ISO 15189 Accreditation Complaint Policy

Purpose:

This document describes COLA's policy for receiving, evaluating, and making decisions with regard to complaints received about ISO 15189 applicant or accredited laboratories. This document is available to any interested party.

Policy for Investigation of Complaints against a Laboratory

Receiving the Complaint:

Complaints about COLA ISO 15189 applicant or accredited laboratories may be received by telephone, fax, email, or letter. Complaints received about a laboratory are forwarded to an Assessor. The Assessor records the identity of the complainant and their contact information, if known, and details of the complaint allegations. The Assessor gathers and records as much information as possible from the complainant, so that COLA can conduct a thorough investigation

The Assessor also advises the complainant that COLA will send periodic status reports until the complaint has been closed, in accordance with ISO 15189. If the complainant will not give his/her identity, inform the complainant that COLA will not be able to provide any information regarding the progress of the investigation or the outcome of the complaint. The Assessor assures the individual that COLA will attempt to protect his/her identity to the extent possible in addressing and resolving the complaint and as permitted by law. If the individual still refuses to be identified, the complainant is recorded as "Anonymous."

Triaging the Complaint

The complaint is triaged to determine if the allegations relate to accreditation activities for which COLA is responsible.

- If it does not, an appropriate response is prepared and sent to the complainant informing him/her that the allegations are not within COLA's jurisdiction to investigate
- If the complaint relates to accreditation activities for which COLA is responsible, an Assessor is assigned to the investigation

The Assessor reviews the laboratory's scope of accreditation and accreditation history in preparation for conducting the investigation.

Planning and Conducting the Investigation

The Assessor creates and sends a complaint notification letter to the laboratory, which includes the allegations associated with the complaint, but does not reveal the identity of the complainant (to guard against any discriminatory actions against the complainant). The letter requests that the laboratory submit the requested documents and records to COLA within 10 business days.

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NOTE 1: If the laboratory is unresponsive or uncooperative, the Assessor may present the laboratory to the IAB with a recommendation to withdraw accreditation.

NOTE 2: The complainant is provided status updates at 30-day intervals.

A video conference with laboratory management is scheduled within 10 business days following receipt of the requested documents. The assessor interviews laboratory management and staff as needed to resolve any questions related to the documentation submitted and the pertinent details of the complaint. Upon conclusion of the video conference, the Assessor prepares their report and conclusions regarding the allegations noted by the complainant and any nonconformities identified during the investigation. Following the review, the report is provided to the laboratory. If nonconformities were identified, the laboratory enters a corrective action cycle. Upon approval by the Director of Standards, Regulations and Policies, the Assessor merges the Cover Letter, Assessment and Audit reports and sends the report to the laboratory's primary contact.

Resolution of Substantiated Allegations or Nonconformities

Minor clause nonconformity requires a root cause analysis and corrective action plan to be submitted within 30 days, with evidence of implementation submitted within the next 30 days. Verification of conformance with requirements will occur at the next scheduled assessment.

Major clause nonconformity requires a root cause analysis and corrective action plan to be submitted within 30 days. An Extraordinary Assessment will be performed to verify that conformance with requirements has been achieved. This is performed at the laboratory's expense.

The Assessor reviews the response(s) to the nonconformity for acceptability.

- If the laboratory's response is satisfactory and an Extraordinary Assessment was not required, the complaint is considered closed
- If an Extraordinary Assessment is required, the complaint cannot be closed until the assessment is completed and conformance with requirements has been verified
- Should an Extraordinary Assessment result in nonconformity, this will be considered an unsatisfactory response and will be presented to the IAB

If the laboratory is unresponsive, uncooperative, or does not provide a satisfactory response, the Assessor presents the laboratory to the IAB with a recommendation to reduce the scope, suspend or withdraw accreditation. For complaints that are closed without being referred to the

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IAB, the Director of Standards, Regulations and Policies will notify the laboratory and the complainant, separately, in writing of the final outcome.

Review by IAB

When a complaint is presented to the IAB, all information obtained regarding the complaint, in addition to a summary of the laboratory's history of ISO 15189 accreditation and any prior complaints, will be included. The IAB may elect to withdraw accreditation, suspend accreditation, or reduce the scope of accreditation. This is a decision that may be appealed by the laboratory.

If the IAB suspends accreditation or reduces the scope of accreditation, the laboratory will be brought back to the IAB, upon COLA's verification of conformance, for a decision regarding continued accreditation. At this time, the IAB will make a final determination with respect to any change in scope and may restore or withdraw accreditation.

Upon the IAB's final decision, the laboratory and the complainant will be notified separately, in writing.

Investigation and decision on complaints will not result in any discriminatory actions against the complainant by COLA.

Responsibility and Authority:

Assessor	• Records incoming complaints • Triages complaints • Notifies laboratories of complaints and associated allegations • Schedules and conducts investigations of complaints utilizing the ISO 15189 Complaint Form • Expands the scope of the assessment from the complaint to other areas based on the findings and her/his professional judgment • Evaluates the laboratory's complaint investigation and corrective actions • Creates necessary communications between COLA and the laboratory regarding complaint resolution

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ISO Accreditation Board (IAB)	• Determines if allegations are substantiated, unsubstantiated, or unable to substantiate • Reviews laboratories that are either unresponsive, uncooperative, or, in judgment of Assessor, fail to provide satisfactory responses to substantiated allegations/nonconformities • Has authority to reduce the scope of accreditation, suspend accreditation, or withdraw accreditation
Director of Standards, Regulations and Policies	• Confirms complaints allegations are within COLA's jurisdiction • Ensures required notifications, investigation, and corrective action processes are completed in a timely manner • Communicates with complainants (acknowledges receipt, progress reports, and outcomes) • Schedules meetings of COLA's ISO Accreditation Board as needed and communicates Board decision to laboratory • Maintains complaint statistics utilizing the ISO 15189 Complaint Tracking Log

Terms and Definitions:

Complaint	An allegation that a laboratory is doing something improper or that violates COLA ISO 15189 accreditation requirements.
Complaint Closure	A complaint shall be considered closed when: • Director of Standards, Regulations and Policies determines the allegations are not within COLA's jurisdiction • IAB determines that allegations are either unsubstantiated or unable to be substantiated, and nonconformities were not identified during the investigation • Assessor determines that substantiated allegations and/or nonconformities identified have been satisfactorily resolved through corrective actions • IAB has made a final accreditation determination after completion of the corrective action process. This only applies to complaints referred to the IAB.

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Extraordinary Assessment	An assessment that is in addition to routine assessments. In this case, an assessment was conducted to verify the resolution of any major nonconformities. COLA has discretion to determine whether to conduct remotely or onsite.
Substantiated	Evidence is found to support an allegation of improper performance or conduct.
Unable to substantiate (Indeterminate)	No evidence was found to support or refute an allegation. (Often occurs when the complaint is vague).
Unsubstantiated	Evidence is found that refutes an allegation of improper performance or conduct.

Supporting Materials:

Process for Handling Complaints about Laboratories
Complaint Letters
ISO 15189 Complaint Form
ISO 15189 Complaint Tracking Log

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