ROYAL CENTRE FOR DISEASE CONTROL

SOP No. RCDC/QMS/QSE/SOP/9.1

STANDARD OPERATING PROCEDURE

FOR

NONCONFORMING EVENT MANAGEMENT

Version 1.00

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1. ACRONYMS AND DEFINITION

CAPA: Corrective Action Preventive Action

SOP: Standard Operating Procedure

QM: Quality Management

Definition

Nonconforming event or Nonconformity: Non-fulfillment of a requirement. *Occurrence*: An event, accident or circumstance that happened without intent, volition or plan.

Reportable nonconforming event or occurrence: Nonconforming event or occurrence to be reported in accordance with the reporting criteria defined in the *SOP Occurrence Report*.

2. PURPOSE

The most non-conforming events are the result of problems with existing processes. Laboratory professionals need to have defined processes to not only report nonconforming events but also to follow through and determine the causes then they can implement processes improvement changes. This document will help identify and address non-conforming events, which would elevate service delivery and bring quality assurance to the next level.

3. APPLICATION

This SOP is applied to all laboratory personnel performing various laboratory tests.

4. RESPONSIBILITIES

All staff shares the responsibility for quality. Therefore, all staff shares the authority and responsibility of:

- Identifying non-compliances or possible improvements;

- Recording nonconforming events so that corrective actions can be taken in order to correct the immediate situation and prevent recurrence.

4.1 The Laboratory Director:

- Approves the Nonconforming Event Management system.

4.2 The Quality Committee:

- Administers the Nonconforming Event Management system;
- Discusses potential corrective actions for nonconforming events that impact laboratory quality.

4.3 The Quality Manager:

- Ensures verification of the effectiveness, efficiency, and adequacy of the Nonconforming Event Management system;
- Discusses with staff the direct implications of nonconforming events concerning quality;
- Helps in quick resolution of nonconforming events that negatively impact quality;
- Decides if a nonconforming event is reportable, and fills in the notification report following the *SOP Occurrence Report*, if needed;
- Carries out investigation to resolve any quality discrepancies;

4.4 The Biosafety Committee:

- Takes part in discussions of potential corrective actions for all significant nonconforming events concerning biosafety.

4.5 The Biosafety Officer:

- Discusses with the staff the direct implications of nonconforming events concerning biosafety;
- Helps in quick resolution of nonconforming events concerning biosafety;
- Decides if a nonconforming event concerning biosafety is reportable, and fills in the notification report following the *SOP Occurrence Report*, if needed;

- Carries out investigation to resolve any biosafety discrepancies;
- Ensures that action is taken in order to improve biosafety processes/activities.

5. PRINCIPLE

Every procedure for the laboratory test is liable for discrepancies. Therefore to address the occurrence of non-conformities is critical in order to maintain smooth running of the lab. The record of non-conformities and their remedial actions would serve as a reference to all the staff performing the test should any similar non-conformities occur in future.

6. ASSOCIATED DOCUMENTS

- CAPA form

7. PRECAUTIONS

Ensure the records for non-conformities are readily accessible to all the laboratory staff.

8. PROCEDURE

- Not every quality issue requires a corrective action and not every corrective action calls for a preventive action.
- The decision on what type of action is needed should be based on a number of factors, such as risk, impact, severity and frequency of the event.
- The depth of a CAPA investigation and implementation should match the risk. Some nonconformity could have occurred earlier and certain other are closely linked to another that has already been addressed.
- Tickets for such events can be closed satisfactorily. If the event requires CAPA, complete the form which will be reviewed by the QM.
- It may require no major interventions and may suffice with a follow-up. However certain events may require CAPA which has been reviewed and approved for effective check by the QM. This may lead to success or failure of the quality check. Flow diagram (Figure 1) depicts the nonconformity event management scheme.

