VIAMED LTD + VST LTD

Internal Audit Check list

HEALTH & SAFETY

Created:	17/May 1995	**Audit No 19**	
Revised:	12 June 2017	*Derek Lamb*	Page 1 of 10
Audit Date	8 Sept 20	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.	Infrastructs Doc index Issues
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.	Appraisals + feedback Issues Review meetings
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.	Tasks + Audit System Roles + responsibilities Infrastructs issues Doc index

VST Ltd ISO9001:2015 7.3	**Awareness** The organization shall ensure that persons doing work under the organization's control are aware of: 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.	Required Reading intrastats
Viamed Ltd ISO13485:2016 5.5.1	**Responsibility and authority** Top management shall ensure that responsibilities and authorities are defined, documented and communicated within the organization. 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.	Company Structure intrastats
Viamed Ltd ISO13485:2016 6.2	**Human resources** Personnel performing work affecting product quality shall be competent on the basis of appropriate education, training, skills and experience. The organization shall document the process(es) for establishing competence, providing needed training, and ensuring awareness of personnel. The organization shall: 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). 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.	Training manager Procedures Task + Audit System Roles + Responsibilities Personnel files Hard copy only GDPR
Viamed Ltd ISO13485:2016 6.3	**Infrastructure** 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. Infrastructure includes, as appropriate: a) buildings, workspace and associated utilities; b) process equipment (both hardware and software); c) supporting services (such as transport, communication, or information systems).	Infrastats procedures Issues

	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 affect product quality. As appropriate, the requirements shall apply to equipment used in production, the control of the work environment and monitoring and measurement. Records of such maintenance shall be maintained	
Viamed Ltd ISO13485:2016 6.4.1	**Work environment** The organization shall document the requirements for the work environment needed to achieve conformity to product requirements. 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. The organization shall: 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. NOTE Further information can be found in ISO 14644 and ISO 14698	feedback/ Issues Review meetings Appraisals.
Viamed Ltd ISO13485:2016 6.4.2	**Contamination control** 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. 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.	Procedure No Sterile products
Viamed Ltd ISO13485:2016 8.2.4	**Internal audit** The organization shall conduct internal audits at planned intervals to determine whether the quality management system: 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. The organization shall document a procedure to describe the responsibilities and requirements for planning and conducting audits and recording and reporting audit results. An audit program shall be planned, taking into consideration	Audit Calendar Doc index Task + Audit System

	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 auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work. 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). 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. NOTE Further information can be found in ISO 19011.	

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.

HSE Issue Not sent yet #198068 Delaying unit Return to work. Covid 19.

	QUESTION:	RESPONSE:	Y/N
1	Review Last years Audit. Update processes if required. Are all follow on Issue resolved satisfactory.	Nothing out standing	Y
2	Check that personnel are aware of the company's H & S policy.	#198069	Y
3	Is the policy readily accessible?	Intrastats	N/A Y
4	Check that new personnel have undergone induction checklist.	Mike Lamb	Y
5	Verify that existing personnel are still aware of locations for First aid and Fire extinguishers & exit routes. Task 12.	#157560	Y
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 No longer have products	NA
7	Check that personnel know where to retrieve information from the company manual.	Intrastats #198069	N/A Y
8	Check that the First aid accident book is reviewed and any action required is taken and recorded. Task 287. # 190643		Y
9	Verify that risk assessments are being carried out in a timely manner. Task 12.	Intrastats	N/A Y
10	Check that the Risk Assessment / Health and Safety report produced, detail all corrective actions required. Task 12. #157560	Audit 13	Y

11	Verify that the corrective actions are completed on time.	*Issues* (handwritten)	Y
12	Verify that these sheets are filed accordingly	Intrastats and Audit file	Y
13	Verify that any hazardous products are safely contained in storage. Check Chemicals cupboard, R+D room and workshop.		Y

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	Notes / Issues
PROCESSID 39 Ensure our Viamed Environment and WEEE Policys are upto date and suitable for current legislation	46 Company Secretary *# 196771*	*in terms*	Freq 1 Risk 0 Overall	Task 12M	
PROCESSID 7741 Review the current Ethical Policy in intrastats	47 Company Secretary *# 196772*		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 *# 174115* Secretary		Freq 1 Risk 1 Overall 1	Task 12M	
PROCESSID 5919 Check outside drain is not BLocked	431 *# 197463* 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 *# 196193* Company Secretary		Freq 3 Risk 1 Overall 3	Task 1M	
PROCESSID 7120 Review any General Maintenance required on the physical Site(s)	602 *# 189606* Company Secretary		Freq 2 Risk 1 Overall 2	Task 3M	
PROCESSID 7742 Get Boiler / Heating Checked / Serviced before Winter	7 *# Covid* Company Secretary *196069*		Freq 1 Risk 1 Overall 1	Task 12M	
PROCESSID 7756	117 *# 189448*		Freq 2	Task 6M	

