
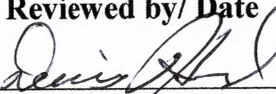
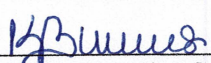
	Standard Operating Procedure	SOP Number D-126	Revision 0
	Non-Conforming Results in the QC Laboratory	Effective Date 04/29/22	Page Page 1 of 6
Written by/ Date  06/03/22	Reviewed by/ Date  06-03-22	Approved by/ Date  06/03/22	
Title: QC Laboratory Director	Title: VP of Quality & Regulatory Affairs	Title: Quality Systems Manager	

1.0 Purpose

The purpose of this procedure is to define, evaluate, and correct Non-Conforming Results (NCR), to prevent their recurrence, and to ensure that actions taken are effective. This procedure will describe the processes used for initiating and processing non-conforming results.

2.0 Scope

This procedure applies to all employees in the QC Laboratory who are involved with the detection and correction of nonconformities, as well as with the identification of potential improvements.

3.0 Responsibility

- 3.1 QC Laboratory Management is responsible for and authorized to administer this process, which includes assigning personnel to determine causes of identified problems, or improvement opportunities, and for assigning personnel to implement corrective actions, as well as to verify the results of such actions.
- 3.2 QC Laboratory Management is responsible for ensuring that this procedure is accurate, understood, and implemented effectively. No changes may be made to this procedure without the authorization of QC Laboratory Management.

4.0 Definitions

- 4.1 **NCR** – Non-Conforming Result; any end value or result that does not meet a pre-established specification or expectation
- 4.2 **First Time Product Validation** – the initial test validation performed to ensure that the product matrix presents acceptable data for each test method to be used. This process is typically only for strength evaluation. During a first time product validation, any

specific testing requirements will be determined and captured in a document for future use when testing occurs.

4.3 **Non-Conforming Categories** – severity levels of non-conforming results as defined below:

4.3.1 **Minor** – non-conforming result which does not lead to what is defined as major. Minor non-conforming results usually are an isolated occurrence, do not impact the customer, and usually are able to be resolved quickly and efficiently.

Example: un-validated test result that does not meet a preset specification or expectation

4.3.2 **Major** – non-conformances which have an impact to a regulatory requirement, may cause major delays in processes, or can be a frequently repeated minor non-conforming result.

Example: validated test result that does not meet a preset specification or expectation

4.4 **LMS** – Laboratory Management System (i.e. ISO 17025:2017)

4.5 **OOS** – Out of Specification

4.6 **QC** – Quality Control

5.0 References

5.1 D-105, SOP, Out of Specification/Out of Trend Investigation

5.2 D-122, SOP, Laboratory Operations

5.3 QS-108, SOP, Corrective and Preventative Actions (CAPA)

5.4 QS-111, SOP, Root Cause Analysis

5.5 QS-112, SOP, Core Quality Systems and Quality Events

5.6 D-103, SOP, Analytical Method Validation

5.7 D-126-F1, Form, Non-Conforming Result (NCR) Initiation

5.8 D-126-F2, Form, Non-Conforming Result (NCR) Closure

6.0 Procedure

6.1 Identifying Non-Conforming Results

6.1.1 QC Laboratory personnel must report NCR observations to QC Laboratory Management.

6.1.2 QC Laboratory Management will assess each reported NCR and determine next steps.

6.1.2.1 If the request bears no merit and warrants no further action, the requestor is notified as appropriate.

6.1.2.2 If the NCR meets the definition of “Minor” proceed with assignment of an NCR number and continue to follow this SOP.

6.1.2.3 If the NCR meets the definition of “Major” do not assign an NCR number and proceed to an OOS investigation as per SOP D-105.

