Internal Audit Check list							
HEALTH & SAFETY							
Created:	17/May 1995	Audit No 19					
Revised:	12 June 2017		Page 1 of 21				
Audit Date		Auditor					

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 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.	
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.	

Viamed Ltd	Human resources	
ISO13485:2016 6.2	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.	
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). 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	
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.	
Viamed Ltd	Internal audit	
ISO13485:2016 8.2.4	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 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.	

	QUESTION:	RESPONSE:	Y/ N
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	Brief Description	Responsibility/Pro cedure/Training	Measurable Objective	Task	Audit	Freq	Risk	Overall	Action
39 - History/Details Ensure our Viamed Environment and WEEE Policys are upto date and suitable for current legislation	Enviromental Policy Document Review	17472 Viamed Environment Policy Inc WEEE 17474 Vandagraph Environment Policy 17851 VST Environmental and Recycling Policy 27244 VOP 02 Personnel and Responsibility, Staff and Staffing Issues, Training, Roles and Tasks	Reviewed within the last 12 months	46 Managing Director		1	0		Task 12M
7741 - History/Details Review the current Ethical Policy in intrastats	Review Ethical Policy	14272 Viamed Ethical Policy 27337 VST Ethical Policy Vandagraph VST Sensors Ethics Ethical Policy 27244 VOP 02 Personnel and Responsibility, Staff and Staffing Issues, Training,	reviewed within the last year	47 Managing Director		1	1	1	Task 12M

Roles and Tasks

Health And Safety Controller

Process Scope	Brief Description	Responsibility/Pro cedure/Training	Measurable Objective	Task	Audit	Freq	Risk	Overall	Action
- History/Details 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.	First Aid	23316 VOP 16 Health and Safety, Company Personnel Manual	check the issues - first aider training still valid, accident book review has been carried out and any health and safety issue that have been put on the system in last 12 month or since last review	712 Company Secretary		1	3	3	Task 12M
6855 - History/Details Update the Site HSE file	Risk Assessment HSE	23316 VOP 16 Health and Safety, Company Personnel Manual 21800 VM3COP19 Health and Safety 27118 HSE Review Premises 27116 Fire risk assessment 15/17 Station Road		12 Managing Director		1	1	1	Task 12M
6856 - History/Details	Fire Alarms	23316 VOP 16 Health and Safety,	check the issues and the manual log book	· -		2	4	8	Task 6M

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		Company Personnel Manual		Secretary				
in. Tested by Keybury (alarms and emergency lights) annually and Airedale Fire protection (Fire extinguishers) annually. Evacuation Drills to check staff readiness.			to verify these have been carried out.					
7867 - History/Details This is a check list to ensure safe use of the bandsaw	Bandsaw Checklist	23316 VOP 16 Health and Safety, Company Personnel Manual		786 Production Processes	1	4	4	Task 6M
7868 - History/Details This is a check list to ensure safe use of the Pillar Drill	Pillar Drill Checklist	23316 VOP 16 Health and Safety, Company Personnel Manual		787 Production Processes	1	4	4	Task 6M
7869 - History/Details This is a check list to	Hand Drill Checklist	23316 VOP 16 Health and Safety, Company Personnel		788 Production Processes	1	3	3	Task 6M

ensure safe use of the Hand Drill	Ma	anual					
	vacuation Per rill Res Sta Issu	rsonnel and	141 Company Secretary	1	4	4	Task 3M

IT Controller

Process Scope	Brief Description	Responsibility/Pro cedure/Training	Measurable Objective	Task	Audit	Freq	Risk	Overall	Action
Check the status of the Main Server	Main Server Status	VM3COP60.05 Viamed Server Review 6294 VM3COP26.00 Changing MAIN Linux Server VMSERVERx 23322 VOP 11 Equipment Control, Office, Warehouse, Pcs and Equipment		139 Managing Director		3	3	9	Task 1M
Check the status of the Backup Server, is done at same time as primary server		20193 VM3COP60.00 Viamed Server Backup System 16432 VM3COP60.05	Check task history is being completed.	454 Managing Director	455 Company Secretary	4	3	12	Task 2W Audit 12M

