

Quality and Competence Requirements  
for Analytical Laboratories

(in Chinese-English)

# 分析实验室 质量和能力要求

(中英文对照)

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## 序

随着国际贸易的不断增长和市场的开放,客户越来越有权根据实际情况在世界范围内来选择自己的产品和相应的服务。这种选择能大大刺激对质量的需求,从而导致检验市场的竞争。今后的趋势为,以往传统的中国进出口商品质量检测的手段需要更新,取而代之为全新的整体运作观念——客户为上帝、预防为主、积极反馈、质量跟踪改进。遵循这些做法则需要许多相应的措施。市场全球化、激烈竞争、供方的压力以及 WTO 贸易技术壁垒等将会对“质量”有一个新的要求——必须遵循 ISO/IEC 17025 的精神,建立相应的质量保证体系。

质量是衡量每一个实验室是否成功的标志,它将完美的设计、高效率的检验以及良好的可靠性融为一体,而这些因素一旦达到,就会带来许多好处,例如减少浪费、降低开支、完善检验和服务,由此避免了客户申诉现象的过多发生。客户的选择标准面较宽,但首先是看检验质量和按期提供数据的能力。所以说,实验室应尽快建立质量体系程序,查找潜在的问题,采取相应的改正措施,这里需要考虑的因素涉及到对薄弱环节的确认、非耗资项目的审查、劳动力的使用、积极性的调动、责任制的强调、仪器的检修等。现代实验室质量管理就是鉴于这种观念,即防患于未然。这意味着实验室的质量管理必须从早期的计划阶段着手,通过检验的实施贯穿于服务中去。质量体系一旦运行,实验室上至主任、下至员工都须全力以赴地遵循所制订的实验室质量方针。

ISO/IEC 17025 的应用,能够不断地对现行测量体系过程做修正。该标准已经作为进入国际贸易的准入证而得到世界的认可。任何组织机构若想在世界检验市场上经得起竞争的考验,就必须遵循该标准来调整自己的质量体系。可以相信,凡是涉及到检验业务的各行各业,特别是测试实验室都会从中得到益处。按标准要求去做,

实验室的体系测量性能就能得到改善,会变得愈来愈好,在未来的市场上更能站得住脚。由此可见,编著本书的重要意义。

本书可供实验室依据 ISO 17025 要求编写中英文质量手册和实施质量控制参考。其内容由两部分组成。第Ⅰ部分“实验室质量手册编写(中英文对照)”,详述了实验室质量手册中管理和技术要求的一些基本要素的中英文编写。第Ⅱ部分“实验室测量体系性能评估”,强调了体系质量水平的统计受控,并对内部质量监控和测量不确定度评估的实施提供了具体的技术指导和帮助,而这些工作的实施,今后会越来越显示出其不可低估的重要性。

考虑到本书进一步的修订,许多同仁针对书中章节内容编制的方方面面给予相应的提示、补充和修改,我们对这些意见表示由衷的感谢。所提出的建议我们会做认真的考虑,再根据情况进行相应的修改和调整。

本书的编著过程中查阅了大量的相关资料,其中参考了大连石油化工品检测中心(DPCTC)的质量手册。编者感谢有关人员所提供的意见、建议和帮助。我们衷心地希望,本书的内容能对大家有所启示,起到借鉴作用。

编辑委员会

2003年5月

## Preface

With the international trade increasing and the markets opening, customers have a wide choice of products and services according to their own conditions from around the world. The choice elevates quality requirements and poses new marketplace challenges as well. There is, moreover, a growing consensus that traditional approaches of China I/ E commodities to quality based on inspection are to be improved and must give way to approaches that are customer-focused, prevention-based, more responsive and directed toward quality improvement—approaches perhaps better described as a pursuit of overall operational excellence. This pursuit requires many managements. The globalization of markets, tough competition, suppliers pressures and WTO barriers to trade have led to “quality” thrusts—ISO 17025 and the establishment of its quality assurance system.

Quality is the hallmark of every successful laboratory. It is a blend of good design, efficient inspection, and reliability which, once achieved, brings benefits such as reduced waste, lower overheads, better inspections and services and, hence, fewer customer complaints. Customer selection criteria are extensive, but at the top of the list are quality and the ability to meet a schedule. Thus the quality system program should be designed to recognize potential problems as soon as possible and apply corrective action as part of the program. The factors to be considered include recognition of bottlenecks; review of non-cost items; utilization of manpower; motivation; responsibility; instrument downtime, etc. . Modern laboratory quality practice is founded on the precept that prevention is better than cure. This means that laboratory quality management must begin at the earliest planning stage and continue through inspection into service. Every and each employee in laboratory from the Director downwards must be dedicated to the overall quality policy if the quality system is to work.

