# **Corrective Action (CAPA) Scenarios**

## 1.1 Scenario #1: Create and Complete an Issue Investigation with Action Items

| **Step#** | | **Test Procedure** | **Expected Results** | **Observed Results** | **Pass/**  **Fail** | **Performed by and Date** |
| --- | --- | --- | --- | --- | --- | --- |
| These scenarios verify the ability to create, route, and complete an Issue Investigation, without creating Corrective Action and creating an Action Item (without verification) record at the draft phase (ISSUE #1 + ACTION #1). It also verifies the form sections and fields.   |  |  |  |  | | --- | --- | --- | --- | | **Start Date:** |  | Environment:  URL: | Test/QA 󠄀󠄀 Production 󠄀󠄀  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |   **Pre-Conditions:**  **Test users’ profile:**  **Test users’ access:** | | | | | | |
| 1. **Log into Reliance** | | | | | | |
|  | | Log in to Reliance using **CA-User1**, then open the **Corrective Action (CAPA)** application. | The application is opened. |  |  |  |
| 1. **Create New Investigation Issue** | | | | | | |
|  | | Click on **New Document and** select **Issue Investigation-Draft** from the menu. | A new Issue Investigation record is opened. |  |  |  |
|  | | In the **Problem Statement tab**, in the **Information** section, verify the following fields are available:   * Link to Source Document * Number * Subject (required) * Location(s) * Originator (required) * Origination Date (required) * Originating Department (required) * Reference to External Documents * Description of Issue/Quality Event (required) * Attachments * Links to Other ETQ Record * External Link(s) | The fields are available. |  |  |  |
|  | | In the **Information** section,  fill in the following required fields:   * **Subject** = <text> * **Originator** = <default to current user > * **Origination Date** = <default to current date> * **Originating Department** = <any option> * **Description of Issue/Quality Event** = <text> | The field is filled in. |  |  |  |
|  | | In the **Problem Statement tab**, in the **Investigation** section, verify the following fields are available:   * Is this a potential safety issue? (required) * Is this issue is related to the product or process? (required) * Investigation(required) * Investigation Conclusion (required) | The fields are available. |  |  |  |
| 2.5 | | In the **Investigation** section,  fill in the following required fields:   * **Is this a potential safety issue?** = <any option> * **Is this issue is related to the product or process?** = <any option> * **Investigation** = <text> * **Investigation Conclusion** = <text> | The field is filled in. |  |  |  |
| 2.6 | | In the **Investigation** section, if the  **Is this issue is related to the product or process?** = Product  A new section **Product** will display under the **Problem Statement** tab. | The new section is displaying. |  |  |  |
| 2.7 | | In **Product** section click on **Add Record** button, and verify if the following fields are available:   * Product Number * Product Name * Drawing Revision Number | The fields are available. |  |  |  |
| 2.8 | | In the **Product** section,  fill in the following fields in the **Product** section:   * **Product Number**<text> * **Product Name**<text> * **Drawing Revision Number**<text> | The field is filled. |  |  |  |
| 2.9 | | In the **Investigation** section, if the  **Is this issue is related to the product or process?** = Process  A new section **Process** will display under the **Problem Statement** tab. | The Process section is displaying. |  |  |  |
| 2.10 | | In **Process** section click on **Add Record** button, verify if the following fields are available:   * Operation Name * Line/MWS * Shift * Operators(s) * Work Team Leader(s) | The fields are available. |  |  |  |
| 2.11 | | In the **Process** section,  fill in the following fields in the **Process**  section:   * **Operation Name** (any option) * **Line/MWS** (any option) * **Shift** (any option) * **Operators(s)** (any option) * **Work Team Leader(s)** (any option) | The fields are filled in. |  |  |  |
| **Pre-Conditions:**  In the **Investigation** section, Is **this a potential safety issue?** = YES | | | | | | |
| 1. **Define Potential Safety Issues** | | | | | | |
