

Checkpoint	Notes	Comply
Do you have a documented procedure for your CA system that covers the requirements of ISO 9001 8.5.2?		
<p>Do you identify and define the sources of product and quality problems in your procedure?</p> <p>Do the sources of information include:</p> <ul style="list-style-type: none"> <li>• Product (service) nonconformity/failure</li> <li>• Internal audits</li> <li>• Customer complaints and feedback</li> <li>• Process and quality issues</li> <li>• Out of specification results</li> <li>• Calibration failures</li> <li>• Supplier issues</li> </ul>		
Do you have a documented nonconformity investigation procedure? Does the procedure control and prevent the release of nonconforming product/delivery of service?		
Does this procedure also include additional 'containment action' to control product/service that is currently being processed and to identify nonconforming product/service which may have been released/delivered?		
Is the data in the CA system reported in an accurate and timely way?		

<p>Is the data in the CA analysed to identify actions to prevent the nonconformity from happening again? Is the amount of time spent on investigating each CAPA appropriate for the significance of the issue?</p>		
<p>Have actions from the CA investigation been identified and implemented to stop the issue from re-occurring? Are the actions appropriate for the significance of the issue?</p>		
<p>Do you analyse trends of product and quality data to identify unfavourable process or product/service trends? Have any trends been identified that may require CA?</p>		
<p>Do you use statistical methods (where necessary) to detect recurring quality problems? Are results analysed across processes to determine the extent of product/service and quality problems?</p>		
<p>Do you communicate the information from CA across the organisation, including the review of this CA information in the management review?</p>		