Internal Audit Check list

Returns, Repairs & Service

Created:	17/May 1995	Audit No 11	VOP 09
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Audit Date	20-7-18	Auditor Helen Lamb	

Company / ISO Section	Criteria of ISO Section	Auditor Comments / Issues
VST Ltd ISO9001:2015 8.2.1	**Customer communication** Communication with customers shall include: a) providing information relating to products and services; b) handling enquiries, contracts or orders, including changes; c) obtaining customer feedback relating to products and services, including customer complaints; d) handling or controlling customer property; e) establishing specific requirements for contingency actions, when relevant.	
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.	
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.	
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).	
Viamed Ltd ISO13485:2016 7.5.4	**Servicing activities** If servicing of the medical device is a specified requirement, the organization shall document servicing procedures, reference materials, and reference measurements, as necessary, for performing servicing activities and verifying that product requirements are met. The organization shall analyse records of servicing activities carried out by the organization or its supplier: a) to determine if the information is to be handled as a complaint; b) as appropriate, for input to the improvement process. Records of servicing activities carried out by the organization or its supplier shall be maintained (see 4.2.5).	
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); 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 7.5.8	**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. 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 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 actions taken and the reporting of verification results. NOTE Further information can be found in ISO 19011.	
Viamed Ltd ISO13485:2016 8.3.4	**Rework** The organization shall perform rework in accordance with documented procedures that takes into account the potential adverse	

effect of the rework on the product. These procedures shall undergo the same review and approval as the original procedure.
After the completion of rework, product shall be verified to ensure that it meets applicable acceptance criteria and regulatory requirements.
Records of rework shall be maintained (see 4.2.5).

QUESTION:	RESPONSE:	Y/N
Check that out of date warranty repairs have received customer approval prior to any repair work being done.	#124873	Y
Verify that goods are identified as a Customer Repair and include ~~a SRN Barcode.~~	#Issue to remove. No Barcode anymore not used.	Y
Check that the QA Records - final inspection, test sheets and safety records are completed. Returns – Repairs Ready for Invoice – View Status. Copy the serial number in to serial number search in Stockbook to get the barcode ID. Paste into QA Report. All available reports will be in here.	SRS 66624 ✓ SRS 66609 ✓ SRS 66605 ✓ SRS 66592 - located on spread sheet ✓ SRS 66550 ✓	Y
Check that anti-static precautions are in place and appropriate checks are recorded. Check the workshop, QA and the R+D room. Should these be in place anywhere else around the company.		Y
Check that the correct coloured duckets are being used for Urgent and Export repairs.		Y
Check that the repairs are being worked in priority, and then date order.		Y
Check that completed duckets are placed on the repaired ~~probes~~ shelf with all appropriate paperwork. Check all duckets on the shelves.	Issue CG #124872 update shelves was #124872	Y
Returns – Returns Completed. Pick 5 Invoiced and check the paperwork in the ORD file matches the customer paperwork and the invoice. 1 INV57898 - ORD93785 ✓ V1000 2 INV57854 - ORD93243 ✓ V1000 3 INV57772 - ORD93176 ✓ Tom Thumb 4 VSTIN01069 - VSORD00962 } Repair added to 5 VSTIN01048 - VSORD00929 } New orders ↳ Invoice Credit (VST0002)		Y
Intrastats Service Logs – are any services overdue, list them. Returns – Service Visits. Look in Notes icon for further info and check any issues attached.	all in date.	Y

overdue - Tracking id 65 on list should be once only #124874

Intrastats Service Logs – are any services in progress. Returns – Service Visits. Check the Notes are they being filled in.		Y
Returns – Repairs in building. Pick 5 from the list and go and find them, check they have the appropriate paperwork. 1 SRS 66643 Lobster VST ✓ RC Shelf. 2 SRS 66636 REVO VST – Received 16-7-18 tested 16-7-18 – Returned to Supplier 3 SRS 66638 Burmingham via ✓ 4 SRS 66568 Pilgrim via ✓ 5 SRS 66555 withybush via – Received 22-5-18 #124881	ordered in error New. Returned to stock?	Y
Check the number of old repairs. Returns – Repairs in building. Find out what is happening with any older than 6 month. Several on list this has now been reviewed and all on Correct.	#124875 Issue sent as 9 on list notes present but think should be resolved.	Y
Returns – Ready for quote. Check the 5 oldest from the list and go and find them on the repairs shelf, check they have the appropriate paperwork. 1 SRS 66638 ✓ 2 SRS 66628 ✓ 3 SAS 661568 ✓ 4 5	No old ones ✓ 3 on list	Y
Returns – Quotes sent. Check the 5 oldest to the Quotes file in the office. Are there notes on intrastats and on the paperwork. 1 SRS 66620 – on list in error ~~Obs~~ pressed. A/C 970 West Cumberlady 2 SRS 66567 – SHA 7542 June 18 ✓ 3 SRS 66697 – Luton 3490 May 18 ✓ 4 5	No old ones ✓ 3 on list	Y
Returns – Rep[airs Ready for Invoice. Check the oldest 5 of the Viamed / VST SRS's. Why have they not been invoiced. 1 List of working Issue sent 2 Checked all all viamed + VST current order and intrastats not matching QUO/IN to SRS 3 4 5 Using the same 5 copy the Barcode into the QA Report and see if they have QA records.	List now up to date + reviewed	Y

