

<b>Alloy Toll Management Sdn Bhd</b>	<b>Doc. No.</b> : PM 03
	<b>Version No.</b> : 2.5
	<b>Effective Date</b> : 30/08/2021
	<b>Page</b> : 1 of 7
<b>Corrective Action</b>	

## 1.0 PURPOSE

This procedure is to ensure appropriate investigation is carried out whenever a non-conformity (NC) is reported in the Quality Management System (QMS), and the appropriate correction and corrective action are determined and implemented, and proper review of effectiveness corrective action are done before close up of NC.

## 2.0 SCOPE

This procedure is to be applied whenever there is a need to initiate a correction and corrective action.

## 3.0. PROCEDURE

### 3.1. Review Non-conformities

#### 3.1.1. A corrective action is taken in the following cases:

- a) When defective / non-conforming products and services are received from external providers.
- b) When circumstances are identified where a preventive initiative can be introduced to eliminate the cause of actual or potential non-conformances.
- c) Unsatisfactory assessment results from any Internal Quality Audit (IQA).
- d) Concerns are raised during a Management Review Meeting.
- e) Customers lodge a formal complaint relating to services supplied. (Customer Complaints)
- f) Any ALLOY TOLL MANAGEMENT SDN BHD (ATMSB) staff member detects a quality concern (e.g. quality, safety issues or general service) which they consider warrants investigation and resolution. (Staff Quality Concern)

- 3.1.2. Whenever non-conformities are reported from process, Internal/External Audit (IEA), product, and customer complaints the person who received the reported NC shall immediately forward the NC to the following personnel for review to determine whether the NC

**CONTROLLED COPY**

<b>Alloy Toll Management Sdn Bhd</b>	<b>Doc. No.</b> : PM 03
	<b>Version No.</b> : 2.5
	<b>Effective Date</b> : 30/08/2021
	<b>Page</b> : 2 of 7
<b>Corrective Action</b>	

is genuine/valid prior to issuing of Corrective Action Request (CAR).

- a) Process non-conformity – to be reviewed by Managers/ Process Owner;
- b) Internal Audit NC – Lead Auditor (LA)/Manager;
- c) Product Non-conformity - Manager;
- d) Customer Complaint – Top Management (TM)/ ‘Head of Department/Division (HOD)’/Process Owner.

### 3.2. Issue CAR

- 3.2.1. Upon receiving the reported NC and if it confirmed as genuine/valid, the authorized personnel as stated in 3.1.2 (a) – (d) shall immediately raise and issue a CAR by hand or via email to the TM/HOD/process owner concerned for correction to react to the NC and determining the causes of NC for initiating corrective action to prevent recurrence.
- 3.2.2. Prior to issuing the CAR, the authorized person who issue the CAR shall assign the First Reply due date on the CAR i.e. **maximum 2 weeks** from the issue date of the CAR for the return of investigation of NC causes, correction plan and corrective action plan from the TM/HOD/process owner.

### 3.3. Monitoring First Reply of the CAR

- 3.3.1. Based on the CAR from, staff assigned by the authorized personnel as stated in 3.1.2 (a) – (d) shall monitor the return of the CAR with cause of NC and correction and/or corrective action plans within the first reply due date, on weekly basis.
  - 3.3.1.1. If the CAR is not returned by the TM/HOD/process owner **after 14 working days** from the issue date, the authorized personnel as stated in 3.1.2 (a) – (d) shall immediately raise and send 1<sup>st</sup> reminder (Return of CAR) via email to the TM/HOD/process owner concerned, and follow-up with verbal call, and record the verbal call in the CAR form.
  - 3.3.1.2. If the CAR is not returned by the TM/HOD/process owner **after 21 working days** from the issue date, the authorized personnel as stated 3.1.2 (a) – (d) shall immediately raise and send 2<sup>nd</sup> reminder (Return of CAR) via email to the TM/HOD/process owner concerned, and follow-up with verbal call, and record the verbal call in the CAR form.

<b>Alloy Toll Management Sdn Bhd</b>	<b>Doc. No. : PM 03</b>
	<b>Version No. : 2.5</b>
<b>Corrective Action</b>	<b>Effective Date : 30/08/2021</b>
	<b>Page : 3 of 7</b>

### **3.4. Determining of cause of the NC**

- 3.4.1. Upon receiving of the CAR, the responsible TM/HOD/process owner concerned shall immediately conduct an investigation to determine the root cause or the most possible cause of the NC by means of interviewing the relevant personnel and assess the relevant records of the relevant processes.
- 3.4.2. During the planning, if necessary, the TM/HOD/process owner concerned shall update the risk and opportunity, determine the root cause of the non-conformity and perform risk assessment and determine controls/corrective actions.

