Change Log Form

GENERAL INFORMATION				
Course Developer Manager**	*[Albina Osmani]*			
Department*	*[Training Development Department]*			
Date*	*2016-11-18*			
Course details*	**Course name:**	**Language**	**Current Version**	**Subsequent Version**
	[ISO 13485 Lead Auditor]	*[English]*	*[7.4]*	*[7.3]*

Day 1:			
Slide Number	**Slide Description:**	**Modifications:**	**Comments**

No.2	*Normative References*	**Main standards:** Updated ISO 13485:2003 with ISO 13485:2016, ISO 17021 with ISO 17021-1. Removed ISO 14969:2004 as a reference from main standards because this standard has been withdrawn by ISO **Other standard references:** Updated ISO 9000:2005 with ISO 2015, ISO 9001:2008 with ISO 9001:2015. ISO 17021 with ISO 17021-1 and 14001:2004 with ISO 14001:2016	*Updated and withdrawn standards*
No.12	*Certified ISO 13485 Lead Auditor*	*Updated credential to:* "PECB Certified ISO 13485 Lead Auditor"	Updated information
No.13	*Certificate*	*Updated certificate*	*Updated information*

No.14	*What is PECB?*	*Slide: Main services:* 1. *Certification of persons* 2. *Certification of products* 3. *Certification of management systems* 4. *Certification of training organizations* 5. *Certification of trainers* 6. *Certification of auditors* *Notes: PECB is a certification body for persons, management systems, and products on a wide range of international standards. As a global provider of training, examination, audit, and certification services, PECB offers its expertise on multiple fields, including but not limited to Information Security, IT, Business Continuity, Service Management, Quality Management Systems, Risk & Management, Health, Safety, and Environment. We help professionals and organizations to show commitment and competence with internationally recognized standards by providing this assurance through the education, evaluation and certification against rigorous, internationally recognized competence requirements. Our mission is to provide our clients comprehensive services that inspire trust, continual improvement, demonstrate recognition, and benefit society as a whole. PECB **is** accredited by IAS against ISO/IEC 17024, ISO/IEC 17021-1, ISO/IEC 17065.*	*Updated information related to PECB services*

No. 20,21	*What is ISO?*	• *ISO is a network of national standardization bodies from over **163** countries* • *Over **21 000** standards have been published since **1947***	*Updated information*
No.24	*Seven ISO Management Principles*	*Seven ISO Management principles:* *1. Customer focus* *2. Leadership* *3. Engagement and competence of people* *4. Process approach* *5. Improvement* *6. Informed decision making* *7. Relationship management*	*Updated information*
No.28	*Integrated Management System*	*Common structure of ISO standards updated*	*Updated information based on the latest standard versions*
No.29	*Other Quality and Medical-Related Standards*	Removed ISO 14969	*Withdrawn standard*
No.31	*History of the ISO 13485 Standard*	Added 2016 as an Important date	*Updated information*
No.32	*ISO 13485*	Updated ISO 13485:2003 with ISO 13485:2016, clause 0.1- general content as in 13486:2016	
No.33	*ISO 14969*	Removed ISO 14969:2004	Withdrawn standard
No.34	*Legal conformity*	Updated clause 1.1 – general of ISO 13485:2003 with clause 1 – Scope of ISO 13485:2016	*Updated information*
No. 35	*Certification Schema*	Updated ANSI with IAS	*Updated information*

No.59	*Accreditation Authority*	Updated the logo of ANSI with the logo of IAS	*Updated logo*
No.61	*Certification body*	Updated 17021 with 17021-1 Clause 1 – Scope, ISO 17021-1 – Introduction and added the logo of PECB	*Updated clauses and information*
No.64	*Personnel Certification Bodies*	Updated ANSI with IAS	*Updated information*
No.68	*What is Quality?*	Updated clauses of ISO 9000:2005 with clauses of ISO 9000:2015 clause 3.1.1 and clause 3.1.2 with 3.6.2 and 3.6.4	*Updated standards*
No.75	*Medical Devices*	Updated ISO 13485:2003 Clause 3- terms and definitions with ISO 13485:2016 Clause 3 – terms and definitions	*Updated content*
No.76	*Medical Devices*	Updated ISO 13485:2003 Clause 3- terms and definitions with ISO 13485:2016 Clause 3 – terms and definitions	*Updated standards*
No.80	*Definition of QMS*	Updated clauses of ISO 9000:2005 with clauses of ISO 9000:2015 Clause 3.1.1 – Quality to Clause 3.6.2 – Quality Clause 3.2.1 – System to Clause 3.5.1 – System	*Updated standards*

