<table>
<tr><td colspan="4">PRL Non-Conformances and Corrective actions</td></tr>
<tr><td>Doc no</td><td>PRL-MGT-009</td><td>Revision 0.0</td><td>Effective Date: 1Sept 2020</td></tr>
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</table>

1.0 Purpose

The purpose of this SOP is to describe /guide Proteus Laboratories personnel on the steps taken to identify, document, control and manage non-conformities identified in pre-examination, examination, post examination, and managerial processes.

2.0 Scope

This procedure is used to identify, control and manage non-conformities in all aspects of the quality management system including pre-examination, examination, post- examination and management processes. This procedure is applicable to all laboratory personnel at Proteus Laboratories.

3.0 Terms, definitions, and abbreviations

3.1 Terms and definitions

Non-conformance - This is a non-fulfilment of a specified, or implied, requirement of the Quality Management System or of a quality work product. (Non-fulfilment of a requirement).

Preventive action - This is a measure put in place to guard against the occurrence of the cause of a potential nonconformity or other potentially undesirable situation. Preventive action is a pro-active process for identifying opportunities for improvement rather than a reaction to the identification of problems or complaints.

Audit: A systematic, independent and documented process for obtaining evidence and evaluating it objectively to determine the extent to which laboratory meets the set standard criteria.

Immediate action: The action taken at the time of the incident to mitigate the immediate effect of a non-conformity.

Corrective action: The action taken to eliminate the cause of a detected nonconformity or other undesirable situation.

Continual improvement: It is a recurring process to increase the ability to fulfil requirements. Continuous improvement is a procedure that identifies gaps and addresses them in the form of improvements within the system and potential sources of nonconformities.

Root cause Analysis: Structured investigations that focuses on identifying the underlying true cause(s) of non-conformity.

3.2 Abbreviations

NC Non-Conformity

QMS Quality Management System

PRL Proteus Laboratories

SOP Standard Operating Procedure

N/A Not Applicable

MGT Management

4.0 Tasks, Responsibilities, and Accountabilities Task	**Responsible**	**Accountable**
Identification, documentation of NCs and defining immediate actions	Laboratory personnel	Quality Manager
Halting of examination results and recalling of results	Laboratory Manager	Laboratory Manager
Authorization for the resumption of testing	Lab Manager	Laboratory Manager
Review of NC records and trend analysis	Quality manager	Quality manager
Initiation of Corrective Action	Quality manager	Laboratory Manager

5.0 Safety and Environment

N/A

6.0 Quality assurance/ Quality control

N/A

7.0 Procedures

7.1 Identification of Nonconformities

Proteus Laboratories ensures that all non-conforming work in the quality management system is identified, investigated, reviewed, analysed and

correctly documented to continually improve on the laboratory services and patient care. The laboratory identifies non-conformance through;

- Review of users' complaints
- Review of internal and external quality control data.
- Calibration reports.
- Evaluation of consumable supplies.
- Inter-laboratory comparisons.
- Staff comments and suggestions
- Reports and certificate review
- Management reviews.
- Internal and external audits
- amongst other processes.

7.2 Identifying, managing and recording non-conformities

The lab personnel identifying the NC performs appropriate immediate actions if applicable.

7.2.1 Immediate actions

When a NC is identified, the personnel identifying the NC performs an appropriate immediate action. Immediate actions include:

- Re-running controls for failed IQCs
- Re-calling test results in case of identified errors
- Alert personnel in case of fire and spills
- Missing results sent to the clinician
- Recalling results in case of analysing wrong samples
- Rerunning of EQA panels in case of unsatisfactory results are undertaken as appropriate for the examination procedures.

The personnel document the NC on the NC form and reviews the documented NC to ensure that the following details are included:

- What is the NC?
- Where the NC occurred?
- When the NC occurred?

● Who identified the NC?

