

Internal Audit Check list

Returns, Repairs & Service

Created:	17/May 1995	Audit No 11	VOP 09
Revised:	02 July 2021		Page 1 of 7
Audit Date	2-7-21	Auditor <i>Helen Lamb</i>	

Company / ISO Section	Criteria of ISO Section	Auditor Comments / Issues
VST Ltd ISO9001:2015 8.2.1	<p>Customer communication</p> <p>Communication with customers shall include:</p> <ul style="list-style-type: none"> 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. 	<i>infrastructure</i> <i>CRM</i> <i>procedures</i>
VST Ltd ISO9001:2015 8.5.3	<p>Property belonging to customers or external providers</p> <p>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.</p> <p>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.</p> <p>NOTE A customer's or external provider's property can include materials, components, tools and equipment, premises, intellectual property and personal data.</p>	<i>Procedures</i> <i>Contracts</i>
Viamed Ltd ISO13485:2011 6.7.2.2	<p>Review of requirements related to product</p> <p>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:</p> <ul style="list-style-type: none"> 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. <p>Records of the results of the review and actions arising from the review shall be maintained (see 4.2.5).</p> <p>When the customer provides no documented statement of requirement, the customer requirements shall be confirmed by the</p>	<i>infrastructure</i> <i>Doc index</i> <i>Route map</i>

	<p>organization before acceptance.</p> <p>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.</p>	
Viamed Ltd ISO13485:201 6.7.5.10	<p>Customer property</p> <p>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).</p>	<i>Procedures intra statis</i>
Viamed Ltd ISO13485:201 6.7.5.4	<p>Servicing activities</p> <p>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.</p> <p>The organization shall analyse records of servicing activities carried out by the organization or its supplier:</p> <ul style="list-style-type: none"> a) to determine if the information is to be handled as a complaint; b) as appropriate, for input to the improvement process. <p>Records of servicing activities carried out by the organization or its supplier shall be maintained (see 4.2.5).</p>	<i>Doc index intra statis</i>
Viamed Ltd ISO13485:201 6.7.5.6	<p>Validation of processes for production and service provision</p> <p>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.</p> <p>Validation shall demonstrate the ability of these processes to achieve planned results consistently.</p> <p>The organization shall document procedures for validation of processes including:</p> <ul style="list-style-type: none"> 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. <p>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</p>	<i>intra statis procedures Doc index Rolling tasks</i>

	<p>specifications.</p> <p>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).</p>	
Viamed Ltd ISO13485:201 6.7.5.8	<p>Identification</p> <p>The organization shall document procedures for product identification and identify product by suitable means throughout product realization.</p> <p>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.</p> <p>If required by applicable regulatory requirements, the organization shall document a system to assign unique device identification to the medical device.</p> <p>The organization shall document procedures to ensure that medical devices returned to the organization are identified and distinguished from conforming product.</p>	<p>Bar codes Intrastats Procedures Doc index</p>
Viamed Ltd ISO13485:201 6.8.2.4	<p>Internal audit</p> <p>The organization shall conduct internal audits at planned intervals to determine whether the quality management system:</p> <p>a) conforms to planned and documented arrangements, requirements of this International Standard, quality management system requirements established by the organization, and applicable regulatory requirements;</p> <p>b) is effectively implemented and maintained.</p> <p>The organization shall document a procedure to describe the responsibilities and requirements for planning and conducting audits and recording and reporting audit results.</p> <p>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).</p> <p>The selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work.</p> <p>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).</p> <p>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.</p> <p>NOTE Further information can be found in ISO 19011.</p>	<p>Audit Calendar Intrastats Doc Index</p>
Viamed Ltd	Rework	

ISO13485:2016 8.3.4	<p>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.</p> <p>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).</p>	<p>Procedures Workshops SLS System</p>
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	<u>QUESTION:</u>	<u>RESPONSE:</u>	Y/N
1	Review Last years Audit. Update processes if required. Are all follow on Issue resolved satisfactory.	# 197840 still ongoing # 198959	
2	Check that out of date warranty repairs have received customer approval prior to any repair work being done.	4 waiting cust	Y
3	Verify that goods are identified as a Customer Repairs.	Approval at present	Y
4	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 67931 ✓ SRS 67923 ✓ Vicame Yes, VST all go back to supplier. SRS67907 - back with Supplier	Y
5	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
6	Check that the correct coloured duckets are being used for Urgent and Export repairs.		Y
7	Check that the repairs are being worked in priority, and then date order.		Y
8	Check that completed duckets are placed on the repaires shelf with all appropriate paperwork. Check all duckets on the shelves.		Y
9	Returns – Returns Completed. Pick 5 Invoiced repairs and check the paperwork in the ORD file matches the customer paperwork and the invoice.	1. 67901 2. 67889 3. 67854 4. 67923 5. 67922 } only Repairs in Building all have paperwork.	Y

