



## Corrective and Preventative Action SOP

### 1. Purpose

The purpose of this SOP is to define the requirements to initiate, investigate, and permanently record a Corrective and Preventative Action (CAPA) issue. The details will need documented on the appropriate form and the final version will be entered into document control. The goal is to correct, or prevent any issues, or potential issues including customer complaints, internal nonconformities and less than satisfactory items noted in a self-inspection/audit within our organization.

### 2. Scope

This SOP describes the Kalitta Charters, LLC. process for:

- Reporting problems, complaints, or nonconformities
- Containment of problems and immediate remedial actions
- Investigating and identifying the root cause of the problem
- Implementation of corrective and/or preventative actions
- Follow-up to determine the effectiveness of actions taken

### 3. Policy

#### 3.1 Responsibility

Any associate at Kalitta Charters, LLC. who becomes aware of a potential, or current nonconformance is required to report it immediately to the Quality Leader, who in turn will determine if a CAPA is warranted.

#### 3.2 Nomenclature

- Issue, Incident, Deviation, Nonconformity are general terms to describe “problems” that are identified and are not in line with Kalitta Charters approved policies and procedures, regulatory requirements, or specific customer requirements without classification of severity.
- Complaint is defined as any reported “problem” that is initiated outside of Kalitta Charters (client, agent, regulatory body). Complaints are adverse and negative findings that relate specifically to the services we provide.



## Corrective and Preventative Action SOP

- Root Cause Analysis (RCA) is the investigative process to determine “how” something happened. Its literally the breakdown of the event to its core reason. This should be performed in accordance with the 5-Why’s or Fishbone Analysis to determine the true root cause.
- Corrective Action is whatever action that is taken to remediate the situation. This includes identification of the root cause and development of an action plan(s) to immediately contain the source of the situation, and permanent action(s) to correct the undesirable situation.
- Preventative Action is the solution which will prevent its reoccurrence in the future.

### 3.3 Initiating a CAPA

- The Quality Leader will start the CAPA process by:
  - Originating the CAPA form
  - Logging the CAPA issue into the permanent CAPA log which is located as a separate tab on the List of QMS Documents – Kalitta Charters, LLC.
  - Follow up with all parties involved who are required to submit responses within 24 hours of initial request.

The Quality Leader will assign a lead Investigator (and where applicable, a co-investigator) to determine the root cause of the problem and develop an action plan.

The Quality Leader will also determine a projected implementation deadline for all actions necessary to close the CAPA.

### 3.4 Root Cause Analysis and Implementation of Corrective and/or Preventative Actions

Once the appropriate investigation/root cause analysis is concluded, the action plan has been recorded (including any assigned corrective and/or preventative actions with their respective due dates), the completed CAPA will be signed (electronic signature is acceptable) by the investigator(s) and submitted to the Quality Leader who will review, approve, and close the CAPA.



## Corrective and Preventative Action SOP

All supporting documentation and objective evidence of corrective and/or preventative action closures will be stored as part of the permanent record and communicated to the customer if appropriate.

### 3.6 Follow-Up and Effectiveness of Actions Taken

Self-inspections, internal audits or individual effectiveness checks will be scheduled and performed in accordance with a predetermined schedule to determine if corrective and/or preventative actions were effective and suited their intended purpose. Records of such effectiveness checks will be maintained as part of the permanent record.

Where actions are found to be ineffective, potentially an additional CAPA could be initiated.

### 3.5 File Name of Final CAPA

It is imperative the file name of the completed, final CAPA contains an identifier for future reference. It may include either the internal, or external reference numbers and/or the client's name.

### 3.8 Related Documents

Kalitta Charters CAPA Form Master

