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MediCertLab
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COMPLAINTS AND CLAIMS PROCEDURE

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1. Purpose and Scope

The purpose of this procedure is to establish the rules for receiving, classifying, investigating, documenting and closing submissions, complaints and claims concerning MCL's activities.

This procedure applies to feedback, objections and expressions of dissatisfaction relating to services provided by MCL, including Laboratory Activities, Design Activities and Training Activities, as well as customer communication, completion times, test reports, other reports, certificates of attendance, impartiality, confidentiality, personnel conduct and other aspects of MCL's operations.

In Laboratory Activities, claims are treated as complaints and handled in accordance with the complaints-handling process required for the laboratory.

2. Normative References

This procedure takes into account the requirements of:

- PN-EN ISO 9001 – Quality management systems – Requirements;

- PN-EN ISO/IEC 17025 – General requirements for the competence of testing and calibration laboratories, insofar as they apply to Laboratory Activities.

The current editions of the standards and other external documents applicable to this procedure are identified and controlled in MCL_F_01.

3. Definitions and Abbreviations

The definitions and abbreviations specified in MCL_F_00 apply to this procedure.

For the purposes of this procedure, the following terms are used:

Submission – a comment, suggestion or feedback concerning MCL's activities that may indicate an opportunity for improvement but does not constitute a complaint or claim, unless its content expresses dissatisfaction requiring a formal response or includes a request to resolve a problem.

Complaint – an expression of dissatisfaction concerning MCL's activities that requires a response.

Claim – a submission concerning the quality of a completed Service, a result, test report, other report, certificate of attendance, completion time or conformity of the Service with agreed requirements.

Complainant – a customer, participant, individual, organisation or another interested party submitting a submission, complaint or claim.

Handling of a complaint or claim – the analysis of the reported matter, collection and verification of the necessary information, decision-making and communication of the response to the Complainant.

4. Responsibilities

The main positions and personnel are described in MCL_P_03. Responsibilities, functions and assigned authorisations are documented in MCL_F_04.

5. Receiving Submissions, Complaints and Claims

Submissions, complaints and claims may be submitted, in particular, through the MediCertLab Customer Portal, by email, telephone or another channel specified in the documents applicable to the relevant Service.

When using the MediCertLab Customer Portal, the Complainant identifies the type of matter, the area concerned and describes the comments, objections or requests being submitted. Where the matter is submitted through the Customer Portal, the information recorded in the system constitutes the primary record of its receipt.

Where a complaint or claim is submitted by telephone, MCL prepares a written note containing at least the information necessary to identify the matter, a description of the submission and the expected course of further action, where specified. The note is sent to the Complainant for confirmation to ensure that the record accurately reflects the content of the submission.

The person receiving a submission, complaint or claim forwards the matter to the Quality Manager or the person responsible for the relevant area. Submissions received through the MediCertLab Customer Portal are forwarded to MCL's contact email address, which is accessible to authorised personnel.

Complaints and claims are recorded in MCL_F_18, in the section designated for complaints and claims. The register contains information necessary to track the matter, its classification, the handling process, actions taken and closure.

Submissions consisting of comments, suggestions or feedback are recorded in MCL_F_18 only where they require further assessment, a decision, monitoring or action.

MCL acknowledges receipt of a complaint or claim where this is possible based on the information provided by the Complainant. Response deadlines are determined by the documents applicable to the relevant Service, the quotation, contract, terms and conditions or applicable law.

Where a matter requires additional analysis, testing, technical clarification or information from a third party, MCL informs the Complainant of the expected completion date. Where possible and justified by the duration or nature of the matter, MCL also provides information on the progress of its handling.

6. Classification of a Submission, Complaint or Claim

Upon receiving a submission, complaint or claim, MCL verifies the subject of the matter, the Service or order to which it relates and the MCL area responsible for handling it.

MCL confirms whether the submission, complaint or claim concerns activities performed by MCL or activities carried out under an order for which MCL is responsible.

The verification includes, in particular, identifying the connection between the matter and the customer, order, sample, Service deliverable, completion time or customer communication.

The submission is assessed to determine whether it constitutes feedback, a suggestion or a comment intended to support improvement, or whether its content constitutes a complaint or claim requiring formal handling.

In Laboratory Activities, every claim concerning the quality of a completed Service, a result, test report, completion time, method of performing a test or conformity of the Service with agreed requirements is treated as a complaint and handled in accordance with the complaints-handling process required for the laboratory.

Where the content indicates that the matter concerns another area or Service, or requires additional information, MCL takes the necessary steps to ensure its correct classification, including contacting the Complainant where necessary and possible.

Where there is uncertainty regarding the classification of a matter, MCL adopts a precautionary approach and handles it through the process applicable to complaints or claims.

7. Investigation of Complaints and Claims

Handling a complaint or claim involves collecting and verifying the information necessary to assess its validity, determine its impact on the Service, identify its cause where necessary for proper handling or the determination of actions, and decide on further steps.