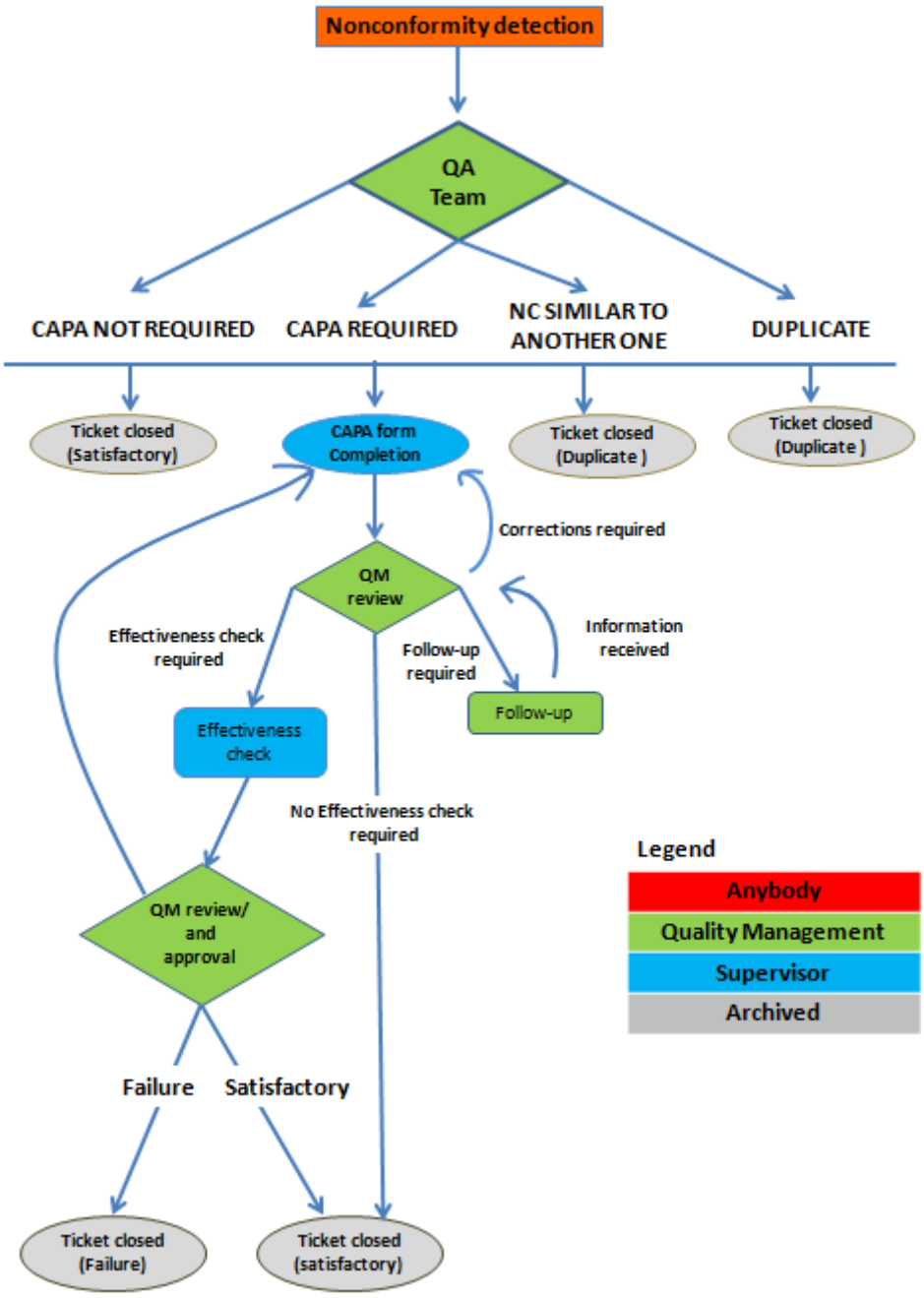

Figure 1; Flow diagram depicts the nonconformity event management scheme

9. REFERENCE

- https://www.ap-next.net/quality-optimizer/m5plus-laboratory-quality-optimizer

10 ANNEXURE

Annexure 1 CAPA form

ID #	DEFICIENCY DESCRIPTION	ACTIONS	IS DEFICIENCY RESOLVED?	RESOURCES	LEAD	PLANNED COMPLETION DATE	ACTUAL COMPLETION DATE	REVIEW DATE