

Quality System Procedure # 2.6.3	Issued Date: 1-13-21
ETQ Instruction for Suppliers to Use the CAPA Application	Date of Revision: NA

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1 SCOPE:

1.1 This document is applicable to all Progress Rail external suppliers.

2 PURPOSE:

2.1 The purpose of this work instruction is to familiarize the supplier on how to use the CAPA module along with the RMA and due date extension workflow in the ETQ software.

3 REQUIREMENTS

3.1 Responsibilities

3.1.1 Progress Rail external suppliers

4 ABBREVIATIONS AND DEFINITIONS

4.1 PR – Progress Rail

4.2 ETQ – Excellence through Quality

4.3 CAPA – Corrective Action Preventive Action

4.4 RCCA – Root Cause and Corrective Action

4.5 SQE- Supplier Quality Engineer

4.6 RMA- Return Material Authorization

4.7 PO- Purchase Order

4.8 ERP- Enterprise Resource Planning

5 ASSOCIATED FORMS AND EXHIBITS

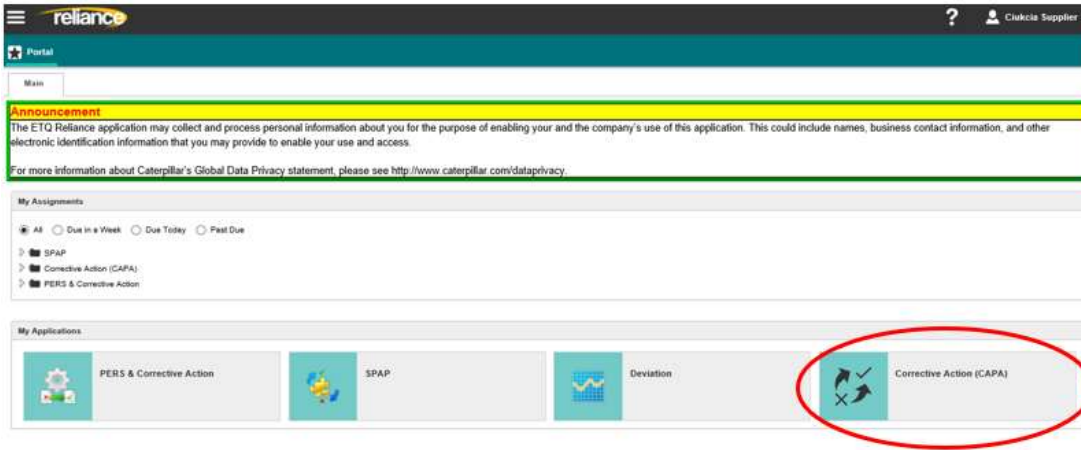
5.1 Supplier Quality Manual (JA-COR-0013)

5.2 ETQ Setup for Suppliers (JA-COR-0067)

5.3 Using ETQ for Quality Notice/ Corrective Action Response (JA-COR-0085)

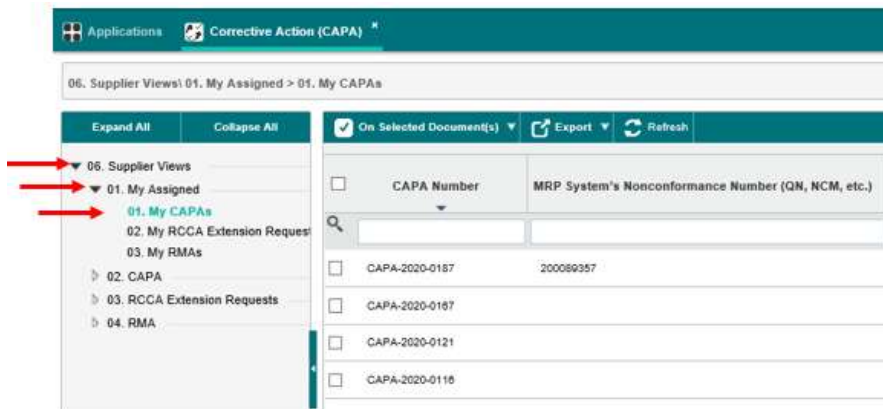
6 HOW TO OPEN THE CAPA MODULE IN ETQ

6.1 From the homepage (portal) view, select the “Corrective Action (CAPA)” module, as shown below:



7 HOW TO INTERPRET THE DIFFERENT VIEWS IN THE CAPA MODULE

7.1 After the user has selected the Corrective Action (CAPA) module, the module will open to the default view called “06. Supplier Views, 01. My Assigned, 01. My CAPAs”, as shown below:



