Internal Audit Check list			
Training			
Created:	17/May 1995	**Audit No 08**	VOP12
Revised:	13 July 2020		Page 1 of 8
Audit Date		Auditor	

SCOPE

Company / ISO Section	Criteria of ISO Section	Auditor Comments / Issues
VST Ltd ISO9001:2015 5.1.1	**General** Top management shall demonstrate leadership and commitment with respect to the quality management system by: a) taking accountability for the effectiveness of the quality management system; b) ensuring that the quality policy and quality objectives are established for the quality management system and are compatible with the context and strategic direction of the organization; c) ensuring the integration of the quality management system requirements into the organization's business processes; d) promoting the use of the process approach and risk-based thinking; e) ensuring that the resources needed for the quality management system are available; f) communicating the importance of effective quality management and of conforming to the quality management system requirements; g) ensuring that the quality management system achieves its intended results; h) engaging, directing and supporting persons to contribute to the effectiveness of the quality management system; i) promoting improvement; j) supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility. NOTE Reference to "business" in this International Standard can be interpreted broadly to mean those activities that are core to the purposes of the organization's existence, whether the organization is public, private, for profit or not for profit.	
VST Ltd ISO9001:2015 7.1.2	**People** The organization shall determine and provide the persons necessary for the effective implementation of its quality management system and for the operation and control of its processes.	
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 7.1.6	**Organizational knowledge** The organization shall determine the knowledge necessary for the operation of its processes and to achieve conformity of products and services. This knowledge shall be maintained and be made available to the extent necessary. When addressing changing needs and trends, the organization shall consider its current knowledge and determine how to acquire or access any necessary additional knowledge and required updates. NOTE 1 Organizational knowledge is knowledge specific to the organization; it is	

	generally gained by experience. It is information that is used and shared to achieve the organization's objectives. NOTE 2 Organizational knowledge can be based on: a) internal sources (e.g. intellectual property; knowledge gained from experience; lessons learned from failures and successful projects; capturing and sharing undocumented knowledge and experience; the results ofimprovements in processes, products and services); b) external sources (e.g. standards; academia; conferences; gathering knowledge from customers or external providers)	
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.	
VST Ltd ISO9001:2015 7.4	**Communication** 7.4 Communication The organization shall determine the internal and external communications relevant to the quality management system, including: a) on what it will communicate; b) when to communicate; c) with whom to communicate; d) how to communicate; e) who communicates.	
VST Ltd ISO9001:2015 8.5.1	**Control of production and service provision** The organization shall implement production and service provision under controlled conditions. Controlled conditions shall include, as applicable: a) the availability of documented information that defines: 1) the characteristics of the products to be produced, the services to be provided, or the activitiesto be performed; 2) the results to be achieved; b) the availability and use of suitable monitoring and measuring resources; c) the implementation of monitoring and measurement activities at appropriate stages to verify that criteria for control of processes or outputs, and acceptance criteria for	

	products and services, have been met; d) the use of suitable infrastructure and environment for the operation of processes; e) the appointment of competent persons, including any required qualification; f) the validation, and periodic revalidation, of the ability to achieve planned results of the processes for production and service provision, where the resulting output cannot be verified by subsequent monitoring or measurement; g) the implementation of actions to prevent human error; h) the implementation of release, delivery and post-delivery activities	
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 6.4.1	**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 7.3.2	**Design and development planning** The organization shall plan and control the design and development of product. As appropriate, design and development planning documents shall be maintained and	

	updated as the design and development progresses. During design and development planning, the organization shall document: a) the design and development stages; b) the review(s) needed at each design and development stage; c) the verification, validation, and design transfer activities that are appropriate at each design and development stage; d) the responsibilities and authorities for design and development; e) the methods to ensure traceability of design and development outputs to design and development inputs; f) the resources needed including necessary competence of personnel	
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.	

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Created:	17/May 1995	**Audit No 08**	VOP12
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Internal audits has been moved totally to the Intrastats system.

- The requirement for every member of staff to re-evaluate their own training record is automatically generated as an Issue in Intrastats annually.
- Each new employee will have an Induction recorded on their personnel file.
- Training records are now held electronically in Intrastats.
- The competence level required is discussed regularly at management meetings.
- The identification of training is discussed at management meetings.
- Actions are taken at these meetings to ensure the company has correctly trained people.

