ECI Management Certification Services LLP

Medical Device Quality Management System

ISO 13485

ECI/P-17

Address

Office No. 708, 7th Floor, Rama Equator,
Next to City International School,
Morwadi Road, Pimpri, Pune - 411018,
Maharashtra, India.

Contents

1. PURPOSE

To describe the Impartiality required to be applied on the activities related to the operations of ECI.

2. SCOPE

The overall aim of third-party audit / assessment and certification is to give confidence to all parties that rely on audit / assessment and certification. The main principles for inspiring confidence are independence, impartiality and competence both in action and appearance. Impartiality and objectivity are basic prerequisites for an effective and consistent audit / assessment and certification activity.

This document only concerns itself with issues relating to the threats and safeguards to auditor independence and impartiality. This also covers our activities under the scope of branch offices, franchisees, agents and partnerships.

3. REFERENCES

- ISO/IEC 17021-1
- Quality Manual

4. RESPONSIBILITY

CEO, and all personnel of ECI.

5. PROCEDURE

The Impartiality committee is formed as per the requirement of the of the standards ISO/IEC 17021. The basic intent of forming the committee is to safeguard the impartiality along with the other interest of the organization.

The committee is formed with the following members

a) CEO
b) Operations Manager
c) Minimum Two of the following
   - Representative office bearer of the national level industrial organization.
   - Representative office bearer of the state level industrial organization.
   - Retired senior most gazetted departmental head from Government/Public limited Company.
   - Any administrative government officer of the rank of IAS or IPS.
   - Any Engineering Graduate with minimum 15 years of work experience in public sector units or in a unit with minimum 100 employee's strength.
   - A Registered Chartered Accountant
   - Manager of a Nationalized Bank
   - A Representative of Clients.
   - Development officer of Insurance Company.
   - Registered Lead Auditor with 15 years of experience.
   - Graduate Engineer with 5-8 years' experience & Lead auditor/ Consultant/ Clinical Investigator and has to a member of CC committee.

The invitations are given to all the interested members who wish to become the member of Impartiality committee. After receipt of the form and scrutiny by the top management the membership is confirmed and committee is formed.

The form of membership consists of the formal responsibility, authority and guidelines for the working of committee.

Once the committee is formed the formal introduction meeting is called and the purpose is explained to the members. Any suggestions on the policies decided are asked to submit. If the procedure /policies are acceptable to the members it is finalised.

The appointment of the committee is for next three years from the date of establishment. For replacement of any member ECI has decided to take consent from the members of committee either in meeting or through e-mail in case of meeting is not possible.

The Impartiality committee is meeting in the month of June every year. But the meeting can be called in-between if required by the Top management of the ECI. The meeting will be conducted at ECI Pune office or the Venue as decided by the ECI. The notice is issued two weeks in advance to every committee member to plan their schedule.
In some such as time limits cases, meeting can be completed online module.

ECI's commitment to impartiality

- The organizational structure and procedures of ECI employing the auditors are able to demonstrate how the primary requirement of IMPARTIALITY is fulfilled.
- ECI demonstrates, by means of policies, procedures and training how it deals with the pressures and other factors that can compromise or can reasonably be expected to compromise an auditor's objectivity and which may arise from a wide variety of activities, relationships, and other circumstances as well as from various personal qualities and characteristics of auditors that may be sources of bias.

Threats to auditor impartiality

Threats to auditor impartiality are sources of potential bias that may compromise, or may reasonably be expected to compromise, an auditor's ability to make unbiased audit observations and conclusions.

Threats are posed by various types of activities, relationships and other circumstances. In order to understand the nature of those threats and their potential impact on auditor impartiality, ECI has identified the types of threats posed by specific activities, relationships or other circumstances. The following list provides examples of the types of threats that may create pressures and other factors that can lead to biased audit behaviour.

Although the list may not be exhaustive, however, it illustrates the wide variety of types of threats that ECI needs to consider when analyzing auditor independence and impartiality issues.

