Internal Audit Check list

Handling & Stock Control

Created:	17/May 1995	**Audit No 07**	
Revised:	23 October 2017		Page 1 of 10
Audit Date	29-4-19	Auditor Helen Lamb	

Company / ISO Section	Criteria of ISO Section	Auditor Comments / Issues
VST Ltd ISO9001:2015 7.1.4	**Environment for the operation of processes** The organization shall determine, provide and maintain the environment necessary for the operation of its processes and to achieve conformity of products and services. NOTE A suitable environment can be a combination of human and physical factors, such as: a) social (e.g. non-discriminatory, calm, non-confrontational); b) psychological (e.g. stress-reducing, burnout prevention, emotionally protective); c) physical (e.g. temperature, heat, humidity, light, airflow, hygiene, noise). These factors can differ substantially depending on the products and services provided.	good communication problem Reporting in Intranets H+S questionaire
VST Ltd ISO9001:2015 7.1.5.1	**General** 7.1.5.1 General The organization shall determine and provide the resources needed to ensure valid and reliable results when monitoring or measuring is used to verify the conformity of products and services to requirements. The organization shall ensure that the resources provided: a) are suitable for the specific type of monitoring and measurement activities being undertaken; b) are maintained to ensure their continuing fitness for their purpose. The organization shall retain appropriate documented information as evidence of fitness for purpose of the monitoring and measurement resources.	Reviews, Calibration Audit meetings to discuss and decide Calibration Audit
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	Regular Reviews, QA, procedures feedback good Communication with Customers and Clinicians Doc Control Intranets Issues Roles + Audits

	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).	Audit Review meetings Supplier Review No out Sourcing
VST Ltd ISO9001:2015 8.4.1	**General** The organization shall ensure that externally provided processes, products and services conform to requirements. The organization shall determine the controls to be applied to externally provided processes, products and services when: a) products and services from external providers are intended for incorporation into the organization's own products and services; b) products and services are provided directly to the customer(s) by external providers on behalf of the organization; c) a process, or part of a process, is provided by an external provider as a result of a decision by the organization. The organization shall determine and apply criteria for the evaluation, selection, monitoring of performance, and re-evaluation of external providers, based on their ability to provide processes or products and services in accordance with requirements. The organization shall retain documented information of these activities and any necessary actions arising from the evaluations.	Supplier Review QA feedback Warrants.
VST Ltd ISO9001:2015 8.4.2	**Type and extent of control** The organization shall ensure that externally provided processes, products and services do not adversely affect the organization's ability to consistently deliver conforming products and services to its customers. The organization shall: a) ensure that externally provided processes remain within the control of its quality management system; b) define both the controls that it intends to apply to an external provider and those it intends to apply to the resulting output; c) take into consideration: 1) the potential impact of the externally provided processes, products and services on the organization's ability to consistently meet customer and applicable statutory and regulatory requirements; 2) the effectiveness of the controls applied by the external provider; d) determine the verification, or other activities, necessary to ensure that the externally provided processes, products and services meet requirements.	Supplier Review ISO
VST Ltd ISO9001:2015 8.5.1	**Control of production and service provision** The organization shall implement production and service provision under controlled conditions. Controlled conditions shall include, as applicable: a) the availability of documented information that defines: 1) the characteristics of the products to be produced, the services to be provided, or the activities to be performed; 2) the results to be achieved; b) the availability and use of suitable monitoring and measuring resources;	Procedures Warrants Doc index

