

VOP			
Viamed Operating sub Process			
<u>CORRECTIVE & PREVENTIVE ACTIONS</u>			
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<u>Charts 08, 27 & 28</u>			

NON-CONFORMANCE CONTROL

The purpose of this process is to show the system in operation within the company for the control of any non-conforming product **or procedure/process**. The measurement control process controls all products. It is the responsibility of each process owner to ensure that non-conforming items within that process are controlled as per this procedure. It is the responsibility of all personnel to ensure that they comply with this procedure and associated documents.

NON-CONFORMING ITEMS

All products undergo an inspection and / or test process. When product is found to be incorrect to the required specification, then it is subject to a "Quarantine / Hold" process. These products are reviewed on a regular basis, with the results and subsequent actions, documented.

Non-Conformance to system

During Audits , between audits or at management/stock meetings non-conformances to the system may be found. Form QC21 is raised.

This is treated in the same way as a non-conformance during an Audit

ACTIONS

The significance of quality problems will be evaluated in terms of their potential impact on such aspects as production costs, quality costs & product performance, reliability, safety and customer satisfaction. The relationship of cause and effect of non-conformance will be investigated. All potential causes will be considered, and important variables affecting non-conformance will be identified. Such investigations and analyses will determine the root cause of the problem before preventive actions are determined. These findings will be documented and reported to the appropriate persons. Permanent changes brought about by corrective actions will be recorded.

Where product has been found faulty at goods-in, then the manufacturers and suppliers will be informed and inspection / testing will be monitored until such time as the problem has been corrected. All preventive actions as defined by the company are inherent in the design and development process, together with any appropriate manufacturing and systems processes. Any actions proposed will be monitored and documented.

Where appropriate, or where required by such as Customer Complaints, Internal problems etc., corrective actions will be addressed and implemented. Where the Sales team or other personnel highlight potential problems, then these will be reviewed and analysed for their possible impact on products or services.

When a problem is highlighted, the General Director will be informed as to all possible scenarios so that all the relevant information is available to enable the correct decision to be made.

The decision made may be one that has a direct bearing on the design of the product or on the integrity of the service provided. Where this is the case then all relevant personnel will input to the problem. Should the actions taken, whether corrective or preventive, have impacts on Customer satisfaction, then the Customer will be immediately informed and actions followed-up to ensure full satisfaction. Subsequent actions such as design modifications will be entered into the design file (CE file where appropriate) and all records amended.

All records pertaining to Non-conformances, Corrective actions , and internal investigations will be held for a minimum of 11 years in Archives, Library, General Office, and will also be held electronically.