Vlamed + VST

Internal Audit Check list

DOCUMENT CONTROL			
Created:	17/May 1995	**Audit No 10**	VOP 01
Revised:	26 June 2019		Page 1 of 25
Audit Date	24-6-19	Auditor Helen Lamb	ISO 4.2 4.2.2

Documentation control is being moved from a paper system to Intrastats
Many of the questions asked are now superfluous as the checks are carried out automatically, and recorded automatically. The hard copies are being replaced and Archived.

Company / ISO Section	Criteria of ISO Section	Auditor Comments / Issues
VST Ltd ISO9001:2015 10.2.1	When a nonconformity occurs, including any arising from complaints, the organization shall: a) react to the nonconformity and, as applicable: 1) take action to control and correct it; 2) deal with the consequences; b) evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by: 1) reviewing and analysing the nonconformity; 2) determining the causes of the nonconformity; 3) determining if similar nonconformities exist, or could potentially occur; c) implement any action needed; d) review the effectiveness of any corrective action taken; e) update risks and opportunities determined during planning, if necessary; f) make changes to the quality management system, if necessary. Corrective actions shall be appropriate to the effects of the nonconformities encountered.	Intrastats issues and procedures. management meetings MD review all nonconformances Rolling issues + tasks
VST Ltd ISO9001:2015 10.2.2	The organization shall retain documented information as evidence of: a) the nature of the nonconformities and any subsequent actions taken; b) the results of any corrective action.	Intrastats issues + Doc index
VST Ltd	**Continual improvement**	

ISO9001:2015 10.3	The organization shall continually improve the suitability, adequacy and effectiveness of the quality management system. The organization shall consider the results of analysis and evaluation, and the outputs from management review, to determine if there are needs or opportunities that shall be addressed as part of continual improvement.	~~Tasks~~ tasks + Audits management meetings
VST Ltd ISO9001:2015 4.4.1	**Quality management system and its processes** The organization shall establish, implement, maintain and continually improve a quality management system, including the processes needed and their interactions, in accordance with the requirements of this International Standard. The organization shall determine the processes needed for the quality management system and their application throughout the organization, and shall: a) determine the inputs required and the outputs expected from these processes; b) determine the sequence and interaction of these processes; c) determine and apply the criteria and methods (including monitoring, measurements and related performance indicators) needed to ensure the effective operation and control of these processes; d) determine the resources needed for these processes and ensure their availability; e) assign the responsibilities and authorities for these processes; f) address the risks and opportunities as determined in accordance with the requirements of 6.1; g) evaluate these processes and implement any changes needed to ensure that these processes achieve their intended results; h) improve the processes and the quality management system	Route map management meetings tasks + Audits
VST Ltd ISO9001:2015 4.4.2	**Quality management system and its processes** To the extent necessary, the organization shall: a) maintain documented information to support the operation of its processes; b) retain documented information to have confidence that the processes are being carried out as planned.	Instants Doc index
VST Ltd ISO9001:2015 5.1.1	**General** Top management shall demonstrate leadership and commitment with respect to the quality	

	management system by: a) taking accountability for the effectiveness of the quality management system; b) ensuring that the quality policy and quality objectives are established for the quality management system and are compatible with the context and strategic direction of the organization; c) ensuring the integration of the quality management system requirements into the organization's business processes; d) promoting the use of the process approach and risk-based thinking; e) ensuring that the resources needed for the quality management system are available; f) communicating the importance of effective quality management and of conforming to the quality management system requirements; g) ensuring that the quality management system achieves its intended results; h) engaging, directing and supporting persons to contribute to the effectiveness of the quality management system; i) promoting improvement; j) supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility. NOTE Reference to "business" in this International Standard can be interpreted broadly to mean those activities that are core to the purposes of the organization's existence, whether the organization is public, private, for profit or not for profit.	management meetings Regular Reviews Udrastats tasks + audits non conformance Reneu
VST Ltd ISO9001:2015 5.2.2	**Communicating the quality policy** The quality policy shall: a) be available and be maintained as documented information; b) be communicated, understood and applied within the organization; c) be available to relevant interested parties, as appropriate.	Reviews + Issues Doc Index
VST Ltd ISO9001:2015 6.2.1	The organization shall establish quality objectives at relevant functions, levels and processes needed for the quality management system. The quality objectives shall: a) be consistent with the quality policy; b) be measurable; c) take into account applicable requirements; d) be relevant to conformity of products and services and to enhancement of customer	Udrastats Route map