The immediate action taken is also documented in the Corrective action form. The NC form is taken to the quality officer who defines and determines the extent of the NC and the next steps for the non-conformity. This is to ensure proper interventions to prevent reoccurrence of the non-conformity and to develop an effective corrective action plan.

7.3 Determining the extent of non-conformity

NCs are classified as major or minor

7.3.1 Major Non-conformities

An NC which is likely to result in the failure of the quality management system or to reduce its ability to assure control processes or products; it can be one or more of the following:

● A non-conformity where the effect is judged to be detrimental to the integrity of the sample

● The absence of, or total breakdown of a system to meet a standard requirement, organizational procedure or customer quality management requirement.

● Any non-conformity that affects patients results

● Any non-conformity identified during the internal audit and still discovered in the next audit

● A condition that could result in the failure or reduce the usability of laboratory services and its intended purpose

7.3.2 Minor Non-conformities

A non-conformity which is not likely to result in the failure of the quality management system or reduce its ability to assure controlled process or product. It can be one of the following

● A single system failure or lapse in conformance with the standard or customer quality management system requirement or

● A single system failure or lapse in conformance with a procedure associated with the organization's quality management system.

NOTE; several minor non-conformities against one requirement e.g. in different sections can represent a total breakdown of the system and thus considered a **major non-conformity**

7.4 Halting of examinations and withholding results

If QC fails or a technical fault with the equipment or method occurs, testing is halted and the lab manager or designate informs the requesting clinicians and the patient.

Troubleshooting on the equipment or method is done to establish the fault and appropriate action is taken to correct the fault.

Authorization for the resumption of testing is given by the laboratory manager or designee after internal quality controls have passed. Tests performed within the time frame the equipment or method became faulty are identified, recalled and are re-run to ensure that the test results are reliable and accurate. This is documented in the non-conformity report form and records maintained.

7.5 Medical significance of non-conforming examinations

In the event where the non-conformity is identified when the results are already dispatched to the requester, the requester is informed, and the issued results recalled. When the non-conformity is addressed, the sample run is repeated, and a new batch of results is issued out as amended results to the clinicians.

7.6 Review of non-conformities

The documented non-conformities report form is reviewed quarterly by the quality officer to detect trends and initiate corrective actions. Results from these reviews are also presented

during management review meetings. Where appropriate, preventive action is put in place to ensure that the NC does not reoccur.

8.0 References/Related documents

- Quality Manual **(PRL- MAN -001)**
- Continual improvement SOP **(PRL- MGT-012)**
- Corrective Action and Preventive Action SOP **(PRL- MGT- 009)**

- ISO 15189:2012

9.0 Attachments/annexes

- Annex 1: SOP Attestation form

1.0 Purpose

This SOP helps in the development of corrective action/preventive actions for the identified NCs, monitoring the effectiveness of the implemented corrective action/preventive actions at Proteus Laboratories.

2.0 Scope

This SOP covers review of non-conformities, determining root cause, evaluating the need for corrective/preventive action, determining and implementing corrective/preventive action, recording the results of corrective/preventive actions taken and reviewing the effectiveness of corrective action/preventive actions taken.
This SOP is applicable to all Proteus Laboratories staff, including volunteers, and students attached to the laboratory.

3.0 Terms, definitions and abbreviations

3.1 Terms and definitions

Non-conformance - This is a non-fulfilment of a specified, or implied, requirement of the Quality Management System. (Non-fulfilment of a requirement).
Corrective action: The action taken to eliminate the underlying cause of a detected nonconformity or other undesirable situation.
Preventive action - This is a measure put in place to guard against the occurrence of the cause of a potential nonconformity or other potentially undesirable situation. Preventive action is a pro-active process for identifying opportunities for improvement rather than a reaction to the identification of problems or complaints.

Immediate action: The action taken at the time of the non-conformity to mitigate its immediate effect.

Root cause Analysis: Structured investigations that focuses on identifying the underlying true cause(s) of Nonconformity.

