TITLE: CORRECTIVE AND PREVENTIVE ACTION

Effective Date: May 30, 2018

Prepared by: Anne Glubis
Quality Assurance Manager

anne.glubis
Digitally signed by anne.glubis
Date: 2018.05.30 17:58:30 -04'00'

Reviewed by: Justin Knoll
Program Manager

justin.knoll
Digitally signed by justin.knoll
Date: 2018.05.30 17:53:17 -04'00'

Annual Review			
Reviewed by:	Title:	Date:	Signature:

Table of Contents

Figures

1 Procedures

1.1 Scope and Applicability

All Chemical Speciation Network (CSN) Filter Shipping and Handling Unit (FiSH) unit and laboratory personnel have responsibility for reporting any quality-related deficiencies (potential or actual) to their supervisor.

This procedure provides requirements for the processing of corrective or preventive actions. The purpose of this procedure is to ensure that potential or actual non-conformance or deficient conditions are adequately documented, the risk reviewed, and the corrective and preventive measures are recorded, implemented, and measured for effectiveness.

1.2 Summary of Method

Overview:

- Notify the Program Manager and Quality Representative
- The Quality Representative assigns a reference number
- An Investigator is assigned by the Program Manager and/or Quality Representative

1.3 Definitions

FiSH	Filter Shipping and Handling Unit
CA	Corrective Action
Corrective Action	An action taken to eliminate the causes of an existing non-conformity, defect or undesirable situation in order to prevent recurrence. Corrective actions will be appropriate to the effect of the non-conformance encountered.
PA	Preventive Action
Preventive Action	An action taken to eliminate the causes of a potential non-conformance, defect or undesirable situation in order to prevent occurrence. Preventive actions are to be appropriate to the effect to the potential problems.
Originator	Any individual who identifies the actual or potential non-conformance.
Quality Representative	Functional representative for quality (CSN Quality Manager or Quality Specialist).
Management Team(s)	Management team with collective responsibility for the project/process or system to which the corrective or preventive action (potential or actual) relates.
Program Manager	Manager responsible (or person to whom responsibility is delegated) for the quality process to which the corrective or preventive action (potential or actual) relates. May also be called the Project Manager.

1.4 Health & Safety Warnings

Not Applicable.

1.5 Personnel Roles/Responsibilities

Roles are defined in Section 1.3, and responsibilities are displayed in Figure 1 - Workflow.

1.6 Inputs

Inputs may include deficiencies identified from:

- Quality audits (internal and external);
- Assessment of subcontractor or supplier;
- Customer complaint or supplier observation;
- Opportunity/recommendation for improvement;
- Request by operational/functional managers;
- Decision by Quality Representative or Management Representative;
- Other identification of actual or potential non-conformance;
- Identification of potential deficiencies from staff;
- Other identification of potential deficiencies.

1.7 Procedures

1.7.1 Non Conformance

Potential or actual non-conformance, for which corrective or preventive action is required, will be documented. The recorded non-conformance must be included in the register.

The potential or actual non-conformance should be initially identified by recording the potential or actual non-conformance on the corrective-preventive action form (Figure 2) which should be passed to the project Quality Representative and entered in the Corrective Action Register. If necessary, the Program Manager or Quality Representative will issue a stop work order until the non-conformance is corrected.

1.7.2 Corrective Action (CA)

When non-conformance in Wood procedures or processes is raised, it is the responsibility of the designated Quality Representative, with input from the relevant Management Teams and Program Manager, to review and determine the basis of the non-conformance and to evaluate the need for action, and when necessary stop work until the required action is completed.

Should action be required, the corrective action procedure should be followed. A corrective action should be raised to document the nature of the non-conformity and assigned to the management personnel responsible for resolving the issue. The management personnel assigned the corrective action will perform root cause analysis for the non-conformity and, if required, agree on the action(s) to be taken with the Quality Representative with input from the Program Manager. The management personnel will implement the agreed action and, where applicable, will circulate a supporting bulletin informing the necessary staff members of the action taken. Processes will be monitored for a defined period as appropriate to ensure effectiveness of the action taken. If a stop work order has been issued, the Management Team will determine when work shall resume.

The Management Team shall assess the need for supporting action to be taken to avoid future recurrence of non-conformity. If preventive action is deemed unnecessary, the actions taken (and its subsequent monitored effectiveness) should be used in future analysis of corrective actions taken. This should also be used as input for management review and continual improvement.

If preventive action is deemed necessary, the preventive action procedure, detailed in Section 1.7.3 – Preventive Action, shall be followed.