	satisfaction; e) be monitored; f) be communicated; g) be updated as appropriate. The organization shall maintain documented information on the quality objectives	Reviews
VST Ltd ISO9001:2015 6.3	**Planning of changes** When the organization determines the need for changes to the quality management system, the changes shall be carried out in a planned manner (see 4.4). The organization shall consider: a) the purpose of the changes and their potential consequences; b) the integrity of the quality management system; c) the availability of resources; d) the allocation or reallocation of responsibilities and authorities.	management Review feedback
VST Ltd ISO9001:2015 7.1.3	**Infrastructure** The organization shall determine, provide and maintain the infrastructure necessary for the operation of its processes and to achieve conformity of products and services. NOTE Infrastructure can include: a) buildings and associated utilities; b) equipment, including hardware and software; c) transportation resources; d) information and communication technology.	Issues Tasks + Audits
VST Ltd ISO9001:2015 7.1.5.2	**Measurement traceability** When measurement traceability is a requirement, or is considered by the organization to be an essential part of providing confidence in the validity of measurement results, measuring equipment shall be: a) calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; when no such standards exist, the basis used for calibration or verification shall be retained as documented information; b) identified in order to determine their status; c) safeguarded from adjustments, damage or deterioration that would invalidate the calibration status and subsequent measurement results. The organization shall determine if the validity of previous measurement results has been adversely affected when measuring	Audits Tasks + Audits Calibration index

	equipment is found to be unfit for its intended purpose, and shall take appropriate action as necessary	
VST Ltd ISO9001:2015 7.1.6	**Organizational knowledge** The organization shall determine the knowledge necessary for the operation of its processes and to achieve conformity of products and services. This knowledge shall be maintained and be made available to the extent necessary. When addressing changing needs and trends, the organization shall consider its current knowledge and determine how to acquire or access any necessary additional knowledge and required updates. NOTE 1 Organizational knowledge is knowledge specific to the organization; it is generally gained by experience. It is information that is used and shared to achieve the organization's objectives. NOTE 2 Organizational knowledge can be based on: a) internal sources (e.g. intellectual property; knowledge gained from experience; lessons learned from failures and successful projects; capturing and sharing undocumented knowledge and experience; the results of improvements in processes, products and services); b) external sources (e.g. standards; academia; conferences; gathering knowledge from customers or external providers)	Intranets + Doc index Vops + Caps Procedures to utilize knowledge in company
VST Ltd ISO9001:2015 7.4	**Communication** 7.4 Communication The organization shall determine the internal and external communications relevant to the quality management system, including: a) on what it will communicate; b) when to communicate; c) with whom to communicate; d) how to communicate; e) who communicates.	Risks - Tasks + Audits from Relevant issues. interested parties
VST Ltd ISO9001:2015 7.5.1	**General** 7.5.1 General The organization's quality management system shall include: a) documented information required by this International Standard; b) documented information determined by the organization as being necessary for the	Doc index

	effectiveness of the quality management system. NOTE The extent of documented information for a quality management system can differ from one organization to another due to: — the size of organization and its type of activities, processes, products and services; — the complexity of processes and their interactions; — the competence of persons.	Rolling tasks + Audits
VST Ltd ISO9001:2015 7.5.2	**Creating and updating** 7.5.2 Creating and updating When creating and updating documented information, the organization shall ensure appropriate: a) identification and description (e.g. a title, date, author, or reference number); b) format (e.g. language, software version, graphics) and media (e.g. paper, electronic); c) review and approval for suitability and adequacy.	Intranets System in place.
VST Ltd ISO9001:2015 7.5.3	**Control of documented information**	
VST Ltd ISO9001:2015 7.5.3.1	Documented information required by the quality management system and by this International Standard shall be controlled to ensure: a) it is available and suitable for use, where and when it is needed; b) it is adequately protected (e.g. from loss of confidentiality, improper use, or loss of integrity).	Intranets Doc index
VST Ltd ISO9001:2015 7.5.3.2	For the control of documented information, the organization shall address the following activities, as applicable: a) distribution, access, retrieval and use; b) storage and preservation, including preservation of legibility; c) control of changes (e.g. version control); d) retention and disposition. Documented information of external origin determined by the organization to be necessary for the planning and operation of the quality management system shall be identified as appropriate, and be controlled. Documented information retained as evidence of conformity shall be protected from unintended alterations. NOTE Access can imply a decision regarding the permission to view the documented	Intranets Doc index + procedure + GDPR

