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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> <ol style="list-style-type: none"> the quality policy; relevant quality objectives; their contribution to the effectiveness of the quality management system, including the benefits of improved performance; 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>	<i>Roles + titles Doc index management Review</i>
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> <ol style="list-style-type: none"> determine the necessary competence for personnel performing work affecting product quality; provide training or take other actions to achieve or maintain the necessary competence; evaluate the effectiveness of the actions taken; 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; 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>	<i>management Review Roles + titles Role Maps Audit Calendar QA System GCR form</i>
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> <ol style="list-style-type: none"> buildings, workspace and associated utilities; process equipment (both hardware and software); 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>	<i>Doc index management Review Procedure HS Review</i>

	<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>	
Viamed Ltd ISO13485:2016 6.4.1	<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> <ul style="list-style-type: none"> 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 competent or supervised by a competent person. <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>
Viamed Ltd ISO13485:2016 6.4.2	<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>
Viamed Ltd ISO13485:2016 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> <ul style="list-style-type: none"> 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. <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 Review May 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 ✓

	<u>QUESTION:</u>	<u>RESPONSE:</u>	<u>Y/N</u>
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 live client have 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 Policies are upto date and suitable for current legislation	46 Company Secretary 271860	✓	Freq 1 Risk 2 Overall 2	Task 12M		
PROCESSID 7741 Review the current Ethical Policy in intrastats	47 Company Secretary 271861	✓	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 Office Processes 299806	✓	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 301469	455 Company Secretary 295583	Freq 1 Risk 3 Overall 3	Task 2W Audit 12M		
PROCESSID 49 Ensure Viamed Wifi is operational	415 299675	416 298756	Freq 1 Risk 1 Overall 1	Task 1M Audit 3M		
PROCESSID 50 Backup Internet Connection	415 Managing Director 299675	416 Company Secretary 298756	Freq 3 Risk 1 Overall 3	Task 1M Audit 3M		

PROCESSID 5903 To record the daily barometric pressure	413 Managing Director <i>302059 ✓</i>	414 Company Secretary <i>299676 ✓</i>	Freq 4 Task Risk 1 1W Overall Audit 4 1M	Referenced in Document
Maintenance Controller				
Process Scope	Roll Task	Roll Audit	Risk	Action
PROCESSID 56 Check the Boiler system before winter	85 Company Secretary <i>292591 ✓</i>		Freq 1 Task Risk 1 12M Overall 1	
PROCESSID 5919 Check outside drain is not Blocked	431 Company Secretary <i>298207 ✓</i>	<i>checked</i>	Freq 2 Task Risk 1 3M Overall 2	
PROCESSID 5921 Check the Archives for Signs of Water, ensure the pump is working	433 Company Secretary <i>300377 ✓</i>		Freq 2 Task Risk 1 1M Overall 2	
PROCESSID 7120 Review any General Maintenance required on the physical Site(s)	602 Company Secretary <i>300055 ✓</i>		Freq 2 Task Risk 1 3M Overall 2	
PROCESSID 7742 Get Boiler / Heating Checked / Serviced before Winter	7 Company Secretary <i>300360 ✓</i>		Freq 1 Task Risk 1 12M Overall 1	
PROCESSID 7756 Check Carbon Monoxide Alarm is working	117 Company Secretary <i>299805 ✓</i>	<i>checked</i>	Freq 2 Task Risk 1 6M Overall 2	
PROCESSID 7820 The renewal of our waste transfer agreement with North Yorkshire County Council	702 Company Secretary <i>281408 ✓</i>		Freq 1 Task Risk 2 12M Overall 2	
PROCESSID 7821 The renewal of our waste transfer agreement with our waste disposal companies	701 Company Secretary <i>284386 ✓</i>		Freq 1 Task Risk 2 12M Overall 2	
PROCESSID 7835 To get the Electrics checked by External Electriction, so certificate can be provided for Employee Safety	164 Managing Director <i>158792 ✓</i>		Freq 1 Task Risk 1 48M Overall 1	
PROCESSID 7836 Reset the Heating for Winter	211		Freq 1 Risk 1	

Process ID	Task ID	Task Description	Process Type	Overall Status	Action	Referenced in Document
PROCESSID 7864 Check the workshop benches ESD equipment is in place	94	Production Processes	95 Office Processes	Freq 2 Task Risk 1 6M Overall Audit	12M	
PROCESSID 7896 To Maintain the Tree in the Car Park	829	Company Secretary	289458 2	Freq 1 Task Risk 3 3M		
PROCESSID 7961 To Clean Tidy the research and development rooms	540	Production Processes	1058 Managing Director	Freq 1 Task Risk 1 1W	Overall Audit	
PROCESSID 7999 To review the physical buildings health and safety, and fire risk assessments.	1143	Managing Director	1144 Company Secretary	Freq 1 Task Risk 2 24M	1 1M Overall Audit	
Health And Safety Controller			301957 299563 302484 302489	2 24M		
Process Scope	Roll Task	Roll Audit	Risk	Action		
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	769807 276139	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 book is 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