1.7.3 Preventive Action (PA)

The Program Manager or appropriate nominee will decide if it is necessary to issue preventive action to avoid occurrence of a potential non-conformance. The specific action taken is decided in collaboration between the Program Manager, the Quality Representative, and the relevant Management Team.

Implementation of the agreed preventive action is the responsibility of the Management Team. The Management Team is also responsible for monitoring the effectiveness of the implemented preventive action.

The Program Manager will ensure that the results of the action taken and its effectiveness are recorded.

It is the responsibility of the Program Manager to include any key learning from the action in subsequent management review.

1.8 Data and Records Management

The following is a list of outputs that are produced by this procedure:

- Actual CA/PA records;
- Corrective /Preventive Action Register revision
- Corrected document, deliverable and work practices;
- Updated policies, manuals, procedures, instructions, software documentation, or forms to reflect any changes.

2 Quality Control and Quality Assurance

The management team, including at a minimum the Program Manager and Quality Representative, reviews each documented CA/PA to determine proper action as shown in Figure 1. The action will be closed when the management team agrees that the evidence demonstrates the corrective action was effective. The agreed upon actions and management team approval will be documented on the corrective action form (Figure 2).

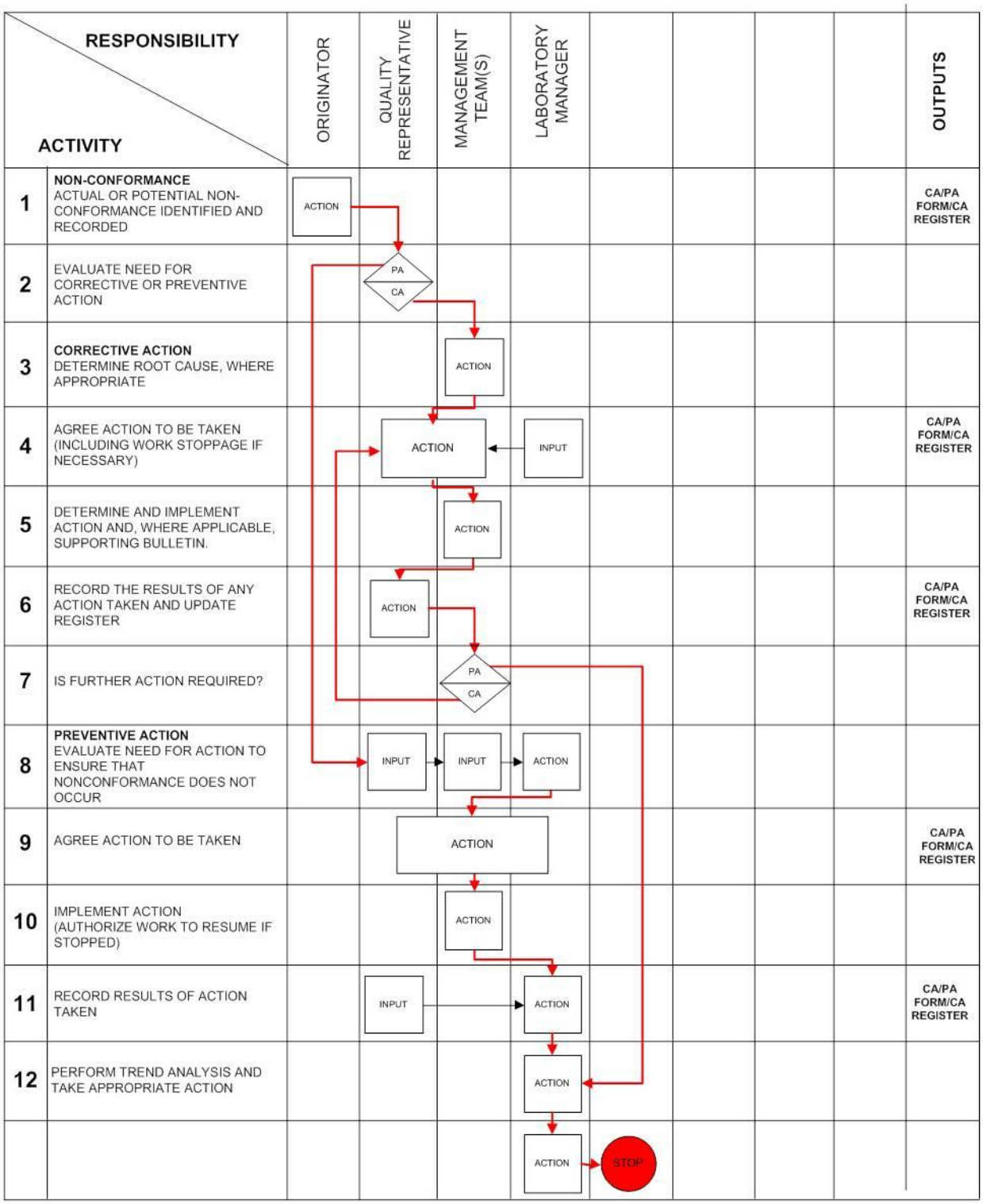
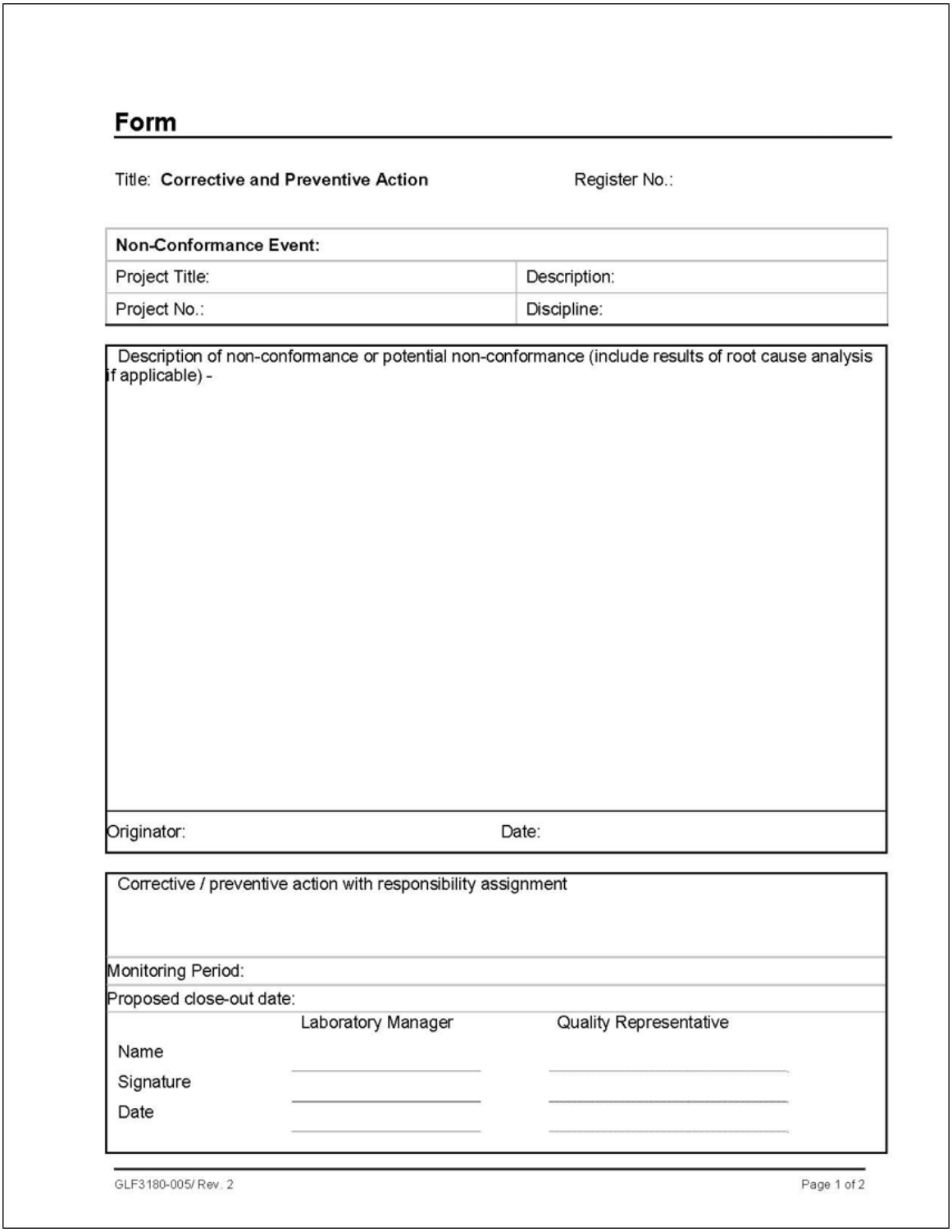


Figure 1. Workflow



Form

Title: **Corrective and Preventive Action** Register No.:

Non-Conformance Event:	
Project Title:	Description:
Project No.:	Discipline:

Description of non-conformance or potential non-conformance (include results of root cause analysis if applicable) -

Originator: Date:

