

Purpose:

This document describes the process for receiving, evaluating and making decisions on appeals submitted by applicants or accredited ISO 15189 laboratories. An appeal challenges an accreditation decision made by COLA, in which the laboratory seeks a formal change to the decision. The following types of decisions may be appealed:

- Decision to terminate accreditation process
- Decisions to grant, suspend, reduce, or withdraw accreditation, and
- Decisions regarding the scope of accreditation.

COLA will not discriminate against any laboratory or individual requesting an appeal. This document is available to any interested party.

Scope:

The process begins when COLA receives an appeal from an applicant or accredited laboratory. The process includes evaluation and review of the case and the decision-making process. It includes scheduling an appeal meeting and notifications to the laboratory. The process ends when one of the following situations occurs:

- The original decision was made and communicated more than 21 days prior to receipt of the appeal, making the appeal untimely.
- The original decision is upheld.
- The original decision is modified (partially upheld, partially reversed)
- The original decision is reversed.
- The laboratory has voluntarily withdrawn its appeal or accreditation with COLA.

Responsibility and Authority:

Assignee	Staff member selected to review the case and prepare for the ISO 15189 Appeals Committee. This individual cannot be a member of the most recent assessment team or member of COLA's ISO Accreditation Board involved in the decision being appealed.
ISO 15189 Appeals Committee	Three-member committee composed of the Chief Operating Officer, the Medical Director and a COLA ISO Assessor who did not participate in the most recent assessment for the laboratory. . No one participating in the ISO Accreditation Board may serve on an ISO 15189 Appeals Committee to maintain impartiality. The committee is responsible for hearing appeals cases and rendering a decision.

Director of Standards,
Regulations, and Policies

Evaluates appeals, assigns review and preparation to staff members, and communicates with the appellant throughout the process.

Maintains Appeal Tracking Log

Presents case to the ISO 15189 Appeals Committee.

Terms and Definitions:

Appeal submission period

21 calendar days from the date of the letter communicating the original decision.

Original Decision

Decision made by COLA's ISO Accreditation Board regarding accreditation status or scope.

Receiving an Appeal

Appeals contesting either the scope of accreditation or accreditation status must be received in writing.

The laboratory has 21 calendar days from the date of the letter communicating the decision to submit a completed ISO 15189 Appeal Form and any supporting materials. The Appeal form can be downloaded from cola.org ([https://www.cola.org/resources-for-ISO 15189 accreditation/](https://www.cola.org/resources-for-ISO-15189-accreditation/)).

When a written request for appeal is received, it is forwarded to the Director of Standards, Regulations, and Policies, who adds it to the ISO 15189 Appeal Tracking Log.

Triaging the Appeal

In accordance with ISO/IEC 17011, COLA is required to provide the laboratory with acknowledgment, progress reports, and the outcome of the appeal.

- 1) The Director of Standards, Regulations, and Policies reviews the appeal and the date the Original Decision that is being appealed was communicated to the laboratory.
 - a) If the appeal date is greater than the 21 calendar days, then the Director of Standards, Regulations, and Policies prepares a response to the laboratory informing it that the appeal is denied because the appealsubmission period has been exceeded.
 - i) The *Request to Appeal Accreditation Decision* form and tracking log are updated.
 - ii) The Director of Standards, Regulations, and Policies creates an *ISO 15189 Appeal Denied Letter*, posts it to the customer files in the ISO database and sends it to the laboratory.
 - b) If the appeal date is within the 21-day submission period, then the Director of Standards, Regulations, and Policies assigns a staff member (not involved in the most recent assessment leading to the decision being appealed) to evaluate the laboratory's case and the accreditation history in preparation for the Appeals Meeting.
 - c) The Director of Standards, Regulations, and Policies creates an *ISO 15189 Appeal Acknowledgment Letter* and posts it to the customer files in the ISO database and sends it to the laboratory.

