Standard Operating Procedure for Handling of Complaints

1. **Purpose:**

   To provide a specific procedure for the documentation and handling of complaints submitted to the AOAC Laboratory Proficiency Testing Program (LPTP).

2. **Scope:**

   The AOAC Laboratory Proficiency Testing Program will implement and use this Standard Operating Procedure to handle complaints for the AOAC Laboratory Proficiency Testing Program.

3. **Outline of Procedure:**

- Notification
- Documentation of complaint
- Investigation of complaint
- Conclusion of investigation
- Appeal of conclusion
- Discriminatory Actions
- Access to Appeal SOP

4. **References:**

   ISO/IEC 17043:2023 Conformity assessment – General requirements for the competence of Proficiency Testing Providers

5. **Specific Procedure:**

5.1 Notification

A. The complaint must be provided to AOAC PT Staff in written communication (e.g. email)
B. The lab filing the complaint must be notified of:
   a. Receipt of the complaint by AOAC PT staff
   b. The unique tracking number assigned by staff for traceability

c. Any outcome
d. Any progress, if applicable

5.2 Documentation of the Complaint

A. Complaints may include but are not limited to:
   a. the quality of the test material
   b. Staff responses.
   c. others

B. Each complaint will be assigned a unique identification number by AOAC staff. This number will be used to trace the complaint through the investigation and resolution.

C. Completed and signed complaint records will be maintained within the PT Quality Management System.

D. Participants will be notified if additional information is required to fully describe the complaint.

E. The PT provider receiving the complaint shall be responsible for gathering all necessary information to determine whether the complaint is valid.

F. The PT provider shall be responsible for all decisions during the process for handling complaints.

5.3 Investigation of the Complaint

A. Upon receipt of a complaint, the PT provider shall confirm whether the complaint relates to PT activities and, if so, shall resolve the complaint.

B. If the complaint is related to the quality of the test material::
   1. Records of test material preparation will be reviewed.
   2. Results from subscribers will be reviewed, if applicable.
   3. Experts from the LPTP Oversight Committee, LPTP Advisory Task Force, or AOAC Methods Committee will be consulted, if needed, to provide scientific advice on the issues.
   4. The identity of the lab filing the complaint will remain confidential.
   5. Additional experiments will be conducted, if requested by the experts.

C. If the complaint is related to data entry:
   1. The raw data will be compared to the data displayed in the report.

D. If the complaint is related to processed and issued result data.
   1. It should be handled as an Appeal.

E. Complaints in other areas shall be documented as well.

5.4 Conclusion of the Investigation

A. The investigation will be summarized in a written document. This document will be maintained within the PT Quality Management System.

B. The decision on the complaint shall be made by, or reviewed and approved by, persons not involved in the decision that is the subject of the complaint in question.

C. A conclusion of the investigation (Outcome) of the complaint will be documented and distributed to the lab that filed the Complaint. A copy of the conclusion will be maintained within the PT Quality Management System.

D. If the conclusion requires corrective action, that action will be implemented within 30 days of the conclusion. All reports that are affected by a conclusion requiring corrective action will be updated and marked as "Amended Report" with a new date issued

5.5 Appeal of the Conclusion of the Investigation

If the lab filing he complaint does not agree with the conclusion of the investigation, they have 30 days to appeal the conclusion. See Appeal SOP.

5.6 Discriminatory Actions

A. Investigation and decision on complaints shall not result in any discriminatory actions.
   a. See Impartiality Policy

5.7 Access to Complaints SOP

A. Complaint SOP shall be listed on the PT Website

Revision Log

Revision #	Revision Date	Reason for Revision
1	11/15/00	Revised the “purpose” and “scope” to include all types of complaints.
2	4/28/05	Revised “purpose” and “scope” plus sections 5.1 A, D, 5.3 B, and 5.4 to include complaints from complainants who are not subscribers.
3	4/24/08	Removed ISO/IEC Guide 43-1:1997-*Proficiency testing by interlaboratory comparisons-Part 1: Development and operation of proficiency testing schemes* from section 4 and updated the date of the ILAC G-13 document.
		5.2.A.3, “LPTP” or “AOAC” was added to the committee or task force names if applicable.
		5.4 “LPTP” or “AOAC” was added to the committee or task force names if applicable.
		Reformatted the Revision log.
4	2/22/13	Section 4-Changed reference from ILAC G-13:08/2007-ILAC to ISO/IEC 17043:2010.
5	2/11/25	Section 4-Updated reference from ISO/IEC 17043:2010 to ISO/IEC 17043:2023.
		Reformatted the document.
		5.2 C – ‘AOAC Headquarters’ updated to ‘PT Quality System’
		5.3 B – ‘AOAC Headquarters’ updated to ‘PT Quality System’
		5.3 C – ‘Corrected Report’ updated to ‘Amended Report’
		5.4 – ‘AOAC Headquarters’ updated to ‘AOAC Staff’
6	07/21/25	5.2.C and 5.2.C.1 were added for appeals
		Original 5.2.C became new 5.3.A and the rest moved down
		5.4 removed some context and made appeals its own SOP
		Updated language in all sections

Written or Prepared by:	Chad Stephan, Manager	Date
Approved By:	Shane Flynn, Senior Director	Date
Approved By:	Stephen Wise, QA Manager	Date