3.2 Abbreviations

CAPA Corrective Action and Preventive Action

PRL: Proteus Laboratories

NCs: Non-conformity

QMS: Quality Management System

RCA Root Cause Analysis

SOP: Standard Operating Procedure

QO Quality Manager

N/A Not Applicable

CA Corrective Action

PA Preventive Action

MGT Management

IQC Internal Quality Control

HOS Head of Section

4.0 Tasks, Responsibilities and Accountabilities

Task	Responsible	Accountable
Reviewing nonconformities	Quality officer	Quality Manager
Determining root causes of non-conformities	Laboratory personnel	Quality Manager
Evaluating the need for corrective action/preventive action	Quality Manager	Quality Manager
Determining and implementing corrective actions/preventive action	Laboratory personnel	Quality Manager
Recording results of corrective actions/preventive action	Laboratory personnel	Quality Manager
Reviewing the effectiveness of corrective action/preventive actions taken	Section heads	Quality Manager
Closure of non-conformity	Quality Manager	Quality Manager

5.0 Safety and Environment

N/A

6.0 Quality assurance and Quality control

N/A

7.0 Procedure

Proteus Laboratories ensures that all nonconforming work in the quality management system is identified, investigated, reviewed, analysed and correctly documented to continually improve on the laboratory services and patient care.
It is the responsibility of the laboratory personnel to ensure that non-conformities are captured in the CA forms. The laboratory personnel identifying the NC performs appropriate immediate actions if required. The personnel documents on the CA form and reviews the documented NC to ensure that the following details are included as appropriate:

- What is the NC?
- Where the NC occurred?
- When the NC occurred?

- Who identified the NC?

The section head or designee forwards the NC to the Quality Officer who is also responsible for assigning the NC number and updating the NC master log.

7.1. Corrective action

7.1.1 Review of non-conformities

The Quality officer reviews the submitted non-conformity form for completeness including;

- Details of the non-conformity i.e. what, where, when, who, how
- Reference number of relevant guide/standard/requirements violated

The quality officer assigns the identified NC, a NC Number (NC No) for tracking the NC throughout the system. NC Numbers are assigned serially as per the calendar year.

i.e. **NC-XXX/YY**

Where:

NC Non-Conformity

XXX Serial number starting at 001

YY- Calendar year

The quality officer categorises the identified non-conformities as minor and major non-conformities which also guides on whether testing is to be halted by the laboratory manager.

7.1.2 Determining root cause of non-conformities

The laboratory performs root cause analysis as the basis for initiation of corrective actions for NCs. NCs are investigated to determine their actual cause and coming up with the most suitable corrective actions to be implemented. Root cause analysis is conducted by the team appointed by the quality officer or section head. The laboratory employs a combination of at least two of the following methods.

- **Fish bone**

Used to identify different contributors of NCs. It is a robust method for handling NCs. At the head of the fish bone is the NC stated in the form of a question. The major bones are the main grouping of causes and may include people, equipment, material, information, methods, measurements and environment. The minor bones are the detailed items under each cause

- 5 whys

Is used to identify the root cause by tracing back through the sequence of events that led to the NCs.

▪ Brainstorming
Is used to generate ideas about a certain NC that would have otherwise been missed. It is excellent for minor NCs
▪ Flow chart

Used to detect the steps of a process at which the NC is generated and brainstorm on the causes of the NC at that step.
▪ Logic Tree

Best for tracking problems when there are multiple answers to the NC at each level.
▪ Histogram and Pareto charts

Used to represent frequency, quantity and time. The charts visually depict which situation of the NCs are more significant
▪ Document and record review

Used to understand the requirements of the process
▪ Interviews

Used to describe documented and undocumented practices and to provide details of what happened by the owners of the system
▪ Brain writing

Used to generate as many ideas as possible. It involves many people and enables anonymity
▪ Pictograms

Used when there is a spatial component to the problem e.g. clutter in the storage area or spaghetti in the Lab.

