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

"Appeal and Complaint Handling"

(Clause 9.7 & 9.8 of ISO/IEC 17021-1: 2015)

Process Description	Name	Signature
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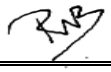
Reviewed & Approved by	Ranjit Rajemahadik	

Revision History

Sr. No.	REVISION NO.	CRN NO.	EFFECTIVE DATE	REASON FOR CHANGE	AUTHORIZED BY
1	00	Not Applicable	15-07-2021	Initial Release	Document Controller
2	01	CRN/23/01	18-04-2023	Review done as per current applicable requirements. -The procedure is updated for references as per organization structure.	Document Controller

1. Purpose

To document and apply procedure for appeal and complaint handling.

2. Scope

This procedure is applicable for all appeals and complaints raised by any interested party.

3. Responsibility

3.1 Director Operations
3.2 CFSI Chairperson

4. Definitions/Abbreviations

4.1 Appeal

Request by the person or organization that provides, or that is, the object of conformity assessment to a conformity assessment body for reconsideration by that body of a decision it has made relating to that object

4.2 Complaint

Expression of dissatisfaction, other than appeal by any person or organization to a conformity assessment body, relating to the activities of that body, where a response is expected.

4.3 CFSI

Committee For Safeguarding Impartiality

Refer 'D-MMS-G-0001 Definitions' for any further definitions.

5. References

5.1 ISO 9000:2015: Quality management systems — Fundamentals and vocabulary
5.2 ISO/IEC 17000:2020 Conformity assessment — Vocabulary and general principles
5.3 ISO/IEC 17021-1: 2015 Conformity assessment — Requirements for bodies providing audit and certification of management systems — Part 1: Requirements

6. Procedure

6.1 Appeal:

6.1.1 DIQC B.V. has documented this procedure to receive, evaluate and make decisions on appeals.
6.1.2 DIQC B.V. is responsible for all decisions at all levels of the appeals-handling process.
6.1.3 DIQC B.V. ensures that the persons engaged in the appeals-handling process are different from those who carried out the audits and made the certification decisions.
6.1.4 Submission, investigation and decision on appeals shall not result in any discriminatory actions against the appellant.
6.1.5 The appeals-handling process includes following elements and methods:

a) Process for receiving, validating and investigating the appeal, and for deciding what actions need to be taken in response to it, taking into account the results of previous similar appeals;
b) Tracking and recording appeals, including actions undertaken to resolve them;
c) Ensuring that any appropriate correction and corrective actions are taken.

6.1.6 A person or organization can log a written appeal with DIQC B.V. through www.diqc.nl website or they can directly write a mail to info@diqc.nl. A certified client or an applicant generally will log an appeal.

6.1.7 Once an appeal is received, it will be documented in Appeal and complaint log.

6.1.8 A unique number for the appeal shall be given as A/YY/XX. Where A-Appeal, YY-year Appeal logged, XX-Serial Number for appeal logged in particular year.

6.1.9 DIQC B.V. shall be responsible for gathering and verifying all necessary information to validate the appeal. This investigation/root cause analysis/correction/corrective action shall be documented in Appeal/Complaint report.

6.1.10 DIQC B.V. shall acknowledge receipt of the appeal within 2 working days and shall provide the appellant with progress reports and the result of the appeal.

6.1.11 The decision to be communicated to the appellant shall be made by, or reviewed and approved by, individual(s) not previously involved in the subject of the appeal.

6.1.12 DIQC B.V. shall give formal notice to the appellant of the end of the appeals handling process. The notice will consist of investigation, finding and correction and/or corrective action taken if any.

6.1.13 Based on the investigation, the Managing Director and/or CFSI Chairperson appointed for hearing the case shall take a final decision on the appeal and a formal notice of the outcome at the end of the appeal process shall be handed over to the appellant. Subsequently, the feedback is sought from the appellant.

