

XYZ	XYZ Incorporated Quality Management System Procedure	QP.105
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Approval:		

Purpose: This procedure has been established by XYZ, inc. to define the system used for the analysis of nonconformances, and for the initiation, implementation, and verification of any subsequent corrective actions.	
ISO 9001:2008 Requirement	QMS Method of Addressing
Reviewing nonconformities (including customer complaints)	<p>XYZ's Management Representative will review identified issues, including but not limited to, NCR's, internal audit results and customer complaints to determine if a need for formal corrective action exists.</p> <p>Such corrective action shall be documented using a Corrective Action Request - CAR form (Form 105.1) and logged on the CAR Master List (Form 105.2) for tracking and reporting.</p> <p>Once a CAR has been generated it shall be assigned to the manager responsible for the affected process for resolution.</p>
Determining the causes nonconformities.	A Root Cause investigation is required for all issues assigned a CAR. Results of the investigation will be documented in the appropriate section of the CAR.
Evaluating the need for action to ensure that nonconformities do not recur.	Action to prevent recurrence is required for all CARs. This action should address and be appropriate to eliminating or mitigating the root cause.
Determining and implementing action needed.	After determining the actions needed, the Management Representative will monitor their implementation to ensure that the desired results are achieved.
Records of the results of action taken.	<p>Results of root cause analysis and action to prevent recurrence taken will be documented on the CAR form.</p> <p>Other supporting documentation may include:</p> <ul style="list-style-type: none"> • NCRs • Internal Audit Reports • Management Review • Records of Customer Complaints • Internal memos

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<p>Reviewing Corrective Actions taken.</p>	<p>The Management Representative shall review each completed CAR to determine if root cause analysis and action to prevent recurrence are adequate.</p> <p>The Management Representative will then verify that the action to prevent recurrence was effectively implemented, and if so, will then sign the CAR as “closed”. Inadequate CAR responses will be returned to the responsible party for further information.</p> <p>Corrective Action records will be made available as a source of information for XYZ’s annual Management Review</p>
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