The probable root cause is identified, and corrective action is implemented. The process of investigation and analysis of the root cause is fully documented by the team assigned to investigate the non-conformity in the CA form.

7.1.3 Evaluating the Need for Corrective action

The quality officer or section head evaluates the corrective action before implementation and either

▪ Approves the corrective

▪ Deems the corrective action unappropriated and the root cause analysis process is repeated.

7.1.4 Implementing Corrective Action needed

Corrective actions are implemented through the Laboratory supervisors. The responsibility for implementation includes recording the corrective action taken on the corrective action form. Corrective actions are implemented within one month following the identification of NC. However, the action plan for the proposed corrective action is taken within a week of the non-conformance. The quality manager will review the proposed corrective action and give guidance as required. And those that cannot be implemented within one month, an extension for completion is sought within a week of the non-conformance been raised. The quality manager will Give approval based on the reasons given for the extension.

7.1.5 Reviewing the Effectiveness and Closure of the Corrective action taken

The effectiveness of the implemented corrective action taken is monitored through conducting audits or trend analysis, at least three months after implementation of CA.

The quality manager verifies the implementation and completion of the corrective action by reviewing the supporting documents or evidence. If the implemented corrective action is effective and the NC does not recur the NC is deemed closed. If the NC recurs, the CA is deemed not effective and the process is repeated. Records for corrective actions are maintained by the

laboratory manager for Managerial NCs and the section head for the technical or examination NCs. It's the responsibility of the quality officer to ensure that the results are communicated during the laboratory meetings and management review meeting.

7.2. Preventive action

The laboratory has procedures in place to identify potential NCs and implement preventive actions to prevent their occurrence.

7.2.1 Reviewing Laboratory data and Information to determine potential NCs

The quality officer ensures that work system processes are monitored, and that data is reviewed quarterly to determine possible pitfalls or potential nonconformities.

The data reviewed include; monthly IQCs, review meetings, quality indicators, post examination processes, risk assessment, trend analysis, and external quality assessments among others. The identified potential NCs are documented in the preventive action form by the laboratory personnel who then reviews the documented potential NC to ensure that the following details are included:

- What is the potential NC?
- Where the potential NC could occur?
- When the potential NC may occur?
- Who identified the potential NC?

The laboratory personnel then forward the PA form to the Quality officer who is also responsible for updating the NC master log.

The quality officer assigns the identified potential NC a PA Number (PA No) for tracking the PA throughout the system. PA Numbers are assigned serially as per the calendar year.

i.e. P**NC- XXX/YY**

Where;

PNC Potential Non-Conformity

XXX- Serial number starting at 001

YY- Calendar year

7.2.2. Determination of Root Cause of Potential Nonconformities

Proteus Laboratory performs root cause analysis as the basis for initiation of preventive actions for potential NCs. Potential NCs are investigated to determine their probable causes and coming up with the most suitable preventive actions to be implemented. Root cause analysis is conducted by the team appointed by the quality officer or section head. The laboratory where possible a combination of at least two of the following methods is used:

▪ Fish bone

Used to identify different contributors of Potential NCs. It's a robust method for handling potential NCs. At the head of the fish bone is the potential NC stated in the form of a question. The major bones are the main grouping of probable causes and may include people, equipment, material, information, methods, measurements and environment. The minor bones are the detailed items under each probable cause.

▪ 5 whys

Is used to identify the root cause by tracing back through the sequence of events that could lead to the probable NCs.

▪ Brainstorming

Is used to generate ideas about a probable NC that would have otherwise been missed.

▪ Flow chart

Used to detect the steps of a process at which the probable NC is generated and brainstorm on the potential causes of the probable NC at that step.

▪ Logic Tree

Best for tracking problems when there are multiple answers to the probable NC at each level.

