



# IAF—ISO公报

《经认可的 ISO 9001 认证的预期结果》

《经认可的 ISO 14001 认证的预期结果》



中国合格评定国家认可委员会秘书处 编译

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## ISO-IAF 公报《经认可的 ISO 9001 认证的预期结果》

## 和《经认可的 ISO 14001 认证的预期结果》

### 制定背景

为了持续改进经认可的认证的有效性，国际认可论坛（IAF）在 2006 年成员大会通过的《IAF 战略计划 2006》中提出：建立用户反馈机制，以获取用户对经认可的 ISO 9001 和 ISO 14001 认证有效性的评价，识别认证的实际效果与用户期望之间可能存在的差距，作为 IAF 持续改进认可和认证的有效性的依据。为此，从 2007 年开始，IAF 技术委员会对经认可的 ISO 9001 和 ISO 14001 认证所应达到的效果进行研究，并做出书面描述，以此统一各方对认证有效性实际含义的理解，为测评认证有效性提供一致的基准，并可用于向各界广泛宣传。这就是《经认可的 ISO 9001 认证的预期结果》和《经认可的 ISO 14001 认证的预期结果》的由来。

在 IAF 技术委员会研究起草上述书面描述同时，IAF 先后于 2007 年 3 月、6 月和 2008 年 3 月，在美国、中国和德国举办了三次主要由最终用户参加的区域性研讨会，听取相关方对认证和认可有效性的意见和建议，并于 2008 年 10 月正式成立了 IAF 用户顾问委员会，作为用户反馈的长效机制。IAF 用户顾问委员会成立后的第一项工作就是与 IAF 技术委员会合作完成了上述对认证所应达到的效果的书面描述，并由 IAF 征得 ISO 同意后，作为 IAF-ISO 联合公报正式发布。

本文是针对 IAF 网站公布的 Expected Outcomes for Accredited Certification to ISO 9001 (2009 年 7 月发布版本)和 Expected Outcomes for Accredited Certification to ISO 14001 (2009 年 7 月发布版本)进行了翻译，供大家参考。

## IAF-ISO 公报

### 《经认可的 ISO 9001 认证的预期结果》

国际认可论坛 (IAF) 和国际标准化组织 (ISO) 支持如下关于经认可的 ISO 9001 认证的预期结果的简要声明。其意图是推动整个合格评定链共同给与关注, 以实现这些预期的结果, 从而增强经认可的认证的价值和意义。

ISO 9001 认证在私营和公共部门均被经常用于增强对组织提供的产品和服务的信任 (商务合作方之间的信任), 对供应链中所选供方的信任, 以及对采购合同投标者资格的信任。

ISO 制定和发布了 ISO 9001, 但其本身并不实施审核或认证, 而是由独立于 ISO 的认证机构提供上述服务。ISO 不控制这些机构, 但制定自愿性国际标准以鼓励他们在世界范围内遵循良好的活动规范。例如: ISO/IEC 17021 给出了对提供管理体系审核和认证的机构的要求。

如果认证机构希望进一步获得相关方对其服务的信任, 可以选择申请获得经 IAF 承认的国家认可机构对其能力的认可。IAF 是一个国际协会, 其成员包括 49 个经济体的国家认可机构。ISO 并不控制这些认可机构, 但制定提供认可活动通用要求的自愿性国际标准, 例如 ISO/IEC 17011。

注: 经认可的认证只是组织可以用来证实符合 ISO 9001 的一种方式。ISO 并不宣传经认可的认证优于其他合格评定方式。

### 经认可的 ISO 9001 认证的预期结果

#### (从组织顾客的角度)

“一个具有获得认证的质量管理体系的组织, 在所确定的认证范围内, 持续地提供满足顾客要求和适用法律法规要求的产品, 并以提高顾客满意度为目标。”

注:

- a) “产品” 也包括 “服务”。
- b) 顾客对产品的要求可以是明示的 (例如在合同或商定的规范中) 或通常隐含的 (例如在组织的宣传材料中, 或是根据行业惯例)。

c) 产品要求可以包括对交付和交付后活动的要求。

## 经认可的 ISO 9001 认证的意义

为了获得合格的产品，经认可的认证过程被期望就组织**具有**一个符合 ISO 9001 的适用要求的质量管理体系而提供信任。组织尤其被期望：

- A. 已建立了适宜于其产品和过程且适合其认证范围的质量管理体系；
- B. 分析并理解顾客的需求和期望以及关于其产品的相关法律法规要求；
- C. 确保产品特性已得到明确，以确保满足顾客要求和法律法规要求；
- D. 已确定了实现预期结果（合格的产品和客户满意度的提高）所需的过程，并对之进行管理；
- E. 已确保了为这些过程的运作和监视提供支持所必需的资源的有效性；
- F. 对所确定的产品特性进行监测和控制
- G. 以预防不符合为目标，并具有系统的改进过程以：
  - 1. 纠正任何确实发生的不符合（包括交付后发现的产品不符合）；
  - 2. 分析不符合原因并采取纠正措施以避免其再次发生；
  - 3. 处理顾客投诉；
- H. 已实施了有效的内部审核和管理评审过程；
- I. 监视、测量和持续改进其质量管理体系的**有效性**。

