Training Module: Handling Nonconformities & Driving Improvement

Focus Areas: QM Sections 4.9 (Nonconforming Work), 4.10 (Corrective Action), and 4.11 (Preventive Action)

1. Scope

This module covers the identification, documentation, and systemic resolution of deviations within the microbiology laboratory. It applies to all technical staff, quality officers, and laboratory management involved in the testing cycle.

2. Introduction and Objectives

The goal of this training is to move beyond "fixing mistakes" toward "preventing recurrence."

- **Primary Objective:** To ensure all staff can independently identify nonconforming work and initiate the standard response protocol.
- **Secondary Objective:** To master Root Cause Analysis (RCA) techniques to ensure laboratory stability and patient safety.

3. Structural Content

The training is divided into three pillars:

- **Pillar 1: Containment (Section 4.9):** What to do the moment a deviation is spotted.
- **Pillar 2: Resolution (Section 4.10):** How to dig deep into why it happened and fix the system.
- **Pillar 3: Foresight (Section 4.11):** How to use data and risk assessment to prevent issues before they occur.

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

- **Scenario Initiation:** When a QC fails or a sample is misplaced, staff must immediately tag the work and notify the QAO.
- **The Paper Trail:** Step-by-step walkthrough of filling out the **Nonconformity Register** and the **Corrective Action Report (CAR)**.
- **The Stop-Work Authority:** Defining who has the power to halt testing and the criteria for resuming it.

5. Visual Aids

- **Flowchart:** The lifecycle of a Nonconformity from detection to closure.

- **Fishbone Template:** Visual guide for brainstorming root causes (Manpower, Method, Material, Machinery, Environment).

6. Methodologies for Teaching & Training

- **Interactive Lecture (30 mins):** Introduction to ISO 15189 requirements and NIHS-specific policies.
- **Group Work (45 mins):** "The Microbiology Case Study." Groups are given a scenario (e.g., a batch of contaminated culture media was used for 10 patient samples) and must:
    1. Fill out an NC Register entry.
    2. Perform a "5-Whys" analysis.
    3. Propose a Corrective Action.
- **Role Play:** Simulating a conversation between a technician and the Head of Lab regarding the need to recall patient reports.

7. Competencies to Develop and Achieve

- **Identification:** Ability to distinguish between a simple "correction" and a "nonconformity."
- **Critical Thinking:** Successful completion of a Root Cause Analysis that identifies a systemic issue rather than just blaming "human error."
- **Documentation:** Accurate and legible completion of laboratory quality records.

8. Assessment Tools

- **Direct Observation:** The trainer observes the trainee filling out a mock CAR form.
- **Scenario Quiz:** "If an incubator temperature is 2 degrees off, what is your first step?"

9. Guidelines for the Trainer

- **Emphasize "No Blame" Culture:** Ensure trainees understand that the NC register is a tool for system improvement, not staff punishment.
- **Focus on Patient Safety:** Always link the technical requirement back to the potential impact on the patient.
- **Real-world Context:** Use actual (anonymized) examples of past errors from the lab to make the training relatable.

10. Pre-Test and Post-Test

Sample Questions:

1. *(Pre/Post)* True/False: Work can resume immediately after an NC is fixed by a technician.
2. *(Pre/Post)* Define the difference between a Correction and a Corrective Action.
3. *(Pre/Post)* In a Fishbone diagram, which "M" would a faulty autoclave fall under?
4. *(Pre/Post)* Who has the final authority to "Close" a Corrective Action Report?

11. Training Record

Upon completion, the trainer and trainee sign the **Competency Assessment Record (NIHS/MICRO/REC/GEN-05)** to be filed in the staff's personal file.

1. The Training Scenario: "The Contaminated Batch"

The Situation: On Monday morning, a Lab Technologist notices that 5 out of 20 Blood Agar plates inoculated with sterile swabs for "Environmental Monitoring" show heavy growth of *Bacillus* species. Simultaneously, three clinical wound swabs processed on the same batch of media show the exact same contaminant pattern.