	information only, or the permission and authority to view and change the documented information.	
VST Ltd ISO9001:2015 8.1	**Operational planning and control** The organization shall plan, implement and control the processes (see 4.4) needed to meet the requirements for the provision of products and services, and to implement the actions determined in Clause 6, by: a) determining the requirements for the products and services; b) establishing criteria for: 1) the processes; 2) the acceptance of products and services; c) determining the resources needed to achieve conformity to the product and service requirements; d) implementing control of the processes in accordance with the criteria; e) determining, maintaining and retaining documented information to the extent necessary: 1) to have confidence that the processes have been carried out as planned; 2) to demonstrate the conformity of products and services to their requirements. The output of this planning shall be suitable for the organizations operations. The organization shall control planned changes and review the consequences of unintended changes, taking action to mitigate any adverse effects, as necessary. The organization shall ensure that outsourced processes are controlled (see 8.4).	Project list Intranets Controlled procedures feedback Issues
VST Ltd ISO9001:2015 8.2.4	Changes to requirements for products and services The organization shall ensure that relevant documented information is amended, and that relevant persons are made aware of the changed requirements, when the requirements for products and services are changed.	Request reading Issues Doc index
VST Ltd ISO9001:2015 8.3.2	**Design and development planning** In determining the stages and controls for design and development, the organization shall consider: a) the nature, duration and complexity of the design and development activities; b) the required process stages, including applicable design and development reviews; c) the required design and development verification and validation activities;	Project list Design Audit No Design.

	d) the responsibilities and authorities involved in the design and development process; e) the internal and external resource needs for the design and development of products and services; f) the need to control interfaces between persons involved in the design and development process; g) the need for involvement of customers and users in the design and development process; h) the requirements for subsequent provision of products and services; i) the level of control expected for the design and development process by customers and other relevant interested parties; j) the documented information needed to demonstrate that design and development requirements have been met.	
VST Ltd ISO9001:2015 8.3.4	**Design and development controls** The organization shall apply controls to the design and development process to ensure that: a) the results to be achieved are defined; b) reviews are conducted to evaluate the ability of the results of design and development to meet requirements; c) verification activities are conducted to ensure that the design and development outputs meet the input requirements; d) validation activities are conducted to ensure that the resulting products and services meet the requirements for the specified application or intended use; e) any necessary actions are taken on problems determined during the reviews, or verification and validation activities; f) documented information of these activities is retained. NOTE Design and development reviews, verification and validation have distinct purposes. They can be conducted separately or in any combination, as is suitable for the products and services of the organization.	No Design. Project list
VST Ltd ISO9001:2015 8.3.5	**Design and development outputs** The organization shall ensure that design and development outputs: a) meet the input requirements; b) are adequate for the subsequent processes for the provision of products and services; c) include or reference monitoring and measuring requirements, as appropriate, and acceptance criteria; d) specify the characteristics of the products and services that are essential for their intended	No Design.

	purpose and their safe and proper provision. The organization shall retain documented information on design and development outputs.	
VST Ltd ISO9001:2015 9.1.1	**General** The organization shall determine: a) what needs to be monitored and measured; b) the methods for monitoring, measurement, analysis and evaluation needed to ensure valid results; c) when the monitoring and measuring shall be performed; d) when the results from monitoring and measurement shall be analysed and evaluated. The organization shall evaluate the performance and the effectiveness of the quality management system. The organization shall retain appropriate documented information as evidence of the results.	Internals, QA procedures management Review
VST Ltd ISO9001:2015 9.2.2	The organization shall: a) plan, establish, implement and maintain an audit programme(s) including the frequency, methods, responsibilities, planning requirements and reporting, which shall take into consideration the importance of the processes concerned, changes affecting the organization, and the results of previous audits; b) define the audit criteria and scope for each audit; c) select auditors and conduct audits to ensure objectivity and the impartiality of the audit process; d) ensure that the results of the audits are reported to relevant management; e) take appropriate correction and corrective actions without undue delay; f) retain documented information as evidence of the implementation of the audit programme and the audit results. NOTE See ISO 19011 for guidance.	Internals Audit calendar Tasks + Audits Rerew Annually
Viamed Ltd ISO13485:2016 4.1.1	**Quality management system** The organization shall document a quality management system and maintain its effectiveness in accordance with the requirements of this International Standard and applicable regulatory requirements. The organization shall establish, implement and maintain any requirement, procedure, activity or arrangement required to be documented by this International Standard or applicable regulatory	Doc index Route map.