7.2 Section 06. Supplier Views, Section 01. My Assigned:

7.2.1 View 01. My CAPAs

- This view will show all CAPAs assigned to the logged in user ready for them to action.

7.2.2 View 02. My RCCA Extension Requests

- This view will show all RCCA Extension Requests assigned to the logged in user ready for them to action.

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7.2.3 View 03. My RMAs

- This view will show all RMAs assigned to the logged in user ready for them to action.

7.3 Section 02. CAPA:

7.3.1 Sub-Section 01.Open

- This view will show all OPEN CAPA Items that are related to the supplier logged in.

7.3.2 Sub-Section 02. Completed

- This view will show all COMPLETED CAPA Items that are related to the supplier logged in.

7.3.3 Sub-Section 03. All Phases

- This view will show all CAPA Items, by Phase, that are related to the supplier logged in.
- This view will show all OPEN Action Items

7.4 Section 03. RCCA Extension Requests:

7.4.1 View 01. Open RCCA Extension Requests

- This view will show all OPEN RCCA Extension Requests, that are related to the supplier logged in.

7.4.2 View 02. All RCCA Extension Requests

- This view will show all RCCA Extension Requests, that are related to the supplier logged in.

7.5 Section 04. RMA:

7.5.1 View 01. Open

- This view will show all Open RMAs

7.5.2 View 02. Completed

- This view will show all Completed RMAs

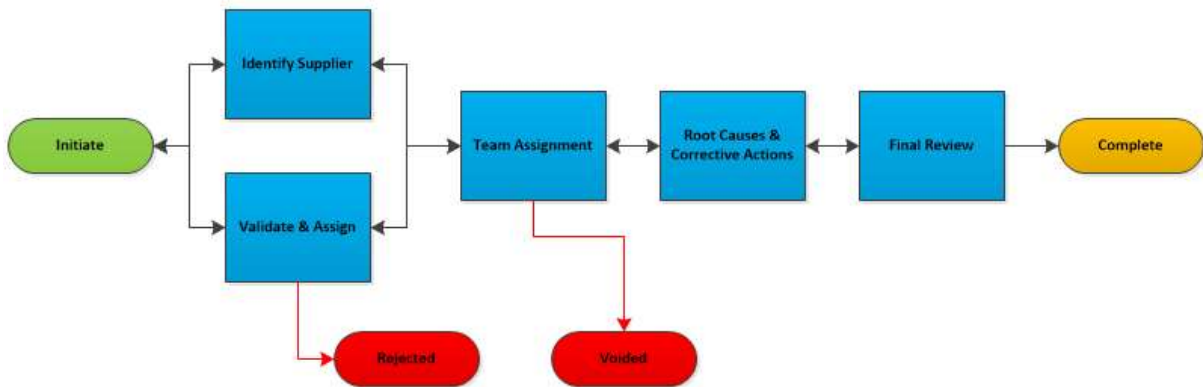
7.5.3 View 04. All Phases

- This view will show all RMAs, by Phase

8 HOW TO INTERPRET THE CAPA WORKFLOW DIAGRAM IN ETQ

8.1 The CAPA Workflow diagram below shows all the different phases the document may travel through prior to being a completed document.

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8.2 The below CAPA Workflow diagram tracker shows the current phase location of the applicable document via a Red Arrow pointing to the current phase within the workflow.

Note: Gray colored tabs are not available in the current document location.



8.3 The below CAPA Workflow diagram tracker also shows others phases that the applicable document may be routed. The available phases to be routed from a documents current phase location will show with a colored tab as shown below:



9 HOW TO INTERPRET AND USE THE ROUTING DIALOG BOX IN ETQ

9.1 In a routing dialog box, the User may add any additional comments for the phase change. Record information about the problem being identified such as the Problem's Category, the related Department, and where the Corrective Action has been reported.



