

<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	

Ed spacing and layout

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	

	<p>the 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</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><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</p>	

	<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.

	<b><u>QUESTION:</u></b>	<b><u>RESPONSE:</u></b>	<b><u>Y/N</u></b>
1	Review Last years Audit. Update processes if required. Are all follow on Issue resolved satisfactory.		
2	Check that personnel are aware of the company's H & S policy.		
3	Is the policy readily accessible?	Intrastats	N/A
4	Check that new personnel have undergone induction checklist.		
5	Verify that existing personnel are still aware of locations for First aid and Fire extinguishers & exit routes. Task 12.		
6	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	
7	Check that personnel know where to retrieve information from the company manual.	Intrastats	N/A
8	Check that the First aid accident book is reviewed and any action required is taken and recorded. Task 287.		
9	Verify that risk assessments are being carried out in a timely manner. Task 12.	Intrastats	N/A
10	Check that the Risk Assessment / Health and Safety report produced, detail all corrective actions required. Task 12.	Audit 13	
11	Verify that the corrective actions are completed on time.		

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

<b>Managing Director</b>					
<b>Process Scope</b>	<b>Roll Task</b>	<b>Roll Audit</b>	<b>Risk</b>	<b>Action</b>	<b>Notes / Issues</b>
<b>PROCESSID 39</b> Ensure our Viamed Environment and WEEE Polycys are upto date and suitable for current legislation	46 Company Secretary		Freq 1 Risk 0 Overall	Task 12M	
<b>PROCESSID 7741</b> Review the current Ethical Policy in intrastats	47 Company Secretary		Freq 1 Risk 1 Overall 1	Task 12M	
<b>Maintenance Controller</b>					
<b>Process Scope</b>	<b>Roll Task</b>	<b>Roll Audit</b>	<b>Risk</b>	<b>Action</b>	<b>Notes / Issues</b>
<b>PROCESSID 56</b> Check the Boiler system before winter	85 Company Secretary		Freq 1 Risk 1 Overall 1	Task 12M	
<b>PROCESSID 5919</b> Check outside drain is not BLocked	431 Company Secretary		Freq 2 Risk 1 Overall 2	Task 3M	
<b>PROCESSID 5921</b> Check the Archives for Signs of Water, ensure the pump is working	433 Company Secretary		Freq 3 Risk 1 Overall 3	Task 1M	
<b>PROCESSID 7120</b> Review any General Maintenance required on the physical Site(s)	602 Company Secretary		Freq 2 Risk 1 Overall 2	Task 3M	
<b>PROCESSID 7742</b> Get Boiler / Heating Checked / Serviced	7 Company		Freq 1 Risk 1	Task 12M	

before Winter	Secretary		Overall 1		
<b>PROCESSID 7756</b> Check Carbon Monoxide Alarm is working	117 Company Secretary		Freq 2 Risk 1 Overall 2	Task 6M	
<b>PROCESSID 7820</b> The renewal of our waste transfer agreement with North Yorkshire County Council	702 Company Secretary		Freq 1 Risk 2 Overall 2	Task 12M	
<b>PROCESSID 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	
<b>PROCESSID 7835</b> To get the Electrics checked by External Electrician, so certificate can be provided for Employee Safety	164 Managing Director		Freq 1 Risk 1 Overall 1	Task 48M	
<b>PROCESSID 7836</b> Reset the Heating for Winter	211		Freq 1 Risk 1 Overall 1		
<b>PROCESSID 7864</b> Check the workshop benches ESD equipment is in place	94 Production Processes	95 Office Processes	Freq 2 Risk 1 Overall 2	Task 6M Audit 12M	
<b>PROCESSID 7896</b> To Maintain the Tree in the Car Park	829 Company Secretary		Freq 1 Risk 1 Overall 1	Task 3M	
<b>PROCESSID 7961</b> To Clean Tidy the r and D rooms	540 Production Processes	1058 Managing Director	Freq 1 Risk 1 Overall 1	Task 1W Audit 1M	
<b>IT Controller</b>					
<b>Process Scope</b>	<b>Roll Task</b>	<b>Roll Audit</b>	<b>Risk</b>	<b>Action</b>	<b>Notes / Issues</b>
<b>PROCESSID 45</b> Check the status of the Main Server	139 Office Processes		Freq 3 Risk 3 Overall 9	Task 1M	
<b>PROCESSID 46</b> Check the status of the Backup Server, is done at same time as primary server	454 Office Processes	455 Company Secret	Freq 4 Risk 3 Overall 12	Task 2W Audit 12M	