### **3.5. Evaluate the Need for Correction and Corrective Action**

- 3.5.1. Based on the results of investigation, the TM/HOD/process owner shall evaluate the needs whether to initiate correction to react to the NC and deal with the consequence and/or corrective action to eliminate the cause of NC in order to prevent the recurrence of similar NC.

### **3.6. Determining appropriate Correction and Corrective Action**

- 3.6.1. After evaluation of the needs of actions to be taken and if there is a need for correction and/or corrective action, the TM/HOD/process owner shall immediately determine the appropriate correction and corrective action to be implemented and documented the correction plan and corrective action plan in the CAR.
- 3.6.2. Upon determining the correction and/or corrective action, the TM/HOD/process owner shall return the CAR by hand or via email to the authorized personnel as stated in 3.1.2 (a) – (d) within the 1<sup>st</sup> reply due date.

### **3.7. Implement Correction and/or Corrective Action**

- 3.7.1. Based on the planned correction and/or corrective action which have been determined in the CAR, the responsible personnel as determined in the CAR shall implement the correction and/or corrective action within the agreed time scales and record the correction and/or corrective action taken in the CAR and submit by hand or via email to the HOD/Head of Unit (HOU) for review and signature.

### **3.8. Review the effectiveness of the correction and corrective action taken.**

- 3.8.1. When receiving the return CAR, the authorized personnel as stated 3.1.2 (a) – (d) shall immediately set a date for the review of the

**CONTROLLED COPY**

<b>Alloy Toll Management Sdn Bhd</b>	<b>Doc. No.</b> : PM 03
	<b>Version No.</b> : 2.5
	<b>Effective Date</b> : 30/08/2021
	<b>Page</b> : 4 of 7
<b>Corrective Action</b>	

effectiveness of the correction and/or corrective action taken in the last column of the CAR, which can normally range from **1 to 6 month** from the actions taken date, case by case basis.

### **3.9. Make changes to the QMS, if necessary.**

- 3.9.1. After reviewing the effectiveness of the correction and/or corrective action taken and if it is found to be effective, TM/HOD/process owner concerned shall formally update and amend the relevant procedures or support documents with the validated methods, criteria, responsibility or resources **within 3 months** from the date of review and obtain approval for implementation as per **Control of Document (PM 02)**

### **3.10. Documented Information Control**

- 3.10.1. As soon as the CAR has been issued to the TM/HOD/Process Owner concerned, staff assigned by the authorized personnel as stated in 3.1.2 (a) – (d) shall immediately file a copy of the CAR/updated CAR in the file.

## **4.0 APPLICABLE CLAUSES**

- 10.2.1 Corrective action.

## **5.0 QUALITY RECORDS**

<b>No.</b>	<b>Title of Records</b>	<b>Person In Charge (PIC)</b>	<b>Retention Period (Year)</b>
1	Corrective Action Request Form (CAR)	DCO	3

<b>Alloy Toll Management Sdn Bhd</b>	<b>Doc. No.</b> : PM 03
	<b>Version No.</b> : 2.5
	<b>Effective Date</b> : 30/08/2021
	<b>Page</b> : 5 of 7
<b>Corrective Action</b>	

### DOCUMENT AMENDMENT REGISTER

NO	DATE	REASON	CHAPTER	VERSION
1	26/5/2000	Initial Release	All	1.1
2	20/07/2002	This procedure is amended to reflect that concerns are raised through letters, faxes, manual concern or other means.	3.2	1.2
3	11/06/2002	Procedure updated to be in-line with ISO 9001:2000	All	2.0
4	21/08/2003	To filled up a concern form for the concern raised during IQA	3.2	2.1
5	01/11/2005	Procedure updated to be in-line with new format	-	2.2
6	02/01/2008	Document Authorization: Management Representative - DGM	-	2.3
7	23/03/2018	Procedure updated to be in-line with ISO 9001:2015.  Amendment; - Revision No. changes to Version No. as agreed in the 4 <sup>th</sup> ISO New Standard Transition meeting. - New format for Quality Records table.	All      5.0	2.4
8	8/03/2021	Rename Procedure Name - "Corrective Action Procedure"  Remove: - "To provide a documented procedure for the analysis and rectification of concerns that arises as a result of operating the Quality System." - Preventive Action  - In any of the above cases, a concern is initiated and documented through letters, memos, faxes or other means including the manual Corrective Action Request (CAR) Form. All concerns raised shall be addressed to the respective staff concerned to address the concern and a copy is extended to the Top Management. In the case of concerns directly affecting the Quality Management System (QMS) and findings of IQA / Management Review, the CAR Form is filled by the designated staff	Header   1.0  2.0/10.2.2/ 3.1 3.2	2.5