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10 HOW TO PROCESS A CAPA DOCUMENT

10.1 Introduction:

10.1.1 The documents that are under the 'My CAPA' view need to be actioned by the supplier.

10.1.2 CAPAs that are in 'Root Cause & Corrective Actions' phase require action from the supplier.



10.1.3 Suppliers have read only access for the CAPAs that are in any of the other phases.

10.2 Phases:

10.2.1 The 'Initiate' phase is the phase in which the CAPA gets generated.

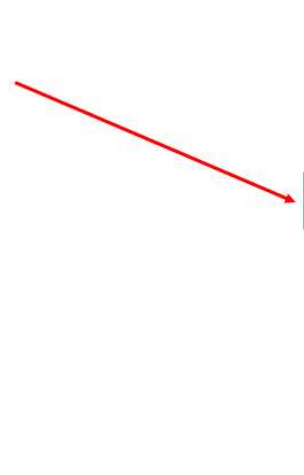
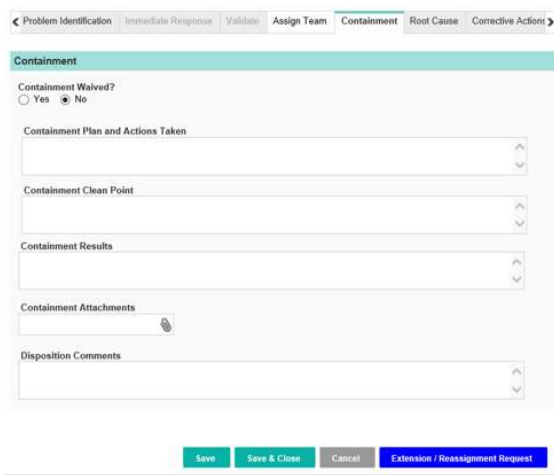
10.2.2 In the 'Identify Supplier' phase, the supplier profile can be added to the CAPA if it isn't already added in the 'Initiate' phase.

10.2.3 In the 'Validate & Assign' phase, the CAPA is reviewed for validity by the SQE.

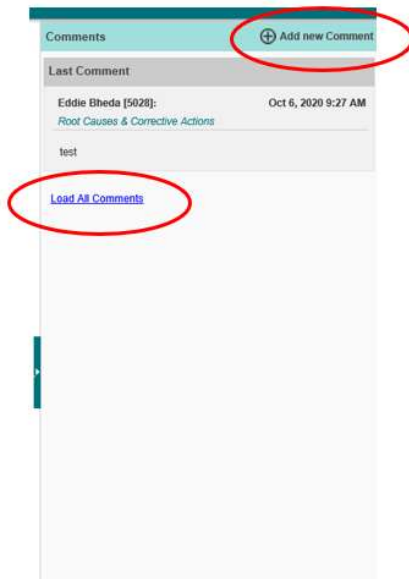
10.2.4 In the 'Team Assignment' phase, the supplier profile and the SQE are assigned as team members.

10.2.5 In the 'Root Cause and Corrective Actions phase', the supplier is responsible to provide all details to repond to the CAPA.

10.2.6 In the 'Final Review' phase, the SQE reviews the supplier's CAPA response for closure. If the SQE finds the response inadequally, they will send the CAPA back to 'Root Cause and Corrective Action' phase for more information. The requested information can be seen in the CAPA form or the 'Comments' bar on the right. Click on the green arrow to pull up the comments bar. See screenshot below.



