Sections in This Document

1. Purpose

The purpose of this procedure is to describe receipt, evaluation, resolution, and maintenance of records of complaints and feedback regarding Office of Regulatory Science (ORS) laboratory activities. Complaints and feedback can provide valuable information on the effectiveness of the organization and can be used to improve the organization with the customer in mind.

2. Scope

This procedure applies to the Office of Regulatory Science (ORS) laboratories and laboratory work products and processes. This procedure directly concerns the laboratory's quality assurance program.

This procedure applies to complaints; positive and negative feedback; results of customer surveys; and internal or external suggestions for improvements

that impact ORS laboratories' work products, services, and processes. This procedure is not used for personnel issues.

---

3. Responsibility

A. Laboratory Management

1. Implements this procedure at their unit level.
2. Collaborates with the Quality System Manager (QSM) to gather and verify all necessary information to validate complaints and to determine the appropriate response.
3. Ensures implementation of corrective and/or preventive actions as necessary.

B. Staff

1. Record complaints and feedback received on the Complaint Feedback (CF) form in QMiS.
2. Initiate Issue Review form for negative feedback or complaints received.

C. Quality System Manager (QSM)

1. Evaluates and processes CF forms entered in QMiS.
2. Works with management to assess the CF (e.g. gathering and evaluating necessary information to validate complaints, reviewing affected processes and procedures, facilitating root cause analysis) and determine appropriate action.
3. Initiates Issue Review form, if not already done, to record evaluation of complaints.
4. Ensures complaints and feedback are recorded, tracked, and trended in QMiS.
5. Recommends and initiates corrective action and/or preventive actions to management as necessary.
6. Monitors the CFs in QMiS to ensure resolution is satisfactory and complete.
7. Reports on complaints and feedback highlights and trends at management meetings and during management review.

---

4. Background

None

5. References

A. ISO/IEC 17025:2017, General requirements for the competence of testing and calibration laboratories, Sections 7.9 and 8.6.

B. AOAC International Guidelines for Laboratories Performing Microbiological and Chemical Analysis of Food, Dietary Supplements, and Pharmaceuticals – An Aid to Interpretation of ISO/IEC 17025:2017; August 2018

C. SOP-000116 Complaints and other Feedback (ORA-Level)

6. Procedure

6.1. Received by the laboratory

Complaints and feedback may be received by various means, such as in writing, e-mail, telephone, web application, information management systems, or in person.

Staff at the laboratory who receive a complaint or feedback shall record it by initiating a Complaint_Feedback (CF) form in QMiS. This form is used to record both positive and negative feedback.

6.2. Evaluate Complaint / Feedback

The QSM consults with management and subject matter experts to evaluate complaints and feedback and determine if they relate to laboratory activities. Results of evaluation and actions taken are recorded on the CF form. The QSM may add others to the CF form to record this information, as needed.

A. If a nonconformance is discovered because of a complaint the corrective action process shall be initiated with generation of an Issue Review form in QMiS which provides escalation to a Corrective Action/Preventive Action (CAPA).

B. The CF is closed once the CAPA is closed out.

C. If an opportunity for improvement is identified the improvement form may be initiated.

D. A qualified person must review complaints for possible failures and investigate where needed (AOAC 2018). A qualified person is an

employee with technical knowledge of the product or activity area (for example dietary supplements and pharmaceuticals) of the complaint.

6.3. Communicating with the Complainant

A. Whenever possible, the QSM or responsible Manager acknowledges receipt of a complaint and provides the individual filing the complaint with progress reports.

B. Outcomes to be communicated to the complainant are reviewed and approved (by individuals not involved in the original laboratory activities in question) through the corrective action approval process or within the complaint process.

C. The QSM or responsible Manager communicates actions taken and outcomes to the complainant as formal notice of the end of the complaint handling process, where possible.

