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Guidelines for auditing quality systems —

Part 2:

Qualification criteria for quality systems

auditors

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Lignes directrices pour l'audit des systèmes qualité —

Partie 2: Critères de qualification pour les auditeurs de systèmes qualité

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

International Standard ISO 10011-2 was prepared by Technical Committee ISO/TC 176, *Quality management and quality assurance*.

ISO 10011 consists of the following parts, under the general title *Guidelines for auditing quality systems*:

- Part 1: *Auditing*
- Part 2: *Qualification criteria for quality systems auditors*
- Part 3: *Management of audit programmes*

Annex A forms an integral part of this part of ISO 10011. Annex B is for information only.

Introduction

In order that quality systems audits are carried out effectively and uniformly as defined in ISO 10011-1, minimum criteria are required to qualify auditors.

This part of ISO 10011 describes these minimum criteria.

It also provides the method by which individual potential auditor's compliance to the criteria should be judged and maintained. This information is contained in annex A, which is an integral part of this part of ISO 10011. Annex B contains information on national auditor certification but is not an integral part of this part of ISO 10011.

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Guidelines for auditing quality systems —

Part 2:

Qualification criteria for quality systems auditors

1 Scope

This part of ISO 10011 gives guidance on qualification criteria for auditors.

It is applicable in the selection of auditors to perform quality systems audits as recommended in ISO 10011-1.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this part of ISO 10011. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this part of ISO 10011 are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 8402:1986, *Quality — Vocabulary*.

ISO 10011-1:1990, *Guidelines for auditing quality systems — Part 1: Auditing*.

ISO 10011-3:1991, *Guidelines for auditing quality systems — Part 3: Management of audit programmes*.

3 Definitions

For the purposes of this part of ISO 10011, the definitions given in ISO 8402 and ISO 10011-1 apply.

4 Education

Auditor candidates should have completed at least secondary education, that is, that part of the national educational system that comes after the primary or elementary stage but prior to that which qualifies for a degree, or as otherwise determined by the evaluation panel described in annex A. Candidates should have demonstrated competence in clearly and fluently expressing concepts and ideas orally and in writing in their officially recognised language.

5 Training

Auditor candidates should have undergone training to the extent necessary to ensure their competence in the skills required for carrying out audits, and for managing audits. Training in the following areas should be regarded as particularly relevant:

- knowledge and understanding of the standards against which quality systems audits may be performed;
- assessment techniques of examining, questioning, evaluating and reporting;
- additional skills required for managing an audit, such as planning, organizing, communicating and directing.

Such competence should be demonstrated through written or oral examinations, or other acceptable means.

6 Experience

Auditor candidates should have a minimum of four years' full-time appropriate practical workplace experience (not including training), at least two years of which should have been in quality assurance activities.

Prior to assuming responsibility for performing audits as an auditor, the candidate should have gained experience in the entire audit process as described in ISO 10011-1. This experience should have been gained by participating in a minimum of four audits, for a total of at least 20 days, including documentation review, actual audit activities and audit reporting.

All relevant experience should be reasonably current.

7 Personal attributes

Auditor candidates should be open-minded and mature; possess sound judgement, analytical skills and tenacity; have the ability to perceive situations in a realistic way, to understand complex operations from a broad perspective, and to understand the role of individual units within the overall organization.

The auditor should be able to apply these attributes in order to

- obtain and assess objective evidence fairly;
- remain true to the purpose of the audit without fear or favour;
- evaluate constantly the effects of audit observations and personal interactions during an audit;
- treat concerned personnel in a way that will best achieve the audit purpose;
- react with sensitivity to the national conventions of the country in which the audit is performed;
- perform the audit process without deviating due to distractions;
- commit full attention and support to the audit process;
- react effectively in stressful situations;
- arrive at generally acceptable conclusions based on audit observations;
- remain true to a conclusion despite pressure to change that is not based on evidence.

8 Management capabilities

Auditor candidates should demonstrate through suitable means their knowledge of, and capability of using, the necessary management skills required in the execution of an audit as recommended in ISO 10011-1.

9 Maintenance of competence

Auditors should maintain their competence by

- ensuring that their knowledge of quality systems standards and requirements is current;
- ensuring that their knowledge of auditing procedures and methods is current;
- participating in refresher training where necessary;
- having their performance reviewed at least every three years by an evaluation panel (see annex A).

These measures should ensure that the auditor continues to meet all the requirements of this part of ISO 10011. Auditor reviews should take into account any additional information, positive or negative, developed subsequent to the previous review.

