

Internal Audit Check list			
HEALTH & SAFETY			
Created:	17/May 1995	Audit No 19	
Revised:	12 June 2017		Page 1 of 11
Audit Date	23-8-18	Auditor	Helen Lang

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.	
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.	
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.	
VST Ltd ISO9001:2015 7.3	<b>Awareness</b> The organization shall ensure that persons doing work under the	



	<p>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>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>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>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 maintenance activities, when such maintenance activities, or lack thereof, can</p>	



	<p>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>	
<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> <ul style="list-style-type: none"> <li>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;</li> <li>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.</li> </ul> <p>NOTE Further information can be found in ISO 14644 and ISO 14698</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>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> <ul style="list-style-type: none"> <li>a) conforms to planned and documented arrangements, requirements of this International Standard, quality management system requirements established by the organization, and applicable regulatory requirements;</li> <li>b) is effectively implemented and maintained.</li> </ul> <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 recorded (see 4.2.5). The selection of</p>	



	<p>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>	
--	---	--

	<b><u>QUESTION:</u></b>	<b><u>RESPONSE:</u></b>	<b><u>Y/ N</u></b>
1	Check that personnel are aware of the company's H & S policy. <i>Due Oct 18</i>	#106729	Y
2	Is the policy readily accessible?	Intrastats ✓	N/A
3	Check that new personnel have undergone induction checklist.	#126629	Y
4	Verify that existing personnel are still aware of locations for First aid and Fire extinguishers & exit routes. (Task 12)	#106729	Y
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. <i>No new products + services</i> See Technical controller for the list	See Technical controller for the list	N/A
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		Y
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 ✓	Y
10	Verify that the corrective actions are completed on time.	<i>ISSUES</i>	Y
11	Verify that these sheets are filed accordingly	Intrastats and Audit file	N/A
12	Verify that any hazardous products are safely contained in storage. Check Chemicals cupboard, R+D room and workshop. <i>None found</i>		Y

### 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	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 ✓ 102836 Managing Director		Freq 1 Risk 0 Overall	Task 12M	
PROCESSID 7741 Review the current Ethical Policy in intrastats	47 ✓ 102837 Managing Director		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 ✓ 118391 Company Secretary		Freq 1 Risk 1 Overall 1	Task 12M	
PROCESSID 5919 Check outside drain is not BLocked	431 ✓ 122626 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 ✓ 125687 Company Secretary		Freq 3 Risk 1 Overall 3	Task 1M	
PROCESSID 7120 Review any General Maintenance required on the physical Site(s)	602 ✓ 123572 Company Secretary		Freq 2 Risk 1 Overall 2	Task 3M	
PROCESSID 7742 Get Boiler / Heating Checked / Serviced before Winter	7 ✓ 123668 Company Secretary	waiting on plumber in terms	Freq 1 Risk 1 Overall 1	Task 12M	
PROCESSID 7756 Check Carbon Monoxide Alarm is working	117 ✓ 123422 Company Secretary		Freq 2 Risk 1 Overall 2	Task 6M	
PROCESSID 7820 The renewal of our waste transfer agreement with North	702 ✓ 114966 Company Secretary		Freq 1 Risk 2 Overall 2	Task 12M	



Yorkshire County  
Couoncil

**PROCESSID 7821**

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

701 ✓ 112831  
Company  
Secretary

Freq 1 Task  
Risk 2 12M  
Overall  
2

**PROCESSID 7835**

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

164 ✓ 64870  
Managing  
Director

Freq 1 Task  
Risk 1 48M  
Overall  
1

**PROCESSID 7836**

Reset the Heating for  
Winter

211 ✓ 101936  
UK Sales  
Controller

Freq 1 Task  
Risk 1 12M  
Overall  
1

**PROCESSID 7864**

Check the workshop  
benches ESD  
equipment is in place

94 ✓ 116167 95 ✓ 116168  
Production Managing  
Processes Director

Freq 2 Task  
Risk 1 6M  
Overall Audit  
2 12M

**IT Controller**

**Process Scope**

**Roll Task**

**Roll Audit**

**Risk**

**Action**

Notes /  
Issues

**PROCESSID 45**

Check the status of the  
Main Server

139 ✓ 125474  
Managing  
Director

Freq 3 Task  
Risk 3 1M  
Overall

**PROCESSID 46**

Check the status of the  
Backup Server,

454 ✓ 126582 455 ✓ 1205309  
Managing Company  
Director Secretary

Freq 4 Task  
Risk 3 2W  
Overall Audit  
12 12M

is done at same time as  
primary server

**PROCESSID 50**

Backup Internet  
Connection

415 ✓ 125500 416 ✓ 122811  
Managing Office  
Director Processes

Freq 3 Task  
Risk 1 1M  
Overall Audit  
3 3M

**PROCESSID 5903**

To record the daily  
barometric pressure

413 ✓ 126578 414 ✓ 125499  
Managing UK Sales  
Director Controller

Freq 4 Task  
Risk 1 1W  
Overall Audit  
4 1M



## Health And Safety Controller

Process Scope	Roll Task	Roll Audit	Risk	Action	Notes / Issues
<b>PROCESSID 6849</b> 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 126606 Company ✓ Secretary		Freq 1 Risk 3 Overall 3	Task 12M	
<b>PROCESSID 6855</b> Update the Site HSE file	12 106729 Managing ✓ Director		Freq 1 Risk 1 Overall 1	Task 12M	
<b>PROCESSID 6856</b> 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 115520 Company ✓ Secretary		Freq 2 Risk 4 Overall 8	Task 6M	
<b>PROCESSID 7092</b> Examination of electrical appliances and equipment to ensure they are safe to use	127 Managing 106336 Director ✓		Freq 1 Risk 3 Overall 3	Task 48M	
<b>PROCESSID 7867</b>	786 118319 Production ✓ Processes		Freq Risk Overall	Task 6M	
<b>PROCESSID 7868</b>	787 118527 Production ✓		Freq Risk	Task 6M	



