Training Module: Complaint Resolution

Focus Area: QM Section 4.8 (ISO 15189:2022 Clause 7.7)

1. Scope

This module applies to all laboratory personnel who interact with service users, including frontline reception staff, technical staff, and management. It covers the end-to-end process from receiving a verbal complaint to formal closure.

2. Introduction and Objectives

Complaints are not failures; they are "free audits." This module aims to standardize the laboratory's response to dissatisfaction to ensure impartiality and service recovery.

- **Objective 1:** To empower staff to receive complaints professionally without becoming defensive.
- **Objective 2:** To ensure 100% compliance in documenting complaints in the Complaints Register.
- **Objective 3:** To understand the requirement of "Closing the Loop" through formal feedback to the complainant.

3. Structural Content

- **The Intake:** Communication techniques for verbal and written complaints.
- **The Analysis:** Categorizing complaints (Pre-analytical, Analytical, Post-analytical, or Behavioral).
- **The Investigation:** Gathering evidence (logs, timestamps, and witness statements).
- **The Resolution:** Determining fair outcomes and systemic changes.

4. Actionable Procedures (The "How-To")

1. **Immediate Response:** Use the "EAR" method (Explore, Acknowledge, Respond).
2. **Logging:** Every grievance, even if resolved on the spot, must be entered into the **Complaints Register**.
3. **Escalation:** If a complaint involves a potential medical error or legal threat, it must be escalated to the Head of Laboratory within 1 hour.
4. **Impartiality Check:** Never allow a staff member named in a complaint to investigate it.

5. Visual Aids

- **The Complaint Lifecycle Flowchart:** From "Grievance Received" to "Outcome Communicated."
- **Anatomy of a Complaints Register:** A highlighted example of a correctly filled entry.

6. Methodologies for Teaching & Training

- **Role-Play (Primary Method):**
    - *Scenario:* A clinician calls, irate because a culture report is 24 hours late.
    - *Exercise:* One trainee plays the clinician, another the lab staff. Focus on staying calm, gathering the "Ref No," and promising a specific callback time.
- **Lecture:** Overview of the ISO 15189:2022 requirements regarding impartiality in complaint handling.
- **Group Work:** Reviewing a "Mystery Complaint" from a suggestion box and determining if it qualifies as a Nonconformity.

7. Competencies to Develop and Achieve

- **Professionalism:** Maintains a neutral, helpful tone under pressure.
- **Accuracy:** Records the complainant's concerns without paraphrasing in a way that changes the meaning.
- **Process Knowledge:** Correctly identifies when a complaint requires a formal Corrective Action Report (CAR).

8. Assessment Tools

- **Documentation Audit:** The trainer reviews a mock Register entry filled out by the trainee for completeness.
- **Simulated Call:** A "test" phone call where the trainer acts as a difficult user to evaluate the trainee's adherence to the QSP.

9. Guidelines for the Trainer

- **De-stigmatization:** Emphasize that a high number of recorded complaints often indicates a healthy, transparent system, not a failing lab.
- **Confidentiality:** Stress that the identity of the complainant must be protected during the investigation.

10. Pre-Test and Post-Test

1. True/False: If a patient complains verbally and you fix the issue immediately, you do not need to record it in the Register. **2. Who is the most appropriate person to investigate a complaint about a delayed report?** a) The technician who processed the sample. b) An independent Quality Officer or the Head of Lab. c) The person who complained. **3. According to ISO 15189, what must be given to the complainant at the end of the process?** a) A refund. b) A formal notice of the outcome. c) An apology letter from the staff involved. **4. If a complaint reveals that the lab used the wrong antibiotic disc, what other process must be started?** a) Staff suspension. b) Nonconformity and Corrective Action (4.9/4.10). c) No other process is needed.

Scenario for Walk-Through:

"A patient arrives at the counter claiming they received someone else's lipid profile report via email."

- **Step 1:** Trainee acknowledges the distress and secures the incorrect report.
- **Step 2:** Trainee logs the incident in the Complaints Register.
- **Step 3:** Trainer walks trainee through why this is a "Critical" complaint (Patient Privacy Breach).
- **Step 4:** Together, they draft the formal response to the patient explaining the steps taken to prevent recurrence.