Instruction of ISO/IEC 17067

GB/T17067—201X 产品认证基础和认证方案指南 介绍

**主要内容**

Main Contents of This Instruction

**1标准历史**Publication and History of this New Standard ISO/IEC 17067

**2 标准主要变化**Major Changes

**3 标准主要内容**Several Questions Help to Understand this New Standard

1. **标准范围**What’s the scope of this new standard?
2. **产品认证基础是什么**What are the fundamentals of product certification?
3. **认证模式有多少种**How many PC Models (scheme types) in total?
4. **典型认证模式有几种**How many Typical PC Models (scheme types) in total?
5. **最常用的认证模式是哪个**Which PC Model (scheme type) is the most popular one?
6. **表1的主要作用是什么**What’s the main role of Table 1?

**4 怎样设计产品认证方案**How to develop a PC Scheme (by the scheme owner)

1. **产品认证方案的目标是什么**What are the objectives of this PC Scheme?
2. **产品认证方案的相关方有哪些**Who are the stakeholders of this PC Scheme?
3. **方案原则是什么**What are the scheme principles?
4. **如何选择认证模式**How to choose PC Model (Scheme type)
5. **如何选择认证功能和认证活动**Which functions and activities should be chosen?
6. **多少内容应被覆盖**How many contents should be covered?
7. **标准历史**Publication and History of this New Standard

* 1982 ISO/IEC Guide 28 *General rules for a model third-party certification system for products*

**GB/T 27028-2008 第三方产品认证制度指南**

* 1983 ISO/IEC Guide 40 General requirements for the acceptance of certification bodies

**未转化成国家标准**

* 1996 ISO/IEC Guide 65 General requirements for bodies operating product certification systems

**GB/T 27065-2004 产品认证机构要求**

* 2004 ISO/IEC Guide 67 Conformity assessment - Fundamentals of product certification

**GB/T 27067-2006 产品认证基础**

* 2012 ISO/IEC 17065 Conformity assessment - Requirements for bodies certifying products, processes and services

**GB/T 27065-20XX 产品、过程和服务认证机构要求**

* 2013 ISO/IEC 17067 Conformity assessment – Fundamentals of product certification and guidelines for product certification schemes Publication 2013-08-01 (First edition)

**GB/T 27067-20XX产品认证基础和认证方案指南**

1. **主要变化**Major Changes

**前言**Foreword

**与2004版导则67相比，主要变化是**

Major changes, Compared with ISO/IEC Guide 67:2004:

**— 增加第6章，设计和运作认证方案的指南**

Clause 6 is new, guidelines on setting up and operating a PC Scheme

**— 部分导则67正文中内容，移至前言；**

Some of the text originally in the main body of ISO/IEC Guide 67 has been moved to the Introduction

**— 功能法被加强**Functional approach been emphasized

**— 表1得到扩展，以体现功能法**Table 1 been extended to reflect the functional approach

**—** **专门条款阐述单一产品或批次产品认证**Explicit provision has been made for type and batch certification schemes

**— 关联至ISO/IEC 17065:2012，取代ISO/IEC Guide 65:1996** References to ISO/IEC 17065:2012 have replaced references to ISO/IEC Guide 65:1996

**— 文字表达更精练**Text has been made more concise in places.

1. **标准主要内容**Several Questions Help to Understand this New Standard
   1. **标准范围**Scope
      * **描述了产品认证基础**Describes the fundamentals of product certification
      * **为理解、设计、运行和保持认证方案提供指南**Provides guidelines for understanding, developing, operating or maintaining certification schemes
   2. **产品认证基础（基本原理）是什么？**What’s the fundamentals of product certification

**标准中无专门条款阐述**No specific clauses for the fundamental

**以下几点帮助理解**Some key points to understand the fundamental:

* + - **市场经济需求**

提供证明Provides attestation (that product conform to specified requirements)

提供信任Provides confidence to interested parties

(that product conform to specified requirements) General Objectives of PC

促进贸易Facilitate trade

* + - **证明方式的经济性【型式试验+工厂检查（一致性核查、产品抽样检测、质量保证能力核查）】**
    - **认证模式的灵活性（与产品特点相匹配）**
  1. **有多少种认证模式（方案类型）**How many Certification Models (scheme types) in total may be existed?

**没有限制**No defined number





**D 字母N表明认证模式（方案类型）的数量是没有限制的**“d The symbol N has been added to show an undefined number of possible other schemes, which can be based on different activities”

* 1. **有多少种常用的认证模式（方案类型）**How many Typical PC Models (scheme types) in total?

