

Internal Audit Check list

VIAMED LTD

HEALTH AND SAFETY, WORKING CONDITIONS AND BUILDING FABRIC ISSUES

Created:	17/May 1995	Audit No 19	
		M Lamb	Page 1 of 11
Audit Date	19-8-21	Auditor H. LAMB	

Company / ISO Section	Criteria of ISO Section	Auditor Comments / Issues
Viamed Ltd ISO13485:2016 5.5.1	<p>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.</p>	Roles + titles Doc index Management Review
Viamed Ltd ISO13485:2016 6.2	<p>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.</p>	Management Review Roles + titles Training Records Doc index
Viamed Ltd ISO13485:2016 6.3	<p>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</p>	Doc index Management Review Procedure HS Review

	<p>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>	
Viamed Ltd ISO13485:2016 6.4.1	<p>Work environment</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"> 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. <p>NOTE Further information can be found in ISO 14644 and ISO 14698</p>	<p>Doc index CPM Training Records It's Review Management Review</p>
Viamed Ltd ISO13485:2016 6.4.2	<p>Contamination control</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>Doc index Roles titles Procedures</p>
Viamed Ltd ISO13485:2016 8.2.4	<p>Internal audit</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"> 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. <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</p>	<p>Doc index Audit Calendar Route map Roles + titles Management Review</p>

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	<p>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).</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.

	<u>QUESTION:</u>	<u>RESPONSE:</u>	Y/N
1	Review Last years Audit. Update processes if required. Are all follow on Issue resolved satisfactory.	Nothing outstanding	Y
2	Check that personnel are aware of the company's H & S policy.	ISSUE 338560 Sent	Y
3	Is the policy readily accessible?	Intrastats	N/A X
4	Check that new personnel have undergone induction checklist.		Y
5	Verify that existing personnel are still aware of locations for First aid and Fire extinguishers & exit routes. Task 12. — ISSUE 310805 ✓		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	Y
7	Check that personnel know where to retrieve information from the company manual.	Intrastats	N/A Y
8	Check that the First aid accident book is reviewed and any action required is taken and recorded. Task 287.	ISSUE - 335344 ✓	Y
9	Verify that risk assessments are being carried out in a timely manner. Task 12.	Intrastats ISSUE 310805 ✓	N/A Y
10	Check that the Risk Assessment / Health and Safety report produced, detail all corrective actions required. Task 12. — ISSUE 310805 ✓	Audit 13	Y
11	Verify that the corrective actions are completed on time.		Y

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

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Managing Director		Roll Task Roll Audit	Risk	Action	*	Notes
Process Scope						
PROCESSID 39 Ensure our Viamed Environment and WEEE Policies are upto date and suitable for current legislation		Task: 46 Company Secretary Audit : 306632 ✓	Freq 1 Risk 2 Overall 2	Task 12M		
PROCESSID 7741 Review the current Ethical Policy in intrastats		Task: 47 366637 ✓ Company Secretary Audit :	Freq 1 Risk 1 Overall 1	Task 12M		
IT Controller						
Process Scope		Roll Task Roll Audit	Risk	Action	*	Notes
PROCESSID 45 Check the status of the Main Server		Task: 139 337076 ✓ Office Processes Audit : 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		Task: 454 338219 Office Processes ✗ Audit : 455 in terms Company Secretary	Freq 1 Risk 3 Overall 3	Task 2W Audit 12M		
PROCESSID 49 Ensure Viamed Wifi is operational		Task: 415 329987 ✓ Managing Director	Freq 1 Risk 1 Overall	Task 1M Audit 3M		