No.87	*Structure of the ISO 13485 Standard*	Annex A (informative) Correspondence between ISO 13485:2003 and ISO 13485:1996 to Annex A (informative) Correspondence between ISO 13485:2003 and ISO 13485:2016. Annex B (informative) Explanation of differences between ISO 13485:2003 and ISO 9001:2000 to Annex B (informative) Explanation of differences between ISO 13485:2016 and ISO 9001:2015	*Updated annexes*
No.88	*Establish the QMS*	Updated clause 4.1: General Requirements content of ISO 13485:2003 with the new information on clause 4.1: General requirements on ISO 13485:2016	*Updated clauses*
No.89	*Documentation Requirements*	ISO 13485:2003 Clause 4.2.1 – ISO 13485 Clause 4.2.3	*Updated clauses*
No.93	*Management Responsibility*	ISO 13485:2003 Clause 5.3 Quality policy to ISO 13485 Clause 5.3 Quality policy	*Updated content*
No.98	*Management Responsibility*	ISO 13485:2003 Clause 5.5.2 Management Representative – ISO 13485:2016 Clause 5.5.2 Management representative	*Updated content*

No.100	*Management Responsibility*	ISO 13485:2003 Clause 5.6 Management Review – ISO 13485:2016 Clause 5.6 Management review	*Updated content*
No.101	*Resource Management*	ISO 13485:2003 Clause 6.1 Provision of resources – ISO 13485:2016 Clause 6.1 Provision of resources	*Updated content*
No.102	*Resource Management*	ISO 13485:2003 Clause 6.2 Human resources – ISO 13485:2016 Clause 6.2 Human resources	*Updated content*
No.103	*Resource Management*	ISO 13485:2003 Clause 6.3 Infrastructure – ISO 13485:2016 Clause 6.3 Infrastructure	*Updated content*
No.104	*Resource Management*	ISO 13485:2003 Clause 6.4 work environment – ISO 13485:2016 Clause 6.4 work environment and contamination control	*Updated content*
No.105	*Product Realization*	ISO 13485:2003 Clause 7.1 planning of Product Realization – ISO 13485:2016 Clause 7.1 planning of Product Realization	*Updated content*
No.106	*Product Realization*	ISO 13485:2003 Clause 7.2 Customer Related Processes – ISO 13485:2016 Clause 7.2 Customer Related Processes	*Updated content*

No.107	*Product Realization*	ISO 13485:2003 Clause 7.3.1 Design and development planning – ISO 13485:2016 Clause 7.3.2 Design and development planning	*Updated content and clause number*
No.108	*Product Realization*	ISO 13485:2003 Clause 7.3.2 & 7.3.3 Design and development inputs and outputs – ISO 13485:2016 Clause 7.3.3&7.3.4 Design and development inputs and outputs	*Updated content and clause number*
No.110	*Product Realization*	ISO 13485:2003 Clause 7.3.3 & 7.3.7 – ISO 13485:2016 Clause 7.3.5 & 7.3.7	*Updated content and clause number*
No.111	*Product Realization*	Added clauses 7.3.8 to 7.3.10	*Added clauses of ISO 13485:2016*
No.112	*Product Realization*	ISO 13485:2003 Clause 7.4 Purchasing – ISO 13485:2016 Clause 7.4 Purchasing	*Updated content*

No.114,114, 116	*Product Realization*	Updated and added new clauses: • **Clause 7.5.1** Control of production and service provision • **Clause 7.5.2** Cleanliness of product • ***Clause7.5.3*** Installation activities • ***Clause 7.5.4*** Servicing activities • ***Clause 7.5.5*** Particular requirements for sterile medical devices • ***Clause 7.5.6*** Validation of processes for production and service provision • ***Clause 7.5.7*** Particular requirements for validation of processes for sterilization and sterile barrier systems • ***Clause 7.5.8*** Identification • ***Clause 7.5.9*** Traceability • ***Clause 7.5.10*** Customer property • ***Clause 7.5.11*** Preservation of product	*Standard updates*
No.118	*Product Realization*	ISO 13485:2003 Clause 7.5.3 Identification and traceability – ISO 13485:2016 Clause 7.5.8 & 7.5.9 Identification, Traceability	*Updated clauses and notes*