6.1.3 If QC Laboratory Management or designated QC laboratory personnel elects to pursue an action as an NCR, the issue is recorded and issued an event number as outlined in SOP QS-112 Core Quality Systems and Quality Events. The initiator will complete form D-126-F1 Non-Conforming Result (NCR) Initiation. Details may include a description of the NCR, or observation, classification as minor or major, and date reported.

6.2 Non-Conforming Test Results

6.2.1 When a non-conforming test result is observed, the below evaluation should occur.

6.2.1.1 If the test/product matrix has been previously validated and the correct process was followed, proceed with an OOS investigation as outlined in SOP D-105 Out of Specification/Out of Trend Investigation.

6.2.1.2 If the test/product matrix has not been previously validated, proceed with validation for this test/product matrix (first time product validation). Refer to SOP D-103 Analytical Method Validation.

6.2.1.3 If the result is still observed to be non-conforming after the first time validation is successful, process with an OOS investigation as outlined in SOP D-105 Out of Specification/Out of Trend Investigation.

6.3 Corrective Actions

6.3.1 Corrective actions include ascertaining action(s) needed to identify, contain, and avoid recurrence of the NCR and other quality concerns.

6.3.2 For each corrective action identified, QC Laboratory Management or designated personnel records the source or reference information for the problem and describes the problem in sufficient detail to all QC Laboratory Management to determine if the perceived problem warrants further action. A CAPA may be initiated at this time. Refer to SOP QS-108 Corrective and Preventative Action (CAPA).

6.3.3 QC Laboratory Management assigns responsibilities to appropriate personnel to investigate and determine the root cause(s) of the problem(s) identified, and to follow the action taken through verification.

6.3.3.1 With assistance from other personnel, as necessary, appropriate problem-solving methods are used to identify the root cause(s). Refer to SOP QS-111 Root Cause Analysis. The root cause(s) attempts to determine if the problem was incident-specific or if it is systemic (repeats are distributed over time or happens to different employees performing the same activity).

6.4 Root Cause Remediation

6.4.1 If the identified root cause(s) could have resulted in additional inaccurate testing and results, ensure that the testing activities are identified, contained, and

managed in accordance with the non-conforming work as described in SOP D-122 QC Laboratory Operations. Where suspect test results have been delivered to the customer, the customer is notified and appropriate action is taken to address the consequences.

6.5 NCR Closure

6.5.1 When a resolution for any NCR has been determined, Form D-126-F2, Non-Conforming Result (NCR) Closure, should be completed and submitted to document control for finalization. Any further actions that may need to be taken are detailed on this form.

