

Purpose:

This document describes the process for receiving, evaluating, and making decisions with regard to complaints submitted by an applicant or accredited laboratory concerning operations of COLA's 17025 Accreditation Program. This document is available to any interested party.

Scope:

The process begins when COLA is made aware of a complaint submitted by an applicant or accredited laboratory. The process includes triage, classification, investigation, responding, corrective action, and reporting. The process ends with communication regarding the resolution of the complaint to the complainant.

Responsibility and Authority:

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| COLA Customer Facing Staff | <ul style="list-style-type: none">• Covers phones and receives incoming correspondence• Submits customer feedback ticket in case management system when communication is recognized as a complaint. |
| Quality Improvement Specialist | <ul style="list-style-type: none">• Monitors the process of triage, investigation, and resolution of complaints.• Escalates customer feedback tickets to ensure timely action• Maintains complaint statistics. |
| Program Manager | <ul style="list-style-type: none">• Triage incoming complaints related to 17025 accreditation program.• Investigates complaints involving accreditation personnel and operations.• Documents investigation and resolution of complaints in case management system.• Prepares outcomes for accreditation activity complaints. |
| COO | <ul style="list-style-type: none">• Complaints concerning COLA operations may be escalated to this individual.• Approves and oversees implementation of corrective actions related to operations. |
| CEO | <ul style="list-style-type: none">• Approves responses for accreditation complaints• Approves responses for legal complaints.• Approves responses for ethical/impartiality complaints. |

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| Chief Counsel | <ul style="list-style-type: none"> • Reviews and investigates legal, ethical, and impartiality complaints. • Documents investigation and resolution of complaints in case management system. • Prepares outcomes for legal, ethical, and impartiality complaints. |
| Director Quality Systems | <ul style="list-style-type: none"> • Ensures complaints are investigated and resolved in a timely manner. • Ensures that complaints are processed in accordance with ISO/IEC 17011/17021 requirements. • Ensures complaints resulting in corrective actions are addressed by COLA’s Change Management Process. • Prepares and sends communications to complainant. • Provides backup to Quality Improvement Specialist when this individual is out of the office. • . |

Terms and Definitions:

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| COLA Complaint | <p>Dissatisfaction with COLA’s 17025 accreditation services, operations, or staff.</p> <p style="text-align: center;">OR</p> <p>An allegation that COLA is doing something improper or that violates ISO/IEC 17011 or 17021 requirements.</p> |
| Case Management System | <p>A system used to log complaints, assign to the appropriate party, document investigation and actions taken, and track closure of the complaint.</p> |
| Change Control Board | <p>Group of COLA system & process owners that meets on bi-weekly basis to review root cause and corrective action plans in response to Customer Feedback and Nonconforming Events.</p> |
| Complaint Tracking Log –
Complaints against COLA | <p>A spreadsheet used to record each complaint received and track communications with the complainant pending resolution of the complaint.</p> |

Receiving the Complaint

- 1) Complaints about COLA operations may be received by telephone, fax, email, or letter.

- 2) When communication is recognized to be a complaint about COLA services, the employee receiving the communication submits a customer feedback ticket in COLA's case management system.
 - a) Identify the complainant and obtain his/her contact information. This is critical to permit COLA to provide the complainant with acknowledgement, progress reports, and outcome of the complaint investigation in accordance with ISO 17011/17021. Complainants may choose to remain anonymous and thereby forfeit their right to receive progress reports or final disposition.
 - b) Gather as much information as possible that will be needed to validate the complaint (the who, what, when, where, why and how), such as:
 - (1) What happened,
 - (2) The dates when it occurred and whether it has happened before. If prior instances, obtain the dates of those occurrences also.
 - (3) Who was involved or aware of the situation (with names and spellings if possible),
 - (4) Request any supporting evidence the complainant can share such as copies of reports or other communications,
 - (5) Inquire as to any other actions the complainant has taken.
 - c) The employee selects the appropriate business line and submits the ticket.
- 3) The case management software routes the ticket to the appropriate system owner for review and investigation.

Triaging Complaints Regarding the 17025 Accreditation Program

- 4) The Program Manager reviews the complaint in the case management system and determines whether it relates to accreditation activity/personnel, or legal, ethical or impartiality concerns.
 - a) If the complaint relates to accreditation, the Program Manager will investigate.
 - b) If the complaint relates to a legal, ethical, or impartiality matter, the complaint is forwarded to the Chief Counsel to address.
- 5) The Director of Quality Systems logs the complaint on the *Complaint Tracking Log – Complaints Against COLA* to facilitate provision of progress reports to the complainant.

