

Title: Procedure for Handling of Appeals and Complaints				
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ECI Management Certification Services LLP

Medical Device Quality Management System

ISO 13485

ECI/P-15

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1. PURPOSE

To establish and maintain a process by which an appeal or complaint made by an applicant, certified client or interested parties against decisions made by ECI are dealt and resolved in a fair and reasonable manner.

2. SCOPE

All appeals and complaints made by applicants, certified or interested parties.

3. REFERENCES

- ISO/IEC 17021-1
- Section 9.7 and 9.8 of Quality Manual

4. RESPONSIBILITY

CEO, and all personnel of ECI, Impartiality Team member/Designee.

5. PROCEDURE**5.1 Appeals**

A statement shall be in writing with identification of the sender for consideration as appeal. An appeal is generally made by a client to reconsider a ECI decision related to certification i.e. granting, maintaining, renewing, extending, reducing, suspending and withdrawing of certification.

The receipt of the appeal is acknowledged to the concerned party in writing and appellant is informed about the progress and outcome.

It is ensured that the person/s engaged in the appeals-handling process are different from those who carried out the audits and made the certification decisions or have been involved in the subject of appeal. If CEO was involved as an auditor or certification decision maker in the case against which the appeal has been made, then the decision on the appeal shall be made by Impartiality Team member/Designee.

Submission, investigation and decision on appeals do not result in any discriminatory actions against the appellant.

Effectiveness of these actions is reviewed by CEO/Partner, as responsible to deal with specific appeal and considering results of previous similar appeals; The decisions taken by CEO/ Impartiality Team member/Designee is binding on ECI to take suitable actions.

ECI gives a formal notice to the appellant at the end of the appeals-handling process. The notice shall comprise of a written statement of the appeal findings including the reasons for the decisions reached. Also, the appellant is informed about the available provision to formally present his case. Based on the presentation made, the CEO/ Impartiality Team member/Designee 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 / concerned client.

Once the appeal has been resolved by ECI CEO/ Impartiality Team member/Designee then no counter claim by either party in dispute can be made to amend or change the decision.

In instances where the appeal has been successful and the Certificate reinstated, then no claim can be made against ECI for reimbursement of costs or any losses incurred as a result of the initial withdrawal notification.

If the outcome of the appeals ingratiation confirms to be substantiated, ECI shall take necessary correction and corrective actions.

5.2 Complaints

A statement shall be in writing with identification of the sender for consideration as complaint. In case of verbal complaint, the complainant shall be requested to put it in writing or the same shall be recorded at ECI by the recipient and shall be confirmed with the complainant.

This process is subjected to requirements for confidentiality, as it relates to the complainant and to the subject of the complaint.

ECI gathers and verifies all necessary information to validate the complaint and acknowledge receipt of the complaint and provides the complainant with progress reports and the outcome.

It is ensured that the person/s engaged in the complaint handling process are different from those who carried out the audits or been involved in the subject of complaint. If CEO was involved as an auditor or certification decision maker in the case against which the appeal has been made, then the decision on the appeal shall be made by Impartiality Team member/Designee.

Submission, investigation and decision on complaints do not result in any discriminatory actions against the appellant.

Effectiveness of these actions is reviewed by CEO/ Impartiality Team member/Designee, as responsible to deal with specific appeal and considering results of previous similar complaints; The decisions taken by CEO is binding on ECI to take suitable actions.

ECI gives a formal notice to the complainant at the end of the complaint handling process and the relevant records are maintained. And the feedback is taken from the complainant / concerned client.

ECI gives a formal notice to the complainant at the end of the complaint handling process and the relevant records are maintained. The feedback is sought from the complainant / concerned client.

ECI determines together with the client and the complainant that to what an extent, the subject of the complaint and its resolution is to be made public.

If the outcome of the complaint ingratiation confirms to be substantiated, ECI shall take necessary correction and corrective actions.

6. RECORDS

- Appeal Complaint Log ECI/F-37
- Appeal and Complaints from ECI/F-38
- Client Feedback Form ECI/F-34

7. REVISION HISTORY

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