Returns – Calibration Certificates. From the list click View, to go to the calibration certificate. Copy the serial number in to serial number search in Stockbook to get the barcode ID. Paste into QA Report. Check there is a QA Report is available.			

Sub Processes Linked to Audit 11

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

Warehouse Team Leader

Process Scope	Roll Task	Roll Audit	Risk	Action	Notes / Issues
PROCESSID **6862** The repairs that are currently in the building. Confirm the Stage and Location of repairs	614 Goods In		Freq 4 Risk 1 Overall 4	Task 1W	ID124134 not done but within terms
PROCESSID **7138** To review any new QC 21 Forms	795 Managing Director	796 Company Secretary	Freq 3 Risk 1 Overall 3	Task 1M Audit 12M	ID124139 ✓ ID106455 ✓
PROCESSID **7674** Review the repairs ready For invoice List in intrastats.	468 Goods In	469 Goods In	Freq 4 Risk 1 Overall 4	Task 2W Audit 3M	ID124035 not done but in terms ID122815 ✓

Audits

Process Scope	Roll Task	Roll Audit	Risk	Action	Notes / Issues
PROCESSID **7724** To carry out Audit 11 Repairs And Service Viamed		ID123466 not done but in terms 171 Company Secretary	Freq 1 Risk 2 Overall 2	Audit 12M	
PROCESSID **7772** To carry out Audit 11 Repairs And Service VST		ID123168 not done but in terms. 179 Company Secretary	Freq 1 Risk 2 Overall 2	Audit 12M	

Repairs Controller

Process Scope	Roll Task	Roll Audit	Risk	Action	Notes / Issues
PROCESSID **7823** Backup the Fluke ESA615 Safety tester CE Copy any files to the Z Drive - safety tester backupdata	79 Production Processes ID99839 ✓	711 Managing Director ID 101864 ✓	Freq 1 Risk 1 Overall 1	Task 12M Audit 12M	

Office Processes

Process Scope	Roll Task	Roll Audit	Risk	Action	Notes / Issues
PROCESSID **5857** Ensuring customer onsite service visits are completed	233 Office Processes ID124549 ✓	234 UK Sales Controller ID 122884 ✓	Freq 4 Risk 1 Overall 4	Task 1W Audit 1M	
PROCESSID **5898** Dispose of depleted oxygen sensors and send customer replacement disposal bags	406 Office Processes ID124108 not done but is items	535 Office Processes ID 124329 ✓	Freq 4 Risk 1 Overall 4	Task 1W Audit 2W	
PROCESSID **7752** Ensure all outstanding repairs are being dealt with	792 Office Processes ID122771 ✓	793 Goods In ID120320 ✓	Freq 3 Risk 1 Overall 3	Task 1M Audit 3M	
PROCESSID **7760** Send letters to existing customers to remind them that a service is due on their equipment	607 Office Processes ID124240 ✓		Freq 4 Risk 1 Overall 4	Task 1W	

Goods Out

Process Scope	Roll Task	Roll Audit	Risk	Action	Notes / Issues
PROCESSID **7690** Review the Repairs completed shelf and ship those items that are ready for return to the customer.	492 Goods Out ID124567 ✓	758 Goods In ID123239 ✓	Freq 5 Risk 1 Overall 5	Task 1D Audit 1M	
PROCESSID **7748** Check the orders	575 Goods Out ID124550 ✓		Freq 5 Risk 2	Task 1D	

against the customer paperwork, that we have generated, for the repair we have received in.		Overall 10	
PROCESSID **7749** Check the quotes that we send out for the repairs we have received in.	576 Goods Out	Freq 5 Risk 2 Overall 10	Task 1D

ID124556