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

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 theperformance 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	

	effectivenessof 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 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.
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 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 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 Questionaire, and the

HSE DSE Personnel Questionaire

and reissue message of the day reminding users all HSE Documents are available in Intrastats

Review Last years Audit see if its still suitable

Before Proceeding you need to update the Processes attached to the Audit

Search the Document in the Index,

View the Admin Page

Copy and Paste the Attached Processes, replacing them in the current audit

Any non Conformances from the Audit:

Create a follow up / related Issue

With a time for Completion

Immediate Action Plan

Corrective Action Plan

Corrective Action

Confirmation of Resolution

if its a major / critical non conformance complete form QC 18.

	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	See Technical controller	
	equipment are reviewed for H & S implications.	for the list	
	This relates to Medical Products only.		
	See Technical controller for the list		
6	Check that personnel know where to retrieve information from the company	Intrastats	N/A
	manual.		
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.	Intrastats	N/A
	Task 12		
9	Check that the Risk Assessment / Health and Safety report produced, details all	Audit 13	
	corrective actions required. Task 12		
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/Procedure/T raining	Measurable Objective	Task	Audit Freq	Risk	Overall Action
39 - History/Details	Enviromental	17472 Viamed Environment	Reviewed within	46	1	0	Task
Ensure our Viamed	Policy	Policy Inc WEEE	the last 12 months	Managing			12M
Environment and	Document	17474 Vandagraph		Director			

WEEE Policys are upto date and suitable for current legislation	Review	Environment Policy 17851 VST Environmental and Recycling Policy 27244 VOP 02 Personnel and Responsibility, Staff and Staffing Issues, Training, Roles and Tasks					
7741 - History/Details Review the current Ethical Policy in intrastats		14272 Viamed Ethical Policy 27337 VST Ethical Policy Vandagraph VST Sensors Ethics Ethical Policy reviewed within 27244 VOP 02 Personnel and the last year Responsibility, Staff and Staffing Issues, Training, Roles and Tasks	47 Managing Director	1	1	1	Task 12M

Health And Safety Controller

Process Scope Brief Descriptio	Responsibility/Procedure/T raining	Measurable Objective	Task	Audit	Freq	Risk	Overall	Action
6849 - History/Details First Aid 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.	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	Secretary		1	3	3	Task 12M

6855 - History/Details Risk Update the Site HSE Assessment file 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		Managing Director	1	1	1	Task 12M
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.	23316 VOP 16 Health and Safety, Company Personnel Manual	check the issues and the manual log book to verify these have been carried out.	Company Secretary	2	4	8	Task 6M
7867 - History/Details Bandsaw This is a check list to Checklist ensure safe use of the bandsaw	23316 VOP 16 Health and Safety, Company Personnel Manual		786 Production Processes	1	4	4	Task 6M

7868 - History/Details Pillar Drill This is a check list to Checklist ensure safe use of the Pillar Drill	23316 VOP 16 Health and Safety, Company Personnel Manual	787 Production Processes	1	4	4	Task 6M
7869 - History/Details Hand Drill This is a check list to Checklist ensure safe use of the Hand Drill	23316 VOP 16 Health and Safety, Company Personnel Manual	788 Production Processes	1	3	3	Task 6M
7891 - History/Details Fire Alarm To test the evacuation Evacuation of the buildings in Drill case of fire	27244 VOP 02 Personnel and Responsibility, Staff and Staffing Issues, Training, Roles and Tasks	141 Company Secretary	1	4	4	Task 3M

IT Controller

Process Scope	Brief Description	Responsibility/Procedure/T raining	Measurable Objective	Task	Audit	Freq	Risk	Overall	Action
45 Check the status of the Main Server	Main Server e Status	16432 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	Backup e Server Status	20193 VM3COP60.00 Viamed Server Backup System 16432 VM3COP60.05 Viamed Server Review 23322 VOP 11 Equipment Control, Office, Warehouse,	Check task history is being completed.	454 Managing Director	455 Comp any Secre tary	4	3	12	Task 2W Audit 12M