Appeal Scenarios and their action plan:

6.1.14 **Notification of Decision not to Grant or Decision to Withdraw Registration**

6.1.14.1 The client shall be informed in writing of any decision made by the Certification Body to either deny certification or withdraw their registration in accordance with

6.1.14.2 Refusal to Issue certification - Decision made by the Certification Decision Maker not to grant certification to a client. Refusal to issue certificate may be based on either of the following situations:

- Results of initial assessment and/or review illustrate that the manufacturer has been issued 3 or more major nonconformities and the auditor has recommended full re-assessment, OR
- DIQC B.V. has rejected for the third time the responses given by the manufacturer to any nonconformity, OR
- The client has not responded to nonconformities within a specified period time after granting of extensions.

6.1.14.3 The notification shall state that the client is free to appeal this decision using the process described in DIQC's program requirements as specified in D-MMS-S-0007

MMS registration requirements, and that the client is free to lodge a formal appeal without concern of discrimination.

6.1.14.4 A refusal to issue a certificate cannot be issued while any dispute is ongoing, but may be issued regardless of whether a dispute is lodged or not or if the dispute was successful or not. It is sufficient that either of the 3 above criteria is established for the refusal to be issued.

6.1.14.5 The decision to refuse certification (or recertification) or to withdraw certification shall be communicated to the customer in writing by the Director Operations. In that communication the client shall be informed that the application for appeal must be made in English within 30 days of the date of the decision letter.

6.1.15 **Appeal review**

6.1.15.1 Any formal appeal should be immediately forwarded to the Director Operations. The Director Operations shall conduct an immediate review of the received documentation and determine whether the documentation is sufficient to lodge an appeal, namely:

- That it is in fact an appeal and not a complaint or dispute
- That it is signed by officer on letterhead,
- That justification is provided on specific requirements
- Is made within the required timeframe
- The appeal and all supporting information are in English
- If the appeal is valid then the Director Operations shall create a unique tracking number for the appeal.

6.1.15.2 The Director Operations shall write to the appellant and inform them of receipt of their documentation and that either that the appeals process has now been enacted providing them with the unique tracking number or inform them of the reasons why the appeals process may not proceed. If the appeal is valid the client should also be informed of the timeline for the decision of the appeal and that they are free to make enquiries on the progress at any time during the appeal process.

6.1.15.3 If the appeal is in fact a complaint then it shall be logged and actioned per section 6.2 of this procedure.

6.1.16 **Appeal Panel Formation**

6.1.15.4 The Director Operations shall convene a panel to assess the appeal. The panel shall consist of DIQC B.V.'s Managing Director, CFSI member and auditors from our list of qualified auditors. It is ensured that, there is no conflict of interest from any panel member participation.

6.1.16 The member of CFSI shall chair the appeals panel.

6.1.17 Once an appeals panel is formed, it shall be verified with the appellant to ensure they have no objection to the composition of the panel. The appellant may state objections to the composition of the appeals panel. Consequently the constitution of the panel may be amended accordingly in order to resolve those objections. Once both sides agree to the composition of the panel, both DIQC B.V. and the appellant agree to abide by the decision formed by the appeals panel.

6.1.18 The chair of the appeals panel shall verify that all facts are equally presented to the individual DIQC B.V. auditors upon the appeals panel. Each DIQC B.V. assessor shall

be requested to independently weigh the organizations appeal with records generated from the audit. Additional requests for information from either the DIQC B.V. audit team of the organization shall be requested through the chair of the appeals panel.

6.1.17 **Panel Review Process**

6.1.18 The Director Operations shall make all known information available to the panel including the previous audit reports, clients appeal justification, and reasoning from the Director Operations that either denied the certification decision or began the withdrawal process. The Director Operations shall also conduct a search of any previous appeals relating to a similar subject (even if different client) and include in the evidence package.

6.1.19 The panel shall then conduct a preliminary review of the information and forward to each of the other members of the appeals panel providing them with a maximum of 7 days to respond. The panel members shall be informed that may not confer with each other or the auditors/ reviewers involved in the original decision. They are however permitted to use whatever reference documentation available to make their judgment if the appeal is valid.