	requirements. The organization shall document the role(s) undertaken by the organization under the applicable regulatory requirements. NOTE Roles undertaken by the organization can include manufacturer, authorized representative, importer or distributor.	
Viamed Ltd ISO13485:2016 4.1.6	**Quality management system** For each quality management system process, the organization shall: The organization shall document procedures for the validation of the application of computer software used in the quality management system. Such software applications shall be validated prior to initial use and, as appropriate, after changes to such software or its application. The specific approach and activities associated with software validation and revalidation shall be proportionate to the risk associated with the use of the software. Records of such activities shall be maintained (see 4.2.5).	Audit Software validation tasks + Audits.
Viamed Ltd ISO13485:2016 4.2	**Documentation requirements**	
Viamed Ltd ISO13485:2016 4.2.1 General	**Documentation requirements** The quality management system documentation (see 4.2.4) shall include: a) documented statements of a quality policy and quality objectives; b) a quality manual; c) documented procedures and records required by this International Standard; d) documents, including records, determined by the organization to be necessary to ensure the effective planning, operation, and control of its processes; e) other documentation specified by applicable regulatory requirements.	Intro starts. Doc index
Viamed Ltd ISO13485:2016 4.2.2 Quality manual	**Documentation requirements** The organization shall document a quality manual that includes: a) the scope of the quality management system, including details of and justification for any exclusion or non-application; b) the documented procedures for the quality management system, or reference to them; c) a description of the interaction between the processes of the quality management system. The quality manual shall outline the structure of the documentation used in the quality management system.	Roadmap Doc index

Viamed Ltd ISO13485:2016 4.2.4 Control of documents	**Documentation requirements** Documents required by the quality management system shall be controlled. Records are a special type of document and shall be controlled according to the requirements given in 4.2.5. A documented procedure shall define the controls needed to: a) review and approve documents for adequacy prior to issue; b) review, update as necessary and re-approve documents; c) ensure that the current revision status of and changes to documents are identified; d) ensure that relevant versions of applicable documents are available at points of use; e) ensure that documents remain legible and readily identifiable; f) ensure that documents of external origin, determined by the organization to be necessary for the planning and operation of the quality management system, are identified and their distribution controlled; g) prevent deterioration or loss of documents; h) prevent the unintended use of obsolete documents and apply suitable identification to them. The organization shall ensure that changes to documents are reviewed and approved either by the original approving function or another designated function that has access to pertinent background information upon which to base its decisions. The organization shall define the period for which at least one copy of obsolete documents shall be retained. This period shall ensure that documents to which medical devices have been manufactured and tested are available for at least the lifetime of the medical device as defined by the organization, but not less than the retention period of any resulting record (see 4.2.5), or as specified by applicable	Doc index Contents
Viamed Ltd ISO13485:2016 4.2.5 Control of records	**Documentation requirements** Records shall be maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system. The organization shall document procedures to define the controls needed for the identification, storage, security and integrity, retrieval, retention time and disposition of records. The organization shall define and implement methods for protecting confidential health information contained in records in accordance with the applicable regulatory requirements. Records shall remain legible, readily identifiable and retrievable. Changes to a record shall	Doc index Audits + GDPR Procedures

	remain identifiable. The organization shall retain the records for at least the lifetime of the medical device as defined by the organization, or as specified by applicable regulatory requirements, but not less than two years from the medical device release by the organization.	
Viamed Ltd ISO13485:2016 5.6.1	**General** The organization shall document procedures for management review. Top management shall review the organization's quality management system at documented planned intervals to ensure its continuing suitability, adequacy, and effectiveness. The review shall include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives. Records from management reviews shall be maintained	management meetings Reviews Issues
Viamed Ltd ISO13485:2016 7.1	**Planning of product realization** The organization shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the quality management system. The organization shall document one or more processes for risk management in product realization. Records of risk management activities shall be maintained (see 4.2.5). In planning product realization, the organization shall determine the following, as appropriate: a) quality objectives and requirements for the product; b) the need to establish processes and documents (see 4.2.4) and to provide resources specific to the product, including infrastructure and work environment; c) required verification, validation, monitoring, measurement, inspection and test, handling, storage, distribution and traceability activities specific to the product together with the criteria for product acceptance; d) records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.5). The output of this planning shall be documented in a form suitable for the organization's method of	No new products If we did Design Vap Audit project list.

	operations. NOTE Further information can be found in ISO 14971.	
Viamed Ltd ISO13485:2016 7.2.2	**Review of requirements related to product** The organization shall review the requirements related to product. This review shall be conducted prior to the organization's commitment to supply product to the customer (e.g. submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and shall ensure that: a) product requirements are defined and documented; b) contract or order requirements differing from those previously expressed are resolved; c) applicable regulatory requirements are met; d) any user training identified in accordance with 7.2.1 is available or planned to be available; e) the organization has the ability to meet the defined requirements. Records of the results of the review and actions arising from the review shall be maintained (see 4.2.5). When the customer provides no documented statement of requirement, the customer requirements shall be confirmed by the organization before acceptance. When product requirements are changed, the organization shall ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements.	Project list feedback + QA procedures + training
Viamed Ltd ISO13485:2016 7.5.6	**Validation of processes for production and service provision** The organization shall validate any processes for production and service provision where the resulting output cannot be or is not verified by subsequent monitoring or measurement and, as a consequence, deficiencies become apparent only after the product is in use or the service has been delivered. Validation shall demonstrate the ability of these processes to achieve planned results consistently. The organization shall document procedures for validation of processes including: a) defined criteria for review and approval of the processes; b) equipment qualification and qualification of personnel; c) use of specific methods, procedures and acceptance criteria; d) as appropriate, statistical techniques with rationale for sample sizes e) requirements for records (see 4.2.5);	procedures production. QA (Inspections.

