

named + VST

# Internal Audit Check list

## HEALTH & SAFETY

Created:	17/May 1995	Audit No 19	
Revised:	12 June 2017		Page 1 of 11
Audit Date	23-8-21	Auditor	Helen Lamb DEREK Lamb

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.	Issues + Reviews
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.	Reviews Issues
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.	Training Records Infrastructure
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>Doc index Wt stats</p>
<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>Rolling tasks crag chart</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>Reviews</p> <p>Training Records</p> <p>Rolling Tasks + Audits</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>Doc index Infrastructure</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>	Doc index Issues
<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> <p>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;</p> <p>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> <p>NOTE Further information can be found in ISO 14644 and ISO 14698</p>	<p>H + S Review annually</p> <p>Procedures</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>Procedures</p> <p>No sterile</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> <p>a) conforms to planned and documented arrangements, requirements of this International Standard, quality management system requirements established by the organization, and applicable regulatory requirements;</p> <p>b) is effectively implemented and maintained.</p> <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>audit calendar intervals</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>	Doc index
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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.

		#233521 ISSUES Sent #233540	
	QUESTION:	RESPONSE:	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.	#233521	Y
3	Is the policy readily accessible?	Intrastats Doc index	N/A
4	Check that new personnel have undergone induction checklist.	No New staff	Y
5	Verify that existing personnel are still aware of locations for First aid and Fire extinguishers & exit routes. Task 12.	Done May 21 #202901	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 New Equipment only bring in other companies CE products	N/A
7	Check that personnel know where to retrieve information from the company manual.	Intrastats Doc index	N/A Y
8	Check that the First aid accident book is reviewed and any action required is taken and recorded. Task 287.	#229264	Y
9	Verify that risk assessments are being carried out in a timely manner. Task 12.	Intrastats #202901	N/A Y
10	Check that the Risk Assessment / Health and Safety report produced, detail all corrective actions required. Task 12.	Audit 13 #202901	Y
11	Verify that the corrective actions are completed on time.		Y

BSI Minors completed with in Required time scale  
checked QC 17 Audit issues too.



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

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 19677 ✓ Company Secretary		Freq 1 Risk 0 Overall	Task 12M	
PROCESSID 7741 Review the current Ethical Policy in intrastats	47 19677 ✓ Company Secretary		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 21980 ✓ Company Secretary		Freq 1 Risk 1 Overall 1	Task 12M	
PROCESSID 5919 Check outside drain is not BLocked	431 22606 ✓ 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 23178 ✓ Company Secretary		Freq 3 Risk 1 Overall 3	Task 1M	
PROCESSID 7120 Review any General Maintenance required on the physical Site(s)	602 22838 ✓ Company Secretary		Freq 2 Risk 1 Overall 2	Task 3M	
PROCESSID 7742 Get Boiler / Heating Checked / Serviced	7 22816 ✓ Company		Freq 1 Risk 1	Task 12M	

before Winter

### PROCESSID 7756

Check Carbon Monoxide Alarm is working

Secretary Overall  
1  
117 228027 ✓ Freq 2 Task 6M  
Company Risk 1  
Secretary Overall

### PROCESSID 7820

The renewal of our waste transfer agreement with North Yorkshire County Council

2  
702 214530 ✓ Freq 1 Task 12M  
Company Risk 2  
Secretary Overall

### PROCESSID 7821

The renewal of our waste transfer agreement with our waste disposal companies

2  
701 211609 ✓ Freq 1 Task 12M  
Company Risk 2  
Secretary Overall

### PROCESSID 7835

To get the Electrics checked by External Electrician, so certificate can be provided for Employee Safety

164 1587922 ✓ Freq 1 Task 48M  
Managing Risk 1  
Director Overall

### PROCESSID 7836

Reset the Heating for Winter

211 Freq 1  
Risk 1  
Overall

### PROCESSID 7864

Check the workshop benches ESD equipment is in place

94 216499 ✓ 95 216520 ✓ Freq 2 Task 6M  
Production Office Risk 1 Audit 12M  
Processes Processes Overall