Self-interest threats

Threats arise from auditors acting in their own interest. Self-interests include auditors' emotional, financial, or other personal interests. Auditors may favour, consciously or subconsciously, those self interests over their interest in performing a management system audit. For example, ECI relationships with clients create a financial self-interest because the clients pay the ECI fees. Auditors also have a financial self-interest if they own shares in an auditee's organization and may have an emotional or financial self-interest if an employment relationship existed between auditor and the client in past.

Self-review threats

Threats arise from auditors reviewing the work done by themselves or by their colleagues. It may be more difficult to evaluate without bias the work of one's own organization than the work of someone else or of some other organization. Therefore, a self-review threat may arise when auditors review judgments and decisions they, or others in their organization, have made.

Familiarity (or trust) threats

Threats arise from auditors being influenced by a close relationship with an auditee. Such a threat is present if auditors are not sufficiently skeptical of an auditee's assertions and, as a result, too readily accept an auditee's viewpoint because of their familiarity with or trust in the auditee. For example, a

familiarity threat may arise when an auditor has a particularly close or long-standing personal or professional relationship with an auditee.

Intimidation threats
Threats that arise from auditors being, or believing that they are being, openly or secretly coerced by auditees or by other interested parties. Such a threat may arise, for example, if an auditor or ECI is threatened with replacement over a disagreement with an auditee's application of a specific requirement of the normative document being used as the reference for the audit.

Safeguards to impartiality
ECI has in place the safeguards that mitigate or eliminate threats to auditor impartiality. Safeguards include prohibitions, restrictions, disclosures, policies, procedures, practices, standards, rules, institutional arrangements, and environmental conditions. These are regularly reviewed to ensure their continuing applicability.

NOTE 1 Safeguards exist in the environment in which audits are performed or can be mandated by independent decision-makers in response to threats posed by various activities, relationships, and other circumstances. One way in which safeguards can be described is by where they reside.

Examples of safeguards that exist in the environment in which audits / assessments are performed include:

- The value ECI and individual auditors place on their reputations;
- Accreditation programmes for ECI that assess organization-wide compliance with professional standards and regulatory requirements regarding impartiality;
- General oversight by ECI committee and governance structures
- Rules, standards, and codes of professional conduct governing auditors' behaviour;
- The raising of sanctions, and the possibility of such actions, by accreditation bodies and others; and
- The legal liability faced by certification bodies.

Examples of safeguards that exist within Certification Bodies / Notified Bodies as part of ECI's management system include:

- Maintaining a culture in ECI that stresses the expectation that auditors will act in the wider interest and the importance of good audits and auditor impartiality;
- Maintaining a professional environment and culture in ECI that supports behaviour of all personnel that is consistent with auditor impartiality;
- Management systems that include policies, procedures, and practices directly related to maintaining auditor impartiality;
- Other policies, procedures, and practices, such as those concerning the rotation of staff, internal audit, and requirements for internal consultation on technical issues; and
- Personnel hiring, training, promotion, retention, and reward policies, procedures, and practices that emphasize the importance of auditor impartiality, the potential threats posed by various circumstances that auditors in ECI may face, and the need for Auditors to evaluate their impartiality with respect to a specific client after considering safeguards in place to mitigate or eliminate those threats.

Another way of describing safeguards is by their nature. Examples include:

- Safeguards that are preventive — for example, an induction programme for newly hired auditors that emphasizes the importance of impartiality;
- Safeguards that relate to threats arising in specific circumstances — for example, prohibitions against certain employment relationships between auditors' family members and the ECI's clients and;

- Safeguards whose effects are to deter violations of other safeguards by punishing violators in terms of taking suitable actions e.g discontinuation of services.

An alternate way in which safeguards can be described is by the extent to which they restrict activities or relationships that are considered threats to auditor impartiality, such as prohibiting auditors from providing consultancy to the clients they are auditing.

In assessing the impartiality of its Auditors, ECI considers:

- the pressures and other factors that might result in, or might reasonably be expected to result in, biased audit behaviour — here described as threats to auditor impartiality;
- the controls that may reduce or eliminate the effects of those pressures and other factors — here described as safeguards to auditor impartiality;
- the significance of those pressures and other factors and the effectiveness of those controls; and
- the likelihood that pressures and other factors, after considering the effectiveness of controls, will reach a level where they compromise, or may reasonably be expected to compromise, an auditor's ability to maintain an unbiased audit behaviour.