	f) revalidation, including criteria for revalidation; g) approval of changes to the processes. The organization shall document procedures for the validation of the application of computer software used in production and service provision. Such software applications shall be validated prior to initial use and, as appropriate, after changes to such software or its application. The specific approach and activities associated with software validation and revalidation shall be proportionate to the risk associated with the use of the software including the effect on the ability of the product to conform to specifications. Records of the results and conclusion of validation and necessary actions from the validation shall be maintained (see 4.2.4 and 4.2.5).	
Viamed Ltd ISO13485:2016 7.5.9.1	**General** The organization shall document procedures for traceability. These procedures shall define the extent of traceability in accordance with applicable regulatory requirements and the records to be maintained (see 4.2.5).	Warstarts. QA
Viamed Ltd ISO13485:2016 8.2.4	**Internal audit** The organization shall conduct internal audits at planned intervals to determine whether the quality management system: a) conforms to planned and documented arrangements, requirements of this International Standard, quality management system requirements established by the organization, and applicable regulatory requirements; b) is effectively implemented and maintained. The organization shall document a procedure to describe the responsibilities and requirements for planning and conducting audits and recording and reporting audit results. An audit program shall be planned, taking into consideration the status and importance of the processes and area to be audited, as well as the results of previous audits. The audit criteria, scope, interval and methods shall be defined and recorded (see 4.2.5). The selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work. Records of the audits and their results, including identification of the processes and areas audited and the conclusions, shall be maintained (see 4.2.5). The management responsible for the area being audited shall ensure that any necessary corrections and corrective actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities shall include the verification of the	Audit Calendar Issues tasks + Audits Annual Review of Audits

	actions taken and the reporting of verification results. NOTE Further information can be found in ISO 19011.	
Viamed Ltd ISO13485:2016 8.2.5	**Monitoring and measurement of processes** The organization shall apply suitable methods for monitoring and, as appropriate, measurement of the quality management system processes. These methods shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action shall be taken, as appropriate.	Rolling tasks + Audits monitoring
Viamed Ltd ISO13485:2016 8.5.2	**Corrective action** The organization shall take action to eliminate the cause of nonconformities in order to prevent recurrence. Any necessary corrective actions shall be taken without undue delay. Corrective actions shall be proportionate to the effects of the nonconformities encountered. The organization shall document a procedure to define requirements for: a) reviewing nonconformities (including complaints); b) determining the causes of nonconformities; c) evaluating the need for action to ensure that nonconformities do not recur; d) planning and documenting action needed and implementing such action, including, as appropriate, updating documentation; e) verifying that the corrective action does not adversely affect the ability to meet applicable regulatory requirements or the safety and performance of the medical device; f) reviewing the effectiveness of corrective action taken. Records of the results of any investigation and action taken shall be maintained (see 4.2.5).	ISSUES non conformance Review tasks + Audits

1	**QUESTION:**	**RESPONSE:**	
2	Is there sole responsibility for company procedures and other documentation.	IT director has sole access to Intrastat system	N/A Y
3	Verify that documentation is checked prior to formal approval and issue and authorisation is unique.	Intrastats	N/A Y
4	Verify that all personnel have access to their relevant areas of the documentation.	Intrastats	N/A Y