Conducting the Investigation

- 6) The Program Manager or Chief Counsel will investigate the allegations without undue delay.
 - a) This may include review of internal policies and procedures, training and competency records of staff, chronology of the accreditation process, and interviewing staff, examining similarities between current allegations and other complaints received.
 - b) Investigation may also include interviews with the complainant or others external to COLA but may have relevant information.

- c) The investigation may include review of complaints submitted by other laboratories to identify any similarities with the current complaint and/or identify corrective actions that were previously taken.
- 7) The Program Manager or Chief Counsel summarizes the investigation process and outcome in the case management system, being careful not to reveal confidential, privileged or sensitive information.
- 8) The Program Manager or Chief Counsel determines if corrective actions are needed and identifies the action plan(s) in the case management system and notifies the Director of Quality Systems.
- 9) The Director of Quality Systems ensures a summary of the issue and action plan is discussed with the Change Control Board. After confirming completion of the action plan(s), Director of Quality Systems closes the ticket in the case management system.

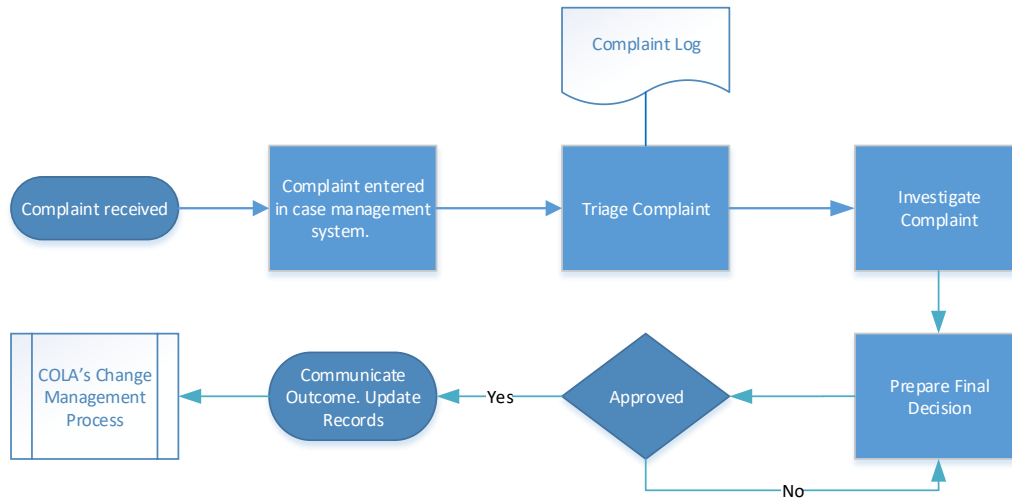
Communicating Progress and Outcomes of Complaint Investigations:

- 10) The Director of Quality Systems uses the *Complaint Tracking Log – Complaints Against COLA* to determine the timing of updates to the complainant. Updates should be provided at approximately 30-day intervals. Updates will indicate that investigation is in process, but will not go into details.
- 11) Upon completion of the complaint investigation, the Director of Quality Systems, Program Manager and Chief Counsel draft a communication to the complainant regarding the outcome of the investigation and any action plans developed as a result of the complaint.
- 12) The CEO reviews the draft communication, either requesting modifications or giving approval for release to the complainant.
 - a) If modifications are requested, the revised version will be provided to the CEO for approval prior to release.
- 13) Once approved, the Director of Quality Systems sends the approved communication to the complainant and updates the *Complaint Tracking Log – Complaints Against COLA*.

NOTE: To ensure that the reporting of a complaint does not result in any discriminatory actions against the complainant:

- **No information concerning a complaint about COLA will be noted in the customer file in the accreditation system.**
- **All information concerning complaints about COLA will be maintained in the case management system, which is separate and distinct from the accreditation system.**

Flow Chart:



Monitoring and Measurement:

Methods Used	Metrics	Target
Complaint Tracking Log – Complaints Against COLA	Timeliness of Complaint Resolution <ul style="list-style-type: none"> • Target closure of complaints within 2 months. • % closed < 2 mm • % closed > 2 mm 	90% within 2 months
Outcome of complaint investigations	% of complaints resulting in corrective actions	trend

Supporting Materials:

Change Management Process
Complaint Tracking Log - Complaints Against COLA

Records:



ISO/IEC 17025 Accreditation Complaints Against COLA Operations

Record ID	Custodian	Where Stored	Retention Period
Complaint Tracking Log – Complaints Against COLA	Director Quality Systems	S:Quality Systems/ 17025 - Cannabis Accreditation	5 years
Complaint Information	Director Quality Systems	Case management system	5 years

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