भारतीय मानक

गुणता तंत्र संपरीक्षण की मार्गदर्शिका

भाग 3 संपरीक्षण कार्यक्रम का प्रबंध

Indian Standard

GUIDELINES FOR AUDITING QUALITY SYSTEMS

PART 3 MANAGEMENT OF AUDIT PROGRAMMES

(First Reprint JUNE 1992)

UDC 658·562

BUREAU OF INDIAN STANDARDS
MANAK BHAVAN, 9 BAHADUR SHAH ZAFAR MARG
NEW DELHI 110002

Indian Standard

GUIDELINES FOR AUDITING QUALITY SYSTEMS

PART 3 MANAGEMENT OF AUDIT PROGRAMMES

NATIONAL FOREWORD

This Indian Standard which is identical with ISO 10011-3 : 1991 'Guidelines for auditing quality systems — Part 3 : Management of audit programmes', issued by the International Organization for Standardization (ISO) was adopted by the Bureau of Indian Standards on the recommendation of the Quality Management Sectional Committee (MSD 2), and approval of the Management and Systems Division Council.

The text of the ISO Standard has been approved as suitable for publication as Indian Standard without deviations. Certain conventions are, however, not identical to those used in Indian Standards. Attention is particularly drawn to the following:

Wherever the words 'International Standard' appear referring to this standard, they should be read as 'Indian Standard'.

In the adopted standard, normative reference appears to certain International Standards for which Indian Standards also exist. The corresponding Indian Standards which are to be substituted in their place are listed below alongwith their degree of equivalence for the editions indicated:

International Standard	*Corresponding Indian Standard*	*Degree of Equivalence*
ISO 8402 : 1986	IS 13999 : 1988 Quality systems — Vocabulary	Identical
ISO 10011 - 1 : 1990	IS 14011 (Part 1) : 1991 Guidelines for auditing quality systems : Part 1 Auditing	Identical
ISO 10011 - 2 : 1991	IS 14011 (Part 2) : 1991 Guidelines for auditing quality systems : Part 2 Qualification criteria for quality systems auditors	Identical

Introduction

Any organization which has an ongoing need to carry out audits of quality systems should establish a capability to provide overall management of the entire process.

This part of ISO 10011 describes the activities that should be addressed by such an organization.

1 Scope

This part of ISO 10011 gives basic guidelines for managing quality systems audit programmes.

It is applicable to the establishment and maintenance of an audit programme management function when performing quality systems audits in accordance with the recommendations given 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 10011-2:1991, *Guidelines for auditing quality systems — Part 2 Qualification criteria for quality systems auditors*

3 Definitions

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

audit programme management: Organization, or function within an organization, given the responsibility to plan and carry out a programmed series of quality systems audits.

4 Managing an audit programme

4.1 Organization

Any organization which has an ongoing need to carry out audits of quality systems should establish a capability to provide overall management of the entire process. This function should be independent of direct responsibility for implementing the quality systems being audited.

4.2 Standards

Audit programme management should determine the quality system standards they may be expected to audit against and develop capabilities to enable them to audit effectively against such standards.

4.3 Qualification of staff

4.3.1 Audit programme management

Management of the audit programme should be carried out by those who have practical knowledge of quality audit procedures and practices.

4.3.2 Auditors

Audit programme management should employ auditors who comply with the recommendations given in ISO 10011-2. Such auditors should be approved by an evaluation panel, acceptable to audit programme management, which complies with the recommendations given in ISO 10011-2.

3

4.4 Suitability of team members

Audit programme management should consider the following factors when selecting auditors and lead auditors for particular assignments in order to ensure that the skills brought to each assignment are appropriate:

— the type of quality system standard against which the audit is to be conducted (for example, manufacturing, computer software or service standards);

— the type of service or product and its associated regulatory requirements (for example, health care, food, insurance, computers, instrumentation, nuclear devices);

— the need for professional qualifications or technical expertise in a particular discipline;

— the size and composition of the audit team;

— the need for skill in managing the team;

— the ability to make effective use of the skills of the various audit team members;

— the personal skills needed to deal with a particular auditee;

— the required language skills;

— the absence of any real or perceived conflict of interest;

— other relevant factors.