▪ Histogram and Pareto charts

Used to represent frequency, quantity and time. The charts visually depict which situation of the probable NCs are more significant

▪ Document and record review

Used to understand the requirements of the process

▪ Interviews

Used to describe documented and undocumented practices and to provide details of what happened by the owners of the system

▪ Brain writing

Used to generate as many ideas as possible. It involves many people and enables anonymity

▪ Pictograms

Used when there is a spatial component to the problem e.g. clutter in the storage area or spaghetti in the Lab

The probable root cause is identified, and preventive action is implemented. The process of investigation and analysis of the root cause is fully documented by the team assigned to investigate the potential non-conformity in the preventive action form.

7.2.3 Evaluating the Need for Preventive action

The quality officer or section head evaluates the preventive action before implementation and either;

▪ Approves the preventive action to be implemented to address the identified potential nonconformity or,

▪ Deems the preventive action unappropriated and the root cause analysis process is repeated.

7.2.4 Implementing Preventive Action needed

Preventive action is implemented through the section heads. The responsibility for implementation includes recording the preventive measures on the preventive action form. Preventive actions are implemented within one month following identification of potential NC. And those that cannot be implemented within one month, are forwarded to laboratory management for final decision.

7.2.5 Reviewing the Effectiveness and Closure of the Preventive action taken

The effectiveness of the implemented preventive action taken is monitored through conducting audits or trend analysis at least three months after implementation of the PA.

The quality officer verifies the implementation and completion of the preventive action by reviewing the supporting documents or evidence. If the implemented preventive action is effective and the potential NC does not occur, the potential NC is deemed closed. In an event that the potential NC occurs, the PA is deemed not effective and the process is repeated. Records for preventive actions are maintained by the lab manager for Managerial potential NCs and at the section for the technical or examination potential NCs. It's the responsibility of the quality officer to ensure that the results are communicated during the lab. Meetings and management review meeting.

8.0 References/Related documents

- Quality Manual **(PRL- MAN-001)**
- Identification and control of nonconformities **(PRL- MGT- 009)**
- Continual improvement SOP **(PRL- MGT -012)**
- ISO 15189:2012

9.0 Attachments /Annexes

- Corrective / Preventive Action Form
- NC Master Log

Appendix 1: Non-Conformity Form

<table>
<tr><td colspan="5">Section I</td></tr>
<tr><td colspan="2">SECTION NC NO:</td><td colspan="3">NC NO:</td></tr>
<tr><td colspan="5">Details of Non-conformance:

Immediate action:</td></tr>
<tr><td>Classification of NC
Major ◯ Minor ◯</td><td colspan="2">Reference no of relevant guide/Standard/requirement</td><td colspan="2">Was test halted?
Yes ◯ NO ◯
Signature/Date:</td></tr>
<tr><td colspan="2">Name of reporter/Identifier:</td><td colspan="2">Date:</td><td>Signature:</td></tr>
<tr><td colspan="5">Section II (Attach Supporting Evidence)</td></tr>
<tr><td colspan="5">Root Cause:

Corrective Action(s) taken: YES ◯ NO ◯

Date: ______________________Sign: _______________________(HOS/QO)

