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|  | DI Quality Certification Services Private Limited | Document no. | D-MMS-S-0001 |
|   | Management of Impartiality                        | Rev. No      | 02           |
|   |   | Date         | 05-09-2024   |

**DI Quality Certification Services Private Limited** *(hereinafter referred as DI QCS)*

**“Management of Impartiality”**

*(Clause 4.2 and 5.2 of ISO/IEC 17021-1: 2015)*

| Process Description    | Designation          | Name        | Signature   |
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### Revision History

| Sr. No. | REVISION NO. | CRN NO.        | EFFECTIVE DATE | REASON FOR CHANGE   | AUTHORIZED BY       |
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| 1       | 00           | Not Applicable | 15-02-2022     | Initial Release   | Document Controller |
| 2       | 01           | CRN/24/04      | 26-08-2024     | The document is updated for revised Roles & Responsibility of Director, Technical & Operations head | Document Controller |
| 3       | 02           | CRN/24/05      | 05-09-2024     | DI QCS new logo updated   | Document Controller |
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## 1. Purpose

To identify, analyse, evaluate, treat, monitor and document the risks related to conflict of interests arising from provision of certification, including any conflicts arising on an ongoing basis from its relationships. This document describes the procedure for management of impartiality in all the certification activities at DI QCS.

## 2. Scope

This procedure is applicable for managing impartiality, conflict of interests and risks associated with the certification process at DI QCS.

## 3. Responsibility

- 3.1 Top Management
- 3.2 Impartiality Committee
- 3.3 All employees involved in certification process

## 4. Definitions/Abbreviations

- 4.1 Impartiality: Presence of objectivity
- 4.2 Refer D-MMS-G-001 for Definitions

## 5. References

- 5.1 ISO/IEC 17000:2020 Conformity assessment — Vocabulary and general principles
- 5.2 ISO/IEC 17021-1: 2015 Conformity assessment — Requirements for bodies providing audit and certification of management systems — Part 1: Requirements

## 6. Procedure

### 6.1 Impartiality Policy

- 6.1.1 Being impartial, and being perceived to be impartial, is necessary for DI QCS to deliver certification that provides confidence. All internal and external personnel associated with DI QCS shall be made aware of the need for impartiality.
- 6.1.2 Conformity assessment activities undertaken by DI QCS shall be impartial. DI QCS is responsible for the impartiality of its conformity assessment activities and shall not allow commercial, financial or other pressures to compromise impartiality.
- 6.1.3 Our top management is committed to impartiality in management system certification activities. DI QCS has established a policy that, it understands the importance of impartiality in carrying out its management system certification activities, manages conflict of interest and ensures the objectivity of its management system certification activities.

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Refer D-MMS-P-0002 Policy Manual.

## 6.2 Threats to Impartiality

**6.2.1 Self-interest:** threats that arise from a person or body acting in their own interest. A concern related to certification, as a threat to impartiality, is financial self-interest.

At DI QCS threats to impartiality may arise from employee acting in their own interest. Self-interests include DI QCS employees' emotional, financial, or other personal interests. DI QCS employee may favour, consciously or subconsciously, those self-interests over the interest of performing the process of management system certification.

For example,

- DI QCS's relationship with its clients creates a financial self-interest, because the clients pay DI QCS for the auditing and certification services.
- DI QCS employees may also have a financial self-interest if they own shares in an auditee's organization and may have an emotional self-interest if there existed a past employment relationship between that employee and the client.

**6.2.2 Self-review:** threats that arise from a person or body reviewing the work done by themselves.

For example,

- An empanelled auditor at DI QCS auditing the management system of a client to whom he/she has provided management system consultancy.
- Auditing the management system of a client to whom DI QCS has provided internal auditing services.
- An employee at DI QCS taking part in certification decision, who was involved in Application review/ auditing activity for that client.

**6.2.3 Familiarity (or trust):** threats that arise from a person or body being too familiar with or trusting of another person instead of seeking audit evidence.

For example,

- A familiarity threat may arise at DI QCS when its employee has a particularly close or long-standing personal or professional relationship with an auditee/client personnel.

**6.2.4 Intimidation:** threats that arise from a person or body having a perception of being coerced openly or secretly, such as a threat to be replaced or reported to a supervisor.

For example,

If an employee from DI QCS is bothered about his replacement over a disagreement with an auditee/client employee, regarding a specific requirement in the normative document being used as the reference for the audit, then it is a threat arising due to intimidation.

## 6.3 Safeguards to impartiality

**6.3.1** DI QCS has established this procedure to safeguard impartiality which mitigates or eliminates threats to impartiality arising during the certification activities.

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- 6.3.2** Safeguarding includes prohibitions, restrictions, disclosures, policies, procedures, practices, standards, rules, institutional arrangements, and environmental conditions. These are regularly reviewed to ensure their continuing applicability.
- 6.3.3** Safeguards exists in the environment where 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.
- 6.3.4** DI QCS shall not certify another certification body for its quality management system.
- 6.3.5** DI QCS and any part of the same legal entity and any entity under the organizational control of DI QCS shall not offer or provide management system consultancy. This also applies to that part of government identified as the certification body DI QCS

NOTE: This does not preclude the possibility of exchange of information (e.g. explanation of findings or clarification of requirements) between the DI QCS and its clients.

