# Internal Audit Check list

## Internal Process Verification

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|---|---|---|---|
| Created: | 17 May 1995 | **Audit No 10b** | Viamed |
| Revised: | 31 August 2016 | Last printed 15/08/2011 | Page 1 of 1 |
| Audit Date | 31-8-16 | Auditor Helen Lamb | |

| | QUESTION: | RESPONSE | Y/N |
|---|---|---|---|
| 1 | Is the Quality Statement Policy and Objectives reviewed annually.<br>ISO – Document Index Task ID (300). Search Issues and review. | | Y |
| 2 | Is the process manual up to date.<br>ISO – Document Index Task ID (548). Search Issues and review. | | |
| 3 | Is documentation checked prior to formal approval and issue. | Done by MD pending. | Y |
| 4 | Check that there is a system in operation for the request for amendments. | Intrastat ~~ISO~~ | Y |
| 5 | Verify that amendments are updated electronically and old copies archived. | | Y |
| 6 | Are sales orientated records filed and archived correctly in the ORD files, in the office and archiving. | | Y |
| 7 | Has organisation Chart changed. | | Y |
| 8 | Has personnel responsibility descriptions changed. | Rdes + Responsibilities | Y |
| 9 | Check that the CE files are maintained by sole responsibility. | by MD | Y |
| 10 | Check that the Notified body is informed of major changes to Documentation. | None as Yet | N/A |
| 11 | Check that electronic documents are regularly backed up and secure off site.<br>ISO – Document Index Task ID (452). Search Issues and review. | | Y |

# INTERNAL PROCESS VERIFICATION

**Audit No: 1:** **Date:** **Auditor:**

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## MANAGEMENT SYSTEM

viamed

| # | 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.. Roles & Responsibilities | |
| | Can processes be identified Instructions | |
| | Are charts produced to this effect? And are they in place in strategic locations for use by personnel. Instructions | |
| | Are regular analyses undertaken to identify any outstanding requirements<br>Is it still on Meeting Agenda Training | |
| | Are necessary changes implemented where and when required Instructions | |
| | Is any outsoureing done | |
| 2 | Check the documented system for its policies and objectives, and its control of the above processes and/procedures. Company Policy Quality Policy Require | |
| | Is the Process Manual is up-to-date.<br>Check issue date<br>Has it been reviewed at a management meeting Roles + Responsibility Trash (548) Search Issue + Review | |
| | Are amendments are controlled by Version & Date issue.<br>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.<br>Do all personnel have access to their relevant areas of the documentation. Instructions<br>Check electronic access | |
| | Are Technical Drawings, available and controlled Instructions<br>Check electronic access | |
| | Are standards available and controlled N/A<br>Check electronic access | |
| | Are manufacturers data sheets are supplied as the latest issue.<br>Has manufacture been approached for latest issue within last 12 months N/A<br>Check electronic access | |
| | Are operators Manuals available and controlled Instructions N/A<br>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;<br>Check 6 at random | |
| | Are documents being checked by operators before use<br>Check that printed copies of production procedures are of the latest issue status<br>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. Archived. | |
| | 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.<br>Check Record files are up to date including:<br>QA | |

# *INTERNAL PROCESS VERIFICATION*

**Audit No: 1:** **Date:** **Auditor:**

10b Named

## *MANAGEMENT SYSTEM*

| | | |
|---|---|---|
| | Production<br>Goods returned<br>Quarantine<br>Warranty | |
| | Are sales orientated records filed and archived ~~by Hospital name (and customer name)~~. | Correct |
| | Are records of inspections filed — Roles + Responsibilities | |
| | Has organisation Chart changed | Y |
| | Has personnel responsibility descriptions changed | X |
| | Check that the C.E. files are maintained by sole responsibility. | X |
| | Check that obsolete data ~~in the files~~ is either Archived or retained. | |
| | Check that the Notified body is informed of major changes to Documentation<br>Check if here have been major changes | Y |
| | Check that electronic documents are regularly backed up and secure off-site — task (452) issue Check | |
| | Check that documents are filed where they say they are and the responsibility is true | |
| | s | |

management systems
IX is viamed quality Statement policy and
objectives Review annually - ISO - Dc index.
Task (300) search issues + review.