	Audit :416 337092 Company Secretary ✓	1			
PROCESSID 50 Backup Internet Connection	Task: 415 329982 Managing Director ✓ Audit :416 333178 Company Secretary	Freq 3 Risk 1 Overall 3	Task 1M Audit 3M		
PROCESSID 5903 To record the daily barometric pressure	Task: 413 338216✓ Managing Director Audit :414 337091✓ Company Secretary	Freq 4 Risk 1 Overall 4	Task 1W Audit 1M		
Maintenance Controller					
Process Scope	Roll Task Roll Audit	Risk	Action	*	Notes
PROCESSID 56 Check the Boiler system before winter	Task: 85 326817✓ Company Secretary Audit :	Freq 1 Risk 1 Overall 1	Task 12M		
PROCESSID 5919 Check outside drain is not Blocked	Task: 431 335549✓ Company Secretary Audit :	Freq 2 Risk 1 Overall 2	Task 3M		
PROCESSID 5921 Check the Archives for Signs of Water, ensure the pump is working	Task: 433 337599✓ Company Secretary Audit :	Freq 2 Risk 1 Overall 2	Task 1M		
PROCESSID 7120 Review any General Maintenance required on the physical Site(s)	Task: 602 Company Secretary 334558✓ Audit :	Freq 2 Risk 1 Overall 2	Task 3M		
PROCESSID 7742 Get the gas Boilers and Hive thermostat Serviced and the Heating Checked before Winter.	Task: 7 334815✓ Company Secretary Audit :	Freq 1 Risk 2 Overall 2	Task 12M		
PROCESSID 7756 Check Carbon Monoxide Alarm is working	Task: 117 334354✓ Company Secretary Audit :	Freq 2 Risk 1 Overall 2	Task 6M		
PROCESSID 7820 The renewal of our waste transfer agreement with North Yorkshire County Couoncil	Task: 702 321481✓ Company Secretary Audit :	Freq 1 Risk 2 Overall 2	Task 12M		
PROCESSID 7821 The renewal of our waste transfer agreement with our waste disposal companies	Task: 701 318284✓ Company Secretary	Freq 1 Risk 2 Overall	Task 12M		

	Audit :	2		
PROCESSID 7835 To get the Electrics checked by External Electricity, so certificate can be provided for Employee Safety	Task: 164 Company Secretary Audit : <i>322187</i>	Freq 1 Risk 1 Overall 1	Task 48M	
PROCESSID 7836 Reset the Heating for Winter	Task: 211 Audit :	Freq 1 Risk 1 Overall 1		
PROCESSID 7864 Check the workshop benches ESD equipment is in place	Task: 94 <i>323689</i> ✓ Production Processes Audit :95 Office Processes	Freq 2 Risk 1 Overall 2	Task 6M Audit 12M	
PROCESSID 7896 To Maintain the Tree in the Car Park	Task: 829 Company Secretary <i>333226</i> ✓ Audit :	Freq 1 Risk 3 Overall 3	Task 3M	
PROCESSID 7961 To Clean Tidy the research and development rooms	Task: 540 Production Processes <i>338113</i> ✓ Audit :1058 <i>336996</i> ✓ Director 3 (Steve)	Freq 1 Risk 1 Overall 1	Task 1W Audit 1M	
PROCESSID 7999 To review the physical buildings health and safety, and fire risk assessments.	Task: 1143 <i>320273</i> ✓ Managing Director Audit :1144 <i>322435</i> ✓ Company Secretary	Freq 1 Risk 2 Overall 2	Task 24M Audit 24M	
PROCESSID 8038 Defrost Fridge / Freezer	Task: 72 Goods Out <i>331486</i> ✓ Audit :	Freq 1 Risk 1 Overall 1	Task 3M	
PROCESSID 8039 Weee Report Due Vandagraph Annual	Task: 77 <i>316313</i> ✓ Managing Director ✓ Audit :	Freq 1 Risk 1 Overall 1	Task 12M	
PROCESSID 8043 Turn off outside tap on the warehouse for winter	Task: 102 <i>311112</i> ✓ Company Secretary Audit :	Freq 1 Risk 2 Overall 2	Task 12M	
PROCESSID 8045 Radiators - Bleed radiators in Vandagraph Room in Warehouse and loft in offices. Check they are heating up fully	Task: 129 <i>305264</i> ✓ Office Processes ✓ Audit :	Freq 1 Risk 1 Overall 1	Task 12M	
PROCESSID 8047 Electric Testing - 5 yearly electric testing due on Warehouse and main office	Task: 145 <i>155101</i> ✓ Company Secretary	Freq 1 Risk 3 Overall	Task 60M	

	Audit :	3			
PROCESSID 8048 Workshop toilet is to be cleaned and rubbish to be binned	Task: 163 Production Processes 337078✓ Audit :	Freq 1 Risk 1 Overall 1	Task 1M		
Health And Safety Controller					
Process Scope	Roll Task Roll Audit	Risk	Action	*	Notes
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.	Task: 712 Company Secretary 304599✓ Audit :	Freq 1 Risk 3 Overall 3	Task 12M		
PROCESSID 6855 Update the Site HSE file. Ensure staff are aware of this and the location of HSE equipment	Task: 12 Company Secretary 310805✓ Audit :	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.	Task: 52 Company Secretary 322549✓ Audit :	Freq 1 Risk 3 Overall 3	Task 6M		
PROCESSID 7867 This is a check list to ensure safe use of the bandsaw BANDSAW HAS BEEN REMOVED, PROCESS CAN BE CLOSED / TASKS CLOSED	Task: 786 Audit :	Freq 1 Risk 1 Overall 1			
PROCESSID 7868 This is a check list to ensure safe use of the Pillar Drill	Task: 787 326984✓ Production Processes Audit :	Freq 1 Risk 3 Overall 3	Task 6M		
PROCESSID 7869 This is a check list to ensure safe use of the Hand Drill	Task: 788 309902✓ Production Processes Audit :	Freq 1 Risk 3 Overall 3	Task 24M		
PROCESSID 7891 To test the evacuation of the buildings in case of fire	Task: 141 336819 X Company Secretary Audit : 952 Managing Director 324246✓	Freq 1 Risk 3 Overall 3	Task 3M Audit 12M		