6.1.20 The panel members shall then provide their decision and rationale for their decision on email directly to the panel chair. The panel chair shall ensure that each of the rationales illustrated that the member has taken into account all of the facts surrounding the appeal and that it was unbiased.

6.1.21 The panel chair shall take the majority as the decision of the appeals panel.

6.1.22 **Notification of Final Decision**

6.1.23 The Director Operations shall be provided the summary of the lead auditors reasoning and summarize this into a letter to be sent to the appellant with the final decision of the appeals panel. The appellant shall be informed that the letter comprises the end of the appeals process. The panel chair shall review the letter from the Director Operations to ensure accuracy of the panel decision and then submit to the appellant.

6.1.24 If the appeal was unsuccessful the Director Operations shall inform the appellant that they are also free to raise the appeal process further by writing directly to DIQC B.V.'s Accreditation Bodies. The Director Operations shall provide the contact details for the Accreditation Bodies requesting that if the appellant informs each Accreditation Body of other Accreditation Bodies, they have escalated the appeal to.

6.1.25 **Corrective Action**

6.1.26 The Director Operations should also consider if any CACAs are necessary even if the appeal is declined. Any CACAs should be opened D-MMS-S-0023 Correction and Corrective action. CACAs should be addressed to the Director Operations for actioning.

6.1.27 The client shall also be notified on any corrective action taken by DIQC B.V. in relation to the appeal, including progress reports where necessary.

6.1.28 The Director Operations shall ascertain whether any precedence setting decision has been made and implement appropriately including program changes, regulatory notification, staff training or other.

6.1.29 **Prohibition on Translation**

6.1.30 In order to preserve the impartiality of the process, DIQC B.V. shall not either internally or externally provide translation of the appeal or supporting documentation. The client is responsible for the translation in to English for all documentation submitted during the appeal. If a significant amount of documentation is required to be translated, the Director Operations in agreement with the Chair of the Appeals panel may allow additional time for the translation to occur.

6.2 Complaint:

6.2.1 DIQC B.V. is responsible for all decisions at all levels of the complaints handling process.

6.2.2 DIQC B.V. makes sure that Submission, investigation and decision on complaints shall not result in any discriminatory actions against the complainant.

6.2.3 The complainant has to log a written complaint with DIQC B.V. through www.diqc.nl website or they can directly write a mail to info@diqc.nl.

6.2.4 Upon receipt of a complaint, the DIQC B.V. will confirm whether the complaint relates to certification activities that it is responsible for and, if so, shall deal with it.

6.2.5 If the complaint relates to a certified client, then examination of the complaint shall consider the effectiveness of the certified management system.

6.2.6 The complaints-handling process shall include the following elements and methods:

a) An outline of the process for receiving, validating, investigating the complaint, and for deciding what actions need to be taken in response to it;

b) Tracking and recording complaints, including actions undertaken in response to them;

c) Ensuring that any appropriate correction and corrective action are taken.

6.2.7 Once a complaint is received, it will be documented in Appeal and complaint log.

6.2.8 A unique number for the complaint shall be given as C/YY/XX. Where C-Complaint, YY-year Appeal logged, XX-Serial Number for appeal logged in particular year.

6.2.9 DIQC B.V. shall be responsible for gathering and verifying all necessary information to validate the Complaint. This investigation/root cause analysis/correction/corrective action shall be documented in Appeal/Complaint report.

6.2.10 The decision to be communicated to the complainant shall be made by, or reviewed and approved by, individual(s) not previously involved in the subject of the appeal.

6.2.11 DIQC B.V. shall give formal notice to the complainant of the end of the complaint handling process. The notice will consist of investigation, finding and correction and/or corrective action taken if any.