	QUESTION:	**RESPONSE**	**Y/ N**
1	Check all issues from the previous audit are completed.		
2	Check all related training issues are completed and no issue have arise from them over the last year.		
3	Is there a mechanism in place for staff and managers to request new or extra training.		
4	Are there any issue for requested training outstanding.		
5	Are arrangements for training personnel satisfactory.		
6	Check that personnel record have been updated with any in-house and external training.		
8	Check that Appraisals have been carried within the last 2 years.		
9	Verify that no personnel records are kept beyond their GDPR limit. CV's not kept longer than 6 months for staff not taken on and no longer than 2 years for those who have left our employment. Review the rolling issues to see if these have been check regularly.		

Sub Processes Linked to Audit 08

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 **7070** To discuss any problems, to assess work load and staffing. To review issues.	83 Managing Director		Freq 2 Risk 1 Overall 2	Task 3M	
PROCESSID **7713** Ensure All tasks allocated to active Members of staff,	548 Managing Director		Freq 3 Risk 2 Overall 6	Task 1M	
Director 3 (Steve)					
Process Scope	**Roll Task**	**Roll Audit**	**Risk**	**Action**	Notes / Issues
PROCESSID **6841** Define whom is responsible for researching and obtaining Grants			Freq 1 Risk 1 Overall 1		
Documentation And Records Controller					
Process Scope	**Roll Task**	**Roll Audit**	**Risk**	**Action**	Notes / Issues
PROCESSID **7907** To review which employees have Access to sensitive areas of Intrastats	887 Company Secretary	888	Freq 1 Risk 1 Overall 1	Task 12M Audit 12M	
IT Controller					
Process Scope	**Roll Task**	**Roll Audit**	**Risk**	**Action**	Notes / Issues
PROCESSID **7951** Check the Server space and Size of important files	139	1033 Managing Director	Freq 1 Risk 5 Overall 5	Task 1M Audit 3M	
Accounts Processes					
Process Scope	**Roll Task**	**Roll Audit**	**Risk**	**Action**	Notes / Issues
PROCESSID **5934** To check that any training that has been done is valid and then checked off the training record.	316 Company Secretary	560	Freq 4 Risk 1 Overall 4	Task 1W Audit 3M	

Audits

Process Scope	Roll Task	Roll Audit	Risk	Action	Notes / Issues
PROCESSID **7720** To carry out Audit 08 Training Viamed		10 Managing Director	Freq 1 Risk 2 Overall 2	Audit 12M	
PROCESSID **7768** To carry out Audit 08 Training VST		184 Managing Director	Freq 1 Risk 2 Overall 2	Audit 12M	

Human Resources

Process Scope	Roll Task	Roll Audit	Risk	Action	Notes / Issues
PROCESSID **5881** Keep Staff Training records upto date	314 Company Secretary	380 Managing Director	Freq 2 Risk 1 Overall 2	Task 3M Audit 6M	
PROCESSID **5904**			Freq Risk Overall		
PROCESSID **5936** To print the time sheets and add any extras, overtime, sick days, or commissions.	448 Company Secretary		Freq 3 Risk 3 Overall 9	Task 1M	
PROCESSID **6837**	314 Company Secretary		Freq Risk Overall	Task 3M	
PROCESSID **6839** Book Holidays for staff			Freq 1 Risk 1 Overall 1		
PROCESSID **6851** To look through the accident book and make sure there were no breaches of Health and Safety that were not reported.	287 Managing Director		Freq 2 Risk 2 Overall 4	Task 6M	
PROCESSID **6877** those that have keys and use the intruder alarm	771 Company Secretary		Freq 2 Risk 3 Overall 6	Task 6M	
PROCESSID **6906**			Freq Risk Overall		
PROCESSID **6928**			Freq Risk Overall		
PROCESSID **7759** Information from the staff that would be used in case of emergency health issue. These are filled in by staff and filled securely.	606 Company Secretary		Freq 1 Risk 3 Overall 3	Task 12M	
PROCESSID **7883** to review the staff, give feedback and discuss	813 Company	814 Managing Director	Freq 1 Risk 1	Task 12M Audit 24M	

issues	Secretary		Overall 1		
PROCESSID **7884** Review the staff pay, ensure its above minimum living wage and at a level appropriate to the work	815 Company Secretary	816 Managing Director	Freq 1 Risk 1 Overall 1	Task 12M Audit 24M	
PROCESSID **7908** remind staff about private information data and that it needs to be looked after and securely.	889 Company Secretary	890	Freq 1 Risk 1 Overall 1	Task 12M Audit 12M	
PROCESSID **7937** Diversity Impact Assessment	992 Managing Director		Freq 1 Risk 1 Overall 1	Task 12M	