

Viamed + VST

Internal Audit Check list			
INTERNAL AUDITS			
Created:	17/May 1995	Audit No 17	
Revised:	24 October 2017		Page 1 of 2
Audit Date	20-12-18	Auditor Helen Long	

Company / ISO Section	Criteria of ISO Section	Auditor Comments / Issues
VST Ltd ISO9001:20 15 9.2.1	<p>The organization shall conduct internal audits at planned intervals to provide information on whether the quality management system:</p> <p>a) conforms to:</p> <p>1) the organization's own requirements for its quality management system;</p> <p>2) the requirements of this International Standard;</p> <p>b) is effectively implemented and maintained.</p>	
Viamed Ltd ISO13485:2 016 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> <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 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>	

QUESTION:	RESPONSE:	Y/N
Verify that audits are performed independently of audit area.		Y
Check that the audit programme shows every area of the system has been covered. Can Check : Intrastats → ISO → Document index File Groups → Processes to Audits VOPs		Y
Verify that check lists are used to conduct the audit.		Y
Check that sufficient objective evidence has been taken to ascertain conformance.		Y
Verify that both parties endorse the audit.		Y
Check that an audit report is produced that highlights agreed corrective actions.	Issues	Y
Check that these actions have followed up in a timely manner.	Issues	X
Check that the audit database and matrix, is updated. (route map to ISO standard : link to QC 17 Cross reference)		Y
Verify that an Audit review has been undertaken. (Audit 21)	DL to carry out	Y

Sub Processes Linked to Audit 17

Review the below processes tasks and audits and ensure they are completed in a timely manner.

Audits

Process Scope	Roll Task	Roll Audit	Risk	Action	Notes / Issues
PROCESSID 7728 To carry out Audit 17 Internal Audits Viamed		11 133304 Company Secretary	Freq 1 Risk 2 Overall 2	Audit 12M	This Audit.
PROCESSID 7776 To carry out Audit 17 Internal Audits VST		191 133314 Company Secretary	Freq 1 Risk 2 Overall 2	Audit 12M	