ISO 17025, a living system of a continuous process of improvement, is gaining in popularity elsewhere in the world and seen as a passport to international trade, and is designed to be within the reach of any organization that wishes to compete in the world market. It is believed that all inspection areas, especially for testing laboratories, can benefit from the newly established quality system on ISO 17025, and as the organization improves its performance measurement, it becomes more effective and efficient, making the organization more competitive. Thus, the importance of this Chinese-English text

establishment cannot be underemphasized.

This text is intended to serve as an aid for a laboratory who wants to meet the requirements of ISO 17025 and introduce quality control in Chinese-English, from hence this text is composed of two parts. Part I “Quality Manual Preparation for Laboratories (in Chinese-English)” covers in detail some basic elements of management and technical requirements for laboratory quality manual in Chinese-English. Part II “Performance Evaluation of Laboratory Measurement System” focuses on the system quality level in statistical-control, gives helpful and concrete technical advice on internal quality monitor and measurement uncertainty evaluation, which would play an increasingly significant role in the years ahead.

We continue to be indebted to colleagues in many parts for their attention to occasional misprints, omissions and errors, and for their suggestions on possible additions and modifications, with a view to rectification in the future edition. These suggestions may be carefully considered and acted where we feel in agreement with them.

In preparing this work many relevant materials have been consulted, among them, Dalian Petroleum and Chemicals Testing Center (DPCTC) Quality Manual provided support in the preparation. Editor is grateful to all individuals or others who make contributed comments, advice and assistance to this Chinese-English text. In closing, we would be happy that this text will serve as the introduction and promotion, and the enlightening for reading.

Composition of Working Group  
May, 2003

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# 第 I 部分 实验室质量手册编写

## (中英文对照)

质量体系的复杂性会随着实验室的不同而有所不同,所以必须进行文件化,切记不要面面俱到,什么该写什么不该写,应心中有数。

质量管理的文件化主要以质量手册来展现,实际上,任何一个组织可能存有构成“质量手册”的好几个文件和手册,此时可称为质量体系文件化。

当今质量手册是实验室的必备工具,大部分认可机构和国家法规都要求实验室具备这种书面的手册,所以质量手册具有外部优越性:它体现了实验室的质量体系标准,并向外界展示实验室是如何来保证其工作的质量和可信度,怎样依据所需质量标准文件化的规定来确保实验室质量体系的有效符合性。

质量手册还具有一些内部优越性:质量手册是描述组织机构中的政策方针、程序规划和操作步骤的指南书,它规定了何项必须要做、谁做、何时完成、如何来实施、使用什么资源、原因所在,由此它集中囊括了实验室的知识、技能和经验。书面手册的制订,能最大限度地减少由于质量体系的运作,给实验室人员带来的曲意和误解,预防其自行做法的行为发生,加强了质量体系的有效实施。正因为手册对规程进行了标准化,则实验室的操作再也不会出现按口述程序的现象,也避免了个人私有知识的垄断。这样,即便是关键的人员不在,手册也会保证实验室能持续不断地有效运作。手册是发布实验室的方针、目标、标准和要求的极其重要的途径,是实验室质量体系运作实施的方向指南和教科书,是人员培训的关键教材。手册是质量体系是否系统计划的证明,它促进了实验室的质量认可,对质量体系的有效审核和评审起着必不可少的作用。

## 第 1 章 必要文件

必须严格遵守质量手册中所做的各项规定程序,否则手册制订得再好也失去其实际使用意义,没能按照书面制订的方针政策或程序行事,会严重地影响整个体系的完整性。有的体系虽然其文件化不完整,但能够很好地跟踪;而有的体系虽然其文件化很全,但没能遵守。对该两者进行比较,一般来说,前者情况会好于后者。所以,要求各方人员必须重视质量手册中所制订的质量体系文件,高级管理层必须予以承认并加以批准认可。

为保证质量体系所做的各项规定能顺利实施,需要做出相应声明,实验室的各级人员都要遵守这些声明,声明通常作为一个必要文件加以交代,例如涉及到前言、授权令、发布令、公正声明、质量方针与目标、引用文件、定义和术语等内容。现分别示例叙述如下。

### 1.1 前言

本实验室是具有第三方公正地位的检测实验室。本实验室经过数十年的发展建设,已形成一个检验设备和环境设施配套齐全、检测技术完善、人员结构合理、管理科学规范的检测机构。本实验室备有技术专家××名,工作人员具有较高的文化程度,并经过各种方式的专业技术培训,胜任本岗位的检验工作,能较熟练地阅读本专业外文文献。目前实验室拥有与检测任务相适应的分析测试仪器×××台,设备总值约×千万元。

