

<b>Internal Audit Check list</b>			
HEALTH & SAFETY			
Created:	17/May 1995	<b>Audit No 19</b>	
Revised:	12 June 2017		Page 1 of 11
Audit Date		Auditor	

Company / ISO Section	Criteria of ISO Section	Auditor Comments / Issues
VST Ltd ISO9001:2015 7.1.3	<b>Infrastructure</b> 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	<b>Environment for the operation of processes</b> 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	<b>Competence</b> 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	<b>Awareness</b> The organization shall ensure that persons doing work under the	

	<p>organization's control are aware of:</p> <ul style="list-style-type: none"> <li>a) the quality policy;</li> <li>b) relevant quality objectives;</li> <li>c) their contribution to the effectiveness of the quality management system, including the benefits of improved performance;</li> <li>d) the implications of not conforming with the quality management system requirements.</li> </ul>	
<p>Viamed Ltd ISO13485:2016 5.5.1</p>	<p><b>Responsibility and authority</b></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>Viamed Ltd ISO13485:2016 6.2</p>	<p><b>Human resources</b></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"> <li>a) determine the necessary competence for personnel performing work affecting product quality;</li> <li>b) provide training or take other actions to achieve or maintain the necessary competence;</li> <li>c) evaluate the effectiveness of the actions taken;</li> <li>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;</li> <li>e) maintain appropriate records of education, training, skills and experience (see 4.2.5).</li> </ul> <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>Viamed Ltd ISO13485:2016 6.3</p>	<p><b>Infrastructure</b></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"> <li>a) buildings, workspace and associated utilities;</li> <li>b) process equipment (both hardware and software);</li> <li>c) supporting services (such as transport, communication, or information systems).</li> </ul> <p>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</p>	

	<p>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><b>Work environment</b></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"> <li>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;</li> <li>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.</li> </ul> <p>NOTE Further information can be found in ISO 14644 and ISO 14698</p>	
<p>Viamed Ltd ISO13485:2016 6.4.2</p>	<p><b>Contamination control</b></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>Viamed Ltd ISO13485:2016 8.2.4</p>	<p><b>Internal audit</b></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"> <li>a) conforms to planned and documented arrangements, requirements of this International Standard, quality management system requirements established by the organization, and applicable regulatory requirements;</li> <li>b) is effectively implemented and maintained.</li> </ul> <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). The selection of</p>	

	<p>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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	<b><u>QUESTION:</u></b>	<b><u>RESPONSE:</u></b>	<b><u>Y/ N</u></b>
1	Check that personnel are aware of the company's H & S policy.		
2	Is the policy readily accessible?	Intrastats	N/ A
3	Check that new personnel have undergone induction checklist.		
4	Verify that existing personnel are still aware of locations for First aid and Fire extinguishers & exit routes. (Task 12)		
5	Check that documentation, data sheets and specs etc. for our new products / 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	
6	Check that personnel know where to retrieve information from the company manual.	Intrastats	N/ A
7	Check that the First aid accident book is reviewed and any action required is taken and recorded. Task 287		
8	Verify that risk assessments are being carried out in a timely manner. Task 12	Intrastats	N/ A
9	Check that the Risk Assessment / Health and Safety report produced, details all corrective actions required. Task 12	Audit 13	
10	Verify that the corrective actions are completed on time.		
11	Verify that these sheets are filed accordingly	Intrastats and Audit file	
12	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.

## Managing Director

Process Scope	Roll Task	Roll Audit	Risk	Action	Notes / Issues
PROCESSID 39 Ensure our Viamed Environment and WEEE Policys are upto date and suitable for current legislation	46 Managing Director		Freq 1 Risk 0 Overall	Task 12M	
PROCESSID 7741 Review the current Ethical Policy in intrastats	47 Managing Director		Freq 1 Risk 1 Overall 1	Task 12M	