No.119	*Product Realization*	ISO 13485:2003 Clause 7.5.4 customer property – ISO 13485:2016 Clause 7.5.10 Customer Property	*Updated clauses*
No.120	*Product Realization*	ISO 13485:2003 Clause 7.5.5 preservation of product – ISO 13485:2016 Clause 7.5.11 preservation of product	*Updated clauses*
No.121	*Measurement, Analysis and Improvement*	ISO 13485:2003 Clause 8 measurement, analysis and improvement – ISO 13485:2016 Clause 8 measurement, analysis	*Updated content*
No.122	*Measurement, Analysis and Improvement – slide notes extension*	ISO 13485:2003 Clause 8 measurement, analysis and improvement – ISO 13485:2016 Clause 8 measurement, analysis	*Updated content*
Day 2:			
Slide Number	**Slide Description:**	**Modifications:**	**Comments**
No.5	ISO 17021-1	*ISO 17021-1: 2015*	*Updated standard*
No.14	*Audit Principles*	*ISO 17021 Clause 4.1.2 - ISO 17021-1 Clause 4.1.2*	*Updated content*
No.17	*Fair presentation – slide notes extension*	*ISO 17021 Clause 5.2 - ISO 17021-1 Clause 5.2*	*Updated content*
No.18	*Fair presentation – slide notes extension*	*ISO 17021 Clause 5.2 - ISO 17021-1 Clause 5.2*	*Updated content*
No. 23	*Confidentiality principles*	*Updated clause 8.4, 17021-1.*	*Updated standard*

No.24	*Confidentiality principles – slide for notes extension*	***ISO 17021-1, clause 8.4 – Confidentiality*** ***8.4 Confidentiality*** ***8.4.1*** *The certification body shall be responsible, through legally enforceable agreements, for the management of all information obtained or created during the performance of certification activities at all levels of its structure, including committees and external bodies or individuals acting on its behalf.* ***8.4.2*** *The certification body shall inform the client, in advance, of the information it intends to place in the public domain. All other information, except for information that is made publicly accessible by the client, shall be considered confidential.* ***8.4.3*** *Except as required in this part of ISO/IEC 17021-1, information about a particular certified client or individual shall not be disclosed to a third party without the written consent of the certified client or individual concerned.* ***8.4.4*** *When the certification body is required by law or authorized by contractual arrangements (such as with the accreditation body) to release confidential information, the client or individual concerned shall, unless prohibited by law, be notified of the information provided.* ***8.4.5*** *Information about the client from sources other than the client (e.g. complainant, regulators) shall be treated as confidential, consistent with the certification body's policy.* ***8.4.6*** *Personnel, including any*	*Updated standard*

No.27	*Threats to independence*	*Updated clause 4.2.4 – threats to impartiality*	*Updated the content*
No.28	*Threats to independence – slide notes extensions*	*Updated clause 4.2.4 – threats to impartiality*	*Updated the content*
No.30	*Consultancy services and audit*	*Updated ISO, 17021-1 clause 3.3 & 5.2.7*	*Updated clauses*
No.35	*Section Summary*	*Updated ISO 17021-1*	*Standard update*
No.37	*Audit approach based on evidence*	*Updated ISO 17021-1, clause 4.2.3*	*Standard update*
No.40	*1. Physical evidence*	*Updated the following clauses of ISO 13485:2016* ***Clause 6.3 (Infrastructure):*** *Documented auditor observations of the infrastructure of the organization such as buildings and workspace after a site tour.* ***Clause 6.4 (Work environment and contamination control):*** *Documented auditor observations and inspection notes of the work environment factors such as temperature, humidity, airflow, air filtration, cleanliness of work surfaces and process.* ***Clause 7.5.8 (Identification):*** *The organization shall document procedures for product identification and identify product by suitable means throughout product realization.* ***Clause 7.5.9 (Traceability):*** *The organization shall document procedures for traceability. These procedures shall define the extent of traceability in accordance with applicable regulatory requirements and the records to be maintained*	*Standard update*