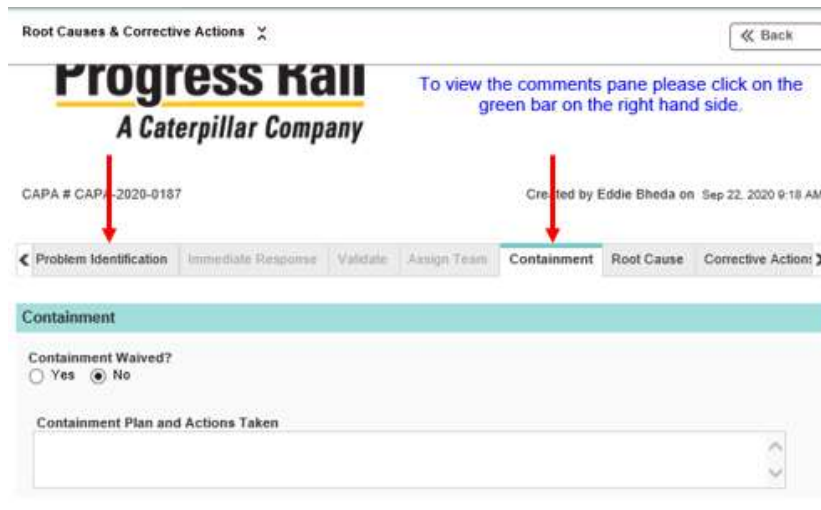
The 'Comments' bar opens up on the right, per below screenshot. 'Load all Comments' button can be used to look at all the older comments. 'Add new Comment' button can be used to add comments to the document. Save the document after the comment is added to save the comment.



10.3 Root Cause and Corrective Actions:

10.3.1 The 'Containment' tab will be shown when the CAPA is opened. The supplier can click on the 'Problem Identification' tab to look at the details of the CAPA. See screenshot below

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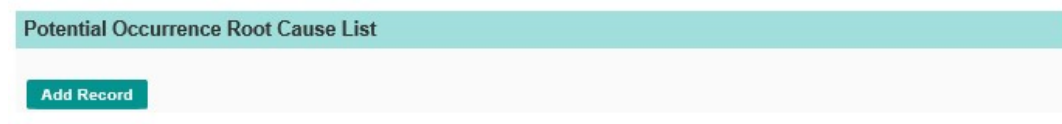


10.3.2 The 'Problem Identification' tab will have all the relevant information about the CAPA like defect description, part number, part name, quantity, serial number, photos, failure date etc.

10.3.3 Click back on the 'Containment' tab to fill out the details of the containment performed.

10.3.4 After 'Containment' sections are complete, click on the 'Root Cause' tab. Fill out all the sections in this tab.

10.3.5 Under the 'Potential Occurrence Root Cause List', there is an 'Add Record' button. This is an optional section.



10.3.6 If you click on this button, new fields for potential root causes are shown per below screenshot. Using 'Add Record' button such multiple potential root causes can be added. The cross button on the top right of this section can be used to delete the records that are not needed.

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10.3.7 Similar process as above can be used to add records for potential detection root cause and potential prevention root cause in the below sections.

10.3.8 Click on the 'Corrective Actions' tab to fill out the details about the corrective actions taken to address the root cause so that the defect doesn't occur again.

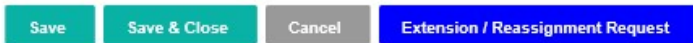
10.3.9 There are conditions that need to be fulfilled to submit the CAPA. The entire form in the Containment, Root Cause and Corrective Actions tab need to be completed. All the required sections which are marked with a red asterisk need to be completed. The 'Corrective Action Implemented?' Question needs to be answered as 'yes'. The effectiveness of verification question i.e. 'Verification data indicates the corrective actions have been effective and the record is ready for final review' should be answered as 'yes'. Once, all these conditions are fulfilled, the CAPA can be submitted to the next phase 'Final Review' for the SQE's review.

10.3.10 The blue button at the bottom of the form 'Extension/Reassignment Request' can be used to request for an extension of the due date of the CAPA. Please refer to section 17 in this document for more details of this workflow.

11 HOW TO PROCESS A DUE DATE EXTENSION DOCUMENT IN THE CAPA MODULE

11.1 If the supplier needs an extension to the due date of a particular CAPA document that is in 'Root Causes and Corrective Actions' phase, click on the blue 'Extension/Reassignment Request' button that is on the very bottom of the form in 'Containment', 'Root Cause' or 'Corrective Actions' tab.

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11.2 A new form opens up, per screenshot below.

