

Vicamed

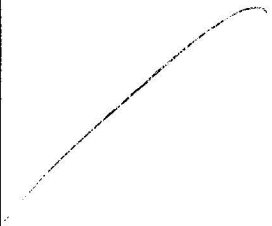
Internal Audit Check list

HEALTH & SAFETY

Created:	17/May 1995	Audit No 19	
Revised:	12 June 2017		Page 1 of 11
Audit Date	1-8-23	Auditor Helen Lamb	

Ed spacing and layout

Company / ISO Section	Criteria of ISO Section	Auditor Comments / Issues
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.	
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.	
VST Ltd ISO9001:2015 7.2	Competence 7.2 Competence The organization shall: a) determine the necessary competence of person(s) doing work under its control that affects the performance and effectiveness of the quality management system; b) ensure that these persons are competent on the basis of appropriate education, training, or experience; c) where applicable, take actions to acquire the necessary competence, and evaluate the effectiveness of the actions taken; d) retain appropriate documented information as evidence of competence. NOTE Applicable actions can include, for example, the provision of training to, the mentoring of, or the reassignment of currently employed persons; or the hiring or contracting of competent persons.	
VST Ltd ISO9001:2015 7.3	Awareness The organization shall ensure that persons doing work under	

	<p>the organization's control are aware of:</p> <ul style="list-style-type: none"> a) the quality policy; b) relevant quality objectives; c) their contribution to the effectiveness of the quality management system, including the benefits of improved performance; d) the implications of not conforming with the quality management system requirements. 	
Viamed Ltd ISO13485:2016 5.5.1	<p>Responsibility and authority</p> <p>Top management shall ensure that responsibilities and authorities are defined, documented and communicated within the organization.</p> <p>Top management shall document the interrelation of all personnel who manage, perform and verify work affecting quality and shall ensure the independence and authority necessary to perform these tasks.</p>	<p>Rules + titles</p> <p>Doc index</p> <p>management</p> <p>Review</p>
Viamed Ltd ISO13485:2016 6.2	<p>Human resources</p> <p>Personnel performing work affecting product quality shall be competent on the basis of appropriate education, training, skills and experience.</p> <p>The organization shall document the process(es) for establishing competence, providing needed training, and ensuring awareness of personnel.</p> <p>The organization shall:</p> <ul style="list-style-type: none"> a) determine the necessary competence for personnel performing work affecting product quality; b) provide training or take other actions to achieve or maintain the necessary competence; c) evaluate the effectiveness of the actions taken; d) ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives; e) maintain appropriate records of education, training, skills and experience (see 4.2.5). <p>NOTE The methodology used to check effectiveness is proportionate to the risk associated with the work for which the training or other action is being provided.</p>	<p>management</p> <p>Review</p> <p>Rules + titles</p> <p>Rank Mgs</p> <p>Audit</p> <p>Calendar</p> <p>QA system</p> <p>QC ZI form</p>
Viamed Ltd ISO13485:2016 6.3	<p>Infrastructure</p> <p>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.</p> <p>Infrastructure includes, as appropriate:</p> <ul style="list-style-type: none"> a) buildings, workspace and associated utilities; b) process equipment (both hardware and software); c) supporting services (such as transport, communication, or information systems). <p>The organization shall document requirements for the maintenance activities, including the interval of performing the</p>	<p>Doc index</p> <p>management</p> <p>Review</p> <p>Procedure</p> <p>HS Review</p>

	<p>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.</p> <p>Records of such maintenance shall be maintained</p>	
<p>Viamed Ltd ISO13485:2016 6.4.1</p>	<p>Work environment</p> <p>The organization shall document the requirements for the work environment needed to achieve conformity to product requirements.</p> <p>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.</p> <p>The organization shall:</p> <p>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;</p> <p>b) ensure that all personnel who are required to work temporarily under special environmental conditions within the work environment are competent or supervised by a competent person.</p> <p>NOTE Further information can be found in ISO 14644 and ISO 14698</p>	<p>Doc index CPM Training Manager HS Review Review meeting</p>
<p>Viamed Ltd ISO13485:2016 6.4.2</p>	<p>Contamination control</p> <p>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.</p> <p>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.</p>	<p>Doc index Roles + titles procedures</p>
<p>Viamed Ltd ISO13485:2016 8.2.4</p>	<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</p>	<p>Doc index Audit calendar Route Map Roles + titles</p>

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	<p>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.</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>	
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Do HSE Audit, Audit No 19.

Send out HSE Personnel Questionnaire, and the HSE DSE Personnel Questionnaire and reissue message of the day reminding users all HSE Documents are available in Intrastats.