6.2.12 Based on the investigation, the Director Operations shall take a final decision on the complaint and a formal notice of the outcome at the end of the complaint process shall be handed over to the complainant. Subsequently, the feedback is sought from the complainant

6.2.13 Complaint/dispute arisen during the audit:

6.3.13.1 An organization may dispute the audit findings and conclusion declared by the DIQC B.V. audit team. In the first instance the dispute should be raised to the lead auditor of the audit team. If the organization is not satisfied, then the dispute can be raised to the DIQC B.V. Director Operations for resolution. If no agreement can still be reached and the nonconformity shall likely result in registration withdrawal then the organization is invited to make a formal appeal.

6.3.13.2 The auditor leading any audit type should be aware of any divergence of opinion between the client and the audit team regarding the classification, context or issuance of any nonconformity.

6.3.13.3 Any such divergence of opinion should be included in the Audit Report under the section Issues affecting Audit Programme of the DIQC B.V. audit report for that assessment. At the closing meeting, if the client still does not agree with the audit recommendation, lead auditor should encourage the client to lodge a complaint against the nonconformity. The lead auditor should explain the appeals and complaint to the client.

6.3.13.4 The client should lodge the complaint in English language only by writing or emailing the lead auditor and asking for their complaint to be considered. The lead auditor should forward the email or documentation from the client to the Director Operations, indicating the identification of the nonconformity (issuing auditor, sequential number, file number and audit date). Disputes should be submitted in English by email to info@diqc.nl and keeping the lead auditor of the audit team in 'cc' for forwarding to the Director Operations.

6.3.13.5 The complaint should contain the client's justification for the complaint, which should directly address the issued nonconformity, and the conditions for issuing the nonconformity or any other issue occurred during the audit that can be treated as a complaint. It should be stressed to the client that they should feel free to make any complaint (or dispute), DIQC B.V. shall ensure that no discriminatory action is taken against a client for lodging complaints, or appeals.

6.3.13.6 The client should be informed that the complaint must be submitted within 7 days for the response to nonconformities as established by DIQC B.V.'s program requirements. Complaints received after that time may not be considered and appropriate action for no response of nonconformities shall be initiated including the invoking of the D-MMS-S-0016 Suspension, Withdrawal or Reduction in scope of Certification.

6.3.13.7 Lodging the Complaint:

I. The complaint should be lodged in English language only by writing or emailing the lead auditor and asking for their complaint to be considered. The lead auditor should forward the email or documentation from the client to the Director Operations, indicating the identification of the nonconformity (issuing auditor, sequential number, file number and audit date). Once a complaint is received, it will be documented in Appeal and complaint log. A unique number for the complaint shall be given as C/YY/XX. Where C-Complaint, YY-year Appeal logged, XX-Serial Number for appeal logged in particular year.

II. The Director Operations shall provide written acknowledgement of the complaint within 2 working days and inform the customer that the subject nonconformity is presently suspended, however the client must continue to make any additional responses to any other issued nonconformities within the required timeframe established by DIQC B.V.'s i.e. 7 days from the issuance of non-conformity.

6.3.13.8 Assessing the Complaint:

I. The Director Operations should assess the validity of the issued nonconformity based on the audit records and client's reasoning and ensure that it was received within the appropriate time frame.

II. If for any reason the Director Operations considers the complaint to be invalid the client shall be informed in writing, additional information may be requested where appropriate. Records of this communication shall be maintained.

III. The Director Operations should avail themselves of all appropriate documented information sources in the course of the evaluation, including but not limited to:

- Audit criteria
- Reference Documents (e.g. ISO 13485:2016 — Medical devices — A practical guide Advice from ISO/TC 210)
- DIQC B.V. Procedures
- Regulatory information including recalls of other device types
- Other audit reports for similar situations
- Discussing any points of clarity with the lead auditor and issuing auditor,

IV. The Director Operations should be cognitive that the client does not need to show that they are in full compliance with the required criteria, only that the nonconformity was not warranted or incorrectly classified.