## 经认可的 ISO 9001 认证所没有的含义

- 1) 重要的是认识到 ISO 9001 给出的是对组织的质量管理体系的要求，而不是对其产品的要求。经认可的 ISO 9001 认证应当为组织“持续地提供满足顾客要求和适用法律法规要求的产品”的能力提供信任。它**不一定**保证组织将总是实现产品百分之百合格，尽管这当然应该是一个永恒的目标。
- 2) 经认可的 ISO 9001 认证**不表示**组织提供优质的产品或产品本身被证明符合 ISO(或任何其他)标准或规范的要求。

## IAF-ISO 公报《经认可的 ISO 14001 认证的预期结果》

国际认可论坛 (IAF) 和国际标准化组织 (ISO) 支持如下关于经认可的 ISO 14001 认证的预期结果的简要声明。其意图是推动整个合格评定链共同给与关注, 以实现这些预期的结果, 从而增强经认可的认证的价值和意义。

ISO 14001 认证在私营和公共部门均被经常用于提高利益相关方对组织的环境管理体系的信任水平。

ISO 制定和发布了 ISO 14001, 但其本身并不实施审核或认证, 而是由独立于 ISO 的认证机构提供上述服务。ISO 不控制这些机构, 但制定自愿性国际标准以鼓励他们在世界范围内遵循良好的活动规范。例如: ISO/IEC 17021 给出了对提供管理体系审核和认证的机构的要求。

如果认证机构希望进一步获得相关方对其服务的信任, 可以选择申请获得经 IAF 承认的国家认可机构对其能力的认可。IAF 是一个国际协会, 其成员包括 49 个经济体的国家认可机构。ISO 并不控制这些认可机构, 但制定提供认可活动通用要求的自愿性国际标准, 例如 ISO/IEC 17011。

注: 经认可的认证只是组织可以用来证实符合 ISO 14001 的一种方式。ISO 并不宣传经认可的认证优于其他合格评定方式。

### 经认可的 ISO 14001 认证的预期结果

#### (从利益相关方的角度)

“一个具有获得认证的环境管理体系的组织, 在所确定的认证范围内, 管理着其与环境的相互作用, 并证实着其如下承诺:

- A. 预防污染;
- B. 满足适用的法定要求和其他要求;
- C. 持续加强其环境管理体系, 以实现其整体环境绩效的改进。”

#### 经认可的 ISO 14001 认证的意义

经认可的认证过程被期望确保组织**具有**一个与其活动、产品和服务的性质相适宜

的、且符合 ISO 14001 要求的环境管理体系，尤其是能够就所确定的认证范围证明组织：

- A. 已确定了适合于其活动、产品和服务的性质、规模和环境影响的环境方针；
- B. 已识别了其能够控制和（或）影响的其活动、产品和服务的环境因素，并确定了那些可能具有重大环境影响的环境因素（包括那些与供方和（或）合同方有关的）；
- C. 有程序识别适用的环境法规和其他相关要求，以确定这些要求以何种方式适用于其环境因素，并使这些信息保持最新；
- D. 已实施了有效的控制，以实现其符合适用的法定要求和其他要求的承诺；
- E. 有确定的环境目标和指标，并有实现这些目标和指标的方案。这些目标和指标是可测量的，且在切实可行时，考虑了法定要求和重大环境因素；
- F. 确保为其工作或代表其工作的人员了解其环境管理体系的要求，并有能力实施有可能产生重大环境影响的任务；
- G. 已实施了程序以进行内部沟通，以及对外部利益相关方做出响应，并在必要时与外部利益相关方进行沟通；
- H. 确保在规定的条件实施那些与重大环境因素相关联的运作，并监视和控制其可能有重大环境影响的运作的关键特性；
- I. 已建立了处理和响应可能影响环境的紧急情况的程序，并在切实可行时，测试了这些程序
- J. 定期评价其对于适用的法定要求和其他要求的符合性；
- K. 以预防不符合为目的，并具有程序以：
  - 1. 纠正任何确实发生的不符合；
  - 2. 分析不符合的原因并采取纠正措施以避免其再次发生；
- L. 已实施了有效的内部审核和管理评审程序。