| 3.1 | | In **Potential Safety Issues** tab, In **Health Risk Evaluation** section  verify the following fields are available:   * Did the event lead to a confirmed patient user or bystander Harm? (required) * Could this type of event lead to a patient-user or bystander Harm? (required) * Is there potential harm resulting from this event? (required) * When does this malfunction occur and what is the potential risk compared with the normal workflow (required) * Is the issue defined in the current Risk Analysis Report? (required) * When the issue is defined in the current Risk Hazard Report cite the Product Hazard/Risk Analysis Report Number, Hazard Id Number, Initial Risk (e.g.3B II) and Residual Risk (e.g. 3A II)   - Describe (required)   * The assessment indicates that the Medical Device is? (required) * Rationale for Selection(required) * Based on the assessment, was there an identified risk or a change in probable benefit that would result in an increase in the likelihood of adverse health consequences? (required) * Rationale for No HRE: (required) | 1. The **Health Risk Evaluation** section is displayed.  2. All fields are displayed. |  |  |  |
| 3.2 | | In **Health Risk Evaluation**  fill in the following required fields:   * **Did the event lead to a confirmed patient user or bystander Harm?** = <any option> * **Could this type of event lead to a patient user or bystander Harm?** = <any option> * **Is there potential harm resulting from this event?** = <any option> * **When does this malfunction occur and what is the potential risk compared with the normal workflow** = <any option> * **Is the issue defined in the current Risk Analysis Report?** = <any option> * **The assessment indicates that the Medical Device is?** <text> * **Rationale for Selection** <text> * **Based on the assessment, was there an identified risk or a change in probable benefit that would result in an increase in the likelihood of adverse health consequences?** <text> * **Rationale for No HRE:** <text> | The fields can be filled in. |  |  |  |
| 3.3 | | In the **Health Risk Evaluation** section, If **Did the event lead to a confirmed patient user or bystander Harm?** =YES  fill in the following field:  **- Person Harmed =** <any option>  If **Person Harmed** = Other,    fill in the following field:  **-** **Rational =** <text> (required) | The field is filled in. |  |  |  |
| 3.4 | | In the **Health Risk Evaluation** section, if **Could this type of event lead to a patient user or bystander Harm** =YES,  fill in the following field:  **- Person Harmed =** <any option>  **- Clinical implications resulting from the event/problem =** <text>  If **Person Harmed** = Other,  fill in the following field:  **- Rational =** <text> (required) | The field is filled in. |  |  |  |
| 3.5 | In the **Health Risk Evaluation** section, **Is there potential harm resulting from this event?** = YES,  fill in the following field:   * **Describe the potential harm resulting from the event** <text> | | The field is filled in. |  |  |  |
| 3.6 | In the **Health Risk Evaluation** section, **Is there potential harm resulting from this event?** =NO,  Fill in the following field:   * **Provide justification there is no potential harm resulting from the event** = <text> | | The field is filled in. |  |  |  |
| 3.7 | In the **Health Risk Evaluation** section, **Is the issue defined in the current Risk Analysis Report? =Yes,**  Fill the following field:   * Describe <text>(required) | | The field is filled. |  |  |  |
| 1. **Define Required Action Section** | | | | | | |
| 4.1 | In the **Potential Safety Issues** tab, In the **Required Action** section  verify the following fields are available:   * **Reference Defect Number** (required) * **Reference Approved PCN Number** (required) * **Reference UI number** (required) | | The fields are available. |  |  |  |
| 4.2 | In the **Required Action** Section  Fill in the following fields:   * **Reference Defect Number** =<text> * **Reference Approved PCN Number** =<text> * **Reference UI number** =<text> | | The field is filled in. |  |  |  |
| 1. **Define The Following Will Likely be Affected Section** | | | | | | |
| 5.1 | In the **Potential Safety Issues** tab, In **The Following Will Likely be Affected** section:  Verify the following fields are available:   * The Following will likely be Affected. * Investigation Conclusion Attachments | | The fields are available. |  |  |  |
