

# 合格评定在 **中国**

CONFORMITY ASSESSMENT  
IN CHINA

全国认证认可标准化技术委员会 (SAC/TC 261) © 编著

National Standardization Technical Committee on  
Certification and Accreditation (SAC/TC 261)



中国标准出版社  
Standards Press of China

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北京  
Beijing

图书在版编目 (CIP) 数据

合格评定在中国: 汉英对照/全国认证认可标准化技术委员会编著. —北京: 中国标准出版社, 2018. 5

ISBN 978-7-5066-8999-1

I. ①合… II. ①全… III. ①产品质量—质量检验—评定—研究—中国—汉、英 IV. ①F273.2

中国版本图书馆 CIP 数据核字 (2018) 第 086166 号

中国质检出版社 出版发行  
中国标准出版社

北京市朝阳区和平里西街甲 2 号 (100029)

北京市西城区三里河北街 16 号 (100045)

网址: [www.spc.net.cn](http://www.spc.net.cn)

总编室: (010) 68533533 发行中心: (010) 51780238

读者服务部: (010) 68523946

北京虎彩文化传播有限公司印刷

各地新华书店经销

\*

开本 787×1092 1/16 印张 9.75 字数 136 千字

2018 年 5 月第一版 2018 年 5 月第一次印刷

\*

定价: 50.00 元

如有印装差错 由本社发行中心调换

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# 序一

合格评定和计量、标准化一起构成了国家质量基础设施（NQI），对于建设质量强国，NQI的基础作用越来越重要。中国经济已由高速增长阶段转向高质量发展阶段。高质量发展，既包括宏观层面经济运行质量提升，也包括微观层面产品和服务质量提高。为此，中国将质量基础设施纳入国家战略，加强集中统一管理，深化标准化工作改革，完善国家量值传递溯源体系，广泛开展认证认可，加快检验检测认证机构整合，加强技术性贸易措施的研究和应对。同时，进一步加强质量国际合作，深化质量技术国际交流。

在质量基础设施建设中，国际标准化组织的合格评定工具箱，提供了很好的工具，对于中国认证认可、检验检测领域的规则制定，给与了技术支撑。同时，中国在合格评定领域也探索出符合中国国情的制度体系，取得了较好的成绩，也总结出一些经验。中国认证认可标准化技术委员会编写了《合格评定在中国》一书，介绍了合格评定在中国的实践与发展，也介绍了合格评定工具箱在中国的推广应用。我向各位读者介绍这本书，是希望在全球质量基础设施发展中，国际同行能够携起手来，提供更多值得借鉴的经验，相互交流，取长补短，为全球质量基础设施建设贡献力量。

我为中国合格评定所取得的成绩而高兴，也为合格评定同仁善于学习、乐于分享的精神感到欣慰。

是以为序。

国际标准化组织（ISO）主席

张立刚 2017

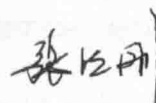
## PREFACE I

National Quality Infrastructure (NQI) is composed of conformity assessment, metrology and standardization, playing an increasing fundamental role in constructing a country with strong quality power. Chinese economy has transited from the stage of high-speed growth to the stage of high quality development that features improvement of quality in both economic operations at the macro level and product/service at the micro level. Therefore, China has integrated national quality infrastructure into the national strategy, enhance the centralized and unified management of such work, further standardization reform, improve the national system for transfer and traceability of quantity values, widely carry out certification and accreditation, accelerate the integration of inspection, testing and certification bodies, and strengthen studies over and countermeasures for technical barriers to trade. Meanwhile, efforts are appealed to further strengthen cooperation in quality and deepen communication of quality technologies at the international level.

In the construction of quality infrastructures, the CASCO Toolbox developed by ISO has provided instrumental technical support for the development of rules for certification, accreditation, inspection and testing in China. At the same time, China's exploration in conformity assessment at the institutional level has also achieved notable results and practical experience. The National Standardization Technical Committee on Certification and Accreditation (SAC/TC 261) has completed this book *Conformity Assessment in China* which introduces the practice and development of conformity assessment work as well as the promoted application of CASCO Toolbox in China. I'd like to recommend this book to you in the hope that all international peers can join hands in the development of global quality infrastructure by providing more worthwhile experience and communicating with mutual advantages to make more contributions worldwide.