### 经认可的 ISO 14001 认证所没有的含义

- 1) ISO 14001 给出了对组织的环境管理体系提出的要求，但没有给出具体的环境绩效

准则。

- 2) 经认可的 ISO 14001 认证为组织实现其自身环境方针（包括并符合适用法定要求得承诺）以预防污染并持续改进其绩效的能力提供信任。它不保证组织当前正在实现最佳的环境绩效。
- 3) 经认可的 ISO 14001 认证不包括完整的合规性审核，也不能确保组织将永不发生违反法定要求的情况，尽管组织应该总是将完全合规做为目标。
- 4) 经认可的 ISO 14001 认证不表示组织将能够避免环境事故的发生。



## **Proposed Joint IAF-ISO Communiqué**

### **Expected Outcomes for Accredited Certification to ISO 9001**

The International Accreditation Forum (IAF) and the International Organization for Standardization (ISO) support the following concise statement of outcomes that are to be expected as a result of accredited certification to ISO 9001. The intent is to promote a common focus throughout the entire conformity assessment chain in order to achieve these expected outcomes and thereby enhance the value and relevance of accredited certification.

ISO 9001 certification is frequently used in both private and public sectors to increase confidence in the products and services provided by organizations, between partners in business-to-business relations, in the selection of suppliers in supply chains and in the right to tender for procurement contracts.

ISO is the developer and publisher of ISO 9001, but does not itself carry out auditing and certification. These services are performed independently of ISO by certification bodies. ISO does not control such bodies, but does develop voluntary International Standards to encourage good practice in their activities on a worldwide basis. For example, ISO/IEC 17021 specifies the requirements for bodies providing auditing and certification of management systems.

One option for certification bodies wishing to provide further confidence in their services is to apply to be accredited as competent by an IAF recognized national accreditation body. The IAF is an international association whose membership includes the national accreditation bodies of 49 economies. ISO does not control such bodies, but does develop voluntary International Standards such as ISO/IEC 17011 which specifies the general requirements for carrying out accreditation.

NOTE: Accredited certification is only one way that an organization may demonstrate conformity to ISO 9001. ISO does not promote accredited certification over other conformity assessment methodologies.

### **Expected Outcomes for Accredited Certification to ISO 9001**

#### **( from the perspective of the organization's customers )**

"For the defined certification scope, an organization with a certified quality management system consistently provides products that meet customer and applicable statutory and regulatory

requirements, and aims to enhance customer satisfaction.”

Notes:

- a. “Products” also include “services.”
- b. Customer requirements for the product may either be stated (for example in a contract or an agreed specification) or generally implied (for example in the organization’s promotional material, or by common practice for that economic/industry sector).
- c. Requirements for the product may include requirements for delivery and post-delivery activities.

### **What accredited certification to ISO 9001 means**

To achieve conforming products, the accredited certification process is expected to provide confidence that the organization has a quality management system that conforms to the applicable requirements of ISO 9001. In particular, it is to be expected that the organization:

- A. has established a quality management system that is suitable for its products and processes, and appropriate for its certification scope
- B. analyzes and understands customer needs and expectations, as well as the relevant statutory and regulatory requirements related to its products
- C. ensures that product characteristics have been specified in order to meet customer and statutory/regulatory requirements
- D. has determined and is managing the processes needed to achieve the expected outcomes (conforming products and enhanced customer satisfaction)
- E. has ensured the availability of resources necessary to support the operation and monitoring of these processes
- F. monitors and controls the defined product characteristics
- G. aims to prevent nonconformities, and has systematic improvement processes in place to
  - 1. Correct any nonconformities that do occur (including product nonconformities that are detected after delivery)
  - 2. Analyze the cause of nonconformities and take corrective action to avoid their recurrence
  - 3. Address customer complaints
- H. has implemented an effective internal audit and management review process

I. is monitoring, measuring and continually improving the effectiveness of its quality management system

### **What accredited certification to ISO 9001 does not mean**

1) It is important to recognize that ISO 9001 defines the requirements for an organization's quality management system, not for its products. Accredited certification to ISO 9001 should provide confidence in the organization's ability to "consistently provide product that meets customer and applicable statutory and regulatory requirements". It does not necessarily ensure that the organization will always achieve 100% product conformity, though this should of course be a permanent goal.