随着检验业务的发展、检测技术的进步、人员的流动和机构的变革,为进一步加强本实验室的科学性、公正性、独立性和权威性,维护委托人的合法权益,提供客户最优质、高效的服务,在总结几年来质量体系运行经验的基础上,本实验室严格按照 ISO/IEC 17025《校准和检测实验室能力的通用要求》中各要素的要求,结合本实验室的多年工作实际,编写而成第×版质量手册。

该手册系本实验室全体员工从事各项质量活动之准则。为了更好地建立良好内部运作机制、加强科学管理、提供高质量和有效服务,手册于 200×年×月发布实施。

××实验室,地址:××××××

邮政编码:××××××,传真:××××××,电话:××××××,实验室主任:×××

## Chapter 1 Mandatory Document

No quality manual, regardless of how well prepared, can serve a useful purpose unless the procedures it describes are actually followed. Not following written policy or procedures undermines the integrity of the entire system. Generally, it is better to have a system that is incompletely documented yet followed, than to have complete documentation of a system that is not followed. Therefore, the need for a quality system documented in a quality manual must be recognized by all concerned. Top management must accept and endorse it.

Present a statement of the goals which are expected to be achieved by implementation of the provisions of the quality system. These statements are mandatory on all staff, and e.g. through the following points, and commonly given as the mandatory information in which Foreword, President Decree, Order Issue, Position Statement, Quality Policy and Objectives, Normative Reference, Definitions and Terms, etc. are discussed individually as the following examples.

### 1.1 Foreword

× × Testing Center, acting independently as a third-party testing laboratory, has been turned into a modern testing center in the course of dozens years development with the present structure; elegant environment, perfect installations, advanced equipments, competent staff, scientific management, rigorous approach. × × Testing lab is staffed with a total of × × qualified experts and technicians in attaining proficiency for various technical training programmes and professional foreign literatures understood. All of them are well-trained with college education. Adapted to the inspection, × × Testing Center is equipped with sophisticated testing instruments and apparatus The gross value of total × × × × pieces test equipment amounts to × millions RMB.

Adapting to the inspection business development, testing technological progress, personnel mobilization and organizational structure adjustment, there is a growing consensus that × × Testing Center must give way to approaches that are in an authentic, impartial, independent and scientific manner in pursuit of protecting the legitimate rights and interests of the parties involved in foreign trade transactions, and providing the customers quality and effective services. The Quality Manual in this × edition has been prepared in the light of the quality system practices in × × Testing Center with an operational experience of several years. It is intended as an aid for × × Testing Center in the demonstration of strictly compliance with requirements of, ISO/IEC 17025 "General Requirements for the Competence of Calibration and Testing Laboratories".

As the basis of the criteria for all staffs of × × Testing Center engaging in different quality activities, this Manual, with the main objective being the establishment of × × Testing Center in satisfactory operation, scientific management strengthening, high quality and efficient service providing, is to be carried into effect as of × . 200 × .

× × Testing Center, Address: × × × × ×

P.C. : × × × × × × , Fax: × × × × × × , Tel: × × × × × × , Director of Testing Center: × × ×

## 1.2 授权令

××实验室系隶属于××出入境检验检疫局(CIQ ××)领导下的独立检验机构,具有第三方公正地位。为确保该实验室的质量体系正常运行,检验活动具有独立性、客观性和公正性,本局领导不利用职权对其检验活动进行不正当的行政干预,同时不接受关系人的委托对该实验室施加人事、行政、财政和其他方面的压力。

授权实验室主任全权负责实验室的经营和管理。

该实验室《质量手册(第×版)》对质量方针、质量目标和质量体系进行了系统的阐述,是实验室的纲领性文件,是质量活动的准则,实验室全体员工应认真贯彻执行。

(CIQ ××) 局长××× 200×年×月×日

## 1.3 发布令

××实验室《质量手册(第×版)》系统阐述了本实验室的质量方针、质量体系、质量活动控制程序以及从事质量工作人员的职责和权限,是本实验室各项质量活动之准则。经质量管理小组审议通过,现予以发布,全体工作人员必须认真贯彻执行。

本手册自 200×年×月×日起实施。

实验室主任 ××× 200×年×月×日

## 1.4 公正声明

本实验室在承接办理有关检验业务、技术咨询等工作中,保证具有独立性、客观性和公正性。

本实验室在检验业务活动中,认真贯彻执行国家有关法律、行政法规,执行相关国家(或地区)的法律、法规,执行国际贸易合同、契约之规定,加强管理,认真检验,公正准确,维护信誉,维护关系人的合法权益,对关系人未公布的技术项目和技术资料严加保密。