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2. Detailed Walk-Through (Step-by-Step)

Step 1: Detection and Containment (Section 4.9)

- **Action:** The technologist recognizes this as **Nonconforming Work**.
- **Immediate Procedure:** 1. Stop using that specific batch of Blood Agar (Batch #BA-2026-05). 2. Place a "DO NOT USE" sign on the remaining plates in the cold room. 3. Notify the Quality Assurance Officer (QAO) and the Head of Laboratory.
- **Containment:** Any patient reports from this batch that are "pending" are put on hold.

Step 2: Documentation (The Register)

- **Action:** The QAO opens the **Nonconformity Register**.
- **Entry:** "Contamination observed in Blood Agar Batch #BA-2026-05 affecting both QC and clinical samples."

Step 3: Clinical Impact Assessment (Section 4.9)

- **Action:** The Consultant Microbiologist reviews the three wound swabs.

- **Decision:** One report was already sent out as "Mixed Growth." A corrected report must be issued stating the potential for contamination, and the clinical team must be notified.

Step 4: Root Cause Analysis (Section 4.10)

- **Activity:** The team uses the **Fishbone Diagram** to investigate.
    - *Materials:* Was the dehydrated powder expired? (Checked: No)
    - *Machinery:* Did the Autoclave reach 121°C? (Checked: The chart shows it only hit 110°C due to a faulty gasket).
    - **Root Cause:** Autoclave failure led to incomplete sterilization of the media batch.

Step 5: Corrective Action (Section 4.10)

- **Action:** 1. Repair the autoclave gasket and recalibrate the temperature sensor. 2. Discard the entire batch of media. 3. Retrain staff on checking autoclave charts *before* pouring media.

Step 6: Preventive Action (Section 4.11)

- **Action:** Update the Preventive Maintenance (PM) schedule to include a monthly gasket inspection and implement the use of "Class 5" chemical integrators inside every media load to provide a secondary visual check of sterilization success.

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3. Assessment Tools

Tool A: Competency Checklist (Observational)

- [ ] Did the trainee identify that the contamination was an NC?
- [ ] Did the trainee correctly identify the "Root Cause" using the 5-Whys?
- [ ] Can the trainee locate the "Nonconformity Register" in the lab?
- [ ] Did the trainee understand why a "Correction" (re-making media) is different from "Corrective Action" (fixing the autoclave)?

Tool B: Case Study Group Worksheet

- *Task:* Provide the group with an EQA report showing a "False Negative" for *Salmonella*. Ask them to fill out a mock **Corrective Action Report (CAR)** including a Root Cause Analysis and a proposed verification plan.

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4. Pre-Test and Post-Test (Knowledge Evaluation)

Use the same questions for both to measure the "Learning Gap."

1. A technician notices the fridge temperature is 12°C (Standard: 2-8°C). The first step is to: a) Ignore it if it's only been an hour. b) Move reagents to a working fridge and notify the QAO. c) Adjust the thermostat and check again tomorrow.

2. Which of the following is a "Corrective Action" (not just a correction)? a) Re-testing a sample. b) Changing a faulty SOP to prevent a labeling error from happening again. c) Cleaning a spill on the bench.

3. Root Cause Analysis is used to: a) Find out who to blame for the mistake. b) Identify the underlying systemic reason why an error occurred. c) Document that the laboratory is busy.

4. According to Section 4.11 (Preventive Action), how do we identify potential problems? a) Waiting for a clinician to complain. b) Analyzing trends in QC data and risk assessments. c) Only after an audit finds a nonconformity.

5. Who has the authority to authorize the resumption of work after a major nonconformity? a) Any laboratory staff member. b) The Head of Laboratory or designated Quality Manager. c) The hospital maintenance team.

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5. Answer Key & Methodology for Trainers

- **Answers:** 1-b, 2-b, 3-b, 4-b, 5-b.
- **Passing Score:** 80% (4/5 correct).
- **Trainer Note:** If a trainee fails the Post-Test, provide a 1-on-1 walk-through of the **Management of Nonconforming Work QSP** and re-evaluate after 48 hours.