

Finding Reference	1970716-202010-N2	Certificate Reference	MD 78787
Certificate Standard	ISO 13485:2016 & EN ISO 13485	Clause	8.2.4
Category	Minor		
Area/process:	Internal Audit process and follow ups, 8.2.4		
Statement of non-conformance:	The internal audit process isn't fully effective as no evidence were provided for the internal auditor to have been trained to the ISO 13485 version 2016.		
Clause requirements	<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>		
Objective Evidence	Interview with the MD and HR Director		
Cause			
Correction/containment			
Corrective action			