I am happy with the achievement of conformity assessment in China, and also pleased with the spirit of my fellows in this field who are truly willing to learn and share.

With my best regards.



ISO President Zhang Xiaogang

Dec. 31, 2017

## PREFACE II

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It is a pleasure to introduce this important book on conformity assessment in China. A book of this nature is very welcome as it is aligned with the CASCO policy of encouraging a consistent approach to conformity assessment. The book introduces the practice of conformity assessment in China, the application of the “CASCO toolbox” and contains specific case studies with a view to sharing China’s practices and experiences with its international counterparts.


In 2006, ISO and the United Nations Industrial Development Organization (UNIDO), as members of the DCMAS group, the Network on Metrology, Accreditation and Standardization for Developing Countries, put forward the concept of a national quality infrastructure; the concept was updated in 2017. A quality infrastructure refers to all aspects of metrology, standardization, accreditation, conformity assessment and market surveillance that have a bearing on conformity assessment and quality.

The CASCO toolbox provides good-practice tools and support for establishing and maintaining a national quality infrastructure. Many countries already have good practice in these areas, and when countries share their practices and experiences, it promotes exchanges with their international counterparts as well as facilitates improving the national quality infrastructure. ISO sees the value in this type of sharing, which results in better and more consistent implementation of the CASCO toolbox.

ISO/CASCO specifically encourages any action by its members that promotes the use of the CASCO toolbox. This book is a good example of such action. It describes how the CASCO toolbox has not only been applied in China, but has played a fundamental role in quality improvement, consumer safety, social governance, trade facilitation and sustainable development. The many case studies demonstrate the importance of the CASCO toolbox in achieving these objectives.

An important function of standards development in ISO is the promotion of the exchange of goods and services by setting standards and coordinating standardization activities. It is very satisfying to see that ISO deliverables are widely used. The fact that China accounts for a fifth of the world’s population, its commitment to the promotion and application of international standards and its support and contribution to ISO are most welcome. I would like to thank my Chinese colleagues for their hard and fruitful work.

Sergio Mujica  
ISO Secretary-General





## 序二

能够介绍这本关于中国合格评定的重要书籍，我倍感荣幸。这本书鼓励采用协调一致的合格评定方法，符合国际标准化组织合格评定委员会（ISO/CASCO）的一贯做法，这是我们最为乐见的。该书介绍了中国的合格评定实践和合格评定工具箱在中国的应用，同时列举了特定领域的实践案例，意在与国际同行分享中国实践和中国经验。

2006年，国际标准化组织（ISO）和联合国工发组织（UNIDO），同为发展中国家计量、认可和标准化合作网络组织（DCMAS）的成员，提出了国家质量基础设施（NQI）的概念，并在2017年对这个概念做了更新。质量基础设施涉及计量、标准化、认可、合格评定以及合格评定和质量有关的市场监督的所有方面。

合格评定工具箱提供了基于良好实践的工具，可用于帮助建立和维持国家质量基础设施。许多国家在这些领域早已拥有很多良好实践，如果各个国家能够分享实践经验，必将促进国际同行之间的经验交流并推动国家质量基础设施的改进。ISO已经认识到了这种分享的重要价值，此类经验分享必将推动合格评定工具箱的更好、更一致的实施应用。

ISO/CASCO尤其鼓励各成员体推动应用合格评定工具箱而采取的各种行动，本书正是这种行动的良好典范。书中不但介绍了合格评定工具箱如何在中国得到应用，而且还介绍了其在质量提升、消费者安全、社会治理、贸易便利化和可持续发展等方面发挥的基础性作用。众多的案例证实了合格评定工具箱在取得这些成绩上的重要性。

ISO制定标准的一个重要作用，就是通过制定标准和协调开展标准化活动，促进货物和服务贸易。ISO的标准能够得到如此广泛的使用，我们对此倍感荣幸。中国是一个占世界人口五分之一的大国，中国对推动使用国际标准的承诺和其对ISO的支持与贡献，是我们所最为乐见的。对于中国同行的辛勤努力和所取得的丰硕成果，我致以特别的感谢。