4.5 Monitoring and maintenance of auditor performance

4.5.1 Performance evaluations

Audit programme management should continually evaluate the performance of their auditors, either through observation of audits or other means. Such information should be used to improve auditor selection and performance and to identify unsuitable performance.

Audit programme management should make this information available to evaluation panels, where required.

4.5.2 Consistency of auditors

Audits conducted by different auditors should arrive at similar conclusions when the same operation is audited under the same conditions. Audit programme management should establish methods to measure and compare auditor performance to

achieve consistency among auditors. Such methods should include:

— auditor training workshops;

— auditor performance comparisons;

— reviews of audit reports;

— performance appraisals;

— rotation of auditors between audit teams.

4.5.3 Training

Audit programme management should regularly assess the training needs of auditors and take appropriate action to maintain and improve audit skills.

4.6 Operational factors

4.6.1 General

Audit programme management should consider the following factors and, where necessary, establish procedures to ensure that their staff can operate in a consistent manner and are adequately supported.

4.6.2 Commitment of resources

Procedures should be established to ensure that adequate resources are available to accomplish audit programme objectives.

4.6.3 Audit programme planning and scheduling

Procedures should be established for planning and scheduling the programme of audits.

4.6.4 Audit reporting

Audit report formats should be formalized to the extent practicable.

4.6.5 Corrective action follow-up

Procedures should be established to control corrective action follow-up, if audit programme management are requested to do so.

4.6.6 Confidentiality

Audit programme management should establish procedures to safeguard the confidentiality of any audit or auditor information that they may hold.

4.7 Joint audits

There may be instances when several auditing organizations cooperate to audit jointly a quality system. Where this is the case, agreement should be

reached on the specific responsibilities of each organization, particularly in regard to lead auditor authority, interfaces with the auditee, methods of operation and distribution of audit results before the audit commences.

4.8 Audit programme improvement

Audit programme management should establish a method of continuously improving the audit programme through feedback and recommendations from all parties concerned.

5 Code of ethics

Audit programme management should consider the need to include a code of ethics into the operation and management of the audit programmes.

AMENDMENT NO. 1 JULY 1996
TO
IS 14011 (Part 3) : 1991/ISO 10011-3 : 1991 GUIDELINES FOR AUDITING QUALITY SYSTEMS — PART 3 : MANAGEMENT OF AUDIT PROGRAMMES

[The designation of the standard IS 14011 (Part 3) : 1991/ISO 10011-3 : 1991 is replaced by IS/ISO 10011-3 : 1991. Wherever the designation IS 14011 (Part 3) : 1991/ISO 10011-3 : 1991 is occurring in the standard, it will be read as IS/ISO 10011-3 : 1991.]

(*Page* 1, *National Foreword*) — Substitute the following for the existing:

"NATIONAL FOREWORD

This Indian Standard which is identical with ISO 10011-3 : 1991 'Guidelines for auditing quality systems — Part 3 : Management of audit programme', issued by the International Organization for Standardization (ISO), was adopted by the Bureau of Indian Standards on the recommendation of the Quality Management Sectional Committee (MSD 2), and approval of the Management and Systems Division Council.

The text of the ISO Standard has been approved as suitable for publication as Indian Standard without deviations. Certain conventions are, however, not identical to those used in Indian Standards. Attention is particularly drawn to the following:

Wherever the words 'International Standard' appear referring to this standard, they should be read as 'Indian Standard'.

In the adopted standard normative references appears to certain International Standards for which Indian Standards also exist. The corresponding Indian Standards which are to be substituted in their place are listed below along with their degree of equivalence for the editions indicated:

International Standard	Corresponding Indian Standard	Degree of Equivalence
ISO 8402 : 1994	IS/ISO 8402 : 1994 Quality management and quality assurance — Vocabulary (*first revision*)	Identical
ISO 10011-1 : 1990	IS/ISO 10011-1 : 1990 Guidelines for auditing quality systems — Part 1 : Auditing	Identical
ISO 10011-2 : 1991	IS/ISO 10011-2 : 1991 Guidelines for auditing quality systems — Part 2 : Qualification criteria for quality systems auditors	Identical"

(MSD 02)