Resumption of testing YES ◯ NO ◯

Date:__________________________ Sign:_____________________(lab director/manager)</td></tr>
<tr><td colspan="5">Section III (Attach Supporting Evidence)</td></tr>
<tr><td colspan="5">Effectiveness
Corrective Action effective: YES ◯ NO ◯
Comment:</td></tr>
<tr><td colspan="5">Quality Officer/HOS Signature: _____________________Date…………………………………...</td></tr>
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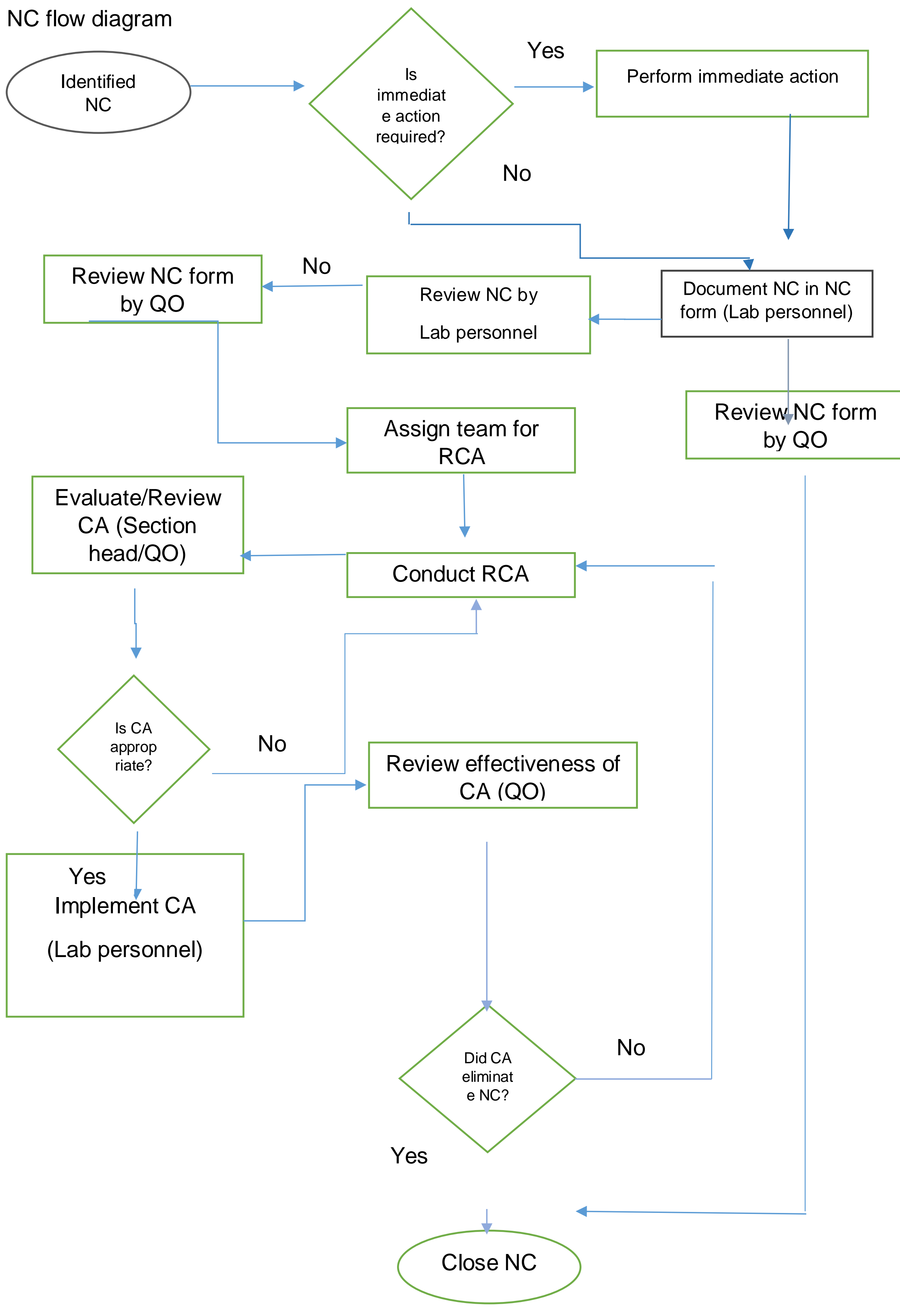