国际标准化组织（ISO）秘书长

塞尔吉奥·穆希卡



# 前言

2017年9月15日，第二届中国质量（上海）大会在上海开幕，国家主席习近平在致大会的贺信中希望各国与会代表推动质量基础设施互联互通，通过提高质量不断促进经济发展、民生改善，为各国人民实现对美好生活的向往做出贡献。中国政府高度重视质量，明确提出要坚持质量第一、效益优先，建设质量强国，完善合格评定体系，加强质量认证体系建设，增强经济质量优势，推动经济发展进入质量时代。

合格评定是国家质量基础设施的重要支柱，是质量管理工具和贸易便利化手段。在推动质量发展中，合格评定起到了重要作用。中国把合格评定作为一项市场经济运行的基础性制度，加强顶层设计，推动有效实施。中国国家认证认可监督管理委员会（CNCA）成立以来，按照“统一管理、共同实施”的原则，建立了与国际接轨的认证认可制度体系，促进了质量提升和产业发展。在这个过程中，合格评定工具箱发挥了不可替代的作用。这些由国际标准化组织合格评定委员会（ISO/CASCO）制定的一系列合格评定国际标准和技术文件，为规范合格评定活动提供了重要的依据。中国在学习借鉴国际合格评定制度的同时，也积极探索和总结中国的实践和案例，希望与国际同行共同分享，进而为“合格评定工具箱”在全世界的推广贡献力量。

本书第一章描述了中国合格评定概况，包括发展历程、主要形式和发展现状。第二章介绍了中国合格评定的工作机制、制度体系、科技标准支撑、国际合作和《认证认可检验检测发展“十三五”规划》以及质量提升行动等方面的典型做法。第三章介绍了合格评定工具箱在中国应用情况。第四章选取了若干案例，体现了合格评定在促进质量提升、保

# FOREWORD

Chinese President Xi Jinping in his congratulatory message to the China Quality Conference (Shanghai) on September 15, 2017 wishes representatives from around the globe to promote the connectivity of global quality infrastructure and to improve quality for sustainable economic development and social livelihood improvement, so as to make contributions to the people's aspiration towards a better life.

The Chinese government always attaches high importance to quality, clearly announcing to uphold the principle of "quality first, benefits foremost", forge the national quality power, improve the national conformity assessment system, strengthen the quality certification system, enhance the economic quality advantage and drive the national economic development into the era of quality.

As a cornerstone for the national quality infrastructure, conformity assessment serves as the pillar for quality management and trade facilitation, playing a critical role in the development of quality. In China, conformity assessment is regarded as a fundamental system for the operation of market economy, and strengthens the top-level design and effective implementation of conformity assessment. With the establishment of Certification and Accreditation Administration of the People's Republic of China (CNCA), China has built up a national certification and accreditation system according to the principle of "unified management, joint implementation", effectively driving the promotion of quality and development of industries. With a portfolio of international standards and technical documents on conformity assessment developed by ISO/CASCO, CASCO Toolbox has provided basis for the normalization of conformity assessment activities.

While learning and applying the international conformity assessment system, China also actively explores and summarizes practical experiences in hope of sharing them with global peers, so as to contribute to the promotion of CASCO Toolbox worldwide.

Chapter I hereof gives an overview of the conformity assessment in China, including history of development, main forms and current development. Chapter II introduces the typical practices of conformity assessment in China, including the working mechanism, institutional system, technical support and international cooperation, *Development Plan for Certification, Accreditation, Inspection and Testing(2016-2020)*, actions on quality improvement and

护消费者安全、促进社会可持续发展、提升社会治理水平、促进贸易便利化等方面的基础作用。在附录中，介绍了认证认可强国评价指标体系，并列出了缩写对照表，供读者参考。

需要说明的是，按照ISO/IEC 17000:2004《合格评定词汇和通用原则》中的定义，合格评定是指与产品、过程、体系、人员或机构有关的规定要求得到满足的证实。主要包括检测、检验和认证，以及对合格评定机构的认可等活动。在中国，将认证、认可和检验检测机构资质认定等合格评定活动统称为“认证认可”，涵盖了合格评定活动的重要内容。鉴于中国国家认证认可监督管理委员会（CNCA）统一管理、监督和综合协调全国的认证认可工作，本书着重描述了中国的认证认可活动。根据国际惯例，我们使用了“合格评定”这一概念。