### PROCESSID 7896

To Maintain the Tree in the Car Park

829 226557 ✓ Freq 1 Task 3M  
Company Risk 1  
Secretary Overall

### PROCESSID 7961

To Clean Tidy the r and D rooms

540 232875 ✓ 1058 230871 ✓ Freq 1 Task 1W  
Production Manag Risk 1 Audit 1M  
Processes ing Overall  
Processes Direct 1  
or

## IT Controller

### Process Scope

#### PROCESSID 45

Check the status of the Main Server

Roll Task Roll Risk Action Notes /  
Audit Issues  
139 231370 ✓ Freq 3 Task 1M  
Office Risk 3  
Processes Overall

#### PROCESSID 46

Check the status of the Backup Server,

is done at same time as primary server

in terms 454 233002 ✓ 455 232997 ✓ Freq 4 Task 2W  
Office Comp Risk 3 Audit 12M  
Processes any Overall  
Secret 12

PROCESSID 49  
Ensure Viamed Wifi is operational

PROCESSID 50  
Backup Internet Connection

PROCESSID 5903  
To record the daily barometric pressure

## Health And Safety Controller

### Process Scope

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.

PROCESSID 6855  
Update the Site HSE file

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.

PROCESSID 7867  
This is a check list to ensure safe use of the bandsaw

PROCESSID 7868  
This is a check list to ensure safe use of the Pillar Drill

PROCESSID 7869  
This is a check list to ensure safe use of the Hand Drill

415	Managing Director	226669	ary	416	Comp any Secret 1	Freq 1 Risk 1 Overall	Task 1M Audit 3M
242	415 ✓	226669	ary	416	Comp any Secret 3	Freq 3 Risk 1 Overall	Task 1M Audit 3M
8 ✓	413	231241	ary	414	UK Sales Contro ller	Freq 4 Risk 1 Overall 4	Task 1W Audit 1M
	Managing Director						
				</			



**PROCESSID 7891**

To test the evacuation of the buildings in case of fire

**PROCESSID 7928**

To Test the Fire alarm glass boxes

**PROCESSID 7929**

The regular review of the Emergency Lighting And Fire Extinguishers.

Processes 141 952 3 217216 ✓  
 Company Manag Risk 4 Audit 12M  
 Secretary ing Overall  
 Direct 4  
 or 217215  
 609 953 Freq 1 Task 1M  
 Goods Comp Risk 1 Audit 12M  
 Out any Overall  
 Secret 1  
 232580 219883  
 954 955 Freq 3 Task 1M  
 Goods Comp Risk 3 Audit 12M  
 Out any Overall  
 Secret 9  
 ary

**Warehouse Team Leader****Process Scope****PROCESSID 54**

Bleech the Gents Toilets

**PROCESSID 5906**

Emptying of the recycling and waste bins into external bin for refuge collectors

**PROCESSID 5907**

Cleaning of floors. Tidying so as to clean more effectively.

**PROCESSID 5908**

Cleaning of floors. Tidying so as to clean more effectively.

**PROCESSID 5909**

Emptying of the waste bins into external bin for refuge collectors

**PROCESSID 5910**

Cleaning of duckets

**PROCESSID 5911**

To remove and dispose of the cardboard with in the company

Roll	Task	Roll	Risk	Action	Notes / Issues
232107 ✓	125	373	Freq 3	Task 1M	
	Goods In	Comp	Risk 1	Audit 1M	
		any	Overall		
		Secret 3			
232901 ✓	541	424	Freq 4	Task 1W	
	Goods In	Office	Risk 1	Audit 1M	
		Proces	Overall		
		ses			
233283 ✓	543	424	Freq 4	Task 1W	
	Goods In	Office	Risk 1	Audit 1M	
		Proces	Overall		
		ses			
233255 ✓	423	424	Freq 4	Task 1W	
	Goods In	Office	Risk 1	Audit 1M	
		Proces	Overall		
		ses			
233021 ✓	542	424	Freq 4	Task 1W	
	Goods In	Office	Risk 1	Audit 1M	
		Proces	Overall		
		ses			
232999 ✓	426	424	Freq 4	Task 1W	
	Goods In	Office	Risk 1	Audit 1M	
		Proces	Overall		
		ses			
232632 ✓	427	424	Freq 4	Task 2W	
	Goods In	Office	Risk 1	Audit 1M	



PROCESSID 7687  
Collecting, cleaning and returning duckets to Vandagraph.

