

Assessment of Complaints and Appeals Procedure

5. Aim and Scope

The purpose of this procedure within the framework of national and international legal regulations defined in the related legislation section is to determine the principles of assessment of suggestions, complaints and appeals received from parties related with the subject in accordance with Standards EN ISO/IEC 17021-1 , EN ISO/IEC 17020 and (EU) 2017/745 Regulation.

Malta Conformity Assessment Ltd. will be referred as 'MCA' in this document.

6. Definitions

Complaint: Expression of dissatisfaction, other than appeal, by any person or organization to MCA, relating to the activities of MCA, its personnel, or products certified by MCA.

Complainant: The person or organization who makes complaint related MCA activities. The complainant can be related parties such as authorities, customer, MCA employee, etc.

Appeal: Requests to object on the decisions on/for certification.

Appeal Holder: The person or organisation who makes appeals to the decisions on/for certification. The appeal holder can be related parties such as authorities, customers, etc.

Appeal Committee: The committee which is authorized to independently and impartially assess and resolve on the appeals that have not resolved by Quality Manager and Department Manager.

Conformity Assessment: It is the demonstration that specified requirements relating to a product, process, system, person or body are fulfilled, and they are the conformity assessment (audit, inspection, testing, exam, surveillance, certification, etc.) methods MCA carries out.

Technical Personnel: The personnel who carry out conformity assessment activities, are lead auditor, site auditor, product reviewer, certification committee members, final reviewers and decision-makers. For EN ISO/IEC 17020, technical manager and technical officer are also technical personnel.

IQMemo/ QMS software: Quality Management System Software

IQMemo Feedback Module: A software module where complaints, appeals, suggestions and information requests received from related parties are recorded and followed up.

Planning Responsible: It is the person who follows the determination of the decisions and the actions taken within the department during the Feedback (Complaint, Appeal, Suggestion, Information Request) stages and records the results to IQMemo. It generally consists of Department Manager/Unit Manager and/or Quality Coordinator and/or MCA Personnel appointed by the Quality Manager when necessary.

Refer PR.MED.15 Procedure for Definitions in Medical Devices Procedures for medical devices.

7. Responsibilities

General Manager, Deputy General Manager, Appeal Committee, Quality Manager, related Department Managers and all relevant MCA personnel are responsible for implementation of this procedure.

8. Method

In the handling of complaints or appeals, personnel who carries out an assessment or passes resolution is elected amongst the persons who are fully independent of the complaint or appeal subject; however, the appeal and complaint committee provide its recommendation as a result of the evaluation. The final decision is taken by the full-time employee of MCA. MCA does not subcontract the decisions taken. When necessary, the relevant committee can provide technical information support from outside. If a person is previously employed by a customer and then later employed by MCA, this person cannot be a part of the team reviewing the appeal or complaint coming from this specific customer within 3 years after the termination of the employment with that specific customer.

For medical devices; permanent ban shall be applied for experienced single devices if this person; previously employed by manufacturer, designer, supplier, installer, purchaser, maintainer, and authorized representative of medical devices or was the designer, manufacturer, supplier, installer, purchaser, maintainer, or authorized representative of devices (Including representing parties engaging with this activities) or involved in the design, manufacture or construction, marketing, installation and use, or maintenance of the devices (including representing parties engaging with this activities).

The appeal committee establishment and working principals are defined in TL.03 Appeal Committee Assignment and Working Instructions.

8.1. Sources of Appeals;

- Appeals made against the decisions on/for certification.

8.2. Sources of Complaint;

- Complaints due to service quality,
- Complaints due to personnel performance, conduct and behavior,
- Complaints regarding possible violations of independence, impartiality and confidentiality by personnel, top management or administrative personnel.

8.3. Handling of Complaints

8.3.1. Suggestions and complaints received from complainant in relation with applications of MCA are kept under record with FR.02 Feedback (Complaint Appeal Suggestion Information Request) Form which is available on the MCA website in electronic media or are recorded with the FR.02 Feedback (Complaint Appeal Suggestion Information Request) Form by the relevant MCA Personnel or the information received by the Quality Manager or the relevant MCA Personnel is recorded in IQMemo Feedback Module. Within 3 days from the day the complaint is received, the complainant shall be informed by e-mail / written or verbal that the complaint has received.

8.3.2. After receipt of the complaint, Quality Manager and relevant department managers shall inquire the complainant to verify that it is related to the activities performed by MCA or not.

8.3.3. If the complaint is not related to MCA activities, written information is provided to complaint-holder by Quality Manager within 7 days.

8.3.4. If the complaint is related to the MCA activities or the personnel working within MCA, the Quality Manager shall decide how to proceed with the risk and assessment of the complaint with together related Department Manager within 7 days together with informing the complaint holder that the complaint shall be processed according to procedures.