本书主要参考数据源自《2016年度全国认证认可检验检测服务业统计数据》、《中国认证认可年鉴》、《认证认可检验检测发展“十三五”规划》等公开出版物。由于编著者水平有限，书中可能存在疏漏，甚至错误，敬请读者批评指正。

2018年3月，在本书付印之际，中国对国家机构进行了改革，涉及合格评定职能的调整。将国家质量监督检验检疫总局职责、国家工商行政管理总局职责、国家食品药品监督管理总局职责等合并组建为国家市场监督管理总局，国家认证认可监督管理委员会职责划入国家市场监督管理总局，对外保留牌子。特此说明。

全国认证认可标准化技术委员会

2018年3月

others. Chapter III introduces the application of CASCO Toolbox in China. Chapter IV presents selected cases of conformity assessment to reflect its fundamental role in promoting quality improvement, protecting consumers' safety, promoting social sustainable development, improving social governance level, facilitating trade, etc. The Annex provides calculation method of certification & accreditation development index (CADI) with a table of abbreviations for readers' reference.

For readers' note, according to ISO/IEC 17000:2004, *Conformity assessment - Vocabulary and general principles*, conformity assessment is defined as the demonstration that specified requirements relating to a product, process, system, personnel or body are fulfilled. It mainly includes testing, inspection and certification, as well as activities such as accreditation of conformity assessment bodies. In China, the term "certification and accreditation" is used to refer to various conformity assessment activities such as certification, accreditation and approval of certification, accreditation, inspection and testing bodies, covering main content of conformity assessment activities. The book principally describes certification and accreditation activities in China, considering CNCA is assigned to uniformly manage, supervise and comprehensively coordinate certification and accreditation works nationwide. However, the concept "conformity assessment" is used hereof based on international practice.

The reference data in this book comes from publications such as Report on statistic analysis of certification, accreditation, inspection and testing in China 2016, Almanac of certification and accreditation in China, *Development Plan for Certification, Accreditation, Inspection and Testing (2016-2020)*, etc. There may be errors due to the limited capability of compilers, we are looking forward to receiving your criticism.

We hereby state that, in March 2018 when the book was about to be printed, central government agency reform took place in China, involving the adjustment in the functions of conformity assessment. General Administration of Quality Supervision, Inspection and Quarantine of the People's Republic of China, the State Administration for Industry & Commerce of the PRC, and China Food and Drug Administration were merged into one government body -- the State Administration for Market Regulation, with Certification and Accreditation Administration of the PRC (CNCA) merged too, while agency names were reserved.

National Standardization Technical Committee  
on Certification and Accreditation  
March 2018

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Overview of Conformity Assessment in China

合格评定在中国  
CONFORMITY ASSESSMENT  
IN CHINA





## 第一章

# 中国合格评定概况

合格评定在消费者、制造商（服务提供者）和监管者之间建立信任，从而保证产品、服务符合承诺的要求。合格评定是质量管理的基础手段，是符合世界贸易组织（WTO）规则的技术性贸易措施，是市场经济运行的基础性制度安排。2001年，中国出于完善市场经济体制的需要，成立了中国国家认证认可监督管理委员会，对全国认证认可工作实施统一管理、监督和综合协调，此后，中国的合格评定活动得到快速发展。

## 第一节 发展历程

中国（本中指中国大陆）的合格评定伴随着改革开放而迅速发展。1957年，中国加入国际电工委员会（IEC）。1978年9月，中国重新加入国际标准化组织（ISO）。1981年4月，中国建立了电子元器件产品认证制度，成立了第一个产品质量认证机构——中国电子元器件质量认证委员会（QCCECC），依据国际电工委员会（IEC）有关技术规范对相关电子元器件开展质量认证。20世纪80年代中期以来，中国在更广泛的领域推行认证制度，相继建立了家用电器、电子娱乐设备、医疗器械、汽车、食品、消防产品等众多的产品认证制度，其管理涉及众多政府部门。以后，又逐步建立了管理体系认证、人员认证、服务认证。

中国引入认证认可制度，为促进国际贸易以及提高国内市场的产品质量起到了重要作用，但也存在国内和进出口两套认证制度并行等问题。为了履行中国政府加入世界贸易组织的承诺，建立内、外统一的认证认可制度，2001年8月，国务院组建并授权中国国家认证认可监督管理