488  
Goods In

Processes 4  
Freq 4 Task 1W  
Risk 1  
Overall

PROCESSID 7698  
Cleaning of surfaces, equipment, floors. Tidying so as to clean more effectively.

503  
Goods In

23267  
231974 in terms  
Freq 4 Task 3W  
Risk 1  
Overall 4

## Audits

### Process Scope

PROCESSID 7729  
To carry out Audit 19 Health And Safety Viamed

Roll Task Roll Audit Risk Action Notes / Issues  
230175 13 Freq 1 Audit 12M  
Comp Risk 2  
any Overall  
Secret 2

This Audit in terms

PROCESSID 7777  
To carry out Audit 19 Health And Safety VST

230182 186 Freq 1 Audit 12M  
Comp Risk 2  
any Overall  
Secret 2

This Audit in terms

## Data Protection Officer

### Process Scope

PROCESSID 7910  
To check the signs we have are appropriate, clear and positioned in the correct

Roll Task Roll Audit Risk Action Notes / Issues  
197936 910 Freq 1 Task 12M  
Company Risk 1  
Secretary Overall  
1

PROCESSID 7911  
Review Security Of The Special Category Personal Data

911199357 911 Freq 1 Task 12M  
Company Risk 2  
Secretary Overall  
2

## Office Processes

### Process Scope

PROCESSID 5853  
Ensure customer facing areas are vacuumed

Roll Task Roll Audit Risk Action Notes / Issues  
233133 243 Freq 4 Task 1W  
Office Comp Risk 1 Audit 1M  
Processes any Overall  
Secret 4  
ary

PROCESSID 5856

227 373 Freq Risk Audit 1M  
Comp

231775

		any Secret ary	Overall	
PROCESSID 5878 Emptying of the recycling and waste bins into external bin for refuge collectors	225 ✓ Office Processes	532	Freq 4 Risk 1 Overall	Task 1W
PROCESSID 5900 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
PROCESSID 5912 To put the bins out	107 Company Secretary	230102 ✓	Freq 3 Risk 1 Overall 3	Task 1M
PROCESSID 7706 Updating of anti-virus software and scanning computers for viruses	519 Office Processes	233135 ✓	Freq 4 Risk 1 Overall	Task 1W
PROCESSID 7802 Cleaning the kitchen surfaces to ensure they are fit for use	655 Office Processes	656 Office Proces ses	Freq 5 Risk 1 Overall	Task 1W Audit 2W
PROCESSID 7803 To ensure crockery and cutlery is cleaned and fit for use	657 Office Processes	658 Office Proces ses	Freq 5 Risk 1 Overall	Task 1D Audit 1W
PROCESSID 7804 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
PROCESSID 7805 Emptying of the recycling and waste bins into external bin for refuge collection	225 ✓ Office Processes	661	Freq 4 Risk 1 Overall 4	Task 1W
Diasbled currently - have Global task on bins				
PROCESSID 7806 To water the plants and ensure their survival	663 Office 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	191936 ✓	Freq 1 Risk 1 Overall 1	Task 12M



## Human Resources

Process Scope	Roll Task	Roll Audit	Risk	Action	Notes / Issues
<p>PROCESSID 7847</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	1071	Freq 1	Task 12M	
	Managing	Comp	Risk 1	Audit 12M	
	Director	any	Overall		
	202901	Secret	1		
	✓	ary			
		209458			
		✓			