



**Dutch Institute of Quality
Certifications**

Management of Impartiality

Document no.

D-MMS-S-0001

Rev. No

01



Date

18-04-2023

Dutch Institute of Quality Certifications *(hereinafter referred as DIQC B.V.)*

“Management of Impartiality”

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

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Revision History

Sr. No.	REVISION NO.	CRN NO.	EFFECTIVE DATE	REASON FOR CHANGE	AUTHORIZED BY
1	00	Not Applicable	15-07-2021	Initial Release	Operations Director
2	01	CRN/23/01	18-04-2023	The procedure is updated in-line with comments raised in RvA Pre-assessment. -Section 5 updated for IAF MD9: 2022 reference. -Section 6.2.5 updated as per requirements of IAF MD9: 2022 MD 5.2.3 -Section 7 is updated	Operations Director



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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 DIQC B.V.

2. Scope

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

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
- 5.3 IAF MD 9: 2022 Application of ISO/IEC 17021-1 in the Field of Medical Device Quality Management Systems (ISO 13485)

6. Procedure

6.1 Impartiality Policy

- 6.1.1 Being impartial, and being perceived to be impartial, is necessary for DIQC B.V. to deliver certification that provides confidence. All internal and external personnel associated with DIQC B.V. shall be made aware of the need for impartiality.
- 6.1.2 Conformity assessment activities undertaken by DIQC B.V. shall be impartial. DIQC B.V. 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. DIQC B.V. 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.

Refer D-MMS-P-0002 Policy Manual.

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

For example,

- DIQC B.V.'s relationship with its clients creates a financial self-interest, because the clients pay DIQC B.V. for the auditing and certification services.
- DIQC B.V. 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 DIQC B.V. 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 DIQC B.V. has provided internal auditing services.
- An employee at DIQC B.V. 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 DIQC B.V. 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 DIQC B.V. 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.

6.2.5 Threats related to individuals involved in certification process:

The DIQC B.V. and its auditors (employed and external) will be impartial and free from engagements and influences which could affect their objectivity, and will not be:

a) involved in the design, manufacture, construction, marketing, installation, servicing or supply of the medical device, or any associated parts and services

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b) involved in the design, construction, implementation, or maintenance of the quality management system being audited

c) an authorized representative of the client organization, nor represent the parties engaged in these activities

To mitigate these risks DIQC B.V. has implemented checkpoints as below;

1. Every personnel working with DIQC B.V. will provide a declaration related to his/her involvement in any other entities (if any)
2. Every personnel will sign a service agreement (F-0003-08) and Confidentiality and Non-Conflict of Interest Statement (F-0003-07).
3. Any person involved with DIQC B.V.'s client management system (employment, consultant, internal auditor etc.) will not be used for that client's certification process minimum of two years following the end of that activity.
4. The auditors and technical experts will provide declaration for every nominated assignment in Auditor Nomination (F-0009-04)

6.3 Safeguards to impartiality

6.3.1 DIQC B.V. has established this procedure to safeguard impartiality which mitigates or eliminates threats to impartiality arising during the certification activities.

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 DIQC B.V. shall not certify another certification body for its quality management system.

6.3.5 DIQC B.V. and any part of the same legal entity and any entity under the organizational control of DIQC B.V. shall not offer or provide management system consultancy. This also applies to that part of government identified as the certification body DIQC B.V.

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

6.3.6 The carrying out of internal audits by DIQC B.V. and any part of the same legal entity to its certified clients is a significant threat to impartiality. Therefore, DIQC B.V. and any part of the same legal entity and any entity under the organizational control of the DIQC B.V. shall not offer or provide internal audits to its certified clients.

6.3.7 A recognized mitigation of this threat is that DIQC B.V. 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 DIQC B.V., this is a significant threat to impartiality. A



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recognized mitigation of this threat is that DIQC B.V. shall not certify the management system for a minimum of two years following the end of consultancy.

- 6.3.9** DIQC B.V. shall not outsource audits to a management system consultancy organization, as this poses an unacceptable threat to the impartiality of DIQC B.V. This does not apply to individuals contracted as auditors covered in clause 7.3 of Quality Manual.
- 6.3.10** DIQC B.V.'s activities shall not be marketed or offered as a link along with the activities of an organization that provides management system consultancy. DIQC B.V. 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 DIQC B.V. were used.
- 6.3.11** DIQC B.V. 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 DIQC B.V. 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.
- 6.3.13** DIQC B.V. 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 DIQC B.V. 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** DIQC B.V. shall require personnel, internal and external, to reveal any situations known to them that can present them or DIQC B.V. with conflict of interests. DIQC B.V. 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 DIQC B.V. and its auditors shall be impartial and free from engagements and influences which could affect their objectivity, and in particular shall not be:
- a) involved in the design, manufacture, construction, marketing, installation, servicing or supply of the medical device, or any associated parts and services
 - b) involved in the design, construction, implementation, or maintenance of the quality management system being audited
 - c) an authorized representative of the client organization, nor represent the parties engaged in these activities.
- 6.4 Processes established by DIQC B.V. for safeguarding Impartiality:**
- 6.4.1** Rules, standards, and codes of professional conduct governing DIQC B.V. employee' behaviour to safeguard impartiality.
- 6.4.2** Maintaining a culture at DIQC B.V. which imparts expectations that employees will act in wider interests and the importance of safeguarding impartiality.

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- 6.4.3 Accreditation programmes for DIQC B.V. that assess organization-wide compliance with professional standards and regulatory requirements regarding impartiality;
- 6.4.4 Be aware of the legal liability faced by DIQC B.V. being a certification body
- 6.4.5 Maintaining a professional environment and culture at DIQC B.V. 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 DIQC B.V. 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;
- 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 DIQC B.V.’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, DIQC B.V. 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 DIQC B.V. 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 DIQC B.V. identifies and assesses the level of



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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:

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

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

DIQC B.V. determines whether the level of impartiality risk is at an acceptable position on the impartiality risk continuum. DIQC B.V. evaluates the acceptability of the level of impartiality risk that arises from specific activities, relationships, and other circumstances. The evaluation requires DIQC B.V. 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, DIQC B.V. 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 DIQC B.V., 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, DIQC B.V. 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 DIQC B.V. can demonstrate its impartiality to an informed and disinterested third party. DIQC B.V. for this matter has established a committee for safeguarding impartiality.

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The structure and organization of DIQC B.V. 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

- 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)
- 7.9 Service Agreement for audit personnel (F-0003-08)
- 7.10 Service Agreement certification personnel (F-0003-09)
- 7.11 Confidentiality and Non-Conflict of Interest Statement (F-0003-07)
- 7.12 Auditor Nomination (F-0009-04)