11.3 Fill out the 'Requested Due Date' and put a valid reason in 'Reason for Extension' field.

11.4 Save the document by clicking on the 'Save' button at the very bottom of the form.

11.5 A Number will be assigned in the 'Number field'. It will be in the [DDE-YYYY-XXXX] format. Use this 'Due Date Extension' document number for future tracking of this pending due date extension request.

11.6 Once you move this document to the next 'Approval' phase, it will be assigned to the responsible SQE for review.

11.7 If the SQE agrees to the extended date, then the document will be approved. The supplier will receive an email notifying that the request has been approved. The due date of the CAPA will be updated in the CAPA document.

11.8 If the SQE has questions about the due date extension request, the document can be sent back to the supplier at 'Request' phase with the question in the 'Comments' section on the right. Supplier can submit the document back to the SQE. A 'Routing Dialog' box will pop

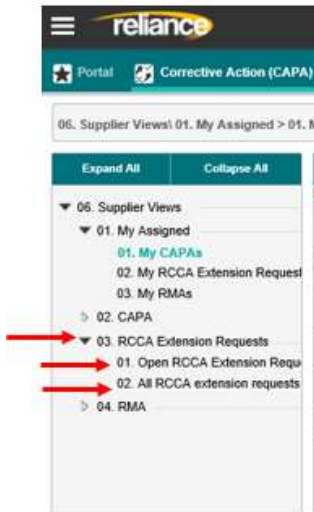
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up. The response to the question can be filled in the 'comment' field in the 'Routing Dialog' box, per screenshot below.

Notify:

Comment:

- 11.9 If the SQE rejects the request for due date extension, the document will be moved to 'Not Approved' phase. The reason for rejection of the request can be seen in the 'Comments' section on the right.
- 11.10 Supplier can go to any open or closed 'Due Date Extension' documents to review the status or updates in them by clicking on the appropriate view under '03. RCCA Extension Requests' view in the left view panel. See screenshot below.



12 HOW TO PROCESS AN RMA DOCUMENT IN THE CAPA MODULE

12.1 Introduction:

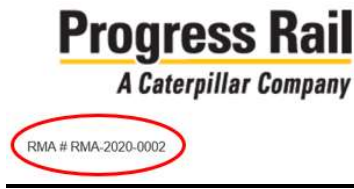
- 12.1.1 PR can send a request for RMA documentation to the supplier through the ETQ system now. The supplier can respond to the request via ETQ too. This will replace the email communication from an RMA process point of view.
- 12.1.2 The RMAs that are in 'Supplier Response' phase require action from the supplier.

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12.1.3 Suppliers have read only access for the RMAs that are in any other phases.

12.1.4 The RMA number stamped at the top of the form can be used as a reference number for identifying the RMA case. Example in screenshot below: RMA-2020-0002



12.2 Phases:

The workflow diagram below shows all the phases in the RMA lifecycle.



12.2.1 The 'Initiate' phase is the phase in which the RMA gets generated.

12.2.2 In the 'Identify Supplier' phase, the supplier profile can be added to the RMA if it isn't already added in the 'Initiate' phase.

12.2.3 In the 'Supplier Response' phase, the supplier is responsible to provide all the details to respond to the RMA request.

12.2.4 In the 'Supplier Rejected' phase, the responsible PR personnel will action the RMA if it is rejected i.e. sent from 'Supplier Response' phase to 'Supplier Rejected' phase by the supplier.

12.2.5 In the 'Create Return PO' phase, the responsible PR personnel will create a PO documentation for returning the part.

12.2.6 In the 'Ship Material' phase, the responsible PR personnel will ship the material and add the relevant shipping information in the RMA form.

12.2.7 In the 'ERP Transaction' phase, the responsible PR personnel will take the necessary steps in PR's ERP system.

12.2.8 The 'Analysis/Report' phase is not applicable for external suppliers. The supplier will provide the analysis/report in the CAPA form that is related to this particular RMA as part of the normal process.

12.2.9 The 'Material Disposition' phase is not applicable for external suppliers.

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12.2.10 No action is needed in the 'Completed' phase. The RMA has completed its lifecycle.

12.3 Supplier Response:

12.3.1 The sections at the top of the form will have all the information regarding the defect like problem description, part number, part name, defective quantity etc.