ISSUE Sent 302812 ✓

	QUESTION:	RESPONSE:	Y/N
1	Review Last years Audit. Update processes if required. Are all follow on Issue resolved satisfactory.	Nothing outstanding	Y
2	Check that personnel are aware of the company's H & S policy.		X
3	Is the policy readily accessible?	Intrastats	N/A Y
4	Check that new personnel have undergone induction checklist.	No one new	Y
5	Verify that existing personnel are still aware of locations for First aid and Fire extinguishers & exit routes. Task 12.	#276137	Y
6	Check that documentation, data sheets and specs etc. for our new products / new services equipment are reviewed for H & S implications. This relates to Medical Products only. See Technical controller for the list.	See Technical controller for the list we don't have any products. No new products	Y
7	Check that personnel know where to retrieve information from the company manual.	Intrastats	N/A Y
8	Check that the First aid accident book is reviewed and any action required is taken and recorded. Task 287.	#276137 ✓ 712 #269807 ✓	Y
9	Verify that risk assessments are being carried out in a timely manner. Task 12.	Intrastats #276137	N/A Y
10	Check that the Risk Assessment / Health and Safety report produced, detail all corrective actions required. Task 12.	Audit 13 #276137	Y
11	Verify that the corrective actions are completed on time.		Y

12	Verify that these sheets are filed accordingly	Intrastats and Audit file	✓
13	Verify that any hazardous products are safely contained in storage. Check Chemicals cupboard, R+D room and workshop.		✓

Sub Processes Linked to Audit

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

List Processes Per Title

Managing Director					
Process Scope	Roll Task	Roll Audit	Risk	Action	Referenced in Document
PROCESSID 39 Ensure our Viamed Environment and WEEE Policys are upto date and suitable for current legislation	46 271 860 ✓ Company Secretary		Freq 1 Risk 2 Overall 2	Task 12M	
PROCESSID 7741 Review the current Ethical Policy in intrastats	47 Company Secretary 271 861 ✓		Freq 1 Risk 1 Overall 1	Task 12M	
IT Controller					
Process Scope	Roll Task	Roll Audit	Risk	Action	Referenced in Document
PROCESSID 45 Check the status of the Main Server	139 299 806 ✓ Office Processes		Freq 3 Risk 3 Overall 9	Task 1M	
PROCESSID 46 Check the status of the Backup Server, is done at same time as primary server	454 Office Processes 301449	455 Company Secretary 295583 ✓	Freq 1 Risk 3 Overall 3	Task 2W Audit 12M	
PROCESSID 49 Ensure Viamed Wifi is operational	415 299 675 ✓ Managing Director	416 298 756 ✓ Company Secretary	Freq 1 Risk 1 Overall 1	Task 1M Audit 3M	
PROCESSID 50 Backup Internet Connection	415 Managing Director 299 675 ✓	416 Company Secretary 298 756 ✓	Freq 3 Risk 1 Overall 3	Task 1M Audit 3M	

PROCESSID 5903 To record the daily barometric pressure	413 Managing Director 302059 ✓	414 Company Secretary ✓ 279674	Freq 4 Risk 1 Overall 4	Task 1W Audit 1M	
Maintenance Controller					
Process Scope	Roll Task	Roll Audit	Risk	Action	Referenced in Document
PROCESSID 56 Check the Boiler system before winter	85 Company Secretary 292591 ✓		Freq 1 Risk 1 Overall 1	Task 12M	
PROCESSID 5919 Check outside drain is not BLocked	431 Company Secretary 298207x	chased	Freq 2 Risk 1 Overall 2	Task 3M	
PROCESSID 5921 Check the Archives for Signs of Water, ensure the pump is working	433 Company Secretary 300377 ✓		Freq 2 Risk 1 Overall 2	Task 1M	
PROCESSID 7120 Review any General Maintenance required on the physical Site(s)	602 Company Secretary 300058 ✓		Freq 2 Risk 1 Overall 2	Task 3M	
PROCESSID 7742 Get Boiler / Heating Checked / Serviced before Winter	7 Company Secretary 300360 ✓		Freq 1 Risk 1 Overall 1	Task 12M	
PROCESSID 7756 Check Carbon Monoxide Alarm is working	117 Company Secretary 297805x	chased	Freq 2 Risk 1 Overall 2	Task 6M	
PROCESSID 7820 The renewal of our waste transfer agreement with North Yorkshire County Council	702 Company Secretary 281408 ✓		Freq 1 Risk 2 Overall 2	Task 12M	
PROCESSID 7821 The renewal of our waste transfer agreement with our waste disposal companies	701 Company Secretary 284386 ✓		Freq 1 Risk 2 Overall 2	Task 12M	
PROCESSID 7835 To get the Electrics checked by External Electrician, so certificate can be provided for Employee Safety	164 Managing Director 158792 ✓		Freq 1 Risk 1 Overall 1	Task 48M	
PROCESSID 7836 Reset the Heating for Winter	211		Freq 1 Risk 1		

