

# Customer Focus: Complaint Management



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# Introduction

This document pulls guidelines from the Clinical and Laboratory Standards Institute document, “QMS19: Customer Focus in a Quality Management System” to bring a comprehensive, structured approach for complaint management in the laboratory setting from both external (i.e., customers) and internal (i.e., employees) claims on a laboratory product or service. This approach has a two-fold outcome to ensure complaints are documented appropriately and handled fairly and consistently towards a resolution. First, it identifies a way for the complainant to submit a complaint. Secondly, the laboratory complaint investigation process ensures a defined analysis and response to the complaint. This process is an important step in improving complaint management and complying with any regulatory requirements.

If a complaint includes any personal health information (PHI), the Health Insurance Portability and Accountability Act of 1996 (HIPAA) protocols must be adhered to throughout the investigation process. HIPAA investigations are separate from this document’s complaint management processes.

A laboratory’s quality management system (QMS) must cover multiple types of complaints received by the organization. The Customer Complaint Process outlined in this document provides guidance for complaint response. However, this guidance does not address adverse events that warrant reporting to the US Food and Drug Administration (FDA) under the FDA Medical Device Reporting (MDR) process. Therefore, a laboratory should follow internally defined processes for MDR reporting to FDA.

## Definitions

- **Complainant:** A person or organization registering a laboratory complaint which may involve testing results, samples, processes or personnel.
- **Complaint:** Any concern about the laboratory’s operation (Clinical and Laboratory Standards Institute).
- **Corrective Action:** Action(s) to eliminate the cause and prevent recurrence of a nonconformity or other undesirable situation (ISO 9001).
- **Document Control System:** An electronic or hard copy system developed for the controlled storage of documents and records.
- **HIPAA:** Health Insurance Portability and Accountability Act of 1996 which addresses the use and disclosure of protected health information, or PHI.
- **Nonconforming Event (NCE):** An occurrence that does not conform to the laboratory’s policies, processes or procedures, does not conform with applicable regulatory or accreditation requirements, or has the potential to affect (or has affected) patient, donor or employee safety.
- **Protected Health Information (PHI):** Any health information that can identify an individual and is related to their past, present or future health. PHI can be in any form or medium, including electronic, paper or oral.
- **Root Cause Analysis (RCA):** A wide range of approaches, tools and techniques used to uncover cause(s) of a problem; RCA may be considered with investigating a nonconforming event.

## Acknowledgments

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APHL also expresses their appreciation to Twila Kunde for compiling this document on complaint management and the APHL Laboratory Systems and Standards committee for reviewing it.

# Complaint Management Process

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An effective complaint management process defines and identifies laboratory policies and processes for receiving and documenting a complaint, investigating the complaint, identifying and implementing any corrective actions, sustaining appropriate document control and ultimately responding to the complainant. Once a complaint is received, the initial steps of the complaint management process should start with acknowledging the complaint with the complainant initially, document communication with the complainant and explain the complaint process so they are aware of the timeline. The complaint investigation should follow the laboratory's nonconforming event (NCE) process, including root cause analysis (RCA) and establishment of corrective actions, as applicable. All staff should be trained in the complaint management process to ensure uniform and timely implementation and response.

This document provides an example of the complaint management process as follows:

- **Complaint Registration**
- **Complaint Receipt**
- **Staff Identification for Complaint Investigation**
- **Complaint Investigation**
- **Complaint Resolution**
- **Complaint Documentation**
- **Management Review**

## Complaint Registration

Complaints may be received via postal, telephone, email, website reporting or other mechanisms. Optimally, the laboratory website should have a complaint section on the homepage that is easily accessible. This streamlines public access and improves public perception of the laboratory's openness.

Items to consider:

- Provide laboratory contact (email, phone number) for complainant to contact.
- Provide an electronic or paper complaint submission form with fields for:
  - Complainant contact information (email, phone number, address). Anonymous complaints do not allow for a thorough investigation, but these types should be managed in the same way as all other complaints, to the extent possible.
  - A detailed description of complaint, such as date/time of incident, sample identification and person/unit involved in the incident.
- Provide a timeline for complainant to expect a laboratory response.
- Provide ability for internal complaints and option for anonymity (e.g., a complaint box outside the laboratory director's office).

# Complaint Receipt

The laboratory must have a process for directing complaints to the appropriate staff so investigations can begin in a timely manner. To ensure consistent processing, direct all complaints to a single person or department, such as the quality manager; this person can then coordinate with the appropriate staff to help investigate the complaint, such as the laboratory director or testing supervisor.

## Staff Identification for Complaint Investigation

The table below demonstrates an example strategy for identifying which staff should be involved in a complaint investigation. Wherever appropriate, staff involved in the complaint investigation should also be involved in the resolution. In this example, all complaints are directed to the quality manager, who then identifies the appropriate staff to be involved in complaints investigations.

Action	Responsibility			
	Laboratory Director/ Deputy Director	Quality Manager	Managers/ Supervisors	Testing Staff
Receives complaints		✓		
Ensures implementation of complaint response	✓	✓		
Confirms accuracy of complaint information with the complainant		✓		
Identifies if complaint is related to a previous complaint		✓		
Ensures NCE process for complaint investigation		✓		
Assigns complaint investigators	✓	✓	✓	
Stops any related lab work, if applicable			✓	✓
Performs complaint investigation (including RCA)		✓	✓	✓
Assigns any corrective actions		✓	✓	
Approves resumption of lab work, if applicable	✓		✓	✓
Communicates complaint resolution with complainant		✓		
Tracks/trends complaint NCE data and information		✓		

# Complaint Investigation

Complaint investigations should follow the laboratory's NCE process and identify root cause(s) and corrective action(s).

Items to consider:

- Bring appropriate staff together for the investigation team.
- Identify root cause(s) using tools that are effective for this process (Five Whys Tool, Fishbone Diagram, peer discussion, etc.).
- Identify corrective action(s) for each identified root cause, the responsible staff to implement actions and an appropriate timeline for completion. Confirm the corrective actions are reasonable and achievable.
- Identify an appropriate time for follow-up with corrective action program and complaint resolution.

# Complaint Resolution

- **Founded complaints:** If the complaint investigation indicates the complaint is valid, the corrective action(s) will be completed, and the complainant will be informed.
- **Unfounded complaints:** If the complaint investigation indicates that the laboratory did not deviate from procedures/policies, the complaint will be determined to be unfounded but will be used for continuous quality improvement. A preventive action review will be completed to determine to further improve the processes associated with the investigation. The final outcome will be reported to the complainant.

# Complaint Documentation

Complaints should follow the laboratory's process for NCE documentation, and the processes for record storage and retention.

# Management Review

Complaints are reviewed with management to monitor for trends and identify possible future customer service improvements.

# References

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- [Public Health Laboratory Model Practices for QMS11-A: Nonconforming Events](#) (APHL, 2021)
- [QMS11-A: Management of Nonconforming Laboratory Events; Approved Guideline](#) (Clinical and Laboratory Standards Institute, 2007)
- Georgia Department of Public Health, Georgia Public Health Laboratory, RRM-QA26 (version 1.0), Laboratory Complaint FAQ.
- University of Iowa State Hygienic Laboratory, Nonconforming Event (NCE) Management, Version 8.0, 11/20/20 (Modified) 21CFR §820.3.



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The Association of Public Health Laboratories (APHL) works to strengthen laboratory systems serving the public's health in the US and globally. APHL's member laboratories protect the public's health by monitoring and detecting infectious and foodborne diseases, environmental contaminants, terrorist agents, genetic disorders in newborns and other health threats.

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