10 Language

No audit personnel should participate in unsupported audits where they are not fluent in the agreed language of the audit. Support in these terms means the audit personnel have at all times available to them a person with the necessary technical language skills, who is not subject to pressures that would affect the performance of the audit.

11 Selection of lead auditor

The lead auditor for a specific audit should be selected by audit programme management from qualified auditors using the factors described in ISO 10011-3, taking into account the following additional criteria:

- the candidates should have acted as qualified auditors in at least three complete audits performed in accordance with the recommendations given in ISO 10011-1;
- the candidates should have demonstrated the capability to communicate effectively both orally and in writing in the agreed language of the audit.

Annex A (normative)

Evaluating auditor candidates

A.1 General

This annex is an integral part of this part of ISO 10011 and provides methods for judging auditor candidates against the criteria defined therein.

A.2 Evaluation panel

A key tool in the implementation of this part of ISO 10011 is the formation and operation of an evaluation panel, that may be internal or external to the auditee, whose main purpose is to evaluate the qualifications of auditor candidates.

This panel should be chaired by an individual currently active in managing significant auditing operations, who has met the auditor qualification recommendations given in this part of ISO 10011, and who is acceptable to a majority of other members of the panel and to the management of the organization responsible for the activities of the panel. The panel should include representatives from other areas with current and informed knowledge of the audit process. These should include clients who require audit reports, and auditees who have been subjects of regular audits of a substantial nature.

Methods of selecting specific members of the panel are dependent on the type of anticipated audit activity, such as:

- Internal audits: panel members should be selected by the organization's management.
- Customer audits: panel members should be selected by the customer unless otherwise agreed.
- Independent third party audits: panel members should be selected by the board of management of a national certification scheme or equivalent.

An evaluation panel should consist of not less than two members.

Evaluation panels should operate under defined rules with procedures that are designed to ensure that the selection process is not arbitrary, that it maintains the criteria established in this part of ISO 10011 and is not susceptible to a conflict of interest.

A.3 Evaluations

A.3.1 Education and training

There should be evidence to show that the candidate has acquired the necessary knowledge and skills to carry out and manage audits. This may take the form of an examination administered by a National Certification Body, or other appropriate means acceptable to the evaluation panel.

In evaluating auditor candidates, the panel should also make use of

- interviews with candidates;
- examinations;
- candidates' written work.

A.3.2 Experience

The panel should satisfy itself that the experience claimed by a candidate has actually been achieved and has been gained within an acceptable time frame.

A.3.3 Personal attributes

The panel should use techniques such as

- interviews with candidates;
- discussions with former employers, colleagues, etc.;
- structured testing for appropriate characteristics;
- role playing;
- observations under actual audit conditions.

A.3.4 Management capabilities

The panel should use techniques such as

- interviews with candidates;
- discussions with former employers, colleagues, etc.;
- structured testing for appropriate characteristics;

- role playing;
- observations under actual audit conditions;
- reviewing records of training and related examinations.

A.3.5 Maintenance of competence

The evaluation panel should periodically review auditor performance, taking into account audit programme

management's assessment of performance. Any re-evaluation of auditor certification arising from these reviews should be carried out by the evaluation panel.

A.3.6 Panel decisions

The evaluation panel should only approve or disapprove the proposed candidates. Review of auditor performance should also result only in approval or disapproval. Decisions should be documented and communicated to the candidates.

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Annex B (informative)

National auditor certification

B.1 General

This annex contains information on national auditor certification but is not an integral part of this part of ISO 10011.

B.2 National certification

Countries may wish to establish their own national body responsible for ensuring that auditors are evaluated in a competent and consistent manner. This body could certify auditors directly and/or accredit other organizations who in turn certify auditors. Such auditor certification should be carried out using the criteria contained in this part of ISO 10011.

The national body should be composed of individuals who meet the requirements of the evaluation panel (see annex A). Those who meet these criteria may

need to be selected from different geographical locations within the country (to facilitate interviewing candidates from various regions), and should represent a sufficient variety of organizations to assure that the significant, knowledgeable viewpoints are represented.

The national body should establish a mechanism to permit the prompt removal of certification from auditors who do not conduct themselves in a proper, professional and ethical manner. This mechanism should include a fair and open appeal procedure. This may be assisted by requiring prospective auditors to sign an appropriate code of ethics as a condition of certification.

Unsatisfactory performance should lead either to loss of certification or to participation in training activities which result in bringing the auditor's performance up to an acceptable level.

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