12.3.2 Scroll to the bottom of the form to the 'Supplier Response' section. Fill out all the details related to the RMA and attach any documents that need to be provided to PR for the RMA process and shipping the parts back to the supplier's facility. See screenshot below.

12.3.3 Provide the decision of whether the 'RMA Request Approved?' is yes/no with the radio button, per screenshot below.

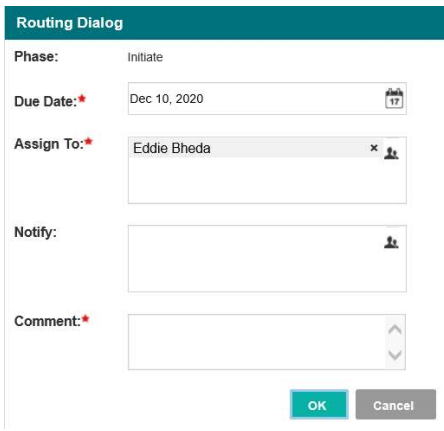
12.3.4 If the RMA request is approved and the 'yes' radio button is selected, the next available phase is 'Create Return PO'. Click on the 'Create Return PO' phase button or the 'Next' button, to submit the RMA to the responsible PR team for next steps. See screenshot below.

12.3.5 If the RMA request is not approved and the 'no' radio button is selected, the next available phase is 'Supplier Rejected'. Provide all the details explaining why the RMA request is being rejected. Click on the 'Supplier Rejected' phase button or the 'Next' button, to submit the RMA to the responsible PR team for next steps. See screenshot below.

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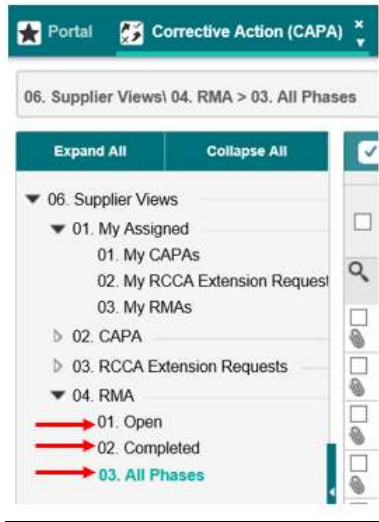
12.3.6 If more information is needed before a decision on the RMA request can be made, the RMA can be moved back to 'Initiate' phase by clicking on the 'Initiate' phase button or the 'Back' button. You can ask for the information needed in the 'comment' field of the routing dialog box that appears after you click the above button, per below screenshot.



12.3.7 The RMA document can be moved back and forth through the different phases and comments can be added at each phase change. This will replace the back and forth email communication and help in organizing all the case relevant information in the corresponding RMA document.

12.3.8 Different views can be selected under '04. RMA' view section to filter all the RMAs related to the user's account. This will help in looking at RMA information for all the cases including the ones that have moved out of 'Supplier Response' phase.

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13 REVISION HISTORY

Revision History		
Revision Date	Revised By	Description of Revision
01-13-21	A. Bheda	Original Issue

Document Submittal / Revision Form (Electronic)				
Initiated By:	G. Studt	Date Initiated:	12-2-2020	
Type of Change:	<input checked="" type="checkbox"/> New Release <input type="checkbox"/> Change/Revision <input type="checkbox"/> Obsolete <input type="checkbox"/> Other:			
Customer Notification:	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No			
Approvals:	LRS Approvals			
	Quality:	Ben Masters	Date:	1/13/21 <input checked="" type="checkbox"/> Approve
	Quality:	Bob Wolbert	Date:	1/13/21 <input checked="" type="checkbox"/> Approve
	Infrastructure Approvals			
	Quality:	Colleen Butler	Date:	1/13/21 <input checked="" type="checkbox"/> Approve
	Quality:	Mark Donnell	Date:	1/13/21 <input checked="" type="checkbox"/> Approve
	LRE Approvals			
	Quality:	Gary Studt	Date:	1/13/21 <input checked="" type="checkbox"/> Approve
Quality:	John Cross	Date:	1/13/21 <input checked="" type="checkbox"/> Approve	