48 Internet Access for building(s)	Internet	Pcs and Equipment 23322 VOP 11 Equipment Control, Office, Warehouse, Pcs and Equipment				2	1	2	
49 Ensure Viamed Wifi is operational	Wifi s	23322 VOP 11 Equipment Control, Office, Warehouse, Pcs and Equipment		415 Managing Director	416 Comp any Secre tary	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 Comp any Secre tary	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	Live date on the weather station should be the correct date	413 Managing Director	414 UK Sales Contr oller	4	1	4	Task 1W Audit 1M
5941 To replace an ageing and or faulty Main server	Replace Main Server	Changing MAIN Linux Server VMSERVERx 23322 VOP 11 Equipment Control, Office, Warehouse, Pcs and Equipment							
7121	General Computer Maintenance	23322 VOP 11 Equipment Control, Office, Warehouse, Pcs and Equipment							

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

Maintenance Controller

Process Scope	Brief Description	Responsibility/Procedure/T raining	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 - History/Details Check outside drain is not BLocked		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 - <i>History/Details</i> Check the Archives for Signs of Water,	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

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ensure the pump is working								
7120 - History/Details Review any General Maintenance required on the physical Site(s)	Maintenance	1 1	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
	Carbon Monoxide Alarm	23316 VOP 16 Health and Safety, Company Personnel Manual	this is now a 8 year battery so we can review the purchase date. Or the button on them can be tested	Company Secretary	2	1	2	Task 6M
waste transfer agreement with North	Yorkshire Council	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
waste transfer	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

companies 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 - <i>History/Details</i> Reset the Heating for Winter		23316 VOP 16 Health and Safety, Company Personnel Manual	none - this is initiated by the external temperature and done when required	211		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 Mana ging Direc tor	2	1	2	Task 6M Audit 12M
7896 - <i>History/Details</i> To Maintain the Tree in the 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/Procedure/T raining	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 Comp any	3	1	3	Task 1M Audit

				Secre tary			1M
5906 - History/Details Empty Pap Emptying of the Bins recycling and waste bins into external bin for refuge collectors	er 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 4 Mana ging Direc tor	1	4	Task 1W Audit 1M
5907 - <i>History/Details</i> Hoover Cleaning of floors. Warehouse Tidying so as to clean more effectively.	23326 VOP 18 Maintenance Building, Fabric and Infrastructure	Floors should be reasonably clean	543 Goods In	424 4 Mana ging Direc tor	1	4	Task 1W Audit 1M
5908 - History/Details Sweep Cleaning of floors. Warehouse Tidying so as to clean more effectively.	23326 VOP 18 Maintenance Building, Fabric and Infrastructure	Floors should be reasonably clean	423 Goods In	424 4 Mana ging Direc tor	1	4	Task 1W Audit 1M
5909 - History/Details Empty Emptying of the waste Warehouse bins into external bin Bins for refuge collectors	23241 VM3COP20.38 Waste Removal / Bin Emptying 23326 VOP 18 Maintenance Building, Fabric and Infrastructure	Waste bins should be empty	542 Goods In	424 4 Mana ging Direc tor	1	4	Task 1W Audit 1M
5910 - History/Details Clean Cleaning of duckets Duckets	23326 VOP 18 Maintenance Building, Fabric and Infrastructure	duckets should be clean	426 Goods In	424 4 Mana ging Direc tor	1	4	Task 1W Audit 1M
5911 - History/Details Clear To remove and Cardboard dispose of the cardboard with in the	23326 VOP 18 Maintenance Building, Fabric and Infrastructure	Cardboard should be in the recycling	427 Goods In	424 4 Mana ging Direc	1	4	Task 2W Audit 1M

company		tor				
7687 - History/Details Vandagraph	23615 VOP 07 Stock	488	4	1	4	Task
Collecting, cleaning Duckets	Control, Handling, Control of	Goods In				1W
and returning duckets	Labelling, Storage,					
to Vandagraph.	Movement					
7698 - History/Details Clean Toilets	23326 VOP 18 Maintenance	503	4	1	4	Task
Cleaning of surfaces,	Building, Fabric and	Goods In				3W
equipment, floors.	Infrastructure					
Tidying so as to clean						
more effectively.						