**CONTROLLED COPY**

<b>Alloy Toll Management Sdn Bhd</b>	<b>Doc. No.</b> : PM 03
	<b>Version No.</b> : 2.5
	<b>Effective Date</b> : 30/08/2021
	<b>Page</b> : 6 of 7
<b>Corrective Action</b>	

NO	DATE	REASON	CHAPTER	VERSION
		<p>concerned to begin the corrective action process.</p> <ul style="list-style-type: none"> <li>- Concerns may be raised to react to specific issues detected while operating the system as defined in the scope above.</li> <li>- <b>Corrective Action:</b> All concerns requiring Corrective Action shall be monitored by Top Management. The respective staff concerned and the Top Management shall review the concern and determine the corrective Action to be taken.</li> <li>- In the case of concerns pertaining to Customer Complaints, the Top Management shall review the Customer Complaints and decide on the course of action.</li> <li>- The Top Management shall assign the staff to take the corrective action, and to verify that the Corrective Action has been effectively implemented.</li> <li>- Preventive Action: ATMSB will use the following to detect, analyse and eliminate potential causes of non-conformities</li> <li>- All Preventive Initiatives are addressed to the Top Management. It is the Top Management responsibilities to monitor the preventive actions initiated and ensure the solutions implemented are effective.</li> <li>- The Top Management is responsible as part of the management review process to collect and submit relevant information to the review meetings.</li> </ul> <p>Added:</p> <ul style="list-style-type: none"> <li>- “This procedure is to ensure appropriate investigation is carried out whenever a non-conformity (NC) is reported in the Quality Management System (QMS), and the appropriate correction and corrective action are determined and implemented, and proper review of effectiveness corrective action are done before close up of NC”</li> <li>- “...and corrective..”</li> <li>- Review Non-conformities</li> <li>- “Whenever non-conformities are reported from process, Internal/External Audit (I/EA), product, and customer complaints the person who receive the reported NC</li> </ul>	<p>3.3</p> <p>3.4</p> <p>3.5</p> <p>3.6</p> <p>3.7 (i) – (iv)</p> <p>3.8</p> <p>3.9</p> <p>1.0</p> <p>2.0</p> <p>3.1</p> <p>3.1.2 (a) – (d)</p>	

<b>Alloy Toll Management Sdn Bhd</b>	<b>Doc. No.</b> : PM 03
	<b>Version No.</b> : 2.5
	<b>Effective Date</b> : 30/08/2021
	<b>Page</b> : 7 of 7
<b>Corrective Action</b>	

NO	DATE	REASON	CHAPTER	VERSION
		<p>shall immediately forward the NC to the following personnel for review to determine whether the NC is genuine/valid prior to issue of Corrective Action Request (CAR)</p> <ul style="list-style-type: none"> <li>- Issue CAR</li> <li>- Monitoring First Reply of the CAR</li> <li>- Determining of cause of the NC</li> <li>- Evaluate the Need for Correction and Corrective Action</li> <li>- Determining appropriate Correction and Corrective Action</li> <li>- Implement Correction and/or Corrective Action</li> <li>- Review the effectiveness of the correction and corrective action taken.</li> <li>- Make changes to the QMS, if necessary.</li> <li>- Documented Information Control</li> </ul>	<p>3.2/ 3.2.1/ 3.2.2 3.3/ 3.3.1/ 3.3.1.1/ 3.3.1.2 3.4.1/ 3.4.2 3.5/ 3.5.1 3.6/ 3.6.1/ 3.6.2 3.7/ 3.7.1 3.8/ 3.8.1 3.9/ 3.9.1 3.10/ 3.10.1</p>	