Assessing the level of impartiality risk

ECI assesses the level of impartiality risk by considering the types and significance of threats to auditor impartiality and the types and effectiveness of safeguards. This basic principle describes a process by which ECI identifies and assesses the level of impartiality risk that arises from various activities, relationships, or other circumstances.

NOTE 1 The level of impartiality risk can be expressed as a point on a continuum that ranges from "no risk" to "maximum risk." One way to describe those endpoints, the segments of the impartiality risk continuum that fall between those endpoints, and the likelihood of compromised objectivity to which the endpoints and segments correspond, is as follows:

Table 1 — Level of impartiality risk

No Risk	Remote risk	Some risk	High risk	Maximum risk
Compromised objectivity is virtually impossible	Compromised objectivity is very unlikely	Compromised objectivity is possible	Compromised objectivity is probable	Compromised objectivity is virtually certain

Increasing likelihood of compromised objectivity →

NOTE 2 Although it cannot be measured precisely, the level of risk for any specific activity, relationship, or other circumstance that may pose a threat to auditor impartiality can be described as being in one of the segments, or at one of the endpoints, on the impartiality risk continuum.

Determining the acceptability of the level of impartiality risk

ECI determines whether the level of impartiality risk is at an acceptable position on the impartiality risk continuum. ECI evaluates the acceptability of the level of impartiality risk that arises from specific activities, relationships, and other circumstances. The evaluation requires ECI to judge whether safeguards eliminate or adequately mitigate threats to auditor impartiality posed by those activities, relationships, or other circumstances. If they do not, ECI decides about additional safeguards (including prohibition) or combination of safeguards would reduce the risk, and the corresponding likelihood of compromised objectivity, to an acceptably low level.

Some threats to auditor impartiality may affect only certain individuals or groups within ECI, and the significance of some threats may be different for different individuals or groups. To ensure that the risk is at an acceptably low level, ECI identifies the individuals or groups affected by threats to impartiality and the significance of those threats. Different types of safeguards may be appropriate for different

individuals and groups depending on their roles in the audit.

Organizational and structural issues

In addition to the aspects outlined above, auditor impartiality needs to be further protected by placing it within an organizational structure, which will guarantee that the safeguards required are implemented. The organizational structure should be such that ECI can demonstrate its impartiality to an informed and disinterested third party. ECI for this matter has established a committee for safeguarding impartiality.

The structure and organization of the ECI chosen to meet these objectives is transparent and supports the development and the application of the processes necessary to meet the above objectives. These processes include:

- understanding the needs and expectations of customers and other stakeholders;
- establishing the policy and objectives of the organization;
- determining the processes and responsibilities necessary to attain the objectives;
- determining and providing the infrastructure and resources necessary to attain the objectives;
- establishing and applying methods to determine the efficiency and effectiveness of each process;
- the identification of potential conflict of interest at the level of both the organization and the individual, and the means of identifying it and dealing with it;
- determining means of preventing nonconformities and eliminating their causes; and
- establishing and applying a process for continual improvement of the above processes.

Other Responsibilities

- When the CEO of the company is involved in the Complaint or Appeal received from the client where he was participated as certification personnel or Auditor the Impartiality team will take decision on that file in cooperation with the Company designee.

6. RECORDS

- Public Statement for Impartiality (ECI/F-25)
- Risk Assessment and Mitigation Plan for Financial Liability (ECI/F-26)
- Risk Assessment & Mitigation Plan for 3rd Party Audit & Cert Activity (ECI/F-27)
- Risks and Opportunities that may Impact Audit Assessment (ECI/F-27A)
- Mitigation Plan to cover Liabilities (ECI/F-28)

7. REVISION HISTORY

Rev. No.	Effective Date	Details
00	01.01.2025	Initial Issue
01	10.11.2025	Change in the Company Name