INTERNAL PROCESS VERIFICATION

Audit No: 1:   Date: 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..	
	Can processes be identified	
	Are charts produced to this effect? And are they in place in strategic locations for use by personnel.	
	Are regular analyses undertaken to identify any outstanding requirements Is it still on Meeting Agenda	
	Are necessary changes implemented where and when required	
	Is any outsourcing done	
2	Check the documented system for its policies and objectives, and its control of the above processes and procedures.	
	Is the Process Manual is up-to-date. Check issue date Has it been reviewed at a management meeting	
	Are amendments are controlled by Version & Date issue. Check amendments page is filled in	
	Does it continue to indicate the company's objectives	
	Is there sole responsibility for company procedures and other documentation.	
	Is documentation is checked prior to formal approval and issue.	
	Are Electronic procedures in place and available, to all. Do all personnel have access to their relevant areas of the documentation. Check electronic access	
	Are Technical Drawings, available and controlled Check electronic access	
	Are standards available and controlled Check electronic access	
	Are manufacturers data sheets are supplied as the latest issue. Has manufacture been approached for latest issue within last 12 months Check electronic access	
	Are operators Manuals available and controlled Check electronic access	
	Establish that all documentation is valid and of the latest status, and that any document changes are controlled.	
	Are documents controlled by date status; 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 Check Repair & production areas	
	Check that there is a system in operation for the request for amendments.	
	Verify that amendments are updated "Electronically " and old copies removed.	
	Check that they are also updated in the company master file & old copies removed.	
	Establish that any records produced are controlled and filed for identity and easy retrieval etc. Check Record files are up to date including: QA	

	Production Goods returned Quarantine Warranty	
	Are sales orientated records filed and archived by Hospital name (and customer name).	
	Are records of inspections filed	
	Has organisation Chart changed	
	Has personnel responsibility descriptions changed	
	Check that the C.E. files are maintained by sole responsibility.	
	Check that obsolete data in the files is either Archived or retained.	
	Check that the Notified body is informed of major changes to Documentation Check if here have been major changes	
	Check that electronic documents are regularly backed up and secure off-site	
	Check that documents are filed where they say they are and the responsibility is true	
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