PROCESSID 7928 To Test the Fire alarm glass boxes	Task: 609 Goods Out Audit :953 Company Secretary	324246 ✓ 324111✓	Freq 1 Risk 1 Overall 1	Task 1M Audit 12M		
PROCESSID 7929 The regular review of the Emergency Lighting And Fire Extinguishers.	Task: 954 Goods Out Audit :955 Company Secretary	338250 ✓ 3 326723✓	Freq 1 Risk 3 Overall 3	Task 1M Audit 12M		
PROCESSID 8044 Carry out global PAT testing	Task: 127 Managing Director Audit :	275372	Freq 1 Risk 1 Overall 1	Task 60M		
Warehouse Team Leader						
Process Scope	Roll Task Roll Audit		Risk	Action	*	Notes
PROCESSID 54 Bleech the Gents Toilets	Task: 125		Freq 3 Risk 1 Overall	Audit 1M		
Process no longer required no urinal	Audit :373 Company Secretary	337594✓ 3				
PROCESSID 5906 Emptying of the recycling and waste bins into external bin for refuge collectors	Task: 541 Goods In Audit :424 Office Processes	338114✓ 338450 x in terms	Freq 1 Risk 1 Overall 1	Task 1W Audit 1M		
PROCESSID 5907 Cleaning of floors. Tidying so as to clean more effectively.	Task: 543 Goods In Audit :424 Office Processes	338471✓ 338450 x in terms	Freq 1 Risk 1 Overall 1	Task 1W Audit 1M		
PROCESSID 5908 Cleaning of floors. Tidying so as to clean more effectively.	Task: 423 Goods In Audit :424 Office Processes	338449✓ 338450 x in terms	Freq 1 Risk 1 Overall 1	Task 1W Audit 1M		
PROCESSID 5909 Emptying of the waste bins into external bin for refuge collectors	Task: 542 Goods In Audit :424 Office Processes	338232✓ 338450 x in terms	Freq 1 Risk 1 Overall 1	Task 1W Audit 1M		
PROCESSID 5910 Cleaning of duckets	Task: 426 Goods In Audit :424 Office Processes	338217✓ 338450 x in terms	Freq 1 Risk 1 Overall 1	Task 1W Audit 1M		

PROCESSID 5911 To remove and dispose of the cardboard within the company	Task: 427 Goods In 337721 ✓ Audit :424 Office Processes 338450 x	Freq 1 Risk 1 Overall 1	Task 2W Audit 1M	interns	
PROCESSID 7687 Collecting, cleaning and returning duckets to Vandagraph.	Task: 488 Goods In 338459 ✓ Audit :	Freq 1 Risk 1 Overall 1	Task 1W		
PROCESSID 7698 Cleaning of surfaces, equipment, floors. Tidying so as to clean more effectively.	Task: 503 Goods In 337354 x Audit : in terms	Freq 1 Risk 1 Overall 1	Task 3W		
Human Resources					
Process Scope	Roll Task Roll Audit	Risk	Action	*	Notes
PROCESSID 7847 Perform HSE Risk Assessment, Re issue Message of the Day or send company issue 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. Check the health and safety signage	Task: 12 30805 ✓ Company Secretary Audit :1071 Managing Director 316319 ✓	Freq 1 Risk 1 Overall 1	Task 12M Audit 12M		
PROCESSID 7982 To Check online and see if there have been any changes to Minimum wage or employment law we need to be aware of.	Task: 1107 321592 ✓ Company Secretary Audit :1109 288809 ✓ Managing Director	Freq 1 Risk 1 Overall 1	Task 12M Audit 24M		
Data Protection Officer					
Process Scope	Roll Task Roll Audit	Risk	Action	*	Notes
PROCESSID 7910 To check the signs we have are appropriate,	Task: 910 307259 ✓ Company Secretary	Freq 1 Risk 1	Task 12M		