## Maintenance Controller

Process Scope	Roll Task	Roll Audit	Risk	Action	Notes / Issues
PROCESSID 56 Check the Boiler system before winter	85 Company Secretary		Freq 1 Risk 1 Overall 1	Task 12M	
PROCESSID 5919 Check outside drain is not BLocked	431 Company Secretary		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		Freq 3 Risk 1 Overall 3	Task 1M	
PROCESSID 7120 Review any General Maintenance required on the physical Site(s)	602 Company Secretary		Freq 2 Risk 1 Overall 2	Task 3M	
PROCESSID 7742 Get Boiler / Heating Checked / Serviced before Winter	7 Company Secretary		Freq 1 Risk 1 Overall 1	Task 12M	
PROCESSID 7756 Check Carbon Monoxide Alarm is working	117 Company Secretary		Freq 2 Risk 1 Overall 2	Task 6M	
PROCESSID 7820 The renewal of our waste transfer agreement with North	702 Company Secretary		Freq 1 Risk 2 Overall 2	Task 12M	

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PROCESSID <b>7821</b> The renewal of our waste transfer agreement with our waste disposal companies	701 Company Secretary		Freq 1 Risk 2 Overall 2	Task 12M
PROCESSID <b>7835</b> To get the Electrics checked by External Electriction, so certificate can be provided for Employee Safety	164 Managing Director		Freq 1 Risk 1 Overall 1	Task 48M
PROCESSID <b>7836</b> Reset the Heating for Winter	211 UK Sales Controller		Freq 1 Risk 1 Overall 1	Task 12M
PROCESSID <b>7864</b> Check the workshop benches ESD equipment is in place	94 Production Processes	95 Managing Director	Freq 2 Risk 1 Overall 2	Task 6M Audit 12M

## IT Controller

Process Scope	Roll Task	Roll Audit	Risk	Action	Notes / Issues
PROCESSID <b>45</b> Check the status of the Main Server	139 Managing Director		Freq 3 Risk 3 Overall 9	Task 1M	
PROCESSID <b>46</b> Check the status of the Backup Server,	454 Managing Director	455 Company Secretary	Freq 4 Risk 3 Overall 12	Task 2W Audit 12M	
is done at same time as primary server					
PROCESSID <b>50</b> Backup Internet Connection	415 Managing Director	416 Office Processes	Freq 3 Risk 1 Overall 3	Task 1M Audit 3M	
PROCESSID <b>5903</b> To record the daily barometric pressure	413 Managing Director	414 UK Sales Controller	Freq 4 Risk 1 Overall 4	Task 1W Audit 1M	

## Health And Safety Controller

Process Scope	Roll Task	Roll Audit	Risk	Action	Notes / Issues
PROCESSID <b>6849</b> 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		Freq 1 Risk 3 Overall 3	Task 12M	
PROCESSID <b>6855</b> Update the Site HSE file	12 Managing Director		Freq 1 Risk 1 Overall 1	Task 12M	
PROCESSID <b>6856</b> 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		Freq 2 Risk 4 Overall 8	Task 6M	
PROCESSID <b>7092</b> Examination of electrical appliances and equipment to ensure they are safe to use	127 Managing Director		Freq 1 Risk 3 Overall 3	Task 48M	
PROCESSID <b>7867</b>	786 Production Processes		Freq Risk Overall	Task 6M	
PROCESSID <b>7868</b>	787 Production		Freq Risk	Task 6M	

	Processes	Overall
PROCESSID 7869	788	Freq Task
	Production	Risk 6M
	Processes	Overall