Audits

Process Scope	Brief Description	Responsibility/Procedure/T raining	Measurable Objective	Task	Audit	Freq	Risk	Overall	Action
7729 - History/Details	Audit 19	27178 VOP 13 Process			13	1	2	2	Audit
To carry out Audit 19	Health And	Monitoring, System Reviews,			Comp				12M
Health And Safety	Saftey	Audits, Management Review,			any				
Viamed	Viamed	Analysis Data			Secre				
					tary				
7777 - History/Details	Audit 19	27178 VOP 13 Process			186	1	2	2	Audit
To carry out Audit 19	Health And	Monitoring, System Reviews,			Comp				12M
Health And Safety	Saftey VST	Audits, Management Review,			any				
VST		Analysis Data			Secre				
					tary				

Office Processes

Process Scope	Brief Description	Responsibility/Procedure/T raining	Measurable Objective	Task	Aud	it Fre	q Risk	Overal	Action
5853 - History/Details	y Vacuuming	18337 VM3COP20.44		243	373	4	1	4	Task
Ensure customer	Of The	Cleaning the Office.		Office	Con	ıp			1W

facing areas are vacuumed	Room	23326 VOP 18 Maintenance Building, Fabric and Infrastructure	Processes	any Secre tary				Audit 1M
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	Empty Office Bins	23241 VM3COP20.38 Waste Removal / Bin Emptying 23326 VOP 18 Maintenance Building, Fabric and Infrastructure	428	532	4	1	4	
disabled for time being as covered by a global emptying of bins								
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		1	3	Task 1M Audit 1M
5912 To put the bins out	Main Recycle Bins	23241 VM3COP20.38 Waste Removal / Bin Emptying 23326 VOP 18 Maintenance Building, Fabric and Infrastructure	107 Company Secretary		3	1	3	Task 1M
7706 - <i>History/Details</i> Updating of anti-virus software and scanning	Software And	23326 VOP 18 Maintenance Building, Fabric and Infrastructure	519 Office Processes		4	1	4	Task 1W

computers for viruses Viruses	24710 VM3COP20.61 Scanning for Viruses and Malware							
7802 - History/Details Clean Cleaning the kitchen Kitchen Side surfaces to ensure they are fit for use	23326 VOP 18 Maintenance as Building, Fabric and Infrastructure		655 Office Processes	656 Offic e Proce sses	5	1	5	Task 1W Audit 2W
7803 - History/Details Dishwashing To ensure crockery and cutlery is cleaned and fit for use	23326 VOP 18 Maintenance Building, Fabric and Infrastructure	Check the Task is being Completed off.	657 Office Processes	658 Offic e Proce sses	5	1	5	Task 1D Audit 1W
7804 - History/Details Sweep To sweep the kitchen Kitchen Floor floor and clear and mess ready for mopping	23326 VOP 18 Maintenance or Building, Fabric and Infrastructure 18333 VM3COP20.45 Cleaning the Kitchen		659 Office Processes	662 Company Secretary		1	4	Task 1W Audit 1W
7805 - History/Details Empty Emptying of the Kitchen Bins recycling and waste bins into external bin for refuge collection Diasbled currently -	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	
have Global task on bins	Creaming the Kitchen							
7806 - History/Details Watering To water the plants Plants and ensure their survival	23326 VOP 18 Maintenance Building, Fabric and Infrastructure		663 Office Processes	664	4	1	4	Task 1W

Human Resources

Process Scope	Brief Description	Responsibility/Procedure/T raining	Measurable Objective	Task	Audit F	req	Risk	Overa	all Action
7042	Work	27244 VOP 02 Personnel and							
	Environment	Responsibility, Staff and							
		Staffing Issues, Training,							
		Roles and Tasks							
7847 - History/Details	Health And	23316 VOP 16 Health and		12	1		1	1	Task
Perform HSE Risk	Safety	Safety, Company Personnel		Managing					12M
Assessment,	Review	Manual		Director					

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.