			Overall 1		
PROCESSID 7864 Check the workshop benches ESD equipment is in place	94 Production Processes 289451 ✓	95 Office Processes 289458 ✓	Freq 2 Task Risk 1 6M Overall Audit 2 12M		
PROCESSID 7896 To Maintain the Tree in the Car Park	829 Company Secretary 298663 ✓		Freq 1 Task Risk 3 3M Overall 3		
PROCESSID 7961 To Clean Tidy the research and development rooms	540 Production Processes 301957 ✓	1058 Managing Director 299563 ✓	Freq 1 Task Risk 1 1W Overall Audit 1 1M		
PROCESSID 7999 To review the physical buildings health and safety, and fire risk assessments.	1143 Managing Director 302484 ✓	1144 Company Secretary 302489 ✓	Freq 1 Task Risk 2 24M Overall Audit 2 24M		
Health And Safety Controller					
Process Scope	Roll Task	Roll Audit	Risk	Action	Referenced in Document
PROCESSID 6849 To make sure we have a qualified member of staff trained in First Aid at Work. With the training up to date. Review the accident book. Check that there were no health and safety issues flagged up from these.	712 Company Secretary 269807 ✓		Freq 1 Task Risk 3 12M Overall 3		
PROCESSID 6855 Update the Site HSE file. Ensure staff are aware of this and the location of HSE equipment	12 Company Secretary 276139 ✓		Freq 1 Task Risk 1 12M Overall 1		
PROCESSID 6856 To ensure the fire alarms, MPC (manual call points), fire extinguishers and emergency lights are all in place, working and tested regularly. The log booked filled in. Tested by Keybury (alarms and emergency lights) annually and Airedale Fire protection (Fire extinguishers) annually. Evacuation Drills to check staff readiness.	52 Company Secretary 288481 ✓		Freq 1 Task Risk 3 6M Overall 3		
PROCESSID 7867	786		Freq 1		

This is a check list to ensure safe use of the bandsaw

BANDSAW HAS BEEN REMOVED, PROCESS CAN BE CLOSED / TASKS CLOSED

PROCESSID 7868

This is a check list to ensure safe use of the Pillar Drill

PROCESSID 7869

This is a check list to ensure safe use of the Hand Drill

PROCESSID 7891

To test the evacuation of the buildings in case of fire

PROCESSID 7928

To Test the Fire alarm glass boxes

PROCESSID 7929

The regular review of the Emergency Lighting And Fire Extinguishers.

Warehouse Team Leader

Process Scope

PROCESSID 54

Bleech the Gents Toilets

PROCESSID 5906

Emptying of the recycling and waste bins into external bin for refuge collectors

PROCESSID 5907

Cleaning of floors. Tidying so as to clean more effectively.

PROCESSID 5908

Cleaning of floors. Tidying so as to clean more effectively.

PROCESSID 5909

787

Production Processes

788

Production Processes

141

Company Secretary

609

Goods Out

954

Goods Out

Roll Task

125

Goods In

541

Goods In

543

Goods In

423

Goods In

542

952

Managing Director

953

Company Secretary

955

Company Secretary

Roll Audit

373

Company Secretary

424

Office Processes

424

Office Processes

424

Office Processes

424

Risk 1

Overall

1

Freq 1

Task

Risk 3

6M

Overall

3

Freq 1

Task

Risk 3

24M

Overall

3

Freq 1

Task

Risk 3

3M

Overall

Audit

12M

Freq 1

Task

Risk 1

1M

Overall

Audit

1

12M

Freq 1

Task

Risk 3

1M

Overall

Audit

3

12M

Referenced in Document

Emptying of the waste bins into external bin for refuse collectors	Goods In	Office Processes	Risk 1	1W
		Overall	Audit	
		1	1M	
PROCESSID 5910	426	424	Freq 1	Task
Cleaning of duckets	Goods In	Office Processes	Risk 1	1W
	302069	301066	Overall	Audit
		1	1M	
PROCESSID 5911	427	424	Freq 1	Task
To remove and dispose of the cardboard with in the company	Goods In	Office Processes	Risk 1	2W
	302185	301066	Overall	Audit
	in terms	1	1M	
PROCESSID 7687	488		Freq 1	Task
Collecting, cleaning and returning duckets to Vandagraph.	Goods In		Risk 1	1W
	302302		Overall	
	in terms	1		
PROCESSID 7698	503		Freq 1	Task
Cleaning of surfaces, equipment, floors. Tidying so as to clean more effectively.	Goods In		Risk 1	3W
	301832		Overall	
	in terms	1		

