

blamed

INTERNAL PROCESS VERIFICATION *ALAMB*

Audit No: 106 **Date: 3-6-15** **Auditor:**

MANAGEMENT SYSTEM

#	Question	O.K.?
1	Establish that the management system applications are a series of process controls, and that they are in place throughout the organisation.. <i>Instructions</i>	<i>Y</i>
	Can processes be identified	<i>Y</i>
	Are charts produced to this effect? And are they in place in strategic locations for use by personnel. <i>Instructions</i>	<i>Y</i>
	Are regular analyses undertaken to identify any outstanding requirements	<i>Y</i>
	Is it still on Meeting Agenda <i>meetings + instructions</i>	<i>Y</i>
	Are necessary changes implemented where and when required	<i>Y</i>
	Is any outsourcing done	<i>No</i>
2	Check the documented system for its policies and objectives, and its control of the above processes and procedures. <i>VIP3COP 00.00</i>	<i>Y</i>
	Is the Process Manual is up-to-date.	<i>Y</i>
	Check issue date	
	Has it been reviewed at a management meeting	
	Are amendments are controlled by Version & Date issue.	<i>Y</i>
	Check amendments page is filled in	<i>Y</i>
	Does it continue to indicate the company's objectives <i>#</i>	<i>Y</i>
	Is there sole responsibility for company procedures and other documentation.	<i>Y</i>
	Is documentation is checked prior to formal approval and issue.	<i>Y</i>
	Are Electronic procedures in place and available, to all.	<i>Y</i>
	Do all personnel have access to their relevant areas of the documentation.	
	Check electronic access	
	Are Technical Drawings, available and controlled	<i>Y</i>
	Check electronic access	
	Are standards available and controlled	<i>Y</i>
	Check electronic access	
	Are manufacturers data sheets are supplied as the latest issue. <i>X 60912</i>	
	Has manufacture been approached for latest issue within last 12 months	
	Check electronic access	
	Are operators Manuals available and controlled	<i>Y</i>
	Check electronic access	
	Establish that all documentation is valid and of the latest status, and that any document changes are controlled.	<i>Y</i>
	Are documents controlled by date status; <i>Not possible Digitally stored</i>	<i>NA</i>
	Check 6 at random	
	Are documents being checked by operators before use	
	Check that printed copies of production procedures are of the latest issue status	<i>NA</i>
	Check Repair & production areas <i>nothing printed</i>	
	Check that there is a system in operation for the request for amendments.	<i>Y</i>
	Verify that amendments are updated "Electronically" and old copies removed.	<i>NA</i>
	Check that they are also updated in the company master file & old copies removed.	<i>NA</i>
	Establish that any records produced are controlled and filed for identity and easy retrieval etc.	
	Check Record files are up to date including: QA <i>✓</i>	

A1 add policy to amendment page

Via med

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MANAGEMENT SYSTEM

Production	✓	
Goods returned	✓	
Quarantine	N/A	
Warranty	N/A	
Are sales orientated records filed and archived by Hospital name (and customer name).		N/A
Are records of inspections filed		Y
Has organisation Chart changed		No
Has personnel responsibility descriptions changed		No
Check that the C.E. files are maintained by sole responsibility.		Y
Check that obsolete data in the files is either Archived or retained.		Y
Check that the Notified body is informed of major changes to Documentation		Y
Check if here have been major changes		Y
Check that electronic documents are regularly backed up and secure off-site		Y
Check that documents are filed where they say they are and the responsibility is true		Y
S		