Planning the Appeals Meeting

- 2) The Director of Standards, Regulations, and Policies notifies the CEO of the request for appeal and the ISO 15189 Appeals Committee is selected. The ISO 15189 Appeals Committee is polled to schedule a meeting to hear the case within 30-45 days. (Appeals meetings are held virtually.)
- 3) As soon as the date and time for the appeals meeting is established, the Director of Standards, Regulations, and Policies updates the laboratory via the *ISO 15189 Appeal Meeting Letter* and requests the laboratory notify COLA no later than two weeks prior to the date of the ISO 15189 Appeals Meeting if they plan to make a presentation to the Appeals Committee during the meeting. If the laboratory plans to participate, the Director of Standards, Regulations, and Policies will obtain the name(s) and title(s) of the persons who will be presenting their case.
- 4) The Director of Standards, Regulations, and Policies updates the *ISO 15189 Request to Appeal Accreditation Decision* form and tracking log.

Evaluating the Appeal Request and Accreditation History

- 5) First, the Assignee reviews the laboratory's rationale for appealing the decision and supporting materials. The Assignee notes any key items identified in the supporting materials that appear to support a different decision. The Assignee records information reviewed and findings in the "Evaluation of Laboratory's Request & Supporting Materials" section of the *ISO 15189 Request to Appeal Accreditation Decision* form.
- 6) Next, the Assignee reviews pertinent information related to the accreditation activities leading to the decision being appealed. This includes:
 - a) The laboratory's application or prior certificate of accreditation;
 - b) Records of the most recent assessment and any associated corrective actions;
 - c) Minutes of COLA's ISO Accreditation Board meeting at which the case was reviewed and the accreditation decision was made;
 - d) Any other correspondence between the laboratory and COLA pertinent to the factors leading to the decision being appealed.
- 7) The Assignee reviews the information, paying close attention to the sequence, timing, and staff involved in the accreditation process and decision. This is compared to current accreditation policies and procedures.
 - a) Any anomalies (by the laboratory or COLA) are noted.
 - b) Information reviewed and findings are recorded in the "Evaluation of Accreditation History" section of the *Request to Appeal Accreditation Decision* form.
- 8) Upon completion of the review, the Assignee updates the *ISO 15189 Request to Appeal Accreditation Decision* form with his/her recommendations to:
 - a) Uphold the original decision;
 - b) Modify the original decision (partially uphold, partially reverse); or
 - c) Reverse the original decision.

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- 9) The *ISO 15189 Request to Appeal Accreditation Decision* form is provided to the Director of Standards, Regulations, and Policies ,along with all materials submitted by the laboratory and any additional pertinent information from the review.

Appeals Meeting

- 10) The Director of Standards, Regulations, and Policies sends a copy of the *ISO 15189 Request to Appeal Accreditation Decision* form and any supporting documentation to the Appeals Committee members at least 5 days in advance of the scheduled meeting. The tracking log is updated with the date materials sent.
- 11) The Director of Standards, Regulations, and Policies provides the next status update the laboratory at least 5 days in advance of the meeting to confirm the virtual arrangements and laboratory participation.
- 12) The Director of Standards, Regulations, and Policies takes attendance and takes minutes of the ISO 15189 Appeals Meeting.
- 13) The Chair of the ISO 15189 Appeals Committee calls the meeting to order.
- 14) The Director of Standards, Regulations, and Policies introduces the case and reviews the timeline and basis for accreditation actions.
- 15) If the laboratory is participating, its representative(s) is connected to the meeting and to present the laboratory's argument. The Appeals Committee is free to ask questions. At the conclusion of the laboratory's presentation, the laboratory participants leave the call.
- 16) The ISO 15189 Appeals Committee discusses information presented by COLA and the laboratory. Each committee member will vote to take one of the following actions:
- a) Uphold the Original Decision;
 - b) Modify the Original Decision with stipulations; or
 - c) Reverse the Original Decision.
- 17) The Director of Standards, Regulations, and Policies records the outcome of the vote in the minutes, on the *ISO 15189 Request to Appeal Accreditation Decision* form and tracking log.
- 18) The Director of Standards, Regulations, and Policies sends the minutes of the meeting to the Chair of the ISO 15189 Appeals Committee for approval. Once approved, minutes will be included in the Board Book for the next meeting of the COLA Board of Directors.