**本标准中给出了7种**7 Type Schemes according to this standard

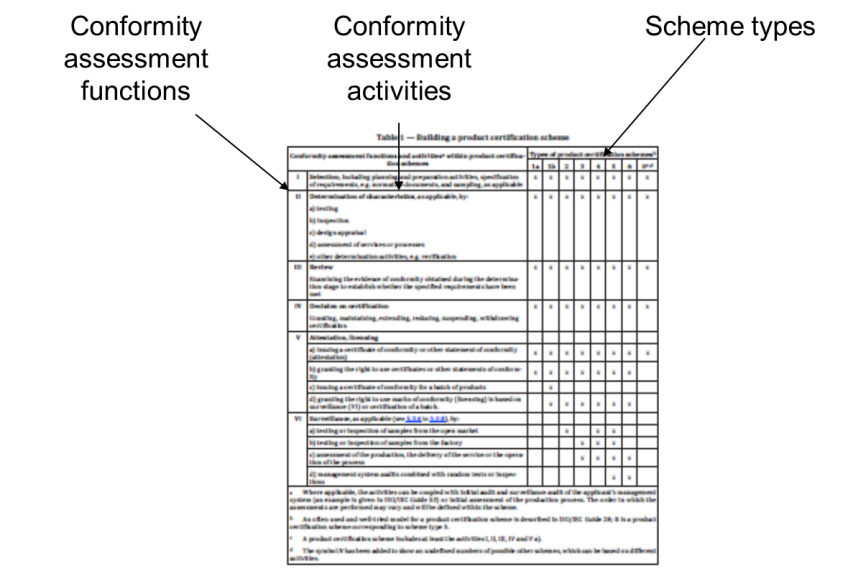


* **模式1a**  Scheme type 1a
* **模式1b**  Scheme type 1b
* **模式2** Scheme type 2
* **模式3**  Scheme type 3
* **模式4** Scheme type 4
* **模式5**  Scheme type 5
* **模式6** Scheme type 6
  1. **哪种模式最常用**Which PC Model (scheme type) is the most popular one?

**第5种认证模式最常用**Scheme type 5 is the most popular one in China.

|  |  |  |
| --- | --- | --- |
| Items | 认证模式Model | 机构数量CB Quantity |
| 1 | Type testing + initial factory inspection + surveillance (Scheme type 5) | 26 |
| 2 | Initial factory inspection + sample testing + surveillance (Scheme type 5) | 17 |
| 3 | Type testing + surveillance | 4 |
| 4 | Sample testing + surveillance | 2 |
| 5 | optimized testing + surveillance | 2 |
| 6 | Design Evaluation + Type testing + initial factory inspection + surveillance | 2 |
| 7 | Design Evaluation + initial factory inspection + surveillance | 1 |
| 8 | Design Evaluation | 1 |
| 9 | Type testing + declaration of conformity + surveillance | 1 |
| 10 | Factory Quality Management Systems Audit + Certificate issued testing + surveillance | 1 |
| 11 | Batch test or examine (Be applicable to wholesale trade) | 1 |
| 12 | First Testing + Design Evaluation | 1 |
|  | Amount to | 59 |

* 1. **表一的作用是什么**What’s the main role of Table 1



**表一用于帮助如何**Table 1 show how to:

**—— 选择合格评定功能，以建立产品认证方案**build a product certification scheme by using these functions （5.2.1）

**——** **给出认证活动组合的框架**outlines some combinations of activities（5.2.1）

1. **如何设计产品认证方案**How to develop PC Scheme (by a scheme owner)

**方案所有者应确定**The Scheme Owner need to confirm:

* 1. **产品认证方案的目的**What are the objectives of this PC Scheme? (6.4.1)
  + **为监管部门实现健康、安全或环保**

For regulators to achieve health, safety or environmental outcomes

* + **帮助客户和消费者区别产品并做出购买决策**

Assisting clients and consumers to differentiate products in the market place and make informed purchasing decisions

* 1. **谁是相关方**Who are the stakeholders? (6.1)
  + **可以是制造商、服务商、认证机构、客户或是公共事务机构**

Could be: manufacturer, service provider, certification body, customer or public authority

* 1. **方案制定的原则是什么**What are the scheme principles? (6.4.4)
  + **确定谁是方案所有者**Confirmation of the ownership
  + **确定监管和决策机制**Confirmation of the governance and decision making mechanisms
  + **确定基础业务和赢利模式**Confirmation of the underlying business and funding model
  + **给出监控和定期复核方案的框架**Providing an outline for monitoring and periodic review of the scheme.
  1. **如何选择认证模式（方案类型）**How to choose PC Model (Scheme type) (Table 1 and 5.3)