5	Verify that amendments can be requested and are controlled by Date issue. are updated Electronically and old copies Archived.	Intrastats	N/A Y
6	Check that the C.E. files are maintained by sole responsibility.		Y
7	Check that obsolete data in the files is Archived	Intrastats also Archives store	N/A Y
8	Are manufacturers data sheets supplied the latest issue.	Intrastats Supplier review	N/A Y
9	Verify that checks are made to ascertain the latest issue data sheets are supplied after design change / modification (from suppliers).	Intrastats	N/A Y
10	Are Intrastat documents regularly backed-up and secure offsite Task ID (452)	Intrastats – Roles and Responsibilities. Task ID (452) #148501 ✓	N/A Y
11	Check that the document register is complete and adequate.	Intrastats automatic	N/A Y
12	Check that documents are filed where they say they are and the responsibility is true.	Intrastats on workstation	N/A ✓
13	Verify that records are easily retrievable for information and analysis.	Intrastats on workstation	N/A Y
14	Are printed copies of production procedures the latest issue status.	No printed copies	N/A ✓
15	Is the procedure for ensuring only the latest issue of drawings and documentation available working correctly Check 6 items in the Index. Task ID (371)	Intrastats. Task ID (371) #148078	N/A
16	Are quality records properly filed and easily retrievable.	Intrastats	N/A Y
17	Is the Company procedures Manual the latest version.	Intrastats	N/A Y
18	Has the organisation chart changed.	GDPR DPO added both	Y
19	Has the responsibility descriptions changed.	Intrastats – Roles and Responsibilities	N/A
20	Stock linked document – have documents been linked to stock correctly. ISO – Document Index Admin – Complete Amendment Log – look down the list for stock related documents, then see if the stock link is present. The list shows the last 3 months.		Y
21	Duplicate Documents – Task ID (370) – ISO – Documentation Index Admin – find duplicate files. This should be empty. Make a note of the number and dates. #147467	30163/30165 } new 30179/30181 } up to date	after issue Y

Sub Processes Linked to Audit 10
Review the below processes tasks and audits and ensure they are completed in a timely manner.

List Processes Per Title

Managing Director

Process Scope	Brief Description	Responsibility/Procedure/ Training	Measurable Objective	Task	Audit	Freq	Risk	Overall	Action
5877 - *History/Details* To review the numbers of various departments. Showing increasing / reducing staff requirements	Review Company Data	27178 VOP 13 Process Monitoring, System Reviews, Audits, Management Review, Analysis Data 22588 VM3COP02.02 VST Company Responsibilities organisation chart structure 27474 VM3COP02.02 Viamed Company Responsibilities organisation chart structure		114 Managing Director 146584 ✓	561 Company Secretary 130238 ✓	3	0		Task 1M Audit 12M

ISO Controller

Process Scope	Brief Description	Responsibility/Procedure/ Training	Measurable Objective	Task	Audit	Freq	Risk	Overall	Action
5890 - *History/Details* Ensure the online available copies of our ISO standards are upto date	Check Website ISO Documents	27438 VOP 01 Documentation / Records – Control, Creation, Storage, Retrieval and Revision control		463 Managing Director 146889 ✓	464 Marketing Processes 135154 ✓	3	1	3	Task 1M Audit 6M

IT Controller

Process Scope	Brief Description	Responsibility/Procedure/ Training	Measurable Objective	Task	Audit	Freq	Risk	Overall	Action
44 - *History/Details* Encrypt data sent back and forth to Intrastats so it can be used off site	Secure Socket Level Certificate	23322 VOP 11 Equipment Control, Office, Warehouse, Pcs and Equipment	Can log into intrastats with out security warning.	412 Managing Director		1	1	1	Task 12M
52 - *History/Details* Keeps a month or so backup emails	Software Verification Clear Down Backup Emails	20193 VM3COP60.00 Viamed Server Backup System 23322 VOP 11 Equipment Control, Office, Warehouse, Pcs and Equipment 27248 VOP 27 Software Validation		368 Managing Director	417 Company Secretary	4	1	4	Task 2W Audit 3M
53 - *History/Details* Maintain the Online Email boxes currently Google and Goldmine	Emails	12269 Viamed Vandagraph VST Email addresses and Routing to Gmail Accounts 8574 VM3COP26.01 Email Routing Hotchilli 23322 VOP 11 Equipment Control, Office, Warehouse, Pcs and Equipment	checking that all emails are clear / forwarded from the main Gmail box daily. This can be done by accessing the Main Google Mail Inbox and checking it does not have emails older than a working day in it.	902 Company Secretary		1	1	1	Audit 1W
5939 Email routing to End Users	Email ISP Routing	8574 VM3COP26.01 Email Routing Hotchilli 11955 VM3COP27.06 Unblocking Stuck Emails in				1	1	1	