Process Scope	Roll Task	Roll Audit	Risk	Action	Notes / Issues
Check Carbon Monoxide Alarm is working	Company Secretary		Risk 1 Overall 2		
PROCESSID **7820** The renewal of our waste transfer agreement with North Yorkshire County Couoncil	702 #166391 Company Secretary		Freq 1 Risk 2 Overall 2	Task 12M	
PROCESSID **7821** The renewal of our waste transfer agreement with our waste disposal companies	701 #162925 Company Secretary		Freq 1 Risk 2 Overall 2	Task 12M	
PROCESSID **7835** To get the Electrics checked by External Electriction, so certificate can be provided for Employee Safety	164 #158792 Managing Director		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 #197023 95 Production Processes #168827		Freq 2 Risk 1 Overall 2	Task 6M Audit 12M	
PROCESSID **7896** To Maintain the Tree in the Car Park	829 Company Secretary		Freq 1 Risk 1 Overall 1	Task 3M	

#198162

IT Controller

Process Scope	Roll Task	Roll Audit	Risk	Action	Notes / Issues
PROCESSID **45** Check the status of the Main Server	139 #195988 in terms		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 #197466	455 Company Secretary #184554	Freq 4 Risk 3 Overall 12	Task 2W Audit 12M	
PROCESSID **48** Internet Access for building(s)		#198302	Freq 2 Risk 1 Overall 2		
PROCESSID **49** Ensure Viamed Wifi is operational	415 #195832 Managing Director	416 Company Secretary	Freq 1 Risk 1 Overall 1	Task 1M Audit 3M	
PROCESSID **50** Backup Internet Connection	415 #195832 Managing Director	416 #198302 Company Secretary	Freq 3 Risk 1 Overall 3	Task 1M Audit 3M	
PROCESSID **51** Maintain working printers	#198472 in terms	#195831	Freq Risk Overall		
PROCESSID **5903** To record the daily barometric pressure	413 Managing	414 UK Sales	Freq 4 Risk 1	Task 1W Audit	

#198472 in terms #195831

		Director	Controller	Overall 4	1M	

PROCESSID **5941** To replace an ageing and or faulty Main server			Freq Risk Overall	

PROCESSID **7121**			Freq Risk Overall	

PROCESSID **7178**			Freq Risk Overall	

PROCESSID **7704** To Keep The computer systems running within the organisation. This is a reactionary process so there is no rolling tasks associated			Freq 3 Risk 1 Overall 3	

Health And Safety Controller

Process Scope	Roll Task	Roll Audit	Risk	Action	Notes / Issues
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	*194697* in forms	Freq 1 Risk 3 Overall 3	Task 12M	
PROCESSID **6855** Update the Site HSE file	12 *157560* Managing Director		Freq 1 Risk 1 Overall 1	Task 12M	
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 *195984* Company Secretary		Freq 2 Risk 4 Overall 8	Task 6M	
PROCESSID **7867** This is a check list to ensure safe use of the bandsaw	786 *173988* Production Processes		Freq 1 Risk 4 Overall 4	Task 6M	
PROCESSID **7868** This is a check list to ensure safe use of the Pillar Drill	787 *174177* Production Processes		Freq 1 Risk 4 Overall 4	Task 6M	
PROCESSID **7869** This is a check list to ensure safe use of the Hand	788 *157051* Production		Freq 1 Risk 3	Task 24M	

Drill	Processes	#16 99 50	Overall 3	
PROCESSID **7891** To test the evacuation of the buildings in case of fire # 192417	141 Company Secretary	952 Managing Director	Freq 1 Risk 4 Overall 4	Task 3M Audit 12M
PROCESSID **7928** To Test the Fire alarm glass boxes # 195412	609 Goods Out	953 #169816 Company Secretary	Freq 1 Risk 1 Overall 1	Task 1M Audit 12M
PROCESSID **7929** The regular review of the Emergency Lighting And Fire Extinguishers. # 197054	954 Goods Out	955 Company Secretary	Freq 3 Risk 3 Overall 9 # 174006	Task 1M Audit 12M