No.41	*2. Mathematical evidence*	*Updated the following clauses of ISO 13485:2016* ***Clause 6.2 (Human Resources):*** *Calculating the number of training hours received by employees related to the QMS and confirm if this meets the objectives.* ***Clause 7.5.1 (Control of production and service provision):*** *Calculation of the average time to perform a work instruction and verify if this meets what in state in the instruction by the auditor.* ***Clause 8.4 (Analysis of data):*** *The auditor can verify how the organization determines, collects and analyzes appropriate data to demonstrate the suitability and effectiveness of the QMS.*	*Standard update*
No.42	*3. Confirmative Evidence*	*Updated the following clauses of ISO 13485:2016* ***Clause 6.2 (Human resources):*** *Professional certificate issued by a recognized professional training organization.* ***Clause 7.5.5 (Preservation of product):*** *Audit report from an external consultant that confirms that the organization complies to this requirement.*	*Standard update*

No.43	*4. Technical Evidence*	*Updated the following clauses of ISO 13485:2016* ***Clause 7.5.1 (Control of production and service provision):*** *The auditor's observation notes on the analysis of the implementation of defined operations for labelling and packaging.* ***Clause 7.5.6 (Validation of processes for production and service provision):*** *The auditor's observation notes on the technical analysis of a production process of the organization.* ***Clause 7.6 (Control of monitoring and measuring equipment):*** *Analysis of the calibration of equipment of the organization.*	*Standard update*
No.44	*5. Analytical Evidence*	*Updated the following clauses of ISO 13485:2016* ***Clause 6.2 (Human Resources):*** *Analysis result of a sample of an employee competency test that measures their understanding of the processes in place in the organization.* ***Clause 8.2.6 (Monitoring and measurement of product):*** *Analysis result on a sample of products to verify that the product requirements have been met.* ***Clause 8.2.1 (Feedback):*** *Analysis result of a customer feedback survey.*	*Standard update*

No.45	*6. Documentary Evidence*	*Updated the following clauses of ISO 13485:2016* ***Clause 4.2.2 (Quality Manual):*** *Verification of the organization's quality manual.* ***Clause 4.2.4 (Control of documents):*** *Verification of the control of documents procedure of the organization.* ***Clause 5.3 (Quality policy):*** *Verification of the quality policy of the organization.*	*Standard update*
No.46	*7. Verbal Evidence*	*Updated the following clauses of ISO 13485:2016* ***Clause 5.1 (Management commitment):*** *Notes on discussions held with management explaining their commitment to the management system.* ***Clause 5.5.2 (Management representative):*** *Notes on the discussion held with the management representative to understand his roles and responsibilities related to the management system.* ***Clause 7.4.1 (Purchasing process):*** *Notes on the discussion held with the procurement manager explaining the purchasing process.*	*Standard update*
No.49	*Reliability of Audit Evidence*	*Updated the number of Clause 7.5.11 (Preservation of product):*	*Standard update*

No.50	*Exercise 5*	*Updated the following clauses of ISO 13485:2016* 1. ***Control of records (4.2.5),*** *Records shall remain legible, readily identifiable and retrievable;* 2. ***Management commitment (5.1a),*** *Top management shall provide evidence of its commitment to the development and implementation of the Quality Management System and maintaining its effectiveness by a) communicating to the organization the importance of meeting customer as well as applicable and regulatory requirements;* 3. ***Planning of product realization (7.1a),*** *In planning product realization, the organization shall determine the following, as appropriate: a) quality objectives and requirements for the product;* 4. ***Design and development verification (7.3.6),*** *Verification shall be performed in accordance with planned and documented arrangements to ensure that the design and development outputs have met the design and development input requirements. Records of the results of the verification and any necessary actions shall be maintained.* 5. ***Internal audit (8.2.4),*** *The organization shall conduct internal audits at planned intervals to determine whether the quality management system conforms to planned and documented arrangements*	*Standard update*

No.61	*1.1 Application Review*	*Updated ISO 17021-1, clause 9.1.2 – Application review*	*Standard update*
No.65	*1.5 Validation of the Audit Scope*	*Updated ISO 17021-1, clause 9.1.5: Multi-site sampling*	*Standard update*
No.70	*1.8 Signing the Certification Agreement*	*ISO 17021-1, clause 5.1.2: Certification agreement*	*Standard update*
No.76	*Certified ISO 13485 Lead Auditor Training*	*Updated (ISO 17021-1, clause 9.2.3.1).*	*Standard update*
No.77	*Objectives of the Stage 1 Audit*	*Updated ISO 17021-1, clause 9.3.1.2.2*	*Standard update*
No.79	*Stage 1 Audit Steps*	*Updated the following clauses from ISO 17021-1* ***9.3.1.2.1*** ***9.3.1.2.2*** ***9.3.1.2.3*** ***9.3.1.2.4***	*Standard update*
No.80	*2.1. Site Visit*	*Updated ISO 17021-1, clause 9.1.9.1: Conducting on-site audits – General*	*Standard update*
No.81	*2.2. Contacts with key stakeholders*	*Updated ISO 17021-1, Clause 9.3.1.2.1*	*Standard update*
No.83	*2.3 Document review*	*Updated ISO 17021-1, Clause 9.3.1.2.2*	*Standard update*

