VST

INTERNAL PROCESS VERIFICATION

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

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.. Intrastats	Y
	Can processes be identified	Y
	Are charts produced to this effect? And are they in place in strategic locations for use by personnel. Intrastats	Y
	Are regular analyses undertaken to identify any outstanding requirements Is it still on Meeting Agenda meeting + intrastats	Y
	Are necessary changes implemented where and when required	Y
	Is any outsourcing done	No
2	Check the documented system for its policies and objectives, and its control of the above processes and procedures. VM3COP 00:00	Y
	Is the Process Manual is up-to-date. Check issue date Has it been reviewed at a management meeting	Y
	Are amendments are controlled by Version & Date issue. Check amendments page is filled in	Y
	Does it continue to indicate the company's objectives ~~X~~ *1	~~Y~~
	Is there sole responsibility for company procedures and other documentation.	Y
	Is documentation is checked prior to formal approval and issue.	Y
	Are Electronic procedures in place and available, to all. Do all personnel have access to their relevant areas of the documentation. Check electronic access	Y
	Are Technical Drawings, available and controlled Check electronic access	Y
	Are standards available and controlled Check electronic access	Y
	Are manufacturers data sheets are supplied as the latest issue. # 60912 Has manufacture been approached for latest issue within last 12 months Check electronic access	
	Are operators Manuals available and controlled Check electronic access	Y
	Establish that all documentation is valid and of the latest status, and that any document changes are controlled.	Y
	Are documents controlled by date status; Check 6 at random Not possible Digitally stached	NA
	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 Nothing Printed	N/A
	Check that there is a system in operation for the request for amendments.	Y
	Verify that amendments are updated "Electronically " and old copies removed.	NA
	Check that they are also updated in the company master file & old copies removed.	NA
	Establish that any records produced are controlled and filed for identity and easy retrieval etc. Check Record files are up to date including: QA	Y

*1 add policy to amendment page

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	Production Goods returned Quarantine Warranty	Y
	Are sales orientated records filed and archived by Hospital name (and customer name).	N/A OLD File
	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 Check if here have been major changes	Y N
	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	