	c) the implementation of monitoring and measurement activities at appropriate stages to verify that criteria for control of processes or outputs, and acceptance criteria for products and services, have been met; d) the use of suitable infrastructure and environment for the operation of processes; e) the appointment of competent persons, including any required qualification; f) the validation, and periodic revalidation, of the ability to achieve planned results of the processes for production and service provision, where the resulting output cannot be verified by subsequent monitoring or measurement; g) the implementation of actions to prevent human error; h) the implementation of release, delivery and post-delivery activities	Procedures + QA Review meetings issues Supplier Review Review meetings QA Infrastructure
VST Ltd ISO9001:2015 8.5.2	**Identification and traceability** The organization shall use suitable means to identify outputs when it is necessary to ensure the conformity of products and services. The organization shall identify the status of outputs with respect to monitoring and measurement requirements throughout production and service provision. The organization shall control the unique identification of the outputs when traceability is a requirement, and shall retain the documented information necessary to enable traceability.	Infrastructure
VST Ltd ISO9001:2015 8.5.3	**Property belonging to customers or external providers** The organization shall exercise care with property belonging to customers or external providers while it is under the organization's control or being used by the organization. The organization shall identify, verify, protect and safeguard customers' or external providers' property provided for use or incorporation into the products and services. When the property of a customer or external provider is lost, damaged or otherwise found to be unsuitable for use, the organization shall report this to the customer or external provider and retain documented information on what has occurred. NOTE A customer's or external provider's property can include materials, components, tools and equipment, premises, intellectual property and personal data.	Infrastructure SRS Process
VST Ltd ISO9001:2015 8.5.4	**Preservation** The organization shall preserve the outputs during production and service provision, to the extent necessary to ensure conformity to requirements. NOTE Preservation can include identification, handling, contamination control, packaging, storage, transmission or transportation, and protection.	QA Infrastructure
VST Ltd ISO9001:2015 8.7.1	The organization shall ensure that outputs that do not conform to their requirements are identified and controlled to prevent their unintended use or delivery. The organization shall take appropriate action based on the nature of the nonconformity and its effect on the conformity of products and services. This shall also apply to nonconforming products and services detected after delivery of products, during or after the provision of services. The organization shall deal with nonconforming outputs in one or more of	QA Supplier Returns

	the following ways: a) correction; b) segregation, containment, return or suspension of provision of products and services; c) informing the customer; d) obtaining authorization for acceptance under concession. Conformity to the requirements shall be verified when nonconforming outputs are corrected.	Warehouse shelves for none sellable Barcodes Intrastats Gmail
VST Ltd ISO9001:201 5 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.	Product Review meetings QA Intrastats feedback
Viamed Ltd ISO13485:20 16 6.3	**Infrastructure** The organization shall document the requirements for the infrastructure needed to achieve conformity to product requirements, prevent product mix-up and ensure orderly handling of product. Infrastructure includes, as appropriate: a) buildings, workspace and associated utilities; b) process equipment (both hardware and software); c) supporting services (such as transport, communication, or information systems). The organization shall document requirements for the maintenance activities, including the interval of performing the maintenance activities, when such maintenance activities, or lack thereof, can affect product quality. As appropriate, the requirements shall apply to equipment used in production, the control of the work environment and monitoring and measurement. Records of such maintenance shall be maintained	Tech files Intrastats Review meetings feedback
Viamed Ltd ISO13485:20 16 6.4.1	**Work environment** The organization shall document the requirements for the work environment needed to achieve conformity to product requirements. If the conditions for the work environment can have an adverse effect on product quality, the organization shall document the requirements for the work environment and the procedures to monitor and control the work environment. The organization shall: a) document requirements for health, cleanliness and clothing of personnel if contact between such personnel and the product or work environment could affect medical device safety or performance; b) ensure that all personnel who are required to work temporarily under special environmental conditions within the work environment are	H+S Questionaire Intrastats ISSues Audits

	competent or supervised by a competent person. NOTE Further information can be found in ISO 14644 and ISO 14698	
Viamed Ltd ISO13485:2016 6.4.2	**Contamination control** As appropriate, the organization shall plan and document arrangements for the control of contaminated or potentially contaminated product in order to prevent contamination of the work environment, personnel, or product. For sterile medical devices, the organization shall document requirements for control of contamination with microorganisms or particulate matter and maintain the required cleanliness during assembly or packaging processes.	Audit + procedures no Sterile products.
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 operations. NOTE Further information can be found in ISO 14971.	Tech files Instructs Doc index QA. procedures
Viamed Ltd ISO13485:2016 7.5.1	**Control of production and service provision** Production and service provision shall be planned, carried out, monitored and controlled to ensure that product conforms to specification. As appropriate, production controls shall include but are not limited to: a) documentation of procedures and methods for the control of production (see 4.2.4); b) qualification of infrastructure; c) implementation of monitoring and measurement of process parameters and product characteristics; d) availability and use of monitoring and measuring equipment; e) implementation of defined operations for labelling and packaging; f) implementation of product release, delivery and post-delivery activities. The organization shall establish and maintain a record (see 4.2.5) for each medical device or batch of medical devices that provides traceability to the extent specified in 7.5.9 and identifies the amount manufactured and amount approved for distribution. The record shall be verified and approved.	QA + instructs procedures Review meetings