## Warehouse Team Leader

Process Scope	Roll Task	Roll Audit	Risk	Action	Notes / Issues
PROCESSID 54 Bleech the Gents Toilets	125 Goods In	373 Company Secretary	Freq 3 Risk 1 Overall 3	Task 1M Audit 1M	
PROCESSID 5906 Emptying of the recycling and waste bins into external bin for refuge collectors	541 Goods In	424 Managing Director	Freq 4 Risk 1 Overall 4	Task 1W Audit 1M	
PROCESSID 5907 Cleaning of floors. Tidying so as to clean more effectively.	543 Goods In	424 Managing Director	Freq 4 Risk 1 Overall 4	Task 1W Audit 1M	
PROCESSID 5908 Cleaning of floors. Tidying so as to clean more effectively.	423 Goods In	424 Managing Director	Freq 4 Risk 1 Overall 4	Task 1W Audit 1M	
PROCESSID 5909 Emptying of the waste bins into external bin for refuge collectors	542 Goods In	424 Managing Director	Freq 4 Risk 1 Overall 4	Task 1W Audit 1M	
PROCESSID 5910 Cleaning of duckets	426 Goods Out	424 Managing Director	Freq 4 Risk 1 Overall 4	Task 1W Audit 1M	
PROCESSID 5911 To remove and dispose of the cardboard with in the company	427 Goods In	424 Managing Director	Freq 4 Risk 1 Overall 4	Task 2W Audit 1M	
PROCESSID 7687 Collecting, cleaning and returning duckets to Vandagraph.	488 Goods Out		Freq 4 Risk 1 Overall 4	Task 1W	
PROCESSID 7698 Cleaning of surfaces, equipment, floors. Tidying so as to clean more effectively.	503 Goods In		Freq 4 Risk 1 Overall 4	Task 3W	



## Audits

Process Scope	Roll Task	Roll Audit	Risk	Action	Notes / Issues
PROCESSID 7729 To carry out Audit 19 Health And Safety Viamed		13 Company Secretary	Freq 1 Risk 2 Overall 2	Audit 12M	
PROCESSID 7777 To carry out Audit 19 Health And Safety VST		186 Company Secretary	Freq 1 Risk 2 Overall 2	Audit 12M	

## Human Resources

Process Scope	Roll Task	Roll Audit	Risk	Action	Notes / Issues
PROCESSID 7847 Perform HSE Risk Assessment,	12 Managing Director		Freq 1 Risk 1 Overall 1	Task 12M	

ReIssue Meesage of the  
Day with regard to  
Employees being aware  
of HSE  
documentation / policy.  
and Location of Fire  
Exits and First Aid  
Kits..

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.

## Office Processes

Process Scope	Roll Task	Roll Audit	Risk	Action	Notes / Issues
PROCESSID <b>5853</b> Ensure customer facing areas are vacuumed	243 Office Processes	373 Company Secretary	Freq 4 Risk 1 Overall 4	Task 2W Audit 1M	
PROCESSID <b>5856</b>	227	373 Company Secretary	Freq Risk Overall	Audit 1M	
PROCESSID <b>5878</b> Emptying of the recycling and waste bins into external bin for refuge collectors	428 Office Processes	532 Office Processes	Freq 4 Risk 1 Overall 4	Task 1W Audit 1W	
PROCESSID <b>5900</b> Cleaning of surfaces, equipment, floors. Tidying so as to clean more effectively.	393 Office Processes	394 Company Secretary	Freq 3 Risk 1 Overall 3	Task 1M Audit 1M	
PROCESSID <b>5912</b> To put the bins out	107 Company Secretary		Freq 3 Risk 1 Overall 3	Task 1M	
PROCESSID <b>7706</b> Updating of anti-virus software and scanning computers for viruses	519 Office Processes		Freq 4 Risk 1 Overall 4	Task 1W	
PROCESSID <b>7802</b> Cleaning the kitchen surfaces to ensure they are fit for use	655 Office Processes	656 Office Processes	Freq 5 Risk 1 Overall 5	Task 2D Audit 1W	
PROCESSID <b>7803</b> To ensure crockery and cutlery is cleaned and fit for use	657 Office Processes	658 Office Processes	Freq 5 Risk 1 Overall 5	Task 1D Audit 1W	
PROCESSID <b>7804</b> To sweep the kitchen floor and clear and mess ready for mopping	659 Office Processes	662 Goods In	Freq 4 Risk 1 Overall 4	Task 1W Audit 1W	
PROCESSID <b>7805</b> Emptying of the recycling and waste bins into external bin for refuge collection	660 Office Processes	661 Office Processes	Freq 4 Risk 1 Overall 4	Task 1W Audit 1W	

PROCESSID <b>7806</b>	663	664	Freq 4	Task
To water the plants and	Office		Risk 1	1W
ensure their survival	Processes		Overall	
			4	