Risk 1
Overall
1

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

787
Production
Processes

Freq 1 Task
Risk 3 6M
Overall
3

PROCESSID 7869

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

788
Production
Processes

Freq 1 Task
Risk 3 24M
Overall
3

PROCESSID 7891

To test the evacuation of the buildings in case of fire

141
Company Secretary

Freq 1 Task
Risk 3 3M
Overall Audit

PROCESSID 7928

To Test the Fire alarm glass boxes

609
Goods Out

Freq 1 Task
Risk 1 1M
Overall Audit

PROCESSID 7929

The regular review of the Emergency Lighting And Fire Extinguishers.

954
Goods Out

Freq 1 Task
Risk 3 1M
Overall Audit

Warehouse Team Leader

Process Scope

PROCESSID 54

Bleech the Gents Toilets

Roll Task
125
Goods In

Roll Audit
373
Company
Secretary

Risk 3 Task
Risk 1 1M
Overall Audit

PROCESSID 5906

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

541
Goods In

424
Office Processes

Freq 1 Task
Risk 1 1W
Overall Audit

PROCESSID 5907

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

543
Goods In

424
Office Processes

Freq 1 Task
Risk 1 1W
Overall Audit

PROCESSID 5908

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

423
Goods In

424
Office Processes

Freq 1 Task
Risk 1 1W
Overall Audit

PROCESSID 5909

542
Goods In

424

Freq 1 Task

Referenced in
Document

Emptying of the waste bins into external bin for refuge collectors	Goods In	Office Processes	Risk 1 1W
PROCESSID 5910 Cleaning of duckets	426 Goods In <i>30/06/2024</i>	424 Office Processes <i>30/06/2024</i>	Overall Audit 1 1M
PROCESSID 5911 To remove and dispose of the cardboard with in the company	427 Goods In <i>30/06/2024</i>	424 Office Processes <i>30/06/2024</i>	Freq 1 Task Risk 1 1W
PROCESSID 7687 Collecting, cleaning and returning duckets to Vandagraph.	488 Goods In <i>30/06/2024</i>	424 Office Processes <i>30/06/2024</i>	Overall Audit 1 1M
PROCESSID 7698 Cleaning of surfaces, equipment, floors. Tidying so as to clean more effectively.	503 Goods In <i>30/06/2024</i>	424 Office Processes <i>30/06/2024</i>	Freq 1 Task Risk 1 2W
Human Resources			Overall Audit 1 1M
Process Scope	Roll Task	Roll Audit	Risk Action
PROCESSID 7847 Perform HSE Risk Assessment, Re issue Message of the Day or send company issue with regard to Employees being aware of HSE documentation / policy. and Location of Fire Exits and First Aid Kits.	12 Company Secretary <i>27/01/2024</i>	1071 Managing Director <i>28/06/2024</i>	Freq 1 Task Risk 1 12M
Send new Issue to Projects Asking if New HSE implications have arisen from new products.			Overall Audit 1 12M
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 To Check online and see if there have been any changes to	1107 Company Secretary <i>28/07/2024</i>	1109 Managing Director <i>28/06/2024</i>	Freq 1 Task Risk 1 12M
			Overall Audit

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 <i>302434 x</i> <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 <i>302180 ✓</i>	Freq 2 Risk 2 Overall 4	Task 1W	
PROCESSID 7802 Cleaning the kitchen surfaces to ensure they are fit for use	655 Office Processes <i>302322 x</i> <i>in terms</i>	656 Office Processes <i>301597 ✓</i>	Freq 1 Risk 1 Overall 1	Task 1W Audit 2W
PROCESSID 7803 To ensure crockery and cutlery is cleaned and fit for use	657 <i>301985 ✓</i>	658 Office Processes <i>301098 ✓</i>	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 <i>302215 ✓</i>	662 Company Secretary <i>299539 ✓</i>	Freq 1 Risk 1 Overall 1	Task 1W Audit 1M
PROCESSID 7805 Emptying of the recycling and waste bins into external bin for refuge collection	225 Office Processes <i>302177 ✓</i>	661	Freq 1 Risk 1 Overall 1	Task 1W
Diasbled currently - have Global task on bins				
PROCESSID 7806 To water the plants and ensure their survival	663 Company Secretary <i>302208 ✓</i>	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 <i>272648 ✓</i>		Freq 1 Risk 1 Overall 1	Task 12M