Creation of Action Item

Record (if needed)

Initiation of Change Control Record with

Justification, Risk Assessment – By Initiator

Additional Info Required

Creation of Action Item

Record (if needed)

Review of CCR – By Department Head

Review and Evaluation of CCR – By QA

Creation of Action Item

Record (if needed

Additional Info

required or action item

implementation

verification

unsatisfactory

Is Change to be

Processed further ?

Cancel CCR with No

Justification

No

Yes

Creation of Action Item

Record (if needed)

Classification of Proposed Change – By QA

Identification of Dept. (s) for Evaluation of CCR – By QA

Creation of Variation Proposal

(if needed)

Evaluation of CCR – By Identified Departments

Creation of Action Item

(as needed)

Variation Proposal Disposition

Done

(i.e., Rejected/Approved)

Verification of Actions / Comments received from Dept. (s), if any – By Initiator

If Approved

Cancel CCR with

Justification

Final Review and Evaluation of CCR and Action Items – By QA

Variation Management

Implementation of Change – ByRP

Approval of CCR for Implementation - By QA

Approval of CCR for Implementation - By QA

Request for Extension of CCR

with Justification – By Initiator to

Approval of Extension Request – By QA

Implementation of Change – By RP

for Discontinuation of CCR with

Justification (if needed) – By Dept. Head to QA

No

Verification of Closure of Action Items &

Verification Proposal, if any – By QA

If Rejected

Re-Open CCR

(if needed considered

**\***Maximum overdue date from all

Action items shall be considered

Closure of CCR – i.e.,. Closed Done

Move to Change Classification / Evaluation

No

Yes

If Rejected

Change Discontinue Request Review

–By QA

If Approved

Closure of CCR – i.e., Closed

Discontinued

Does Implementation

Meet Criteria?

Post - Implementation Evaluation of Change

Final Closure of CCR by QA – i.e. Closed Implemented

Yes

Are all

Action Items and Variation

Proposals (if any)

closed?