| 5.2 | In **The Following Will Likely be Affected** section:  Fill in the following fields:   * **The Following will likely be Affected** <any option> * **Investigation Conclusion**<text> * **Attachments** =attachment. Docs | | The field is filled in. |  |  |  |
| 1. **Define Determination Tab** | | | | | | |
| 6.1 | In the **Determination** tab**, the** **Immediate Corrections and Containment** section**:**  Verify the following fields are available:   * Performed By * Date Performed * Immediate Corrections and Containment * Attachments | | The fields are available. |  |  |  |
| 6.2 | Inthe **Immediate Corrections and Containment** section,  Fill in the following fields:   * **Performed By**<text> * **Date Performed**<text> * **Immediate Corrections and Containment** <text> * **Attachments**<attach file> | | The field is filled in. |  |  |  |
| 1. **Define CAPA/HRE Determination Risk Assessment** | | | | | | |
| 7.1 | In **CAPA/HRE Determination Risk Assessment** section, verify the following buttons available:   * CAPA Determination Risk Assessment * HRE Determination Risk Assessment | | The buttons are available. |  |  |  |
| 7.2 | In **CAPA/HRE Determination Risk Assessment** section, Click on   * CAPA Determination Risk Assessment * The user should be able to create new document.   Click on   * HRE Determination Risk Assessment * User should be able to create new document. | | User able to create new document. |  |  |  |
| 1. **Define Recommendation section** | | | | | | |
| 8.1 | In the **Determination** tab, In the **Recommendation** section:  Verify the following fields are available:   * Corrective Action Required? (required) * Reason for Recommendation * HRE Required? (required) | | The fields are available. |  |  |  |
| 8.2 | In the **Determination** tab, In the **Recommendation** section:  Fill in the following fields:   * **Corrective Action Required?** <any option> * **Reason for** **Recommendation**<text> * **HRE Required?** <any option> | | The field is filled in. |  |  |  |
| 8.3 | In **HRE Required?** field = No | | The radio option No is selected. |  |  |  |
| 8.4 | In **Corrective Action Required? =**No | | The radio option No is selected. |  |  |  |
| 8.5 | In the **Activities** section, verify the following fields are available:  -Link to Activity Documents  - New Activity | | The fields are available. |  |  |  |
| 8.6 | If user clicks on the **New Activity** button a dialogue will appear, It will have two options:   1. **Close**: Click on this will close the dialogue. 2. **Create:** The user will redirect to **Activity** form page. | | The dialogue is displaying the options. |  |  |  |
| 1. **Creating Action item** | | | | | | |
| 9.1 | If the user clicks on **Create,** In **Action Item tab,** In the **Subject** section. Verify the following fields are available:   * Link to Parent * Activity Number * Action Type(required) * Due Date (required) * Assign Action Item To (required) * Subject (required) * Description * Attachments * Verification Required? * Link to Activity Documents * Link to other Documents | | The fields are available. |  |  |  |
| 9.2 | In the **Subject** section fill the following fields:   * Link to Parent (automated) * Activity Number * Action Type<any-option> * Due Date <any date> * Assign Action Item To <any-option> * Subject<text> * Description<text> * Attachments * Verification Required? <any-option> * Link to Activity Documents * Link to other Documents | | The field is filled in. |  |  |  |
| 9.3 | If **Verification Required? = No,**  Do not select the check box.  Verify the following fields are not available:   * Assign Verification To (required) * Verifications to be Performed. | | The fields are not available. |  |  |  |
| 1. **Access Control Tab** | | | | | | |
| 10.1 | In **Access Control** Tab, In **Phase Tracking** section, verify the following fields are available:   * Assigned to (logged in user) * Phase (Draft Phase) * Submitted Date * Due date * Completed Date | | The Fields are available. |  |  |  |
| 10.2 | In Access Control Tab, In **Additional Document Security,** verify the following fields are available:   * Managers * Editors * Readers * Created By * Created Date * Last Editors * Modified date | | The Fields are available. |  |  |  |
| 10.3 | Click on Save and verify the Activity Number is auto-generated. | | Activity number is generated. |  |  |  |