PROCESSID 7869

Processes  
788  
Production  
Processes

Overall

Freq Task  
Risk 6M  
Overall**Warehouse Team  
Leader****Process Scope****Roll Task****Roll Audit****Risk****Action**Notes /  
Issues

PROCESSID 54

Bleech the Gents  
Toilets125 ✓  
126254  
Goods In373 ✓  
125680  
Company  
Secretary

Freq 3

Task

Risk 1

1M

Overall  
3Audit  
1M

PROCESSID 5906

Emptying of the  
recycling and waste  
bins into external bin  
for refuge collectors541 ✓  
126511  
Goods In424 ✓  
126269  
Managing  
Director

Freq 4

Task

Risk 1

1W

Overall  
4Audit  
1M

PROCESSID 5907

Cleaning of floors.  
Tidying so as to clean  
more effectively.543 ✓  
126318  
Goods In424 ✓  
126269  
Managing  
Director

Freq 4

Task

Risk 1

1W

Overall  
4Audit  
1M

PROCESSID 5908

Cleaning of floors.  
Tidying so as to clean  
more effectively.423 ✓  
126347  
Goods In424 ✓  
126269  
Managing  
Director

Freq 4

Task

Risk 1

1W

Overall  
4Audit  
1M

PROCESSID 5909

Emptying of the waste  
bins into external bin  
for refuge collectors542 ✓  
126603  
Goods In424 ✓  
126269  
Managing  
Director

Freq 4

Task

Risk 1

1W

Overall  
4Audit  
1M

PROCESSID 5910

Cleaning of duckets

426 ✓  
126519  
Goods Out424 ✓  
126269  
Managing  
Director

Freq 4

Task

Risk 1

1W

Overall  
4Audit  
1M

PROCESSID 5911

To remove and dispose  
of the cardboard with in  
the company427 ✓  
126132  
Goods In424 ✓  
126269  
Managing  
Director

Freq 4

Task

Risk 1

2W

Overall  
4Audit  
1M

PROCESSID 7687

Collecting, cleaning  
and returning duckets  
to Vandagraph.488 ✓  
126358  
Goods Out

Freq 4

Task

Risk 1

1W

Overall  
4

PROCESSID 7698

Cleaning of surfaces,  
equipment, floors.  
Tidying so as to clean  
more effectively.503 ✓  
125964  
Goods In

Freq 4

Task

Risk 1

3W

Overall  
4



## Audits

Process Scope	Roll Task	Roll Audit	Risk	Action	Notes / Issues
PROCESSID 7729 To carry out Audit 19 Health And Safety Viamed		13125068 Company Secretary	Not done within terms Freq 1 Risk 2 Overall	Audit 12M	
PROCESSID 7777 To carry out Audit 19 Health And Safety VST		125076 Company Secretary	not done within terms Freq 1 Risk 2 Overall 2	Audit 12M	

## Human Resources

Process Scope	Roll Task	Roll Audit	Risk	Action	Notes / Issues
PROCESSID 7847 Perform HSE Risk Assessment,	12 Managing Director	✓ 106729	Freq 1 Risk 1 Overall 1	Task 12M	

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.



## Office Processes

Process Scope	Roll Task	Roll Audit	Risk	Action	Notes / Issues
PROCESSID 5853 Ensure customer facing areas are vacuumed	126256 243 ✓ Office Processes	125680 373 ✓ Company Secretary	Freq 4 Risk 1 Overall 4	Task 2W Audit 1M	not done within terms
PROCESSID 5856	227	125680 373 ✓ Company Secretary	Freq Risk Overall 4	Audit 1M	not done within terms
PROCESSID 5878 Emptying of the recycling and waste bins into external bin for refuge collectors	428 Office Processes	532 Office Processes	Freq 4 Risk 1 Overall 4	Task 1W Audit 1W	
PROCESSID 5900 Cleaning of surfaces, equipment, floors. Tidying so as to clean more effectively.	125890 393 ✓ Office Processes	125619 394 ✓ Company Secretary	Freq 3 Risk 1 Overall 3	Task 1M Audit 1M	
PROCESSID 5912 To put the bins out	126709 107 ✓ Company Secretary		Freq 3 Risk 1 Overall 3	Task 1M	
PROCESSID 7706 Updating of anti-virus software and scanning computers for viruses	519 126259 Office Processes		Freq 4 Risk 1 Overall 4	Task 1W	
PROCESSID 7802 Cleaning the kitchen surfaces to ensure they are fit for use	655 126385 Office Processes	125856 656 ✓ Office Processes	Freq 5 Risk 1 Overall 5	Task 2D Audit 1W	
PROCESSID 7803 To ensure crockery and cutlery is cleaned and fit for use	126609 657 ✓ Office Processes	126308 658 ✓ Office Processes	Freq 5 Risk 1 Overall 5	Task 1D Audit 1W	
PROCESSID 7804 To sweep the kitchen floor and clear and mess ready for mopping	126309 659 ✓ Office Processes	126311 662 ✓ Goods In	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	660 Office Processes	661 Office Processes	Freq 4 Risk 1 Overall 4	Task 1W Audit 1W	



PROCESSID 7806  
To water the plants and  
ensure their survival

126300 ✓  
663  
Office  
Processes

664

Freq 4    Task  
Risk 1    1W  
Overall  
4