China National Accreditation Service for Conformity Assessment), local QTSBs (Quality and Technical Supervision Bureaus) and CIQs (Entry-Exit Inspection and Quarantine Bureaus). A full list of those involved is mentioned in the report “ISO 9001 Relevance and Impact in China”, UNIDO, Vienna, 2015;
- **PROJECT 140107 (BRAZIL)** – co-funded by UNIDO and Inmetro (Brazilian National Institute for Metrology, Quality and Technology), and conducted as a collaboration between UNIDO and Cgcre (the Brazilian National Accreditation Body), with support from ABRAC (Brazilian Association of Conformity Assessment Bodies), ABNT (Brazilian National Standards Body), ABNT/CB-25 (Brazil’s National Quality Committee), and SEBRAE (Brazilian Support Service to Small and Medium Sized Enterprises). A full list of those involved is mentioned in the report “ISO 9001 Relevance and Impact in Brazil”, UNIDO, Vienna, 2016.

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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 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

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