The scope of the investigation is adapted to the nature of the matter and may include, in particular, a review of the order, correspondence, records from the MediCertLab Customer Portal, samples or test items, results, test reports, other reports, certificates of attendance, technical records, equipment records, environmental conditions, personnel records, supplier information or other evidence relating to the matter.

MCL is responsible for collecting and verifying the information necessary to establish the validity of a complaint or claim to the extent that the matter concerns MCL's activities or an order performed by MCL.

Where additional information from the Complainant is necessary to investigate the matter, MCL requests that information. The absence of information necessary for assessment may limit the ability to handle the matter, and the Complainant is informed accordingly where applicable.

During the investigation, MCL assesses whether the matter requires actions appropriate to its nature and impact.

For complaints and claims concerning Laboratory Activities, the investigation includes, where applicable, an assessment of the impact on the validity of results, test reports, samples or test items, methods, equipment, environmental conditions, personnel, external providers, confidentiality, impartiality and customer communication.

8. Decision, Response and Closure

Following completion of the investigation, MCL decides how the complaint or claim will be resolved and what actions are required in connection with the matter.

The outcome of the investigation includes, at a minimum, an assessment of the validity of the matter, justification for the decision and identification of any required actions.

The outcome of the handling of a complaint concerning Laboratory Activities, which is to be communicated to the Complainant, is prepared by a person who was not involved in the original laboratory activities concerned by the complaint, or is reviewed and approved by such a person. Where necessary, MCL may engage a competent external person.

MCL formally informs the Complainant of the outcome of the complaint or claim and the completion of the handling process.

The information provided to the Complainant is adapted to the nature of the matter, the scope of the findings, confidentiality requirements and the requirements applicable to the relevant Service.

The matter is closed after the response has been provided to the Complainant and any actions resulting from the investigation have been completed or planned, where applicable.

Closure is recorded in MCL_F_18, in the section designated for complaints and claims.

9. Impartiality and Independence of Complaint Handling

Complaints and claims are handled with impartiality, confidentiality and a professional approach towards the Complainant and the subject of the matter.

A person directly involved in the activities concerned by a complaint or claim shall not independently make the final decision regarding its resolution. However, that person may provide information, explanations, records or data necessary to assess the matter.

MCL ensures that a person who was not directly involved in the matter participates in preparing, reviewing or approving the outcome, as appropriate to the nature of the matter.

Where no person within MCL possesses the required competence and independence, MCL may engage a competent external person.

Decisions made at every stage of the complaints and claims handling process remain the responsibility of MCL.

10. Actions Arising from Complaints or Claims

Actions arising from a complaint or claim are selected according to the nature of the matter, its validity and its impact on the customer, Service, result, document, confidentiality, impartiality or effectiveness of the Integrated Management System.

Such actions may include, in particular:

- correction or reissuance of a document;
- repetition of an activity or performance of additional verification;
- provision of supplementary information;
- restriction of the use of a result or document;
- modification of communication methods, work organisation or cooperation arrangements;
- contacting an external provider or submitting a complaint to the provider;
- supervised work or additional competence development;
- implementation of the process for handling nonconforming work;
- recording a nonconformity;
- implementation of corrective action or improvement action.

Where a complaint or claim indicates a nonconformity, nonconforming work, a risk to the validity of results, a breach of confidentiality, a threat to impartiality or ineffective established arrangements, MCL takes appropriate action in accordance with the rules for controlling nonconformities and implementing corrective and improvement actions, as specified in procedure MCL_P_06.

Not every complaint or claim requires corrective action. Corrective action is taken where the matter indicates a need to eliminate the cause of a nonconformity, particularly where the issue is significant, recurring or systemic.

11. Availability of the Process Description

A description of the complaints and claims handling process is made available to interested parties on the website and upon request.

The description includes the general rules for receiving, classifying, investigating and closing complaints and claims, as well as information on how to submit matters to MCL.

The publicly available process description does not include confidential information, data relating to other customers, MCL's internal records, personnel assessments, supplier assessments or details of proceedings concerning other matters.

12. Records of Submissions, Complaints and Claims

Complaints and claims are recorded and controlled to an extent that allows each matter to be tracked from receipt to closure. The primary register for complaints and claims is MCL_F_18.

Submissions consisting of comments, suggestions or feedback are recorded in MCL_F_18 where they require monitoring, a decision, further assessment, improvement action or another action.

Records relating to a matter may include, in particular, a submission received through the MediCertLab Customer Portal, correspondence, a note of a telephone submission confirmed by the Complainant, acknowledgement of receipt, information on the progress of the investigation, investigation records, the decision, the response provided to the Complainant, evidence of actions completed, document corrections, reissued documents and related records concerning nonconformities, nonconforming work, corrective actions or improvement actions.

The scope of records is adapted to the nature of the matter and should make it possible to demonstrate what the matter concerned, how it was classified, what information was collected, the outcome of the investigation, what actions were taken and when the matter was closed.