		ary			
<b>PROCESSID 49</b> Ensure Viamed Wifi is operational	415 Managing Director	416 Comp any Secret ary	Freq 1 Risk 1 Overall 1	Task 1M Audit 3M	
<b>PROCESSID 50</b> Backup Internet Connection	415 Managing Director	416 Comp any Secret ary	Freq 3 Risk 1 Overall 3	Task 1M Audit 3M	
<b>PROCESSID 5903</b> To record the daily barometric pressure	413 Managing Director	414 UK Sales Contro ller	Freq 4 Risk 1 Overall 4	Task 1W Audit 1M	
<b>Health And Safety Controller</b>					
<b>Process Scope</b>	<b>Roll Task</b>	<b>Roll Audit</b>	<b>Risk</b>	<b>Action</b>	<b>Notes / Issues</b>
<b>PROCESSID 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	
<b>PROCESSID 6855</b> Update the Site HSE file	12 Managing Director		Freq 1 Risk 1 Overall 1	Task 12M	
<b>PROCESSID 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	
<b>PROCESSID 7867</b> This is a check list to ensure safe use of the bandsaw	786 Productio n Processes		Freq 1 Risk 4 Overall 4	Task 6M	
<b>PROCESSID 7868</b> This is a check list to ensure safe use of the Pillar Drill	787 Productio n Processes		Freq 1 Risk 4 Overall 4	Task 6M	
<b>PROCESSID 7869</b> This is a check list to ensure safe use of the Hand Drill	788 Productio n		Freq 1 Risk 3 Overall	Task 24M	

	Processes		3		
<b>PROCESSID 7891</b> To test the evacuation of the buildings in case of fire	141 Company Secretary	952 Manag ing Direct or	Freq 1 Risk 4 Overall 4	Task 3M Audit 12M	
<b>PROCESSID 7928</b> To Test the Fire alarm glass boxes	609 Goods Out	953 Comp any Secret ary	Freq 1 Risk 1 Overall 1	Task 1M Audit 12M	
<b>PROCESSID 7929</b> The regular review of the Emergency Lighting And Fire Extinguishers.	954 Goods Out	955 Comp any Secret ary	Freq 3 Risk 3 Overall 9	Task 1M Audit 12M	
<b>Warehouse Team Leader</b>					
<b>Process Scope</b>	<b>Roll Task</b>	<b>Roll Audit</b>	<b>Risk</b>	<b>Action</b>	<b>Notes / Issues</b>
<b>PROCESSID 54</b> Bleech the Gents Toilets	125 Goods In	373 Comp any Secret ary	Freq 3 Risk 1 Overall 3	Task 1M Audit 1M	
<b>PROCESSID 5906</b> Emptying of the recycling and waste bins into external bin for refuge collectors	541 Goods In	424 Office Proces ses	Freq 4 Risk 1 Overall 4	Task 1W Audit 1M	
<b>PROCESSID 5907</b> Cleaning of floors. Tidying so as to clean more effectively.	543 Goods In	424 Office Proces ses	Freq 4 Risk 1 Overall 4	Task 1W Audit 1M	
<b>PROCESSID 5908</b> Cleaning of floors. Tidying so as to clean more effectively.	423 Goods In	424 Office Proces ses	Freq 4 Risk 1 Overall 4	Task 1W Audit 1M	
<b>PROCESSID 5909</b> Emptying of the waste bins into external bin for refuge collectors	542 Goods In	424 Office Proces ses	Freq 4 Risk 1 Overall 4	Task 1W Audit 1M	
<b>PROCESSID 5910</b> Cleaning of duckets	426 Goods In	424 Office Proces ses	Freq 4 Risk 1 Overall 4	Task 1W Audit 1M	
<b>PROCESSID 5911</b> To remove and dispose of the cardboard with in the company	427 Goods In	424 Office	Freq 4 Risk 1	Task 2W Audit 1M	