No.87	*Documentation requirements*	*Updated ISO 13485:2016 documented procedures:* *4.2.4 Control of documents* *4.2.5 Control of records* *8.2.4 Internal audit* *8.3 Control of nonconforming product* *8.5.2 Corrective action* *8.5.3 Preventive action* *7.1 Planning of product realization* *7.2.2 Review of requirements related to the product* *7.3.1 Design and development* *7.4.1 Purchasing process* *7.5.1 Control of production and service provision* *7.5.2 Cleanliness of product* *7.5.3 Installation activities* *7.5.4 Servicing activities* *7.5.6 Validation of processes for production and service provision* *7.5.7 Particular requirements for validation of processes for sterilization and sterile barrier systems* *7.5.8 Identification* *7.5.9 Traceability* *7.5.11 Preservation of product* *7.6 Control of monitoring and measuring equipment* *8.2.1 Feedback* *8.4 Analysis of data* *8.5 Improvement*	*Standard update*
No.90	*Verification of Internal Audit Documents*	*Updated content that included clause 8.2.4 of ISO 13485:2016*	*Standard update*
No.91	*Verification of the Control of Documents*	*Updated ISO 13485, clause 4.2.4: Control of documents*	*Standard update*
No. 92	*Control of Records*	*Updated the content of ISO 13485, Clause 4.2.5*	*Standard update*

No.94	*2.4 Stage 1 Audit Report*	*Updated ISO 17021-1, clause 9.3.1.2.3*	*Standard update*
No.97	*Certified ISO 13485 Lead Auditor Training*	*Updated ISO 17021-1, clause 9.4.1 : Conducting audits – General*	*Standard update*
No.98	*Stage 2 Audit Objectives*	*Updated ISO 17021-1, clause 9.3.1.3*	*Standard update*
No.100	*3.1 Preparing the Audit Plan*	*Updated ISO 17021-1, clause 9.2.3.4: Communication of audit plan*	*Standard update*
No.101	*Audit Plan Details*	*Updated ISO 17021-1, clause 9.2.3.2: Preparing the audit plan*	*Standard update*
No.110	*Certified ISO 13485 Lead Auditor Training*	*Updated ISO 17021-1, clause 9.4: Conducting audits– General*	*Standard update*
No.112	*4.1 Conducting the opening meeting*	*Updated ISO 17021-1, clause 9.4.2 : Conducting the opening meeting*	*Standard update*

Day 3:			
Slide Number	**Slide Description:**	**Modifications:**	**Comments**
No.23	*Communication with the Management*	*Updated clauses of ISO 13485:2016* 1. QMS general requirements (4.1) 2. Management commitment (5.1) 3. Quality policy (5.3) 4. Quality objectives (5.4.1) 5. QMS planning (5.4.2) 6. Responsibility and authority (5.5.1) 7. Management review (5.6) 8. Human resources (6.2) 9. Infrastructure (6.3) 10. Work environment and contamination control (6.4) 11. Results of internal audits (8.2.4)	*Standard update*
No. 47	*Examples of Frequent Analyses*	*Updated clauses of ISO 13485:2016* Control of documents (4.2.4) Control of records (4.2.5) Human Resources (6.2) Communication (7.2.3) Design and development (7.3) Purchasing information (7.4.2) Identification (7.5.8) Traceability (7.5.9) Feedback (8.2.1) Analysis of data (8.4) Corrective action (8.5.2) Preventive action (8.5.3)	*Standard update*
No.64	*Example 1: Control of Records*	*Updated ISO 13485, Clause 4.2.5*	*Standard update*
No.65	*Example 2: Responsibility and Authority*	*Updated ISO 13485, Clause 5.5.1*	*Standard update*