| 1. **Route Action Item (ACTION#1) to Open Phase** | | | | | | |
| 11.1 | Click on **Open** Phase, and verify the following fields are available:   * **Select Phase**(disabled) * **Due Date**(read-only) * **Assign To** (read-only) * **Notify** <any option> * **Comment**<text> | | The Fields are available. |  |  |  |
| 11.2 | Click on **Send** button will Redirect user to **draft** phase of **Issue Investigation** document showing link to the activity Action Item created. | | User redirected to Draft phase of main document. |  |  |  |
| 1. **Verify The Open Phase of Action Item(ACTION#1)** | | | | | | |
| 12.1 | Close the current document and follow the below steps:   * Log out of the CA-user1. * Log in with the user assigned for **Open phase** of the **action item(ACTION#1).** * Select the Issue Investigation from **ALL Views**. * Select the **Action Items** tab and search for the respective action item Id. | | Action item document displayed. |  |  |  |
| 12.2 | In **Subject** Section, verify the following fields are read-only:   * Link to Parent (displaying the parent document link) * Activity Number * Activity Type * Due Date * Assign Action Item To * Subject * Description * Attachments * Verification Required? * Link to Activity Documents * Link to Other Documents | | The fields are read-only. |  |  |  |
| 12.3 | In the **Action Taken** section, verify the following fields are available:   * Action Taken(required) * Attachments | | The fields are available. |  |  |  |
| 12.4 | In the **Action Taken** section, fill the following fields:   * Action Taken<text> * Attachments=attachment.Docs | | The field is filled in. |  |  |  |
| 12.5 | In **Access Control** tab, verify the following sections are read only:   * Phase Tracking * Additional Document Security | | The sections are read-only. |  |  |  |
| 1. **Route (ACTION#1) to Completed Phase** | | | | | | |
| 13.1 | Click on **Save** and click on the **Completed** phase link, verify the following fields:   * **Select Phase** (Completed) * **Notify** <any option> * **Comment**<text>   Click on **Send** button. | | Document routed to completed phase. |  |  |  |
| 1. **Route Issue Investigation document from Draft to Collaboration Phase** | | | | | | |
| 14.1 | Login with **CA-User1**, **open Corrective Action (CAPA)**, Go to my assignment search the Issue Investigation document and click to open the document. | | Issue investigation document is opened. |  |  |  |
| 14.2 | In **Access Control** Tab verify the following sections are available and readable:   * **Electronics Signature** * **Phase Tracking** * **Additional Document Security** | | Sections are available and readable. |  |  |  |
| 14.3 | Click the **Save** button and store **Document ID,** click on the **Collaboration** phase link, and verify the following fields are available and filled in :   * **Select Phase** <collaboration already selected and disabled> * **Due Date**<any option> * **Assign To**<any option> * **Notify**<any option> * **Comment**<text> | | The fields are available and filled in. |  |  |  |
| 14.4 | Click on **Send** button. | | Document send successfully. |  |  |  |
| 1. **Verify The Collaboration Phase** | | | | | | |
| 15.1 | Logout **CA\_user1**, log in with the **CA-user2** user have the **Collaboration** phase assigned, and follow the below steps:   * Click on Corrective Action (CAPA) * Search Issue investigation document with document ID | | The document opened in Collaboration phase. |  |  |  |
| 15.2 | In **Problem Statement tab**, verify the following sections are editable and read only:   * Information(editable) * Investigation (read-only) * Product (read-only) * Related Issue Investigation and CAPA (read-only) | | The editable and readable sections are verified. |  |  |  |
| 15.3 | In **Potential Safety Issues tab**, verify the following section are editable and read-only:   * Health Risk Evaluation (read-only) * Required Action(editable) * The Following Will Likely be Affected(editable) | | The editable and readable sections are verified. |  |  |  |
| 15.4 | In **Determination** Tab, verify the following sections are editable and read-only:   * Immediate Corrections and Containment (editable) * CAPA/HRE Determination Risk Assessment (editable) * Recommendation (editable) | | The editable and readable sections are verified. |  |  |  |