V. The Director Operations shall conduct the investigation along-with the team involved, based on the investigation, the Managing Director and/or CFSI Chairperson appointed for hearing the case shall take a final decision on the complaint.

6.3.13.9 Complaint Successful: If the decision was in favour of the client, then the lead auditor should amend the audit report clearing or amending the nonconformity and re-issue to the client.

6.3.13.10 Complaint Denied: If the Managing Director and/or CFSI Chairperson upholds the nonconformity, then the report should continue as normal and the lead auditor should await the response of the nonconformity. The normal process may then continue including invoking the suspensions and withdrawals procedure if the client does not respond to the Audit Recommendation.

6.3.13.11 Closing the Complaint:

The Director Operations shall conduct the investigation along-with the team involved, based on the investigation a final decision on the complaint is informed to the client in writing. The client should be informed that the regular certification process per DIQC B.V.'s program requirements shall continue.

6.3.13.12 Corrective Action:

The Director Operations should also consider if any additional training is needed, or if CACA are necessary even if the complaint is denied. Any CACA should be opened per D-MMS-S-0023 Correction and Corrective action. CACA's should be addressed to the Director Operations for actioning.

6.3 Complaints About DIQC B.V. registered/certified client

6.3.1 When DIQC B.V. receives a complaint about a registered client, confidentiality of the client's files and any other associated information must be maintained in accordance with DIQC B.V. policy and the agreements DIQC B.V. has signed with the client.

6.3.2 If DIQC B.V. receives a complaint(s) by a client's customer(s) about that client, management shall communicate the complaint to the client if agreeable to the customer and depending on the significance and impact on the system.

6.3.3 Only complainants who are willing to identify themselves to the DIQC B.V. client will be made aware of their complaint's resolution (i.e. the resolution would be communicated by the DIQC B.V. client during resolution). DIQC B.V. shall encourage its client to work with the complainant through their quality system's complaint handling mechanism to resolve the issue. DIQC B.V. can follow up during the subsequent routine surveillance assessment(s) by evaluating the client's resolution of the complaint.

6.3.4 Any valid complaint about a certified client shall be referred by the DIQC B.V. to the certified client in question within 7 days from receipt of the complaint.

6.3.5 DIQC B.V. evaluates and make decisions on complaints considering requirements for confidentiality, as it relates to the complainant and to the subject of the complaint.

6.3.6 DIQC B.V. shall enter all written complaints into DIQC B.V.'s corrective action system so it may be investigated and the client's resolution of the complaint tracked.

6.3.7 If the investigation into the complaint leads DIQC B.V. to determine that further investigation is necessary, yet without an on-site visit, management shall request that the client provide a Corrective action plan including root cause analysis, planned actions and timing.

6.3.8 If a representative of DIQC B.V. management determines after review of the complaint and any other associated evidence, that an on-site visit is required, the following shall be observed:

6.3.9 Depending on the severity of the complaint, certain elements/systems may have to be evaluated at the next Surveillance Assessment, or an immediate assessment of the client may need to be scheduled.

6.3.10 If a major nonconformance is found during the assessment of the complaint, it is to be documented in the assessment report and a response by the Organization shall be required within 10 days of the last day of the assessment.

6.3.11 DIQC B.V. shall provide monthly progress reports to the complainant should the process take in excess of one month to conclude. The complainant may also enquire at any time the status of the complaint. However DIQC B.V. shall not release any confidential information regarding the DIQC B.V. client unless as otherwise stated in the document.

6.3.12 DIQC B.V. shall determine, together with the certified client and the complainant, whether and, if so to what extent, the subject of the complaint and its resolution shall be made public. E.g. in cases, if the subject related to complaint is directly affecting the product quality.

6.4 The details of appeals and complaints will be reviewed during Management reviews.

6.5 Records of all of the above activities shall be maintained.

7. Associated Procedures/Documents/Formats

7.1 F-0018-01 Appeal/Complaint Log

7.2 F-0018-02 Appeal/Complaint Report

7.3 Records of Appeal and Complaints