本实验室主任对其业务范围内的工作质量负责,本实验室不接受影响质量活动的任何不正当的财政支持,不受任何来自行政的、商业的、财政的和其他方面的压力干预。

## 1.2 President Decree

× × Testing lab is the independent-third-party inspection entity under the direction of China inspection Quarantine × × (CIQ × ×). The quality system activities within the × × Testing Center are to be approved as suitable for its normal operation in a fair, impartial or independent manner by ensuring that the President shall preclude any interference or pressure which might adversely affect its quality, from the his group with the authority or clients concerned in personnel, administration, finance and other respects bringing to bear upon.

The authorized Director of × × Testing Center is fully responsible for engaging in the lab operation.

This Quality Manual defines and documents its policy and objective for, and commitment to, quality system. As the program and criterion for quality activities, it shall be understood, implemented and maintained at all levels in × × Testing Center.

(CIQ × ×) President × × × × , × , 200 ×

## 1.3 Order Issue

“Quality Manual (× × edition)” of × × Testing Center, which is to establish the framework and to assign responsibilities to ensure that testing services conform to the process control of quality policy, quality system, quality activities that are the criteria in different quality activities of × × Testing Center, was passed by Quality Management Group (QMG).

This is hereby to attest that the Manual, intended as basic guidance for × × Testing Center, has been granted for release. Each and every member of × × Testing Center staff must make sure that the above is understood, put into action and kept that way.

The Manual shall be put into effect as of × × , 200 × .

Director of × × Testing lab × × × × , × , 200 ×

## 1.4 Position Statement

It is the policy of × × Testing Center and its personnel to provide related inspection business, consultancy service and others in an independent, objective and impartial manner.

The defined responsibility and authority of × × Testing Center in inspection business need to ensure that the following are implemented and maintained: inspection as stipulated in other laws and administrative rules and regulations; inspection conducted by relevant international (regional) treaties and statute; inspection undertaken for international trade transactions on the basis of charters, contracts and agreements; adherence to the principles of supervision strengthening, inspection rigorously, equity focused, reputation defended in all its inspection.

× × Testing Center, where Director is responsible for the word quality within her business range, shall ensure that it is free from any unlawful financial support, and administrative, commercial, financial and other pressures which might adversely affect the quality activities.

本实验室全体工作人员严格执行本《质量手册(第×版)》之规定,为客户提供正确的检验数据和检验报告,遵守职业道德,严守工作纪律,不在与关系人有关的单位兼职,不从事商业活动,不从事影响自身公正地位的任何活动(见附录规章制度)。

××实验室主任 ××× 200×年×月

## 1.5 质量方针与目标

为加强实验室的科学管理,保证质量体系的正常运营,杜绝质量活动中的纰漏,确保检验结果的真实、准确,维护对外贸易关系人的合法权益,为客户提供最优质、高效的服务,达到预期的质量目标,特制订本手册。

本手册对实验室的质量方针、质量目标、质量体系和实验室运营的准则进行了系统阐述,是本实验室的基本规章和纲领性文件。全室工作人员在从事质量活动中必须遵照执行。

同时,为开展国际、国内检测实验室的认可,作为考核本实验室技术能力和运营水平的主要文件,提供给认可机构进行审阅、评估。本实验室坚决贯彻“加强管理、认真检验、公正准确、维护信誉”的方针,依法施检,为对外贸易关系人提供高效优质的服务。

让全世界皆知××实验室先进的检测手段、精良的技术队伍、严谨的工作作风、科学的实验室管理、独立客观的检验、准确公正的数据、优质高效的服务。永远保持“质量第一、信誉第一、客户第一”,以实现国际间实验室的认可,成为国内外权威性的专业检测机构。辽宁出入境检验检疫实验室入选 ASTM 科技咨询与专家鉴定名录,收入内容摘录如下:

### 辽宁出入境检验检疫实验室

中国大连市人民路 81 号, 邮编:116001, 电话: 86-0411-2637725,

传真: 0411-2807754, 电子邮件: ×××@163.com, 联系人: ×××

评论:

我中心属于中国实验室国家认可委员会 CNACL 认可的实验室,为综合性研究和质量分析机构,下属 6 个实验室——石油化工实验室、理化实验室、金属材料实验室、矿产实验室、生物实验室、植物隔离中心,承担着独立第三方的咨询和测试任务。

Each and every member within × × Testing Center, as of the date of this Manual issue, is requested to ensure that he/she shall be full aware of his/her obligations set out in the Manual by providing the accurate inspection data reports, following the occupational morality, observing the working discipline on CIQ personnel, and refraining from holding other posts within the related client's respect of being engaged in any business activities affecting his/her own equity image.