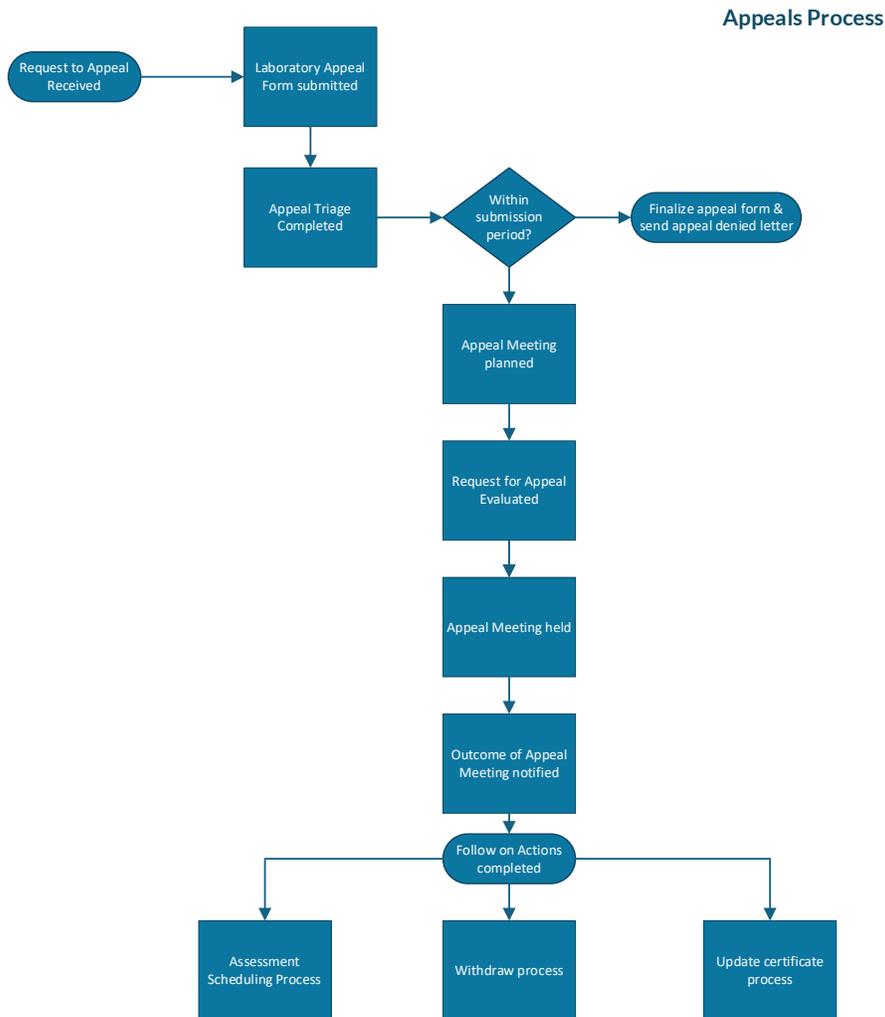
Laboratory Notification of Outcome

- 19) The Director of Standards, Regulations, and Policies notifies the laboratory in writing, via traceable mail, of the decision of the ISO 15189 Appeals Committee, within 5 days of the meeting and updates the tracking log.
- 20) The Director of Standards, Regulations, and Policies updates the *ISO 15189 to Appeal Accreditation Decision* form with any follow-up actions needed based on the decision (e.g. withdrawn from the ISO database, Schedule extraordinary assessment, grant a new certificate of accreditation, etc.).
- a) Actions are communicated to applicable Accreditation staff.

b) *ISO 15189 Request to Appeal Accreditation Decision* form is uploaded to the ISO database and final entry is made in the tracking log.

Investigation and decision on appeals will not result in any discriminatory actions against the laboratory.

Flow Chart:



Monitoring and Measurement:

Methods Used	Metrics	Target
ISO 15189 Appeals Tracking Log	Status of ISO 15189 Appeals investigations: <ul style="list-style-type: none"> • # received • # pending • # closed 	trend
Outcome of ISO 15189 Appeals investigations	% upheld % modified % reversed	trend

Supporting Materials:

Request to Appeal Accreditation Decision form
15189 Appeal Tracking Log

Records:

Record ID	Custodian	Where Stored	Retention Period
ISO 15189 Laboratory Appeals Tracking Log	Director of Standards, Regulations, and Policies	S:\ISO 15189 Accreditation	5 years
Request to Appeal Accreditation Decision form	Director of Standards, Regulations, and Policies	ISO database	8 years after termination of relationship with COLA

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