		Processes	Overall 4		
PROCESSID 7687 Collecting, cleaning and returning duckets to Vandagraph.	488 Goods In		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	
<b>Audits</b>					
<b>Process Scope</b>	<b>Roll Task</b>	<b>Roll Audit</b>	<b>Risk</b>	<b>Action</b>	<b>Notes / Issues</b>
PROCESSID 7729 To carry out Audit 19 Health And Safety Viamed		13 Comp any Secret ary	Freq 1 Risk 2 Overall 2	Audit 12M	
PROCESSID 7777 To carry out Audit 19 Health And Safety VST		186 Comp any Secret ary	Freq 1 Risk 2 Overall 2	Audit 12M	
<b>Data Protection Officer</b>					
<b>Process Scope</b>	<b>Roll Task</b>	<b>Roll Audit</b>	<b>Risk</b>	<b>Action</b>	<b>Notes / Issues</b>
PROCESSID 7910 To check the signs we have are appropriate, clear and positioned in the correct	910 Company Secretary		Freq 1 Risk 1 Overall 1	Task 12M	
PROCESSID 7911 Review Security Of The Special Category Personal Data	911 Company Secretary		Freq 1 Risk 2 Overall 2	Task 12M	
<b>Office Processes</b>					
<b>Process Scope</b>	<b>Roll Task</b>	<b>Roll Audit</b>	<b>Risk</b>	<b>Action</b>	<b>Notes / Issues</b>
PROCESSID 5853 Ensure customer facing areas are vacuumed	243 Office Processes	373 Comp any Secret ary	Freq 4 Risk 1 Overall 4	Task 1W Audit 1M	
PROCESSID 5856	227	373 Comp	Freq Risk	Audit 1M	

		any Secret ary	Overall		
<b>PROCESSID 5878</b> Emptying of the recycling and waste bins into external bin for refuge collectors	225 Office Processes	532	Freq 4 Risk 1 Overall 4	Task 1W	
<b>PROCESSID 5900</b> Cleaning of surfaces, equipment, floors. Tidying so as to clean more effectively.	393 Office Processes	394 Comp any Secret ary	Freq 3 Risk 1 Overall 3	Task 1M Audit 1M	
<b>PROCESSID 5912</b> To put the bins out	107 Company Secretary		Freq 3 Risk 1 Overall 3	Task 1M	
<b>PROCESSID 7706</b> Updating of anti-virus software and scanning computers for viruses	519 Office Processes		Freq 4 Risk 1 Overall 4	Task 1W	
<b>PROCESSID 7802</b> Cleaning the kitchen surfaces to ensure they are fit for use	655 Office Processes	656 Office Proces ses	Freq 5 Risk 1 Overall 5	Task 1W Audit 2W	
<b>PROCESSID 7803</b> To ensure crockery and cutlery is cleaned and fit for use	657 Office Processes	658 Office Proces ses	Freq 5 Risk 1 Overall 5	Task 1D Audit 1W	
<b>PROCESSID 7804</b> To sweep the kitchen floor and clear and mess ready for mopping	659 Office Processes	662 Comp any Secret ary	Freq 4 Risk 1 Overall 4	Task 1W Audit 1W	
<b>PROCESSID 7805</b> Emptying of the recycling and waste bins into external bin for refuge collection  Diasbled currently - have Global task on bins	225 Office Processes	661	Freq 4 Risk 1 Overall 4	Task 1W	
<b>PROCESSID 7806</b> To water the plants and ensure their survival	663 Office Processes	664	Freq 3 Risk 1 Overall 3	Task 1W	
<b>PROCESSID 7910</b> To check the signs we have are appropriate, clear and positioned in the correct	910 Company Secretary		Freq 1 Risk 1 Overall 1	Task 12M	

<b>Human Resources</b>					
<b>Process Scope</b>	<b>Roll Task</b>	<b>Roll Audit</b>	<b>Risk</b>	<b>Action</b>	<b>Notes / Issues</b>
<p><b>PROCESSID 7847</b></p> <p>Perform HSE Risk Assessment,</p> <p>Re issue Message of the Day or send company issue with regard to Employees being aware of HSE documentation / policy.</p> <p>and Location of Fire Exits and First Aid Kits.</p> <p>Send new Issue to Projects Asking if New HSE implications have arisen from new products.</p> <p>Review Online the Local Community Risk Register.</p> <p>Check the Viamed Overall Risk Analysis Program Document in the Index to check its still current.</p>	12 Managing Director	1071 Company Secretary	Freq 1 Risk 1 Overall 1	Task 12M Audit 12M	