QUALITY PROCEDURE

MS ISO/IEC 17025

Prepared By:

[Signature]

ASSISTANT QUALITY MANAGER

Reviewed By:

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Technical Manager
(Materials)

[Signature]
Technical Manager
(Environment)

[Signature]
Technical Manager
(Bioprocess)

Approved By:

[Signature]
PM Dr Nasrul Hamidin
Quality Manager
1.0 PURPOSE AND SCOPE

The purpose of this procedure to ensure that all complaints received from customers are resolved within a specified time.

2.0 RESPONSIBILITIES

The Technical Manager to decide the time limit to resolve the complaints and maintains the records of all complaints, investigations and corrective actions taken by the laboratory.

3.0 DEFINITIONS AND/OR REFERENCES

Definitions:
CAPA : Corrective Action And Preventive Action

References:
- MS ISO/IEC 17025
- UniMAP Testing Laboratory Quality Manual

4.0 PROCEDURES

4.1 Receiving the Complaint

4.1.1 Technical Manager is responsible for the implementation of this procedure.

4.1.2 Complaints may be received in verbal, written or electronic form.

4.1.3 This information may be received via telephone, facsimile, written correspondence or electronic mail from internal and external customers.
4.1.4 Complaints from customers serviced by the laboratory shall be recorded in Customer Complaint Form *(UTL/FO/06-01)* for the further action.

4.1.5 Information required in a complaint includes:

- Name, designation, department, and for external customers, the address (company, organization or personal) and contact number and email of person making the complaint;
- Date of complaint;
- Product/project in question, with reference number or date where applicable;
- Nature of complaint including quality of service, document content or test result that is unsatisfactory.

4.2 Reviewing and Evaluating the Complaint

4.2.1 All complaints and related information shall be reviewed and evaluated by the respective laboratory chaired by Technical Manager.

4.2.2 The result of the evaluation will determine the validity of the complaint, the possible cause(s) of the complaint, and what action (if necessary) to prevent further occurrences.

4.2.3 If the complaint is valid, then an investigation will be initiated to determine the cause of the complaint. If the complaint is deemed not valid and no investigation is made, then the reason and the person responsible for making this decision is recorded on the Complaint Form and the document is filed for record purposes.

4.2.4 The customer shall be informed of the outcome where necessary.

4.3 Investigating the Complaint

4.3.1 When the complaint is deemed valid as per item 4.2.2, an investigation will be conducted in the department where the issue of the complaint originated. The investigation shall be headed by the respective laboratory team member.
4.3.2 The investigation report shall be completed on the Complaint Form and the root cause identified, where possible.

4.3.3 The immediate remedial action taken shall be recorded on the form and signed off and dated by the person responsible for the action. The customer shall be informed as necessary.

4.3.4 The investigation team shall determine whether a CAPA is necessary to avoid future occurrence. If CAPA is required, then a CAPA form shall be raised and procedures for the actions shall be followed (see Procedure on Corrective and Preventive Action and the investigation) shall be closed out.

4.3.5 If not, then the investigation shall be closed out immediately.

4.4 Filing the Complaint

4.4.1 The complaint form is filed together with any relevant support document, investigation material and any communications with the customer as part of the investigation records.

4.4.2 All records of complaints are maintained by the analyst in the document room.

5.0 RECORDS (If Applicable)

<table>
<thead>
<tr>
<th>No.</th>
<th>Record</th>
<th>Location</th>
<th>Person maintaining records</th>
<th>Retention Period</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Customer Complaint Form</td>
<td>Document Room</td>
<td>Analyst</td>
<td>At least 6 years</td>
</tr>
</tbody>
</table>
6.0 FLOWCHART

Complaints received

Valid?

Requires CAPA?

Immedite Action

Raise CAPA

Close out

7.0 APPENDIX

- Customer Complaint Form