Human Resources

Process Scope	Roll Task	Roll Audit	Risk	Action	Referenced in Document
PROCESSID 7847	12	1071	Freq 1	Task	
Perform HSE Risk Assessment,	Company Secretary	Managing	Risk 1	12M	
Re issue Message of the Day or send company issue with regard to Employees being aware of HSE documentation / policy.	276137	281966	Overall	Audit	
and Location of Fire Exits and First Aid Kits.		1	12M		
Send new Issue to Projects Asking if New HSE implications have arisen from new products.					
Review Online the Local Community Risk Register.					
Check the Viamed Overall Risk Analysis Program Document in the Index to check its still current.					
Check the health and safety signage					
PROCESSID 7982	1107	1109	Freq 1	Task	
To Check online and see if there have been any changes to	Company Secretary	Managing	Risk 1	12M	
	287569	Director	Overall	Audit	
		288800			

Minimum wage or employment law we need to be aware of.			1	24M	
Data Protection Officer					
Process Scope	Roll Task	Roll Audit	Risk	Action	Referenced in Document
PROCESSID 7910 To check the signs we have are appropriate, clear and positioned in the correct	910 Company Secretary 272448 ✓		Freq 1 Risk 1 Overall 1	Task 12M	
PROCESSID 7911 Review Security Of The Special Category Personal Data	911 Company Secretary 273514 ✓		Freq 1 Risk 2 Overall 2	Task 12M	
Audits					
Process Scope	Roll Task	Roll Audit	Risk	Action	Referenced in Document
PROCESSID 7729 To carry out Audit 19 Health And Safety Viamed	This Audit	13 302429 Company Secretary ✗	Freq 1 Risk 2 Overall 2	Audit 12M	
PROCESSID 7777 To carry out Audit 19 Health And Safety VST	VST Audit	186 Company Secretary 302436 ✗	Freq 1 Risk 2 Overall 2	Audit 12M	
Office Processes					
Process Scope	Roll Task	Roll Audit	Risk	Action	Referenced in Document
PROCESSID 5853 Ensure customer facing areas are vacuumed	243 302179 ✓	373 Company Secretary 300367 ✓	Freq 1 Risk 1 Overall 1	Task 1W Audit 1M	
PROCESSID 5856 to clean the kitchen, work tops and floor. make sure it is safe for people to use	227	373 Company Secretary 300367 ✓	Freq 1 Risk 1 Overall 1	Audit 1M	
PROCESSID 5878 Emptying of the recycling and waste bins into external bin for refuge collectors	225 Office Processes 302177 ✓	532	Freq 1 Risk 1 Overall 1	Task 1W	
PROCESSID 5900 Cleaning of surfaces, equipment, floors. Tidying so as to clean more effectively.	393 Office Processes 300847 ✓	394 Company Secretary 300064 ✓	Freq 3 Risk 1 Overall 3	Task 1M Audit 1M	

PROCESSID 5912 To put the recycling bins out	107 Goods Out 302434 x <i>in terms</i>		Freq 3 Risk 1 Overall 3	Task 2W	
PROCESSID 7706 Updating of anti-virus software and scanning computers for viruses	519 Office Processes 302180 ✓		Freq 2 Risk 2 Overall 4	Task 1W	
PROCESSID 7802 Cleaning the kitchen surfaces to ensure they are fit for use	655 Office Processes 302322 x <i>in terms</i>	656 Office Processes 301597 ✓	Freq 1 Risk 1 Overall 1	Task 1W Audit 2W	
PROCESSID 7803 To ensure crockery and cutlery is cleaned and fit for use	657 301985 ✓	658 Office Processes 301098 ✓	Freq 1 Risk 1 Overall 1	Task 1W Audit 1M	
PROCESSID 7804 To sweep the kitchen floor and clear and mess ready for mopping	659 302215 ✓	662 Company Secretary 299539 ✓	Freq 1 Risk 1 Overall 1	Task 1W Audit 1M	
PROCESSID 7805 Emptying of the recycling and waste bins into external bin for refuse collection	225 Office Processes 302177 ✓	661	Freq 1 Risk 1 Overall 1	Task 1W	
Diasedled currently - have Global task on bins					
PROCESSID 7806 To water the plants and ensure their survival	663 Company Secretary 302208 ✓	664	Freq 1 Risk 1 Overall 1	Task 1W	
PROCESSID 7910 To check the signs we have are appropriate, clear and positioned in the correct	910 Company Secretary 272648 ✓		Freq 1 Risk 1 Overall 1	Task 12M	