10	Intrastats Service Logs – are any services overdue, list them. Intrastats – Returns – Service Visits. Look in Notes icon for further info and check any issues attached.	2 overdue Still Covid 19 Notes	Y
11	Intrastats Service Logs – are any services in progress. Returns – Service Visits. Check the Notes are they being filled in.	# 234171 Non in progress	
12	Check in the workshops and make sure all sealant, glues, greases, sprays, tapes and gases are in date and have a data sheet, if no date is present make sure there is a review to check purchase date and lifespan in Intrastats. List any without and check recurring issues for this.	Task lots 1010 1011 1012 228548✓ 228550✓ 205925✓	Y
13	Returns – Repairs in building. Pick 5 from the list and go and find them, check they have the appropriate paperwork.	See Question 9 only 5 in building all correct all have paperwork	Y
14	Check the number of old repairs. Intrastats – Returns – Repairs in building. Find out what is happening with any older than 6 month. List any anomalies.	# 233876 # 233879	
15	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.	See Question 9 only 5 in building all correct all have paperwork	Y
16	Returns – Quotes sent. Check the 5 oldest to the Quotes file in the office. Are there notes on Intrastats and on the paperwork.	1. 130481 28 June 21 with supplier ✓ waiting customer 2. 13705 21 July 21 with supplier ✓ "customer" ✓ 3. 131901 18 Aug 21 Quoted waiting on customer ✓ only 3 on Quotes list	Y

New task added STH + RS Quotes/Proformas
1017970 + 1017971

17	<p>Returns – Repairs Ready for Invoice.</p> <p>Check the oldest 5 of the Viamed and VST SRS's. Why have they not been invoiced.</p> <p>1. SRS 66920 Bluepoint #233815 2019 ongoing issue. No QA form</p> <p>2. SRS 67814 SCCR #233816</p> <p>3. SRS 67854 Samsoon - Returning item back to them. Yes, QA ✓</p> <p>4. SRS 67855 SCCR Replacing under warranty.</p> <p>5. SRS 67874 IFD Replacing under warranty</p> <p>Using the same 5 copy the Barcode into the QA Report and see if they have QA records. VST all go back to supplier – QA shown in SRS when needed.</p>	VST QA forms needed for SRS # 233819	
18	<p>Returns – Calibration Certificates.</p> <p>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.</p> <p>Paste into QA Report. Check there is a QA Report is available.</p>	QA Reports available on our products. Those that are not ours do not have QA Reports.	

Sub Processes Linked to Audit 11

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

List Processes Per Title

Warehouse Team Leader		Roll Task	Roll Audit	Risk	Action	Notes / Issues
Process Scope		614	895	✓	Task 1W	
PROCESSID 6862	The repairs that are currently in the building.	Goods Out	Managing	Freq 4	Audit 3M	
	Confirm the Stage and Location of repairs	732743	Director	Risk 1		
		795	796	Overall 4		
PROCESSID 7138	To review any new QC 21 Forms	Managing	20195	Freq 3	Task 1M	
		Director	Company	Risk 1	Audit	
		Secretary	✓	Overall 3	12M	
PROCESSID 7674	Review the repairs ready For invoice List in intrastats.	468	23261469	Freq 4	Task 2W	
		Goods Out	226199	Goods In	Audit 3M	
		882	883	✓	Overall 4	
PROCESSID 7905	To arrange Supplier Returns	23276	227968	Freq 1	Task 1W	
	Generate RMA box, link items and add faults	Company	✓	Risk 1	Audit 3M	
		Secretary	✓	Overall 1		

Audits

Process Scope	Roll Task	Roll Audit	Risk	Action	Notes / Issues
PROCESSID 7724	171	227553	Freq 1	Audit	
To carry out Audit 11 Repairs And Service Viamed	Company	✓	Risk 2	12M	
	Secretary	✓	Overall 2		
	Audit				

PROCESSID 7772
To carry out Audit 11 Repairs And Service VST

179 Freq 1 Audit
Company Risk 2 12M
Secretary Overall
2275 > This Audit

Repairs Controller

Process Scope

PROCESSID 7823
Backup the Fluke ESA615 Safety tester CE

Copy any files to the Z Drive - safety tester backupdata

Roll Task	Roll Audit	Risk	Action	Notes / Issues
79 230771 Production Processes	711 195440 Managing Director	Freq 1 Risk 1 Overall 1	Task 12M Audit 12M	

Goods Out

Process Scope

PROCESSID 7690

Review the Repairs completed shelf and ship those items that are ready for return to the customer.

PROCESSID 7748

Check the orders against the customer paperwork, that we have generated, for the repair we have received in.

PROCESSID 7749

Check the quotes that we send out for the repairs we have received in.

PROCESSID 7906

Obtain Returns paperwork / authorisation from supplier to return Items.

Roll Task	Roll Audit	Risk	Action	Notes / Issues
492 233269 Goods Out	758 230849 Goods In	Freq 5 Risk 1 Overall 5	Task 1D Audit 1M	
575 232993 Goods Out	1054 231844 Managing Director	Freq 3 Risk 2 Overall 6	Task 7D Audit 1M	
576 233254 Goods Out		Freq 5 Risk 2 Overall 10	Task 1D	
884 233245 Goods Out		Freq 1 Risk 1 Overall 1	Task 1W	

Office Processes

Process Scope

PROCESSID 5857

Ensuring customer onsite service visits are completed

PROCESSID 5898

Dispose of depleted oxygen sensors and send customer replacement disposal bags

PROCESSID 7752

Ensure all outstanding repairs are being dealt with

PROCESSID 7760

Send letters to existing customers to remind them that a service is due on their equipment

Roll Task	Roll Audit	Risk	Action	Notes / Issues
233 232711 Office Processes	234 230107 UK Sales Controller	Freq 4 Risk 1 Overall 4	Task 1W Audit 1M	
406 231977 Goods In	535 232654 Office Processes	Freq 4 Risk 1 Overall 4	Task 2W Audit 2W	
792 233204 Office Processes	93 232604 Managing Director	Freq 3 Risk 1 Overall 3	Task 1M Audit 3M	
607 232741 Marketing Processes	898 230669 Company Secretary	Freq 1 Risk 1 Overall 1	Task 1W Audit 4W	