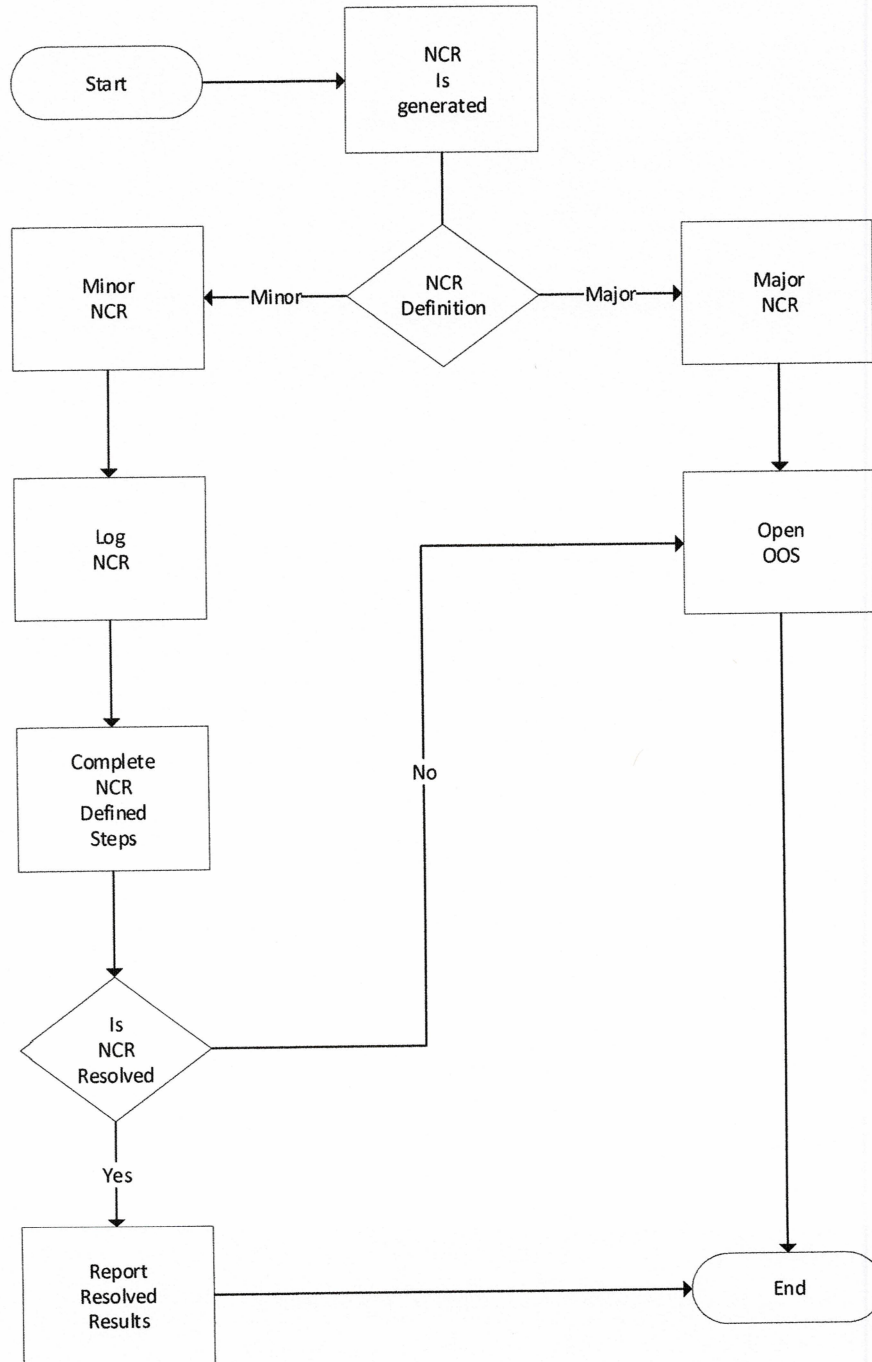
7.0 Revision History

Revision	Date	Description of Changes	CCR #	By
0	06/01/22	New procedure.	N/A	J. Sassman

8.0 Attachments

8.1 Attachment 1 – NCR Flow Chart

ATTACHMENT 1 – NCR FLOW CHART





Non-Conforming Result (NCR) Initiation

Form: D-126-F1

CCR No. N/A

Revision: 0

NCR #

Copy #

Rev #

Instructions: Use this form to describe and initiate a non-conformance report.

Description of Non-Conformance

--

Source / Lot of Non-Conformance	
Reported By / Date	

Plan

--

Name	Title	Signature	Date
Completed By			
Assigned To:			
Reviewed By QC Lab Management			
Approved By at Close QC Doc Control (DC)			



Non-Conforming Result (NCR) Closure

Form: D-126-F2

CCR No. N/A

Revision: 0

NCR #

Copy #

Rev #

Instructions: Use this form to describe and initiate a non-conformance report.

Description of Non-Conformance

--

Closure Summary

Include as applicable: Evidence and/or statement of closure, cross references to supporting documentation, general conclusions, outcome, etc.

--

Additional Actions Necessary? Yes (Proceed with description below) No

Include as applicable: References to supporting documentation for additional actions.

--

Name	Title	Signature	Date
Completed By			
Reviewed By QC Lab Management			
Approved By at Close QC Doc Control (DC)			