clear and positioned in the correct	Audit :	Overall 1			
PROCESSID 7911 Review Security Of The Special Category Personal Data	Task: 911 Company Secretary Audit : <i>308139</i>	Freq 1 Risk 2 Overall 2	Task 12M		
Audits					
Process Scope	Roll Task Roll Audit	Risk	Action	*	Notes
PROCESSID 7729 To carry out Audit 19 Health And Safety Viamed	Task: <i>336814</i> Audit :13 <i>in terms</i> Company Secretary	Freq 1 Risk 2 Overall 2	Audit 12M		
PROCESSID 7777 To carry out Audit 19 Health And Safety VST	Task: <i>336820</i> Audit :186 <i>in terms</i> Company Secretary	Freq 1 Risk 2 Overall 2	Audit 12M		
Office Processes					
Process Scope	Roll Task Roll Audit	Risk	Action	*	Notes
PROCESSID 5853 Ensure customer facing areas are vacuumed	Task: 243 <i>338348</i> Office Processes ✓ Audit :373 <i>337594</i> Company Secretary	Freq 1 Risk 1 Overall 1	Task 1W Audit 1M		
PROCESSID 5856 to clean the kitchen, work tops and floor. make sure it is safe for people to use	Task: 227 <i>337594</i> Audit :373 <i>337594</i> Company Secretary	Freq 1 Risk 1 Overall 1	Audit 1M		
PROCESSID 5878 Emptying of the recycling and waste bins into external bin for refuge collectors	Task: 225 <i>338347</i> Office Processes <i>in terms</i> Audit :532 <i>337988</i>	Freq 1 Risk 1 Overall 1	Task 1W		
PROCESSID 5900 Cleaning of surfaces, equipment, floors. Tidying so as to clean more effectively.	Task: 393 <i>337988</i> Office Processes ✓ Audit :394 <i>337449</i> Company Secretary	Freq 3 Risk 1 Overall 3	Task 1M Audit 1M		
PROCESSID 5912 To put the recycling bins out	Task: 107 <i>337986</i> Goods Out ✓ Audit :	Freq 3 Risk 1 Overall 3	Task 2W		

PROCESSID 7706 Updating of anti-virus software and scanning computers for viruses	Task: 519 Office Processes Audit: 338363 X	Freq 2 Risk 2 Overall 4	Task 1W	
PROCESSID 7802 Cleaning the kitchen surfaces to ensure they are fit for use	Task: 655 in terms. Office Processes Audit: 656 in term Office Processes	Freq 1 Risk 1 Overall 1	Task 1W Audit 2W	
PROCESSID 7803 To ensure crockery and cutlery is cleaned and fit for use	Task: 657 Office Processes Audit: 658 338241 Office Processes	Freq 1 Risk 1 Overall 1	Task 1W Audit 1M	
PROCESSID 7804 To sweep the kitchen floor and clear and mess ready for mopping	Task: 659 Office Processes Audit: 662 338380 X Company Secretary 336983 ✓	Freq 1 Risk 1 Overall 1	Task 1W Audit 1M	
PROCESSID 7805 Emptying of the recycling and waste bins into external bin for refuge collection	Task: 225 338347 Office Processes X Audit: 661 - in terms	Freq 1 Risk 1 Overall 1	Task 1W	
PROCESSID 7806 To water the plants and ensure their survival	Task: 663 Company Secretary 338381 ✓ Audit: 664	Freq 1 Risk 1 Overall 1	Task 1W	
PROCESSID 7910 To check the signs we have are appropriate, clear and positioned in the correct	Task: 910 Company Secretary 307250 . Audit:	Freq 1 Risk 1 Overall 1	Task 12M	

Rolling Tasks Linked to Document : Task (13) Task (243) Task (227) Task (225) Task (393) Task (107) Task (519) Task (655) Task (657) Task (659) Task (663) Task (186) Task (125) Task (541) Task (543) Task (423) Task (542) Task (426) Task (427) Task (488) Task (503) Task (712) Task (12) Task (52) Task (85) Task (431) Task (433) Task (602) Task (7) Task (117) Task (702) Task (701) Task (139) Task (454) Task (415) Task (413) Task (164) Task (211) Task (94) Task (46) Task (47) Task (786) Task (787) Task (788) Task (141) Task (829) Task (609) Task (954) Task (910) Task (911) Task (540) Task (1107) Task (1143) Task (72) Task (77) Task (102) Task (129) Task (145) Task (163) Task (127)