Corrective / preventive action with responsibility assignment

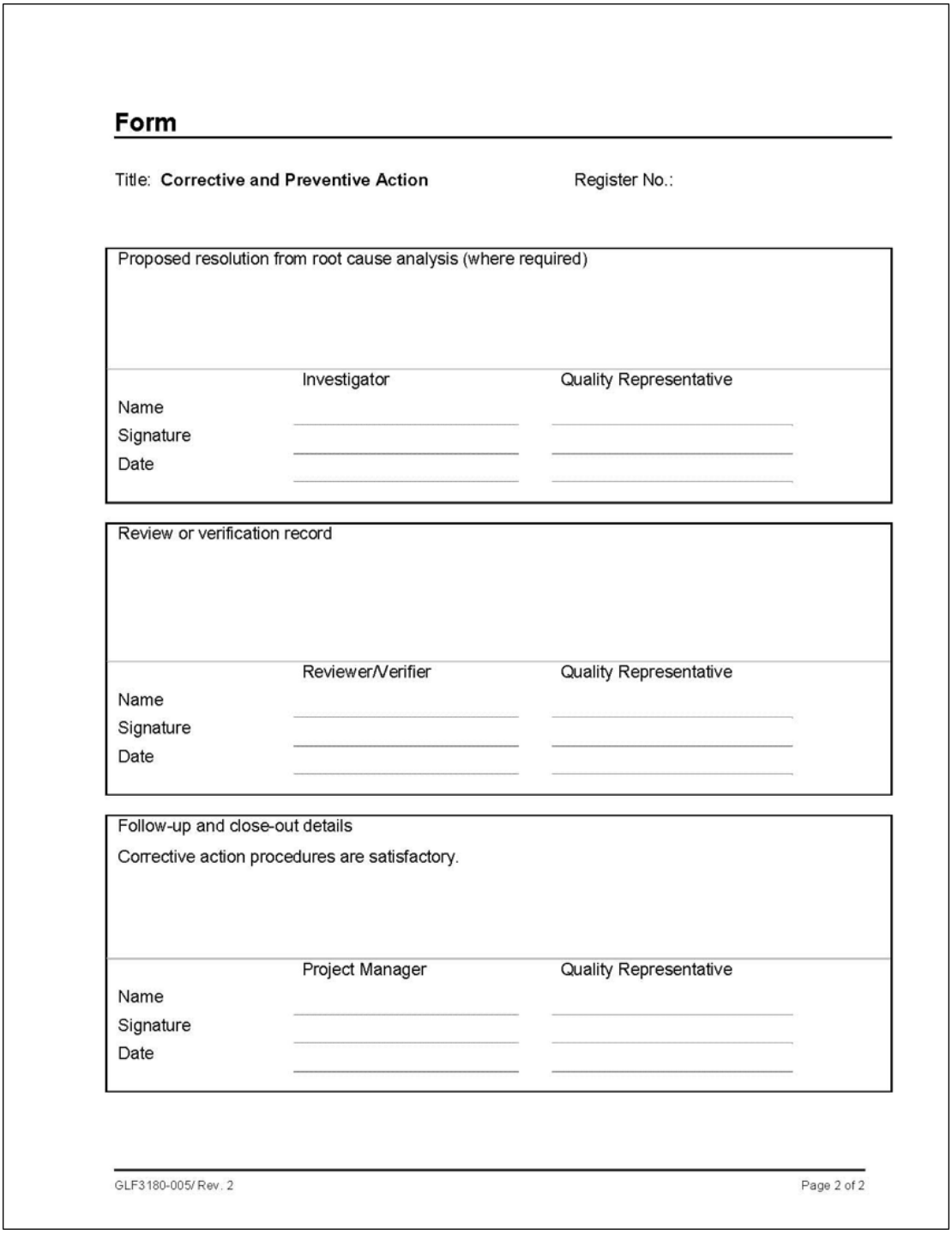
Monitoring Period:

Proposed close-out date:

	Laboratory Manager	Quality Representative
Name		
Signature		
Date		

GLF3180-005/ Rev. 2 Page 1 of 2

Figure 2. **Example:** Corrective and Preventive Action Form GLF-3180-005/Rev2 (1 of 2)



Form

Title: **Corrective and Preventive Action** Register No.:

Proposed resolution from root cause analysis (where required)

	Investigator	Quality Representative
Name		
Signature		
Date		

Review or verification record

	Reviewer/Verifier	Quality Representative
Name		
Signature		
Date		

Follow-up and close-out details

Corrective action procedures are satisfactory.

	Project Manager	Quality Representative
Name		
Signature		
Date		

GLF3180-005/ Rev. 2 Page 2 of 2

Figure 2. **Example:** Corrective and Preventive Action Form GLF-3180-005/Rev2 (2 of 2)

3 References

There are no references associated with this document.