48 Internet Access for building(s)	Internet	Viamed Server Review 23322 VOP 11 Equipment Control, Office, Warehouse, Pcs and Equipment 23322 VOP 11 Equipment Control, Office, Warehouse,				2	1	2	
		Pcs and Equipment							
49 Ensure Viamed Wifi is operational	Wifi	23322 VOP 11 Equipment Control, Office, Warehouse, Pcs and Equipment		415 Managing Director	416 Company Secretary	1	1	1	Task 1M Audit 3M
50 Backup Internet Connection	Guest Access Wifi	23322 VOP 11 Equipment Control, Office, Warehouse, Pcs and Equipment		415 Managing Director	416 Company Secretary	3	1	3	Task 1M Audit 3M
51 Maintain working printers	Printers	23322 VOP 11 Equipment Control, Office, Warehouse, Pcs and Equipment							
5903 To record the daily barometric pressure	Weather Station	23322 VOP 11 Equipment Control, Office, Warehouse, Pcs and Equipment	should be the correct	413 Managing Director	414 UK Sales Controller	4	1	4	Task 1W Audit 1M
5941 To replace an ageing and or faulty Main server	Replace Main Server	6294 VM3COP26.00 Changing MAIN Linux Server VMSERVERx							

		23322 VOP 11		
		Equipment Control,		
		Office, Warehouse,		
		Pcs and Equipment		
7121	General	23322 VOP 11		
	Computer	Equipment Control,		
	Maintenance	Office, Warehouse,		
		Pcs and Equipment		
7178	Systems	23322 VOP 11		
	Innovation	Equipment Control,		
		Office, Warehouse,		
		Pcs and Equipment		
7704	Computer	6724	3 1	3
To Keep The	Failure	VM3COP60.02		
computer systems	Diagnostics	Computer/System		
running within the	, and the second	Failure Diagnostics		
organisation.		8446		
		VM3COP60.03		
This is a reactionary		Computer Issues		
process so there is no		affecting all Clients		
rolling tasks associate	ed	8444		
		VM3COP60.01		
		Computer Issues		
		affecting Single		
		Client		
		23322 VOP 11		
		Equipment Control,		
		Office, Warehouse,		
		Pcs and Equipment		

Maintenance Controller

Process Scope	Brief Description	Responsibility/Pro cedure/Training	Measurable Objective	Task	Audit	Freq	Risk	Overall	Action
56 - History/Details Check the Boiler system before winter	Warehouse Outside Heating Guard	23316 VOP 16 Health and Safety, Company Personnel Manual	the gas man will check this when they come in to do a boiler safety check	85 Company Secretary		1	1	1	Task 12M
5919 - <i>History/Details</i> Check outside drain is not BLocked	Check Out Side Drain	23316 VOP 16 Health and Safety, Company Personnel Manual	have a look at the drains outside	431 Company Secretary		2	1	2	Task 3M
5921 - History/Details Check the Archives for Signs of Water, ensure the pump is working	Clearing Water Downstairs	23316 VOP 16 Health and Safety, Company Personnel Manual	have a look in archiving	433 Company Secretary		3	1	3	Task 1M
7120 - History/Details Review any General Maintenance required on the physical Site(s)	General Maintenance Requirements	23316 VOP 16 Health and Safety, Company Personnel Manual	look at the meeting General Maintenance and check they are up to date and reviewed	602 Company Secretary		2	1	2	Task 3M
7742 - History/Details Get Boiler / Heating Checked / Serviced before Winter	Boiler Check	23316 VOP 16 Health and Safety, Company Personnel Manual	the gas man comes in every 12 months, there is a sticker on the boiler where they sign and date this	7 Company Secretary		1	1	1	Task 12M
7756	Carbon	23316 VOP 16	this is now a 8 year	117		2	1	2	Task