**本标准主要给出了3个影响因素**Generally speaking, it depends on 3 elements:

* + **认证对象**what is going to be certified (Certification objects)
  + **在哪和如何抽样**where and how to sampling
  + **证明程度**the attestation extent of the certification

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 认证对象Certification object | 产品状态Status | 抽样Sampling | 证明程度  Attestation Extent | 认证模式  PC Model |
| **一个产品**  One product | **已生产的**  Produced | **不抽样**  No sampling |  | **方案类型1a**  Scheme Type 1a |
| **一批产品**  Batch products | **已生产的**  Produced | **抽自批次**  From batch |  | **方案类型1b**  Scheme Type 1b |
| **已上市产品**  Products  (on the market) | **已上市并持续供应**  On the market and on-going offer | **抽自市场**  From market | **识别分销渠道的影响**  -Identify the impact of the distribution channel  **纠正措施效果有限**  -Effective correction measure maybe limited | **方案类型2**  Scheme Type 2 |
| **未出厂产品**  Products  (before out of factory) | **工厂内已有成品并持续生产**  In factory and on-going production | 抽自工厂  From factory | **不能识别分销渠道的影响**  -Not identify the impact of the distribution channel  **可以阻止不合格品进入市场**  -Prevent non-conformity products to market | **方案类型3**  Scheme Type 3 |
| **已生产并已上市产品**  Products  (in factory and on market) | **工厂内有成品，已上市，并持续供应**In factory, on market and on-going offer | **抽自工厂和/或市场**  From factory/market | **识别分销渠道的影响**  -Identify the impact of the distribution channel  **阻止不合格品进入市场**  -Prevent non-conformity products to market | **方案类型4**  Scheme Type 4 |
| **已生产并已上市产品**  Products  (in factory and on market) | **工厂内有成品，已上市，并持续供应**  In factory, on market and on-going offer | **抽自工厂和/或市场**  From factory/market  **管理体系审核及随机检测和检查**  MS Audit and random testing and inspection | **常用的且被证明有效的产品认证方案模式**  often used and well-tried model | **方案类型5**  Scheme Type 5 |
| **服务/过程**  Services/processes | **持续供应**  On-going offer |  |  | **方案类型6**  Scheme Type 6 |
| …… | …… |  | …… | …… |

哪种方案类型证明“产品是否符合要求”的程度最高？

* 1. **如何选择各功能和活动**Which functions and activities should be chosen? (Table 1 ,5.3 and 6)
  + **表一中功能和活动**I, II, III, IV 和 V a不可缺少 Functions and activities I, II, III, IV and V a) in Talbe1 shall be included at least
  + **认证对象是什么**what is going to be certified (Certification objects)
  + **选择哪个认证模式**which Model be chosen
  + **认证证明的程度**the attestation extent of the certification
  1. **方案中应涵盖哪些内容**How many contents should be covered? (6.5.1)

**方案中应包括21项内容**21 contents should be included in a scheme:

* 1. **范围**Scope
  2. **产品要求**Product requirements
  3. **合格评定活动**CA activities
  4. **认证要求**Certification requirements
  5. **合格评定机构要求**Requirements for CA bodies: Accreditation? Peer assessment?
  6. **合格评定方法和程序**CA methods and procedures
  7. **客户提供的信息**Information supplied by client
  8. **符合性声明**Statement of conformity
  9. **符合性标志**Mark of conformity
  10. **证书和标志的使用**Use of certificate and mark
  11. **运作方案所需的资源-公正性、能力和分包** Resources for operating scheme - impartiality, competence, outsourcing
  12. **评价和监督结果的报告**Reporting results of determination and surveillance activities
  13. **不符合项的处理**Dealing with non-conformities: client, product
  14. **监督程序**Surveillance procedures
  15. **获取方案的准则**Criteria for access to scheme: CBs, clients
  16. **获证产品名录**Directory of certified products
  17. **合同**Contracts: owner, CB, client
  18. **授予、暂停认证等的条件**Conditions for certification: granting, withdrawing, etc.
  19. **客户的投诉记录**Clients’ complaints records, need for verification by CBs
  20. **在公开媒介上获取方案的途径**Clients’ reference to scheme in publicity material
  21. **方案所有者和认证机构保存的记录**Records to be retained by scheme owner and CBs