

# INTERNAL PROCESS VERIFICATION

**Audit No: 105**

**Date:**

**Auditor:**

**MANAGEMENT SYSTEM**

VST

**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..		Y
	Can processes be identified		Y
	Are charts produced to this effect? And are they in place in strategic locations for use by personnel.		Y
	Are regular analyses undertaken to identify any outstanding requirements Is it still on Meeting Agenda		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.		X
	Is the Process Manual is up-to-date. Check issue date <i>2014:14342</i>		Y
	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
	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. Has manufacture been approached for latest issue within last 12 months Check electronic access		Y
	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		Y
	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		Y
	Check that there is a system in operation for the request for amendments.		Y
	Verify that amendments are updated "Electronically" and old copies removed.		Y
	Check that they are also updated in the company master file & old copies removed.		Y
	Establish that any records produced are controlled and filed for identity and easy retrieval etc. Check Record files are up to date including: QA		X

## INTERNAL PROCESS VERIFICATION

**Audit No: 106**

**Date:**

*VST*

**Auditor:**

**MANAGEMENT SYSTEM**

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