		Goldmine 23322 VOP 11 Equipment Control, Office, Warehouse, Pcs and Equipment						
7124 No Process, Responsibilities only	Intrastats	23322 VOP 11 Equipment Control, Office, Warehouse, Pcs and Equipment						
7125 To fix Urgent Problems with Intrastats	Intrastats Urgent Problems	20193 VM3COP60.00 Viamed Server Backup System 23322 VOP 11 Equipment Control, Office, Warehouse, Pcs and Equipment			1	1	1	
7126 - *History/Details* Fix general errors in intrastats such as Spelling errors or columns not lining up	Intrastats Requested Page updates	23322 VOP 11 Equipment Control, Office, Warehouse, Pcs and Equipment	458 Managing Director		3	1	3	Task 1M
7127	Intrastats Unfinished in progress Processes	23322 VOP 11 Equipment Control, Office, Warehouse, Pcs and Equipment						
7128	Intrastats Future Features needed	23322 VOP 11 Equipment Control, Office, Warehouse, Pcs and Equipment						
7129 - *History/Details* Update the online Cross reference guides with latest intrastats data.	Intrastats Cross Reference Database Tables Updates	23322 VOP 11 Equipment Control, Office, Warehouse, Pcs and Equipment	462 Managing Director	457 Director 3 (Steve)	3	1	3	Task 1M Audit 3M

146600 ✓

14689 ✓

14559 ✗ in terms.

7130 - *History/Details* To Review the L Drive Library is in sync with Intrastats Documentation	Intrastats Information for Intrastats and L Drive	27438 VOP 01 Documentation / Records - Control, Creation, Storage, Retrieval and Revision control	791 Managing Director	3	1	3	Task 1M	a lot outstanding SN 139470, 141696 from March.
7131 Maintain Syncronization Between Accounts package Opera and Intrastats	Intrastats Opera	23326 VOP 18 Maintenance Building, Fabric and Infrastructure		1	3	3		
7133	Intrastats Contact Manager	23326 VOP 18 Maintenance Building, Fabric and Infrastructure						
7672 - *History/Details* To take a copy of the important data off-site	Off Site Backup	20193 VM3COP60.00 Viamed Server Backup System 23322 VOP 11 Equipment Control, Office, Warehouse, Pcs and Equipment	452 Managing Director 453 Company Secretary	5	1	5	Task 3D Audit 1M	148086 ✓ 148380
7700 - *History/Details* Maintain Domains for websites	Domain Name Management	26744 VM3COP27.14 Domain Name Management 23322 VOP 11 Equipment Control, Office, Warehouse, Pcs and Equipment	510 ✓ Managing Director	3	1	3	Task 1M	147806
7739 - *History/Details* Intrastat Changes updates. Logging system to enable roll back should anything break	Intrastats Amendment Log	23322 VOP 11 Equipment Control, Office, Warehouse, Pcs and Equipment	562 Managing Director	4	1	4	Task 1W	147919 ✓

Documentation And Records Controller

Process Scope	Brief Description	Responsibility/Procedure/ Training	Measurable Objective	Task	Audit	Freq	Risk	Overall	Action
41 Allocation of overall responsibility	Documentation Control	27438 VOP 01 Documentation / Records – Control, Creation, Storage, Retrieval and Revision control							
59 - *History/Details* Check the Document Index for any out of date documents,	Out Of Date Documents	27438 VOP 01 Documentation / Records – Control, Creation, Storage, Retrieval and Revision control	All out of date documents should have an Issue chasing the update status of the document, or have gone out of date within the last 30 days	371 Managing Director	372 Company Secretary	3	1	3	Task 1M Audit 6M
5851 - *History/Details* Removal of Duplicate documents	Duplicate Documents	27438 VOP 01 Documentation / Records – Control, Creation, Storage, Retrieval and Revision control	should be no duplicate documents in either list over a month old	370 Managing Director	369 Company Secretary	3	1	3	Task 1M Audit 6M
5852	Retention Of Records	27438 VOP 01 Documentation / Records – Control, Creation, Storage, Retrieval and Revision control							
5940 - *History/Details* Generate the Thumbs nails for the document Index	Thumb Nail Processor	15030 VM3COP20.19 Intrastats Document Index Thumbnail Generation 27438 VOP 01		155 Managing Director		3	1	3	Task 1M

		Documentation / Records – Control, Creation, Storage, Retrieval and Revision control							

Product Controller

Process Scope	Brief Description	Responsibility/Procedure/ Training	Measurable Objective	Task	Audit	Freq	Risk	Overall	Action
7032	Document Requirements	27438 VOP 01 Documentation / Records – Control, Creation, Storage, Retrieval and Revision control							
7863 - *History/Details* To confirm the current repairs codes for various products in the system are up to date. and available to office members of staff.	Maintain Repair Codes List	24730 VOP 03 Contract Review, Enquires, Office Processes		772 Director 3 (Steve)	773 Managing Director	1	1	1	Task 12M Audit 24M