- History/Details Check Carbon Monoxide Alarm is working	Monoxide Alarm	Health and Safety, Company Personnel Manual	battery so we can review the purchase date. Or the button on them can be tested	Company Secretary				6M
7820 - History/Details The renewal of our waste transfer agreement with North Yorkshire County Couoncil	North Yorkshire Council Waste Tranfer	20608 North Yorkshire Council waste tranfer note 23316 VOP 16 Health and Safety, Company Personnel Manual	this is initiated by the council, check the box file for most up to date waste transfer notice	702 Company Secretary	1	2	2	Task 12M
7821 - History/Details The renewal of our waste transfer agreement with our waste disposal companies	Controlled Waste Description And Transfer	20606 Biffa Controlled waste description and transfer note 23316 VOP 16 Health and Safety, Company Personnel Manual		701 Company Secretary	1	2	2	Task 12M
7835 - History/Details To get the Electrics checked by External Electriction, so certificate can be provided for Employee Safety	Electrics Need Checking	23316 VOP 16 Health and Safety, Company Personnel Manual		164 Managing Director	1	1	1	Task 48M
7836 - History/Details Reset the Heating for Winter	Central Heating For Winter	Health and Safety,	none - this is initiated by the external temperature and done when required		1	1	1	

7864 - History/Details Check the workshop benches ESD equipment is in place	ESD Work Stations	23615 VOP 07 Stock Control, Handling, Control of Labelling, Storage, Movement		94 Production Processes	95 Managing Director	2	1	2	Task 6M Audit 12M
7896 - History/Details To Maintain the Tree in the Car Park	Tree In Car Park	23326 VOP 18 Maintenance Building, Fabric and Infrastructure	None	829 Company Secretary		1	1	1	Task 3M

Warehouse Team Leader

Process Scope	Brief Description	Responsibility/Pro cedure/Training	Measurable Objective	Task	Audit	Freq	Risk	Overall	Action
54 Bleech the Gents Toilets	Gents Toilets	23326 VOP 18 Maintenance Building, Fabric and Infrastructure	none	125 Goods In	373 Company Secretary	3	1	3	Task 1M Audit 1M
5906 - History/Details Emptying of the recycling and waste bins into external bin for refuge collectors	Empty Paper Bins	23241 VM3COP20.38 Waste Removal / Bin Emptying 23326 VOP 18 Maintenance Building, Fabric and Infrastructure	Office recycle bins should be empty.	541 Goods In	424 Managing Director	4	1	4	Task 1W Audit 1M
5907History/DetailsCleaning of floors.Tidying so as to clean	Hoover Warehouse	23326 VOP 18 Maintenance Building, Fabric and Infrastructure	Floors should be reasonably clean	543 Goods In	424 Managing Director	4	1	4	Task 1W Audit 1M

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more effectively.									
5908 - <i>History/Details</i> Cleaning of floors. Tidying so as to clean more effectively.	Sweep Warehouse	23326 VOP 18 Maintenance Building, Fabric and Infrastructure	Floors should be reasonably clean	423 Goods In	424 Managing Director	4	1	4	Task 1W Audit 1M
5909 - <i>History/Details</i> Emptying of the waste bins into external bin for refuge collectors	Empty Warehouse Bins	23241 VM3COP20.38 Waste Removal / Bin Emptying 23326 VOP 18 Maintenance Building, Fabric and Infrastructure	Waste bins should be empty	542 Goods In	424 Managing Director	4	1	4	Task 1W Audit 1M
5910 - <i>History/Details</i> Cleaning of duckets	Clean Duckets	23326 VOP 18 Maintenance Building, Fabric and Infrastructure	duckets should be clean	426 Goods In	424 Managing Director	4	1	4	Task 1W Audit 1M
5911 - <i>History/Details</i> To remove and dispose of the cardboard with in the company	Clear Cardboard	23326 VOP 18 Maintenance Building, Fabric and Infrastructure	Cardboard should be in the recycling	427 Goods In	424 Managing Director	4	1	4	Task 2W Audit 1M
7687 - History/Details Collecting, cleaning and returning duckets to Vandagraph.	Vandagraph Duckets	23615 VOP 07 Stock Control, Handling, Control of Labelling, Storage, Movement		488 Goods In		4	1	4	Task 1W
7698 - History/Details	Clean Toilets	23326 VOP 18 Maintenance		503 Goods In		4	1	4	Task 3W

Cleaning of surfaces, equipment, floors.
Tidying so as to clean more effectively.