If the complaint includes the identification of a situation that causes a systematic error in the activities and a serious risk is detected that does not comply with the MCA Impartiality, Independence and Confidentiality policies 3 individuals from appeal committee who are not related and free from the complaint shall be selected. The members shall be invited and asked to make a decision by evaluating the complaint within 7 days.

If the complaint does not include the situations mentioned in the previous sentence, the Quality Manager and the Department Manager shall investigate the activities to be done to determine the complaint and determine the necessary activities. In both cases, decisions and actions are recorded in the IQMemo Feedback Module by the Quality Manager. Unless otherwise requested, Written information shall be communicated to the complainant about the outcome of the assessment within 7 days. If the complaint is forwarded to the institution / organization by requesting a return on a certain deadline, the relevant period shall be taken into consideration for written information.

8.3.5. If the complaint is received about a person or entity above the level of authority of the Quality Manager (Example: about the General Manager) or complaint related with Quality Manager, the appeal committee members who are not related and free from complaint shall be invited by Quality Manager or Deputy General Manager and asked to make a decision by evaluating the complaint within 7 days. (Section 8.3.6, 8.3.7 and 8.3.8 are carried out by the Deputy General Manager specifically for his item, for a complaint about the Quality Manager.)

8.3.6 The Quality Manager may decide to initiate a Corrective / Preventive Action as a result of the evaluation of activities regarding the complaint recorded in the IQMemo Feedback Module. If such a decision is taken, the action is followed up with a Corrective / Preventive Action in accordance with the PR.09 Corrective and Preventive Action Procedure.

8.3.7. Approval of customer on the activity carried out is recorded in the IQMemo Feedback Module.

8.3.8. If the customer is dissatisfied of the activity carried out, the issue shall be notified by the Quality Manager in the IQMemo Feedback Module to appeal committee and written information is provided to the customer.

8.3.9 Complaints that are related to the complainant of MCA shall be accepted/treated by the same methods defined as above and evaluated by the Quality Manager. Additionally, unannounced site audits might be performed due to the nature of the complaint.

8.4. Handling of Appeals

8.4.1. Appeals received from appeal holder in relation with decisions adopted by MCA shall be kept under record with FR.02 Feedback (Complaint Appeal Suggestion Information Request) Form by the Management Representative or Quality Manager or relevant MCA personnel in electronic media or the information received by the Quality Manager or the relevant MCA Personnel is recorded in IQMemo Feedback Module. Appeals shall be accepted in 30 days after the notification date of MCA decision.

For the Medical Department activities,

The customer may appeal to a decision taken by MCA within 10 working days. MCA shall publish the status and scope of the certificate through an available national database, through its certificate search module on its website and through EUDAMED this includes the status of these certificates during the acceptance of the appeal and its resolution period.

8.4.2. After receipt of the appeal, the Quality Manager and relevant Department Manager shall inquire the appeals to verify that it is related to the decision on/for certification or not.

8.4.3. If the appeal is not related to the decision on/for certification, then written information shall be provided by the Quality Manager to the appeal holder within 7 days.

8.4.4. If the appeal is related with the decision on/for certification, then the Quality Manager shall notify the issue to appeal committee with FR.02 Feedback (Complaint Appeal Suggestion Information Request) Form and provides written information to the appeal holder within 7 days.

8.4.5. Appeal committee shall convene in order to evaluate the appeals within 7 days and shall discuss the issue.

8.4.6. If necessary, the appeal committee may receive information and help from experts in the field and/or parties in dispute. Appeal committee takes the decision within 7 days and records the decision taken in FR.02 Feedback (Complaint Appeal Suggestion Information Request) Form and notifies it to the Quality Manager and relevant Department Manager. The result of the assessment performed by the appeal committee shall be forwarded to relevant decision makers. A certification committee consist of a final reviewer and decision maker shall be implemented and final actions to be implemented shall be decided by the certification committee.

8.4.7. Written information shall be provided about the appeal holder related to the decision taken and actions to be taken within 7 days.

8.4.8. Quality Manager shall initiate corrective action in relation to the activity to be carried and its follow-up shall be done in accordance with PR.09 Corrective and Preventive Action Procedure.

8.4.9. After completion of corrective action, Quality Manager shall provides written information to appeal holder and requests his/her feedback. The evaluation and assessment which is specified above shall be finalized within 30 days after the appeal received.

8.4.10. If appeal holder is dissatisfied with the decision of certification committee or actions are taken, then appeal holder may seek the legal remedies. The appeal holder has the right to appeal to MCA for a second time if the appeal holder is not satisfied with the decision and action taken by the committee. MCA shall allows the appeal holder to object to the decision and shall ensures that the appeal is evaluated by a person or persons who have no prior relationship with this decision, but who have sufficient knowledge and experience on the subject and who can act independently. When the result of the activity is notified to the appeal holder, if the appeal holder is not satisfied again, MCA shall notify the appeal holder of the current legal rights and the periods regarding the exercise of these rights.