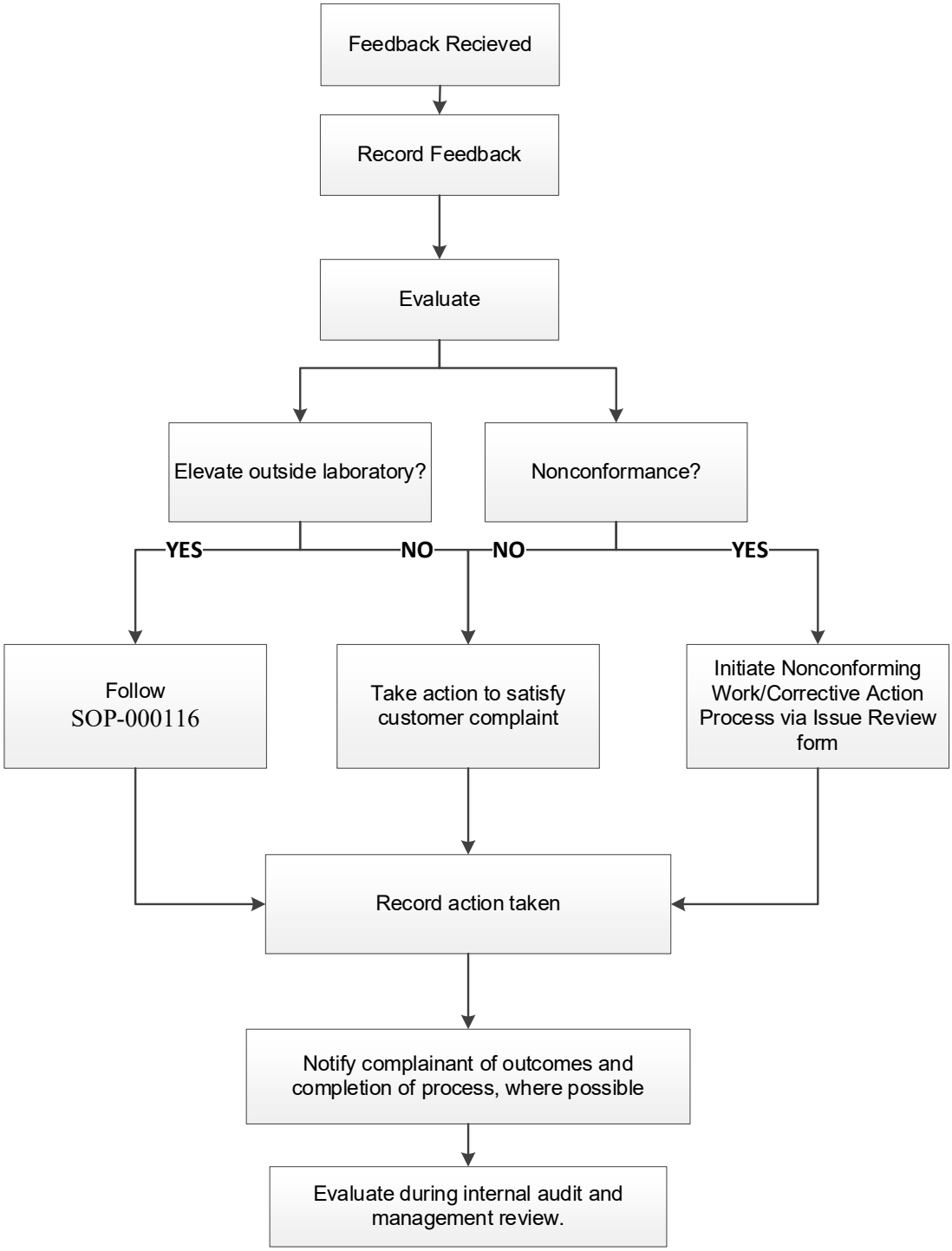
6.4. Escalation outside of laboratory

Complaints or other feedback (CF) may be escalated if the issue cannot be resolved locally or if the issue impacts multiple units. Refer to SOP-000116 Complaints and Other Feedback.

6.5. Records

Complaint and feedback records are maintained in QMiS. The complaints and feedback are reviewed as part of the internal audit and management review to identify any trends and to ensure any changes from a complaint or feedback were proper, effective, timely and successful.

6.6. Process Map


Feedback Recieved
Record Feedback
Evaluate
Elevate outside laboratory?
Nonconformance?
YES
NO
NO
YES
Follow SOP-000116
Take action to satisfy customer complaint
Initiate Nonconforming Work/Corrective Action Process via Issue Review form
Record action taken
Notify complainant of outcomes and completion of process, where possible
Evaluate during internal audit and management review.

7. Glossary/Definitions

A. Complaints – Complaints are negative reactions usually in written form made to the organization related to a specific product or service produced or provided by the organization after the product has been released or service completed.

B. Corrective action – This is the action taken to eliminate the causes of a detected non-conformance, defect, or other undesirable situation to prevent reoccurrence.

C. Feedback – Can be positive or negative. It is important to include reviews of positive feedback as this can provide evidence of what is working well in the quality system.

8. Records

A. Complaint Feedback form

B. Issue Review/CAPA form

C. **Improvement** Action form

9. Supporting Documents

A. MAN-000029 ORA Laboratory Manual, Volume II, ORA-LAB.4.9, Control of Nonconforming Work

B. MAN-000030 ORA Laboratory Manual, Volume II, ORA-LAB.4.11, Corrective Action Procedure

10. Document History

Revision #	I	Date	Author Name and Title	Approving Official Name and Title
02	I	See QMiS	LMEB	LMEB
03	R	See QMiS	LMEB	LMEB

* - D: Draft, I: Initial, R: Revision

11. Change History

Revision #	Change
02	Updated formatting. Added “feedback” to title/scope. Added evaluation guidance for nonconformance vs. feedback. Added section for escalation; updated process flow chart. Other revisions to align with recently revised ISO and AOAC standards.
03	Updated with missing step to initiate Issue Review form to evaluate complaints and escalate to CAPA, if needed. Removed references to Preventive Action form (no longer in use) and replaced with Improvement form. Added “Feedback” to Glossary. Added QMiS ID numbers to supporting documents cited.

12. Attachments

NONE