Building, Fabric and Infrastructure

Audits

Process Scope	Brief Description	Responsibility/Pro cedure/Training	Measurable Objective	Task	Audit	Freq	Risk	Overall	Action
7729 - History/Details To carry out Audit 19 Health And Safety Viamed	Audit 19 Health And Saftey Viamed	27178 VOP 13 Process Monitoring, System Reviews, Audits, Management Review, Analysis Data			13 Company Secretary	1	2	2	Audit 12M
7777 - History/Details To carry out Audit 19 Health And Safety VST	Audit 19 Health And Saftey VST	27178 VOP 13 Process Monitoring, System Reviews, Audits, Management Review, Analysis Data			186 Company Secretary	1	2	2	Audit 12M

Office Processes

Process Scope	Brief Description	Responsibility/Pro cedure/Training	Measurable Objective	Task	Audit	Freq	Risk	Overall	Action
5853	Vacuuming Of	18337		243	373	4	1	4	Task
- History/Details	The Office,	VM3COP20.44		Office	Company				1W
Ensure customer	Hall And	Cleaning the Office.		Processes	Secretary				Audit
facing areas are	Meeting Room	23326 VOP 18							1M

vacuumed		Maintenance Building, Fabric and Infrastructure						
5856 - History/Details	Cleaning The Kitchen	18333 VM3COP20.45 Cleaning the Kitchen 23326 VOP 18 Maintenance Building, Fabric and Infrastructure	227	373 Company Secretary				Audit 1M
5878 - History/Details Emptying of the recycling and waste bins into external bin for refuge collectors disabled for time being as covered by a global emptying of bins	Empty Office Bins	23241 VM3COP20.38 Waste Removal / Bin Emptying 23326 VOP 18 Maintenance Building, Fabric and Infrastructure	428	532	4	1	4	
5900 - History/Details Cleaning of surfaces, equipment, floors. Tidying so as to clean more effectively.	Cleaning Of Office Windows	18337 VM3COP20.44 Cleaning the Office. 23326 VOP 18 Maintenance Building, Fabric and Infrastructure	393 Office Processes	394 Company Secretary	3	1	3	Task 1M Audit 1M
5912 To put the bins out	Main Recycle Bins	23241 VM3COP20.38 Waste Removal /	107 Company Secretary		3	1	3	Task 1M

		Bin Emptying 23326 VOP 18 Maintenance							
		Building, Fabric and Infrastructure							
7706 - History/Details Updating of anti-virus software and scanning computers for viruses		23326 VOP 18 Maintenance Building, Fabric and Infrastructure 24710 VM3COP20.61 Scanning for Viruses and Malware		519 Office Processes		4	1	4	Task 1W
7802 - History/Details Cleaning the kitchen surfaces to ensure they are fit for use	Clean Kitchen Sides	23326 VOP 18 Maintenance Building, Fabric and Infrastructure		655 Office Processes	656 Office Processes	5	1	5	Task 1W Audit 2W
7803 - History/Details To ensure crockery and cutlery is cleaned and fit for use	Dishwashing	23326 VOP 18 Maintenance Building, Fabric and Infrastructure	Check the Task is being Completed off.	657 Office Processes	658 Office Processes	5	1	5	Task 1D Audit 1W
7804 - History/Details To sweep the kitchen floor and clear and mess ready for mopping	Sweep Kitchen Floor	23326 VOP 18 Maintenance Building, Fabric and Infrastructure 18333 VM3COP20.45 Cleaning the		659 Office Processes	662 Company Secretary	4	1	4	Task 1W Audit 1W

		Kitchen						
7805 - History/Details Emptying of the recycling and waste bins into external bin for refuge collection Diasbled currently - have Global task on bins	Empty Kitchen Bins	23241 VM3COP20.38 Waste Removal / Bin Emptying 23326 VOP 18 Maintenance Building, Fabric and Infrastructure 18333 VM3COP20.45 Cleaning the Kitchen	660	661	4	1	4	
7806 - History/Details To water the plants and ensure their survival	Watering Plants	23326 VOP 18 Maintenance Building, Fabric and Infrastructure	663 Office Processes	664	4	1	4	Task 1W

Human Resources

Process Scope	Brief Description	Responsibility/Pro cedure/Training	Measurable Objective	Task	Audit	Freq	Risk	Overall	Action
7042	Work Environment	27244 VOP 02 Personnel and Responsibility, Staff and Staffing Issues, Training, Roles and Tasks							
7847 - <i>History/Details</i> Perform HSE Risk	Health And Safety Review	23316 VOP 16 Health and Safety, Company Personnel		12 Managing Director		1	1	1	Task 12M

Assessment, Manual 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.