Director of Testing Center × × × × × . 200 ×

## 1.5 Quality Policy and Objectives

The Manual formulated for the purpose of attaining the desired quality objective is aimed primarily at strengthening the scientific management of labs in × × Testing Center, assuring the quality system in satisfactory operation, preventing occurrence of defects from quality activities, ensuring the inspection results true and precise, protecting the legal rights and interests of the parties involved in trade transactions, proving the quality and efficient services for the clients.

The Manual is a basic statute and program document. Conformance with the requirements of quality policy, quality objective, quality system, and operational criteria stipulated in the Manual is mandatory on everyone engaging in quality activities in × × Testing Center.

The Manual on implementation is also given as a key reference document for the national and international recognition of × × Testing Center's technical competence and operational level, and as a prerequisite for the services of reviews and assessments from a competent accrediting body.

With the guiding principles "supervision strengthening, inspection rigorously, equity adherence, reputation defended", × × Testing Center persists in the execution of inspection on the basis of laws, and the rendering of efficient-quality services for the parties involved in foreign trade transactions.

Let × × Testing Center be known worldwide as its competence such as, advanced testing means, well-trained technical staff, cautious word style, objective-fair inspection, impartial-precise data, high efficient service. To be accepted and recognized as an authority both domestically and abroad, × × Testing Center will always keep up its "Quality-Oriented, Reputation-Based, Customer-Focused" principle, see the following.

### **Liaoning Entry-Exit Inspection and Quarantine Testing Center**

**81 Renmin Road, Dalian; 116001, China; Phone: 86-0411-2637725;**

**Fax: 0411-2807754; E-mail: × × × @163.com; Contact: × × ×**

Comments:

Our Center is a CNACL (China National Accreditation Committee for Laboratories) accredited, independent third-party consulting and testing, comprehensive research and quality analysis facility, in which six laboratories (petrochemical lab, physicochemical lab, metal material lab, mineral lab, biological lab, plant quarantine isolation center) are responsible for the entry-exit inspections and quarantines.



作为全方位服务的测试实验室,本中心的质量目标计划符合 ISO/IEC 17025 标准的要求。

我们的专业人员为化学分析、工程技术和科学研究人员。他们完全可以胜任并能出色地完成以下专业的检测:化学组分、物理特性、食品理化和微生物检测。在我们所能承担的各种检测业务中,尤其可以胜任实验室分析技术,这些技术涉及到有机和无机材料的化学分析和物理特性测量,主要的检测产品有:石油产品、橡胶塑料、化工品、燃料、石化产品、动植物油、农药残留、DNA 分析、金属合金、矿石和矿产品、涂料以及其它一些产品。并具有专家鉴定资格。

本中心配备仪器设备有:原子吸收分光光度计、等离子光谱/质谱、电感耦合等离子光谱仪、气相色谱仪、高效液相色谱、色谱/质谱联用机、质谱、液相色谱/质谱、傅立叶红外、红外线碳硫自动测定仪、X 射线衍射仪、X 射线荧光光谱仪、双束紫外可见分光光度计、INSTRON 电子式拉力试验机、汽油辛烷值机、注塑机、PONA 值测定仪(PONA 石油烃组分测定仪)、分析仪、自动滴定仪、卡尔-费休微量水分测定仪、热量计、全套 ASTM 石油产品分析仪器。

其它服务业务:承担技术诉讼、质量控制/保证评估、药物和化妆品分析、扦样、粒度。

地理服务区域:国际。

专家鉴定:有。

专长领域:微生物检测、物理化学分析、质量控制/保证评估。

## 1.6 引用文件

GB/T 19000—2000(idt ISO 9000:2000) 质量管理体系 基本原理和术语

GB/T 19001—2000(idt ISO 9001:2000) 质量管理体系 要求

GB/T 19022.1—1994(idt ISO 10012-1:1992) 测量管理体系 测量过程和测量设备的要求

ISO/IEC 指南 2 标准化及其相关活动的一般术语及其定义

GB/T 15481—2000(idt ISO/IEC 17025:1999) 校准和检验实验室能力的通用要求

ISO/IEC 指南 30 标准物质术语及其定义

GB/T 19023—1996(idt ISO/IEC 10013:1995) 质量手册编制指南

EN 45001 实验室运营的一般准则