Warehouse Team Leader

Process Scope	Roll Task	Roll Audit	Risk	Action	Notes / Issues
PROCESSID **54** Bleech the Gents Toilets # 197445	125 Goods In	373 #196186 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 *in terms* *Soch left* # 198322	541 Goods In	424 #197460 *in terms*	Freq 4 Risk 1 Overall 4	Task 1W Audit 1M	
PROCESSID **5907** Cleaning of floors. Tidying so as to clean more effectively. *in terms* # 197913	543 Goods In	424 #197460 *in terms*	Freq 4 Risk 1 Overall 4	Task 1W Audit 1M	
PROCESSID **5908** Cleaning of floors. Tidying so as to clean more effectively. *in terms* #197883	423 Goods In	424 #197460 *in terms*	Freq 4 Risk 1 Overall 4	Task 1W Audit 1M	
PROCESSID **5909** Emptying of the waste bins into external bin for refuge collectors *in terms* #198693	542 Goods In	424 #197460 *in terms*	Freq 4 Risk 1 Overall 4	Task 1W Audit 1M	
PROCESSID **5910** Cleaning of duckets *in terms* # 198473	426 Goods In	424 #197460 *in terms*	Freq 4 Risk 1 Overall 4	Task 1W Audit 1M	
PROCESSID **5911** To remove and dispose of the cardboard with in the company #196603	427 Goods In	424 #197460 *in terms*	Freq 4 Risk 1 Overall 4	Task 2W Audit 1M	
PROCESSID **7687** Collecting, cleaning and returning duckets to Vandagraph. # 197896 *in terms*	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. # 196185	503 Goods In		Freq 4 Risk 1 Overall 4	Task 3W	

Audits

Process Scope	Roll Task	Roll Audit	Risk	Action	Notes / Issues

Process Scope	Roll Task	Roll Audit	Risk	Action	Notes / Issues
PROCESSID 7729 To carry out Audit 19 Health And Safety Viamed	# 192408	13 Company Secretary	Freq 1 Risk 2 Overall 2	Audit 12M	
PROCESSID 7777 To carry out Audit 19 Health And Safety VST	# 192419	186 Company Secretary	Freq 1 Risk 2 Overall 2	Audit 12M	

Data Protection Officer

Process Scope	Roll Task	Roll Audit	Risk	Action	Notes / Issues
PROCESSID 7910 To check the signs we have are appropriate, clear and positioned in the correct	910 # 197936 Company Secretary	✓	Freq 1 Risk 1 Overall 1	Task 12M	
PROCESSID 7911 Review Security Of The Special Category Personal Data	911 # 155750 Company Secretary	✓	Freq 1 Risk 2 Overall 2	Task 12M	

Office Processes

Process Scope	Roll Task	Roll Audit	Risk	Action	Notes / Issues
PROCESSID 5853 Ensure customer facing areas are vacuumed	# 197756 243 ✓ Office Processes	373 # 196189 Company Secretary	Freq 4 Risk 1 Overall 4	Task 1W Audit 1M	
PROCESSID 5856	227 # 197730 ✓	373 # 196186 Company Secretary	Freq Risk Overall	Audit 1M	
PROCESSID 5878 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	
PROCESSID 5900 Cleaning of surfaces, equipment, floors. Tidying so as to clean more effectively.	393 # 196787 Office Processes	394 # 196000 Company Secretary	Freq 3 Risk 1 Overall 3	Task 1M Audit 1M	
PROCESSID 5912 To put the bins out	107 # 194956 ✓ Company Secretary		Freq 3 Risk 1 Overall 3	Task 1M	
PROCESSID 7706 Updating of anti-virus software and scanning computers for viruses	519 # 197736 ✓ Office Processes		Freq 4 Risk 1 Overall 4	Task 1W	
PROCESSID 7802 Cleaning the kitchen surfaces to ensure they are fit for use	655 # 197720 ✓ Office Processes	# 191774 656 ✓ Office Processes	Freq 5 Risk 1 Overall 5	Task 1W Audit 2W	
PROCESSID 7803 To ensure crockery and cutlery is cleaned and fit for use	# 198477 657 ✓ Office Processes	# 197776 658 ✓ Office Processes	Freq 5 Risk 1 Overall 5	Task 1D Audit 1W	
PROCESSID 7804 To sweep the kitchen floor and clear and mess	659 Office # 197777 ✓	662 Company # 197779	Freq 4 Risk 1	Task 1W Audit	

ready for mopping	Processes	Secretary	Overall 4	1W	
PROCESSID **7805** Emptying of the recycling and waste bins into external bin for refuge collection Diasbled currently - have Global task on bins #197730	225 Office Processes	661	Freq 4 Risk 1 Overall 4	Task 1W	
PROCESSID **7806** To water the plants and ensure their survival	663 Office #197769 Processes	664	Freq 3 Risk 1 Overall 3	Task 1W	
PROCESSID **7910** To check the signs we have are appropriate, clear and positioned in the correct	910 Company Secretary #197936		Freq 1 Risk 1 Overall 1	Task 12M	

Human Resources

Process Scope	Roll Task	Roll Audit	Risk	Action	Notes / Issues
PROCESSID **7042**			Freq Risk Overall		
PROCESSID **7847** Perform HSE Risk Assessment, #157560 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.	12 Managing Director		Freq 1 Risk 1 Overall 1	Task 12M	