No.66	*Example 3: Provision of Resources*	*Updated ISO 13485, Clause 6.1*	*Standard update*
No.67	*Example 4: Human Resources*	*Updated ISO 13485, Clause 6.2*	*Standard update*
No.68	*Example 5: Internal Audit*	*Updated ISO 13485, Clause 8.2.4 (Extract)*	*Standard update*
No.69	*Example 6: Management Review*	*Updated ISO 13485, Clause 5.6 (extract)*	*Standard update*
No.75	*Non-conformity*	*Updated ISO 9000* ***3.6.11 Conformity:*** *Fulfilment of a requirement* ***3.6.9 Nonconformity:*** *Non-fulfilment of a requirement.*	*Standard update*
No.77	*Minor Non-conformity*	*Updated* *ISO 13485, clause 8.5.2d: Corrective action* *ISO 13485, clause 5.3: Policy*	*Standard update*
No.79	*Major Non-conformity*	*Updated* *ISO 13485, clause 6.2: Human Resources* *ISO 13485, clause 5.6.1*	*Standard update*
No.84	*Drafting a Non-conformity Report*	*Updated* Clause number: 5.6.1	*Standard update*
No.86	*Questions?*	*Updated section summary* *ISO 9000 (clause 3.6.9)*	*Standard update*

Day 4:

Slide Number	Slide Description:	Modifications:	Comments
No. 4	*Work Document Example*	*Updated Clauses 5.4., 8.5.1*	*Standard update*
No.10	*Documenting the Quality Review*	*Updated 5.1 Management commitment, 8.5 Improvement*	*Standard update*
No.15	*5.1. Preparing Audit Conclusions*	*Updated ISO 17021-1, clause 4.4.2*	*Standard update*
No.24	*5.4. Preparing the Audit Report*	*Updated ISO 17021-1, clause 9.4.8.1: Audit report*	*Standard update*
No.27	*Writing Recommendations for Improvement*	*Updated ISO 17021-1, Clause 9.4.8.1*	*Standard update*
No.28	*Recommendations for Improvement*	*Updated content for clause 7.5.11 and 7.5.9*	*Standard update*
No.30	*5.6. Audit Follow-up*	*Updated ISO 17021-1 Clause 9.4.10: Effectiveness of corrections and corrective actions*	*Standard update*
No.32	*5.7. Certification Decision*	*Updated* ISO 17021-1, Clauses 7.5.2, 9.5.3.1, 9.5.3.2 & 9.5.1.1	*Standard update*
No.38	*Submission of Action Plans by the Auditee*	*Updated* ISO 17021-1, Clause 9.4.9	*Standard update*
No.47	*6.1. Surveillance Activities*	*Updated* ISO 17021-1, Clauses 9.6.2.1.2 & 9.6.4.2	*Standard update*
No.48	*Surveillance Activities*	*Updated* ISO 17021-1, Clauses 9.6.2.1.2 & 9.6.4.2	*Standard update*

No.49	*6.2. Surveillance Audit*	*Updated* ISO 17021-1, Clauses 9.6.2.2	*Standard update*
No.50	*Main Elements to Audit during a Surveillance Audit*	*Updated* *ISO 17021-1, clause 9.6.2.2 Surveillance audit*	*Standard update*
No.52	*6.3. Recertification Audit*	*Updated* ISO 17021-1, Clause 9.6.3	*Standard update*
No.54	*Certification*	*Updated* *ISO 17021-1, clause 9.6.4.2 Short-notice audits* *ISO 17021-1, clause 9.6.4.1 Expanding scope*	*Standard update*
No.55	*Certification*	*Updated* *ISO 17021-1, clause* 9.6.5 Suspending, withdrawing or reducing the scope of certification	*Standard update*
No.56	*Use of ISO Trademarks*	*Updated* *ISO 17021-1, clause 8.3.1*	*Standard update and added PECB logo*
No.74	*Monitoring, Evaluating, Reviewing and Improving an Audit Programme*	*Updated* ISO 17021-1, Clause 7.2.5	*Standard update*
No.88	*PECB Certification Process*	*Updated credential to:* "PECB Certified ISO 13485 Lead Auditor"	*Information update*
No.90	*2. Course Completion Certificate*	*Updated the certificate*	
No.92	*4. Applying for Certification*	*Updated the references*	*Information update*
No.95	*6. Certification*	*Updated credential to:* "PECB Certified ISO 13485 Lead Auditor"	*Information update*
No.96	*7. Maintaining Certification*	Updated content, added annual maintenance fee	*Content update*

Comments:

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