Office Team Leader

Process Scope	Brief Description	Responsibility/Procedure/ Training	Measurable Objective	Task	Audit	Freq	Risk	Overall	Action
6938 Updating the data base with new and updated customer information, treating it with respect and keeping it secure.	Customer Database Updates	24730 VOP 03 Contract Review, Enquires, Office Processes	none – this is done constantly but on na ad hock basis.			1	1	1	
6940	Customer Ongoing task List	24730 VOP 03 Contract Review, Enquires, Office Processes							
7090	Office	27178 VOP 13 Process							

	Procedures	Monitoring, System Reviews, Audits, Management Review, Analysis Data							

Audits

Process Scope	Brief Description	Responsibility/Procedure/ Training	Measurable Objective	Task	Audit	Freq	Risk	Overall	Action
7722 - *History/Details* To carry out Audit 10 Documentation Control Viamed	Audit 10 Documentation Control Viamed	27178 VOP 13 Process Monitoring, System Reviews, Audits, Management Review, Analysis Data	This Audit	146850	27 Company Secretary	1	2	2	Audit 12M
7770 - *History/Details* To carry out Audit 10 Documentation Control VST	Audit 10 Documentation Control VST	27178 VOP 13 Process Monitoring, System Reviews, Audits, Management Review, Analysis Data		146855	183 Company Secretary	1	2	2	Audit 12M

Office Processes

Process Scope	Brief Description	Responsibility/Procedure/ Training	Measurable Objective	Task	Audit	Freq	Risk	Overall	Action
6 Updating Contact Management System	Updating Contact Management System	24022 VM3COP20.081 Adding Amending Contact Records in the CRM Goldmine and Intrastats 24730 VOP 03 Contract Review, Enquires, Office Processes				1	1	1	
9 - *History/Details* Distribute received faxes	Distribution Of Faxes	25412 VM3COP03.11 Distribution Of Faxes 24730 VOP 03 Contract		~~824~~ NO Issues No more faxes		1	1	1	

		Review, Enquires, Office Processes						
10 - *History/Details* Distribute Emails	Distribution Of Emails	20131 VM3COP27.02 Collecting Emails and Distributing 24730 VOP 03 Contract Review, Enquires, Office Processes	Global Inbox is up to date with no emails From previous days.	366 Managing Director	3	1	3	Audit 1M
11 - *History/Details* Distibuting incoming post to correct person	Distribution Of Mail	18641 VM3COP20.01 Post In Distributing the Post 24730 VOP 03 Contract Review, Enquires, Office Processes		599 Office Processes	5	1	5	Task 1D
12 To receive, collate and store the sales and technical information received in to the companies	Sales And Technical Information Processing	24730 VOP 03 Contract Review, Enquires, Office Processes	None – this are done on an ad hock basis when relevant information and data is received		1	1	1	
15 - *History/Details* Paperwork to be filed in the correct order	Filing and Archiving	23823 VM3COP20.28 Office Filing and Archiving 24730 VOP 03 Contract Review, Enquires, Office Processes		567 Office Processes	16 Company Secretary	4	1	4	Task 1D Audit 12M
16	Photocopying	24730 VOP 03 Contract Review, Enquires, Office Processes						
5901 - *History/Details* To link new calls to Contacts in the CRM	Link Call Log Contacts To The CRM	24730 VOP 03 Contract Review, Enquires, Office Processes 24014 VM3COP27.08 Intrastat Telephone Logging System.	Review the Call Log list, Ignoring Empty Names and contacts. other lines should be green.	404 Office Processes	405 Company Secretary	4	1	4	Task 1W Audit 1M

7693 - *History/Details* Collect the filing form the warehouse	Collect Repair Filing From Warehouse	17485 VM3COP20.47 Collecting Repair Paperwork 24730 VOP 03 Contract Review, Enquires, Office Processes		506 Office Processes	507 Managing Director	4	1	4	Task 1W Audit 1M
7699 - *History/Details* Shredding of sensitive information	Shred Sensitive Paperwork In JL Office	24730 VOP 03 Contract Review, Enquires, Office Processes		508 Office Processes	509 Office Processes	4	1	4	Task 1W Audit 1M
7705 - *History/Details* Checking if a customer has uploaded an order directly to our website	Checking For Uploaded Files	24730 VOP 03 Contract Review, Enquires, Office Processes	Should be no files in the list older than a day old	517 Office Processes	518 Office Processes	5	1	5	Task 1D Audit 1W
7711 - *History/Details* Download the most recent bank statement from the bank website	Import Bank CSV	17483 VM3COP20.39 Importing Bank Statements 23381 VOP 04 Accounts, Bank, Loans, Debtors, Creditors, Accountant Processes.	Check intrastats bank receipts, last date should be within 3 days of today	526 Office Processes	527 Company Secretary	5	1	5	Task 1D Audit 1W