- 6.3.6** The carrying out of internal audits by DI QCS and any part of the same legal entity to its certified clients is a significant threat to impartiality. Therefore, DI QCS and any part of the same legal entity and any entity under the organizational control of the DI QCS shall not offer or provide internal audits to its certified clients.
- 6.3.7** A recognized mitigation of this threat is that DI QCS shall not certify a management system to which it provided internal audits for a minimum of two years following the completion of internal audits.
- 6.3.8** Where a client has received management system consultancy from a body/individual that has a relationship with DI QCS, this is a significant threat to impartiality. A recognized mitigation of this threat is that DI QCS shall not certify the management system for a minimum of two years following the end of consultancy.
- 6.3.9** DI QCS shall not outsource audits to a management system consultancy organization, as this poses an unacceptable threat to the impartiality of DI QCS This does not apply to individuals contracted as auditors covered in clause 7.3 of Quality Manual.
- 6.3.10** DI QCS's activities shall not be marketed or offered as a link along with the activities of an organization that provides management system consultancy. DI QCS shall take action to correct inappropriate links or statements by any consultancy organization stating or implying that certification would be simpler, easier, faster or less expensive if services from DI QCS were used.
- 6.3.11** DI QCS shall not state or imply that certification would be simpler, easier, faster or less expensive if a specified consultancy organization were used.
- 6.3.12** In order to ensure that there is no conflict of interests, personnel who have provided management system consultancy, including those acting in a managerial capacity, shall not be involved by DI QCS to take part in an audit or other certification activities if they have been involved in management system consultancy towards the client. A recognized mitigation of this threat is that personnel shall not be involved for a minimum of two years following the end of the consultancy.

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- 6.3.13** DI QCS shall take actions to respond to any threats to its impartiality arising from the actions of other persons, bodies or organizations.
- 6.3.14** All DI QCS personnel, either internal or external, or committees, who could influence the certification activities, shall act impartially and shall not allow commercial, financial or other pressures to compromise impartiality.
- 6.3.15** DI QCS shall require personnel, internal and external, to reveal any situations known to them that can present them or DI QCS with conflict of interests. DI QCS shall record and use this information as inputs in identifying threats to impartiality raised by the activities of such personnel or by the organizations that employ them, and shall not involve such personnel, internal or external, unless they can demonstrate that there is no conflict of interest.
- 6.3.16** The DI QCS and its auditors shall be impartial and free from engagements and influences which could affect their objectivity, and in particular shall not be:
- involved in the design, manufacture, construction, marketing, installation, servicing or supply of the medical device, or any associated parts and services
  - involved in the design, construction, implementation, or maintenance of the quality management system being audited
  - an authorized representative of the client organization, nor represent the parties engaged in these activities.

**6.4 Processes established by DI QCS for safeguarding Impartiality:**

- 6.4.1** Rules, standards, and codes of professional conduct governing DI QCS employee' behaviour to safeguard impartiality.
- 6.4.2** Maintaining a culture at DI QCS which imparts expectations that employees will act in wider interests and the importance of safeguarding impartiality.
- 6.4.3** Accreditation programmes for DI QCS that assess organization-wide compliance with professional standards and regulatory requirements regarding impartiality;
- 6.4.4** Be aware of the legal liability faced by DI QCS being a certification body
- 6.4.5** Maintaining a professional environment and culture at DI QCS which supports behaviour of all personnel that is consistent with auditor impartiality
- 6.4.6** Implementing management system that includes policies, procedures, and practices directly related to maintaining auditor impartiality
- 6.4.7** Implementing other policies, procedures, and practices, such as those concerning the rotation of staff, internal audit, and requirements for internal consultation regarding 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 the auditors at DI QCS may face, and the need for auditors to evaluate their impartiality with respect to a specific client after verifying that the safeguards are in place, to mitigate or eliminate those threats.
- 6.4.8** Assess and take preventive actions as safeguards that are preventive, for example, an induction programme for the newly hired auditors that emphasizes the importance of impartiality;

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**6.4.9** Assess and take preventive actions as safeguards that relate to threats arising in specific circumstances — for example, prohibitions against certain employment relationships between auditors’ family members and DI QCS’s clients and;

**6.4.10** Assess and take preventive actions as safeguards whose effects are to deter violations of other safeguards by punishing violators in terms of taking suitable actions e.g., discontinuation from services.

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

In assessing the impartiality of its auditors, DI QCS 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.

**6.5 Assessing the level of impartiality risk**

**6.5.1** DI QCS 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 DI QCS identifies and assesses the level of impartiality risks that arises from various activities, relationships, or other circumstances.

**6.5.2** 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:

| <b>No risk</b>                                  | <b>Remote risk</b>                       | <b>Some risk</b>                    | <b>High risk</b>                    | <b>Maximum risk</b>                          |
|---|--|-------------------------------------|-------------------------------------|--|
| Compromised objectivity is virtually impossible | Compromised objectivity is very unlikely | Compromised objectivity is possible | Compromised objectivity is probable | Compromised objectivity is virtually certain |

**6.5.3 Increasing likelihood of compromised objectivity**

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

**6.5.4 Determining the acceptability of the level of impartiality risk**



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

Some threats to the auditor impartiality may affect only certain individuals or groups within DI QCS, 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, DI QCS 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.

### 6.5.5 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 DI QCS can demonstrate its impartiality to an informed and disinterested third party. DI QCS for this matter has established a committee for safeguarding impartiality.

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

- understanding the needs and expectations of clients 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
- identification of potential conflict of interests 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.

## 7. Associated Procedures/Documents/Formats



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- 7.1 Procedure for the operation of ‘Committee For Safeguarding Impartiality’ (D-MMS-S-0026)
- 7.2 CFSI Meeting Agenda (F-0026-01)
- 7.3 List of CFSI Members (F-0026-02)
- 7.4 CFSI Minutes of Meeting (F-0026-03)
- 7.5 Declaration of Independence and Confidentiality Agreement (F-0026-04)
- 7.6 Policy manual (D-MMS-P-0002)
- 7.7 Risk Assessment and Mitigation (D-MMS-S-0002)
- 7.8 Risk Assessment Report (D-MMS-G-0009)