2) ISO 9001 accredited certification does not imply that the organization is providing a superior product, or that the product itself is certified as meeting the requirements of an ISO (or any other) standard or specification.

(本文摘自 IAF 网站 2009 年 7 月发布的 Expected Outcomes for Accredited Certification to ISO 9001 原文)

## **Proposed Joint IAF-ISO Communiqué**

### **Expected Outcomes for Accredited Certification to ISO 14001**

The International Accreditation Forum (IAF) and the International Organization for Standardization (ISO) support the following concise statement of outcomes that are to be expected as a result of accredited certification to ISO 14001. The intent is to promote a common focus throughout the entire conformity assessment chain in order to achieve these expected outcomes and thereby enhance the value and relevance of accredited certification.

ISO 14001 certification is frequently used in both private and public sectors to increase the confidence level of interested parties in an organization's environmental management system.

ISO is the developer and publisher of ISO 14001, but does not itself carry out auditing and certification. These services are performed independently of ISO by certification bodies. ISO does not control such bodies, but does develop voluntary International Standards to encourage good practice in their activities on a worldwide basis. For example, ISO/IEC 17021 specifies the requirements for bodies providing auditing and certification of management systems.

One option for certification bodies wishing to provide further confidence in their services is to apply to be accredited as competent by an IAF recognized national accreditation body. The IAF is an international association whose membership includes the national accreditation bodies of 49 economies. ISO does not control such bodies, but does develop voluntary International Standards such as ISO/IEC 17011 which specifies the general requirements for carrying out accreditation.

NOTE: Accredited certification is only one way that an organization may demonstrate conformity to ISO 14001. ISO does not promote accredited certification over other conformity assessment methodologies.

### **Expected Outcomes for Accredited Certification to ISO 14001**

#### **(from the perspective of interested parties)**

"For the defined certification scope, an organization with a certified environmental management system is managing its interactions with the environment and is demonstrating its commitment to:

A. Preventing pollution.

B. Meeting applicable legal and other requirements.

C. Continually enhancing its environmental management system in order to achieve improvements in

its overall environmental performance.”

### **What accredited certification to ISO 14001 means**

The accredited certification process is expected to ensure that the organization has an environmental management system, suitable for the nature of its activities, products and services, that conforms to the requirements of ISO 14001, and in particular can demonstrate for the defined scope that the organization:

A. has defined an environmental policy appropriate to the nature, scale and environmental impacts of its activities, products and services

B. has identified the environmental aspects of its activities, products and services that it can control and /or influence and determined those that can have a significant environmental impact (including those related to suppliers / contractors).

C. has procedures in place to identify applicable environmental legislation and other relevant requirements, to determine how these apply to its environmental aspects and to keep this information up to date.

D. has implemented effective controls in order to meet its commitment to comply with applicable legal and other requirements.

E. has defined environmental objectives and targets that are measurable, where practicable, taking into account legal requirements and significant environmental aspects, and has programmes in place to achieve these objectives and targets

F. ensures that people working for or on behalf of the organization are aware of the requirements of its environmental management system and are competent to perform tasks that have the potential to cause significant environmental impacts

G. has implemented procedures for communicating internally, as well as responding to and communicating (as necessary) with interested external parties

H. ensures that those operations associated with significant environmental aspects are carried out under specified conditions and monitors and controls the key characteristics of its operations that can have a significant environmental impact

J. has established and (where practicable) tested procedures to address and respond to

emergencies that can have an effect on the environment

K. periodically evaluates its compliance with applicable legal and other requirements

L. aims to prevent nonconformities, and has procedures in place to

1. correct any nonconformities that do occur
2. analyze the cause of any such nonconformities and take corrective action to avoid their recurrence

M. has implemented effective internal audit and management review procedures

### **What accredited certification to ISO 14001 does not mean**

1) ISO 14001 defines the requirements for an organization's environmental management system, but does not define specific environmental performance criteria.

2) Accredited certification to ISO 14001 provides confidence in the organization's ability to meet its own environmental policy, including the commitment to comply with applicable legislation, to prevent pollution, and to continually improve its performance. It does not ensure that the organization is currently achieving optimal environmental performance.

3) The ISO 14001 accredited certification process does not include a full regulatory compliance audit and cannot ensure that violations of legal requirements will never occur, though full legal compliance should always be the organization's goal.

4) Accredited certification to ISO 14001 does not necessarily indicate that the organization will be able to prevent environmental accidents from occurring.

(本文摘自 IAF 网站 2009 年 7 月发布的 Expected Outcomes for Accredited Certification to ISO 14001 原文)