Viamed Ltd ISO13485:2016 7.5.10	**Customer property** The organization shall identify, verify, protect, and safeguard customer property provided for use or incorporation into the product while it is under the organization's control or being used by the organization. If any customer property is lost, damaged or otherwise found to be unsuitable for use, the organization shall report this to the customer and maintain records (see 4.2.5).	QA + Contracts Procedures + Audit.
Viamed Ltd ISO13485:2016 7.5.11	**Preservation of product** The organization shall document procedures for preserving the conformity of product to requirements during processing, storage, handling, and distribution. Preservation shall apply to the constituent parts of a medical device. The organization shall protect product from alteration, contamination or damage when exposed to expected conditions and hazards during processing, storage, handling, and distribution by: a) designing and constructing suitable packaging and shipping containers; b) documenting requirements for special conditions needed if packaging alone cannot provide preservation. If special conditions are required, they shall be controlled and recorded (see 4.2.5).	Procedures Tech files Issues.
Viamed Ltd ISO13485:2016 7.5.2	**Cleanliness of product** The organization shall document requirements for cleanliness of product or contamination control of product if: a) product is cleaned by the organization prior to sterilization or its use; b) product is supplied non-sterile and is to be subjected to a cleaning process prior to sterilization or its use; c) product cannot be cleaned prior to sterilization or its use, and its cleanliness is of significance in use; d) product is supplied to be used non-sterile, and its cleanliness is of significance in use; e) process agents are to be removed from product during manufacture. If product is cleaned in accordance with a) or b) above, the requirements contained in 6.4.1 do not apply prior to the cleaning process.	No Sterile products
Viamed Ltd ISO13485:2016 7.5.8	**Identification** The organization shall document procedures for product identification and identify product by suitable means throughout product realization. The organization shall identify product status with respect to monitoring and measurement requirements throughout product realization. Identification of product status shall be maintained throughout production, storage, installation and servicing of product to ensure that only product that has passed the required inspections and tests or released under an authorized concession is dispatched, used or installed.	procedures Tech files Audits

	If required by applicable regulatory requirements, the organization shall document a system to assign unique device identification to the medical device. The organization shall document procedures to ensure that medical devices returned to the organization are identified and distinguished from conforming product.	
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).	QA Work instructs
Viamed Ltd ISO13485:2016 8.2.6	**Monitoring and measurement of product** The organization shall monitor and measure the characteristics of the product to verify that product requirements have been met. This shall be carried out at applicable stages of the product realization process in accordance with the planned and documented arrangements and documented procedures. Evidence of conformity with the acceptance criteria shall be maintained. The identity of the person authorizing release of product shall be recorded (see 4.2.5). As appropriate, records shall identify the test equipment used to perform measurement activities. Product release and service delivery shall not proceed until the planned and documented arrangements have been satisfactorily completed. For implantable medical devices, the organization shall record the identity of personnel performing any inspection or testing.	QA Doc index Work instructs.
Viamed Ltd ISO13485:2016 8.3.1	**General** The organization shall ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. The organization shall document a procedure to define the controls and related responsibilities and authorities for the identification, documentation, segregation, evaluation, and disposition of nonconforming product. The evaluation of nonconformity shall include a determination of the need for an investigation and notification of any external party responsible for the nonconformity. Records of the nature of the nonconformities and any subsequent action taken, including the evaluation, any investigation and the rationale for decisions shall be maintained (see 4.2.5)	Procedures Work instructs
Viamed Ltd ISO13485:2016 8.3.2	**Actions in response to nonconforming product detected before delivery** The organization shall deal with nonconforming product by one or more of the following ways: a) taking action to eliminate the detected nonconformity; b) taking action to preclude its original intended use or application; c) authorizing its use, release or acceptance under concession. The organization shall ensure that nonconforming product is accepted by concession only if the justification is provided, approval is obtained, and applicable regulatory requirements are met. Records of the acceptance by concession and the identity of the person authorizing the concession shall be maintained (see 4.2.5).	QA Barcoding