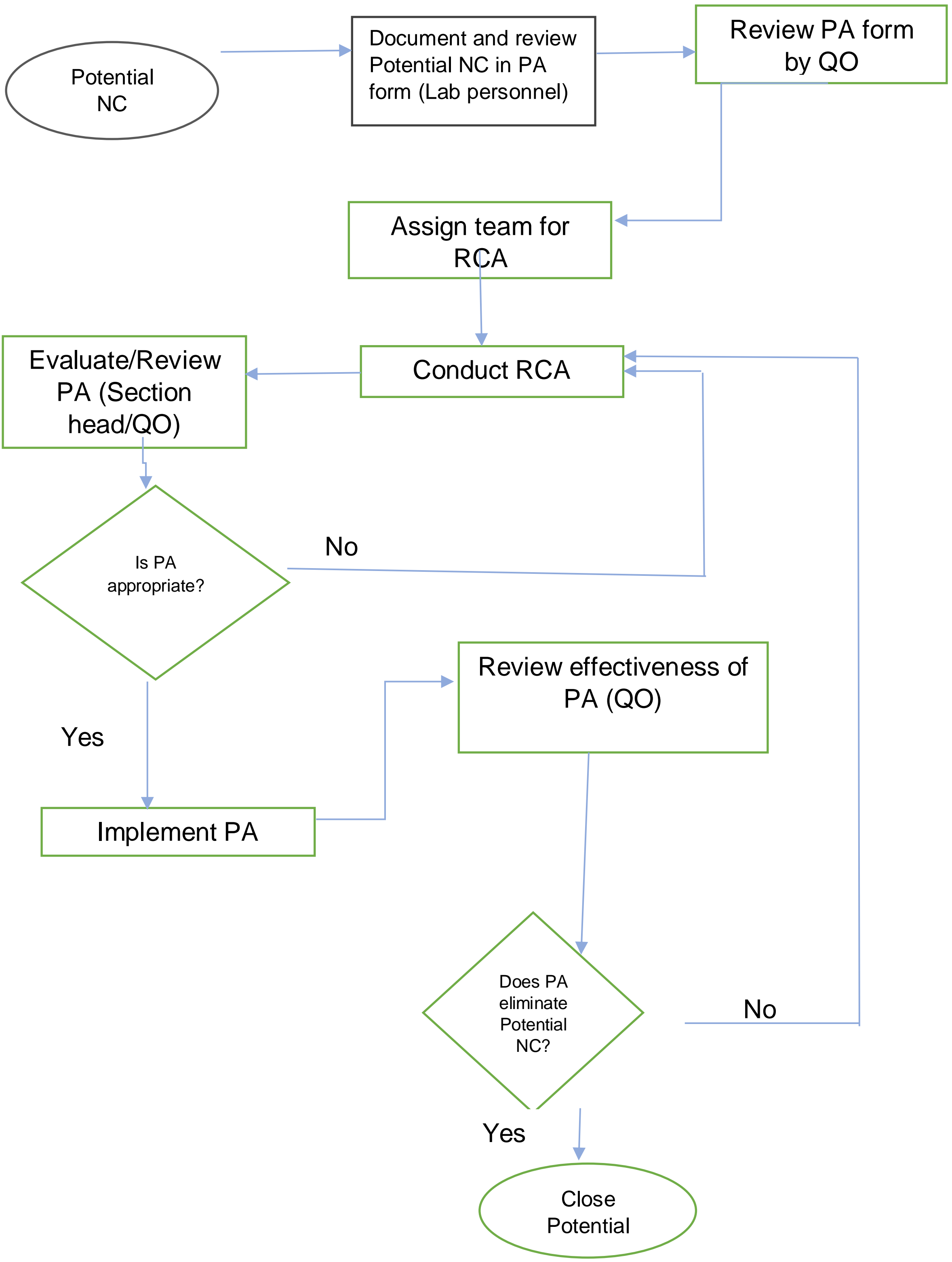
NC flow diagram



PA flow diagram



Non-conformances Log

N/C Number	Detailed Non-Conformance	Proposed CA/PA	Target date of Completion	Verification of completion date

Version review history table

Version No	Date of next review	Date reviewed	Action taken/Remarks	Reviewed by

ACKNOWLEDGEMENT OF READING FORM

Title………………………………

My signature confirms that I have read and understood the contents of this document

Name	Signature	Date