[Organization's Logo]

[Organization's Name]

Commented [170251]: All fields in this document marked by square brackets [ ] must be filled in.

COMPLAINT, NONCONFORMITY AND CORRECTIVE ACTION PROCEDURE

Code:	
Version:	0.1
Created by:	
Approved by:	
Date of version:	
Signature:	

Commented [170252]: Adapt to the existing practice in organization.

Distribution List for Paper-based Documents

Commented [17A3]: This is only necessary if document is in paper form; otherwise, this table should be deleted.

Copy No.	Distributed to	Date	Signature	Returned	
				Date	Signature

Change History

Date	Version	Created by	Description of change
	0.1	17025Academy	Basic document outline

Table of Contents

1. Purpose, Scope and Users

The purpose of this procedure is to define the activities that take place when complaints are received, nonconforming work is identified, and corrective actions are required.

This procedure and process apply to all laboratory activities that may be the subject of complaints or nonconformities.

The users of this procedure are laboratory personnel for its implementation, maintenance and making improvements by using corrective actions.

Commented [170254]: This procedure assigns most of the administrative duties to the quality manager. Laboratories that do not have an assigned quality manager can assign these duties to another qualified person.

2. References

- ISO/IEC 17025:2017; Clause 7.9, 7.10, 8.5, 8.6, and 8.7
- Quality Manual

Commented [17A5]: You will find this document in the ISO 17025 Toolkit folder "03_Quality_Manual".

3. Complaints

Complaints received from organizations outside of the laboratory should be directed to [job title],

Commented [170256]: Quality manager or person designated by quality manager for resolving complaints.

possible to assist determining a good corrective action outcome.

Upon receipt, [job title] validates the complaint and decides the best path for problem resolution. Once

Commented [170257]: Quality manager or person designated by quality manager for resolving complaints.

Commented [17A8]: You can use a process flow as a document that will describe the process regarding how a complaint is treated.

a customer requests an explanation of the process.

[Job title] determines the magnitude of the problem and the urgency required to correct the problem. In

Commented [170259]: Quality manager or person designated by quality manager for resolving complaints.

Commented [1702510]: Quality manager

prevent further spread of the problem and then initiate a corrective action if needed.

If [job title] decides that the type, magnitude and nature of the complaint requires a formal corrective

Commented [1702511]: Laboratory or Quality manager.

[Job title] must track the progress of the corrective action, ensure that appropriate action is taken and [illegible]

Complaints along with their CARs, if any, are recorded in the Complaint, Nonconformity and CAR Log.

4. Nonconforming Work

Nonconformance is defined as an event when there is any aspect of the laboratory's results or activities [illegible]

- deviation from specified environmental conditions
- [illegible]
- [illegible]

[Job title] has full responsibility for dealing with defined nonconformities and the authority to make decisions as to whether formal corrective action is required.

[illegible]

- Investigate the nonconformance.
- [illegible]
- [illegible] of the organization.
- Make a decision on the acceptability of any nonconforming work and, when necessary, determine if the customer should be notified and previous work recalled.
- [illegible]
- [illegible] of the nonconforming work in the Complaint, Nonconformity and CAR Log.

After determining all aspects of the nonconformance, [job title] may authorize work to resume.

5. Corrective Action

A corrective action must be initiated in response to any nonconforming work and should be initiated as [illegible] nature, a containment action may be initiated.

Commented [1702512]: Laboratory or Quality manager.

Commented [1702513]: Laboratory or Quality manager.

Commented [1702514]: Laboratory or Quality manager.

Commented [1702515]: Records may be kept electronically.

Commented [1702516]: Laboratory or Quality manager.

Commented [17A17]: Laboratory or Quality manager.

Whenever [job title] initiates formal corrective action each corrective action must be logged and [illegible]

- Identify members of the corrective action team including, when possible, customer and supplier personnel who participate in the corrective action.
- [illegible]
- [illegible]
- [illegible]
- [illegible]
- [illegible]

[Job title] must verify each corrective action and formally close out the CAR. Copies of the completed [illegible] customers as a way to close the loop in the complaint process.

Commented [1702518]: Laboratory or Quality manager.

Commented [1702519]: Laboratory or Quality manager.

Commented [17A20]: Laboratory or Quality manager.

6. Managing Records Kept on the Basis of this Document

Record name	Code	Storage		Responsibility
		Retention time	Location	
Corrective Action Report (CAR)	PR.14.1	7 years	[office of [job title]]	[job title]
Complaint, Nonconformity and CAR Log	PR.14.2	7 years	[office of [job title]]	[job title]

Commented [1702521]: Laboratory manager, quality manager or a trained and qualified employee who is responsible for the laboratory complaint and corrective action program.

Commented [1702522]: These training records may be kept in an HR department, the laboratory manager's office or the quality Manager's office. Adapt to your organizations current practice.

If the record is in electronic form, write the name of the folder on [job title]'s computer.

7. Appendices

- Appendix 1 – Corrective Action Report (CAR)
- Appendix 2 – Complaint, Nonconformity and CAR Log