ISO 9001 Auditing Practices Group

Guidance on:

Expected Outcomes

The “expected outcomes” documents (given in the annexes below) on ISO 9001 and ISO 14001 have been developed by the members of the IAF, ISO/TC 176, ISO/207 and ISO/CASCO, and agreed by consensus.

The aim of this document is to promote the use and understanding of the expected outcomes documents by auditors, accreditation body assessors and other certification and accreditation body personnel, to reinforce the application of the principles contained within the “expected outcomes” documents during certification activities.

The benefits of doing so for certification are a) that the certification bodies will have increased confidence that their clients will satisfy their customer’s expected outcomes, and b) that the market will have a realistic expectation of what certification achieves.

To accomplish this certification and accreditation bodies are encouraged to promote the concepts within these documents in their organization, e.g. through auditor training, to verify that the overall purpose of an ISO 9001 or ISO 14001 management system is achieved.

The marketing and communications functions should also be made aware of the concepts and should promote them in their contacts with clients.

The “expected outcomes” documents should be included in any future auditor and accreditation body assessor training materials.
Annex A - 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 and services that meet customer and applicable statutory and regulatory requirements, and aims to enhance customer satisfaction.”

Notes:
1. Customer requirements for the products and services 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).
2. Requirements for the products and services may include requirements for delivery and post-delivery activities.

What accredited certification to ISO 9001 means

To achieve conforming products and services, 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, services 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 and services
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 services, as well as 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 and service characteristics

G. aims to prevent nonconformities, and has systematic improvement processes in place to
   1. Correct any nonconformities that do occur (including product or service 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 and services. 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 service, or that the product or service itself is certified as meeting the requirements of an ISO (or any other) standard or specification.
Annex B - 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

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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

I. has established and (where practicable) tested procedures to address and respond to emergencies that can have an effect on the environment

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

K. 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

L. 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

For further information on the ISO 9001 Auditing Practices Group, please refer to the paper: Introduction to the ISO 9001 Auditing Practices Group

Feedback from users will be used by the ISO 9001 Auditing Practices Group to determine whether additional guidance documents should be developed, or if these current ones should be revised.

Comments on the papers or presentations can be sent to the following email address: charles.corrie@bsigroup.com.

The other papers and presentations may be downloaded from the web site: www.iso.org/tc176/ISO9001AuditingPracticesGroup

Disclaimer

These papers have not been subject to an endorsement process by the International Organization for Standardization (ISO), the ISO Policy Committee for Conformity

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