Purpose

To control any aspect of testing work or the results of testing work that does not conform with its procedures.

Scope

Nonconforming work or any part thereof.

Definitions and Acronyms

Nonconformity – nonfulfillment of a specified requirement.

Disposition of Nonconformity – outcome of action taken.

Responsibilities

The technical leader/quality manager can halt work when nonconformities are identified.

The technical leader/quality manager is responsible for authorizing the resumption of work after effective corrective action has been taken to prevent the release of unacceptable test results. **This requires the use of the corrective action procedure, SOP#** *QSP 4-11-1,Corrective Action* to find the root cause of the nonconformance.

Materials Required

Corrective Action Request form
Equipment logbook
Maintenance Records
Preventive Action Requests
Non conformity record
Approved Vendor List
Vendor Evaluation
Deviation request form
Procedures

Procedure

Technical or administrative case-related non-conformities shall be grouped into two classes as determined by the impact on the Laboratory.

Class I non-conformities shall be documented and corrected on the spot, while Class II, non-conformities require management involvement.

Class I non-conformities generally:

- Are discovered prior to case completion.
- Are foreseeable.
- Have a clear-cut, immediate cause.
- Have a defined remedial action, which shall be adequately documented by a simple entry on the examination documentation, or noted in the administrative or technical review.
- Shall be corrected on the spot by the individual who discovers them or by the original examiner when administrative or technical review is returned.
- Do not compromise the overall quality of work if properly addressed.
- Are not required to be documented on the Non-conformity Record.

Examples: administrative or transcription error, or failure in a quality control check such as carry-over in a blank, etc. (Some Class I non-conformities may be Section-specific and defined by the Technical Leader.) Class I non-conformities occur as part of casework. Remediation for such Class I non-conformities shall be made on the spot by Analyst.

Staff shall take appropriate measures to correct or repair non-conforming data, reporting or equipment.

Class II non-conformities generally:

- Are discovered prior to case completion.
- Are unexpected.
- Have a clear-cut, immediate cause.
- Do not compromise the overall quality of work if properly addressed.
- Are required to be documented on the Non-conformity Record and in the case file.

Examples: contamination issues, non-systemic identification of a Laboratory employee by Fingerprints or non-conformities not immediately corrected during the review process.

The individual who identifies any Class II non-conformity shall inform the individual and/or Technical Leader within two business days and initiate the Non-conformity Record (NCR) to document the issue. The Quality Manager/Technical Leader shall conduct basic fact finding.

The QM, in collaboration with the Technical Leader, shall determine if the non-conformity rises to the level of a Corrective Action.

Remedial actions shall be documented in the case file if applicable.

The QM or designee shall keep a file of all Class II Non-conformities and place them on the Nonconformity Record Log.

1. Record the occurrence of a nonconforming event in the Non-conformity record Form# 4-8-1-F1, Nonconformity Record (NCR).

2. Report the nonconforming event to the supervisor.

3. Evaluate the significance of nonconforming work.

4. If necessary, suspend further work.

5. Complete Non-conformity Record.

   Non Conformity Record

   The record shall be completed when there is Class II nonconformity with testing, documentation or other quality issues.

   The nonconformity record shall be completed as follows;

   Section I, II and III shall be filled out by the Originator.

   The Originator shall identify the individuals involved along with case details such as, date, case number, type of testing and person identifying the nonconformity. The originator shall write a statement of events in which the nonconformity occurred.

   Section IV shall be completed by the Quality Manager/Technical Leader. The quality manager/technical leader shall be the basic fact finder and recommend whether further action should be taken. A full explanation shall be provided in this section.

6. If necessary, initiate corrective action.

7. Notify client if applicable.

Documentation

Equipment problems are recorded in the appropriate equipment maintenance log. All nonconformities are recorded in the Non-conformity record or Corrective Action Request form.

Root cause analysis and closed loop corrective actions taken to prevent recurrence of nonconformities are recorded as described in *QSP 4-11-1,Corrective Action*.

Required Record	Custodian
Deviation Request Form when required	Quality manager
Nonconformity (first section of CAR/NCR)	Quality manager
"Out of Service – Do Not Use" label	Technical Leader

Reference Procedures

QSP 4-11-1,Corrective Action

References

Quality Manual – Sections 4.9

REVISION HISTORY		
CURRENT VERSION	**EFFECTIVE DATE**	**SUMMARY OF CHANGES**
1	2016/07/01	Original version
2	2018/04/01	Add classification of level 1 and level 2 non-conformity, change issue date to effective date, change rev# to ver#.