	QUESTION:	RESPONSE	Y/N
1	Check that incoming products are stored correctly on receipt.		Y
2	Check that the in-house stores area is adequate, safe and accessible.		Y
3	Verify that products for repair are suitably boxed prior to movement. i.e. In ducket with correct paperwork		Y
4	Verify that stock items are suitable packed for entry into stock.		Y
5	Check that gloves and or hand sanitiser are available and used when probes are received from hospitals.	gloves for sensors No Probes	Y
6	Check in Intrastats that COSHH data sheets are available for all products.		Y
7	Check that items in a stock locations is correct to Intrastats. Verify that the quantity of an item in stock is correct to that in Opera and Intrastats. Check that the packing of finished product is appropriate and will preserve quality to the end user. Check 5 items. on shelf loc 1 0014753 6 837845-15-3-4-3 2 44220952 4 838009 15-7-6-2 3 8010017 50 12657 2-1-3 4 0014910 6 165223 5-1-2-3 5 8030498 26 126536 2-1-1-2	TO Intrastats. ✓ ✓ ✓ ✓	
8	Verify that they are regularly updated and maintained.		Y
9	Check that demonstration and exhibition stock is separate from other stock.		Y
10	Verify that product in the non-conforming area can only be removed by authorised personnel. Verify that transfer of non-conformance stock is done by use form QC19.		Y
11	Verify that special requirement areas are available should the product require it.		Y
12	Check that completed products are adequately stored.		Y

	List those checked.	8010012 2810006 1010057 1114005 0110122 0014890	Y
13	Verify that there are adequate storage areas in the workshop for a working stock of assembly components.		Y
14	Check that product movement around the workshop is by ducket only.		Y
15	Are stores and storage areas secure and suitably identified with signs. List problem areas.		Y
16	Are uncontrolled material and parts identified as such: Check that items in Quarantine have HOLD labels. Check unentered and pre QA items are labelled and/or are in the correct area and have a hold label with Issue number on.		Y
17	Are all parts in the warehouse properly identified with Viamed Location Tracking barcodes. Identify unmarked items.		Y
18	If more space is required for answers use the reverse of this form.		

Sub Processes Linked to Audit 07

Review the below processes tasks and audits and ensure they are completed in a timely manner.

Warehouse Team Leader 143575 ✓ 143696 4 items

Process Scope	**Roll Task**	**Roll Audit**	**Risk**	**Action**	Notes / Issues
PROCESSID **5858** Opera Counts bulk stock in and issues stock out against orders. Multiple processes cause stock to be used internally, Opera requires a weekly update to bring the stock count into line with whats been used outside the	110 Goods In	261 Goods Out	Freq 4 Risk 1 Overall 4	Task 1W Audit 1M	

invoicing systems				
PROCESSID **5935** To allocate stock that has not automatically be linked to a repair or invoice.	447 Company Secretary		Freq 4 Risk 1 Overall 4	Task 2W
PROCESSID **6850** Review current stock levels	615 Goods In	778 Managing Director	Freq 4 Risk 1 Overall 4	Task 2W Audit 6M
PROCESSID **6945** To synchronise Opera stock Count against Intrastats internal movement of stock, E.G. Items that wont uniquely appear on an opera order - such as production parts.	110 Goods In	783 Managing Director	Freq 4 Risk 2 Overall 8	Task 1W Audit 3M
PROCESSID **7673** To check that all the stock on the selves are within their use by dates.	294 Goods In	477 Managing Director	Freq 3 Risk 2 Overall 6	Task 1M Audit 3M
PROCESSID **7689** Move Stock From QA Shelf To Stock Shelf	545 Goods Out		Freq 4 Risk 1 Overall 4	Task 1W
PROCESSID **7694** Move Stock From QA Shelf To Stock Shelf	544 Goods In	782 Goods In	Freq 4 Risk 1 Overall 4	Task 1W Audit 12M
PROCESSID **7695** Move Stock From QA Shelf To Quick Shipping Shelves	495 Goods In		Freq 4 Risk 1 Overall 4	Task 1W

Audits

Process Scope	**Roll Task**	**Roll Audit**	**Risk**	**Action**	Notes / Issues
PROCESSID **7719** To carry out Audit Audit 07 Handling And Storage Viamed		25 Company Secretary	Freq 1 Risk 2 Overall 2	Audit 12M	
PROCESSID **7767** To carry out Audit 07 Handling And Storage VST		178 Company Secretary	Freq 1 Risk 2 Overall 2	Audit 12M	