| 15.5 | In **Activities** tab, verify the following fields are read-only,   * Links to Activity Documents   Click on activity link document will redirect to the activity **Action Item Completed** document. | | The read-only fields are available. |  |  |  |
| 1. **Phase Tracker** | | | | | | |
| 16.1 | In **Collaboration** phase, verify the following phases are available to route:   * **Draft** (backward routing) * **Approval (**forward routing) | | The phases are available. |  |  |  |
| 16.2 | In **Collaboration** phase, verify the following phases are disabled for routing:   * **CAPA/HRE Creation** * **Closed** * **Voided** | | The phases are disabled. |  |  |  |
| 1. **Routing Document from Collaboration to Approval Phase** | | | | | | |
| 17.1 | Click on **Approval** phase link, and verify the following fields are available:   * Select Phase <Approval> * Due date <Today’s date+2days> * Assign To <any option> * Notify <any option> * Comment <text> | | The fields are available. |  |  |  |
| 17.2 | Click on **Send** button. | | The document is sent. |  |  |  |
| 1. **Verify the Approval Phase** | | | | | | |
| 18.1 | Logout **CA\_user2**, log in with the user have the **Approval** phase assigned(**CA-user1**), and follow the below steps:   * Click on Corrective Action (CAPA) * Search Issue investigation document with document ID | | The document is opened in approval phase. |  |  |  |
| 18.2 | In the **Problem Statement tab**, verify the following sections are editable and read-only:   * Information(read-only) * Investigation (read-only) * Product (read-only) * Related Issue Investigation and CAPA (read-only) | | The editable and readable sections are verified. |  |  |  |
| 18.3 | In the **Potential Safety Issues tab**, verify the following section are editable and read-only:   * Health Risk Evaluation (read-only) * Required Action(read-only) * The Following Will Likely be Affected(read-only) | | The editable and readable sections are verified. |  |  |  |
| 18.4 | In **Determination** Tab, verify the following sections are editable and read-only:   * Immediate Corrections and Containment (read-only) * CAPA/HRE Determination Risk Assessment (editable) * Recommendation (read-only) | | The editable and readable sections are verified. |  |  |  |
| 18.5 | In **Activities** tab, verify the completed action item link is present with **New Activity** creation button. | | The completed action item link is available. |  |  |  |
| 1. **Phase Tracker Approval Phase** | | | | | | |
| 19.1 | In the **Approval** phase, verify the following phases are available for routing:   * **Collaboration** (backward routing) * **Closed (**forward routing) * **Voided (**forward routing) | | The phases are available. |  |  |  |
| 19.2 | In the **Approval** phase, verify the following phases are disabled for routing:   * **Draft** * **CAPA/HRE Creation** | | The phases are disabled. |  |  |  |
| 1. **Routing Document from Approval to Closed Phase** | | | | | | |
| 20.1 | Click on the **Closed** phase link, and verify the following fields are available:   * Select Phase <Closed> * Notify <any option> * Comment <text> | | The fields are available. |  |  |  |
| 20.2 | Click on **Send** button. | | Document is sent. |  |  |  |
| 20.3 | Enter the **CA-user1 user's password in Electronic Signature** and click the **Sign** button, log out the user. | | CA-user1 password accepted successfully. |  |  |  |
| 1. **Verify the Closed Phase** | | | | | | |
| 21.1 | Login with **CA-user1**, follow the below steps:   * Open Corrective action (CAPA) application. * Click on **ALL Views>Issue Investigation>Closed** * Search for **ISSUE#1** doc with document ID | | The doc ISSUE#1 is found and opened. |  |  |  |
| 21.2 | Verify the following sections are available and read only:   * Problem Statement * Potential Safety Issues * Determination * Activities * Access Control | | The sections are available and read only. |  |  |  |
| **Summary of Actual Results / Deviation Number(s)** | | | | | | |
| **Result:** | | | Pass 󠄀 󠄀 󠄀 󠄀󠄀                 Pass with Deviation 󠄀 󠄀 󠄀 󠄀 󠄀󠄀                 Fail 󠄀 󠄀 󠄀 󠄀 | | | |
| **Comments:** | | |  | | | |
| **Tester Signature:** | | |  | **Date**:  (DD-MMM-YYYY | |  |
| **Reviewer Signature:** | | |  | **Date**:  (DD-MMM-YYYY | |  |