

Adequacy Audit Checklist based on MS ISO/IEC 17025:2017

Laboratory Name:

Note: *Laboratory to specify the clause number from the relevant documents. Where documents/procedures are not applicable, the laboratory are required to provide information on the implementation.

Clause	Requirement	Comparable Laboratory Documents Clauses / Info on the Implementation*	Remarks
4	General requirements		
4.1	Impartiality		
4.1.1	Laboratory activities shall be undertaken impartially and structured and managed so as to safeguard impartiality.		
4.1.2	The laboratory management shall be committed to impartiality.		
4.1.3	The laboratory shall be responsible for the impartiality of its laboratory activities and shall not allow commercial, financial or other pressures to compromise impartiality.		
4.1.4	The laboratory shall identify risks to its impartiality on an on-going basis. This shall include those risks that arise from its activities, or from its relationships, or from the relationships of its personnel. However, such relationships do not necessarily present a laboratory with a risk to impartiality.		
4.1.5	If a risk to impartiality is identified, the laboratory shall be able to demonstrate how it eliminates or minimizes such risk.		
4.2	Confidentiality		
4.2.1	The laboratory shall be responsible, through legally enforceable commitments, for the management of all information obtained or created during the performance of laboratory activities. The laboratory shall inform the customer in advance, of the information it intends to place in the public domain. Except for information that the customer makes publicly available, or when agreed between the laboratory and the customer (e.g. for the purpose of responding to complaints), all other information is considered proprietary information and shall be regarded as confidential.		
4.2.2	When the laboratory is required by law or authorized by contractual arrangements to release confidential information, the customer or individual concerned shall, unless prohibited by law, be notified of the information provided.		
4.2.3	Information about the customer obtained from sources other than the customer (e.g. complainant, regulators) shall be confidential between the customer and the laboratory. The provider (source) of this information shall be confidential to the laboratory and shall not be shared with the customer, unless agreed by the source.		
4.2.4	Personnel, including any committee members, contractors,		

Iso 17025 Procedures Checklist Documents By

Guy Wingate



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Implementing Quality in Laboratory Policies and Processes Donnell R. Christian Jr., Stephanie Drilling, 2009-11-24

In order to gain accreditation every laboratory must have a superior quality assurance program. The keys to a successful program are the operational and technical manuals and associated documents which define the program and its various components. Written by experts with global experience in setting up laboratories, *Implementing Quality in Laboratory Policies and Processes Using Templates* Project Management and Six Sigma provides templates for the various policies, procedures, and forms that should be contained in the quality assurance operational and technical manuals of a laboratory seeking accreditation. Templates for the entire project life cycle. The book begins with a general introduction and overview of quality assurance and then moves on to cover implementation strategies. It contains best practices and templates for the project management of the design and implementation of the laboratory operational and technical manuals required to establish a quality assurance program. The templates span the entire project life cycle from initiation to planning to execution to monitoring and finally to closure. The book also examines how Six Sigma concepts can be used to optimize laboratories and contains templates that cover administrative issues, quality assurance, sample control, and health and safety issues. In addition, there is a section of criteria files that relate the individual document templates to specific accreditation criteria. Addresses the standards of ISO 17025. The results of any laboratory examination have the potential to be presented in court and can ultimately affect the life and liberty of the parties involved. Therefore, a stringent quality assurance program including well documented policies and a procedure manual is essential. Ensuring that laboratories meet the standards of ISO 17025, this volume is a critical component of any laboratory's accreditation process.

Forensic Laboratory Management W. Mark Dale, Wendy S. Becker, 2014-09-26. New technologies including DNA and digital databases that can compare known and questioned exemplars have transformed forensic science and greatly impacted the investigative process. They have also made the work more complicated. Obtaining proper resources to provide quality and timely forensic services is frequently a challenge for forensic managers who are often promoted from casework duties and must now learn a whole new set of leadership skills. The interdisciplinary and scientific nature of laboratories requires strong leadership ability to manage complex issues often in adversarial settings. *Forensic Laboratory Management: Applying Business Principles* provides laboratory managers with business tools that apply the best science to the best evidence in a manner that increases the efficiency and effectiveness of their management decision making. The authors present a performance model with seven recommendations to implement, illustrating how forensic managers can serve as leaders and strategically improve the operation and management in scientific laboratories. Topics include: Key business metrics and cost benefit analyses, Ethical lapses, why they occur, possible motives, and how problems can be prevented. Forensic training, education, and institutes, ISO IEC 17025 accreditation implementation. The book includes case studies simulating a working laboratory in which readers

can apply business tools with actual data reinforcing discussion concepts Each chapter also includes a brief review of current literature of the best management theories and practice The downloadable resources supply two mock trial transcripts and associated case files along with PowerPoint slides from Dr George Carmody s workshop on Forensic DNA Statistics and Dr Doug Lucas s presentation on ethics

Laboratory Quality/Management Kenneth N. Parson,2012-12-29 This book should be of interest to the management of all types of laboratories supporting all types of scientific disciplines Even though the scientific processes may be different the overall approach to management is very similar including how technical processes should be managed and controlled The book addresses principal elements of laboratory management technical and support operations and offers several detailed how to procedures designed to help laboratory management to establish and maintain control through a continuous low level internal audit self assessment process This activity enables management to take prompt corrective action maintain control and provides the ability to measure improvement over time toward achieving a higher more efficient cost effective level of quality services to its assigned customers The objective of this book is to expand on the knowledge and understanding of laboratory quality management system process

Forensic Anthropology and the United States Judicial System Laura C. Fulginiti,Kristen Hartnett-McCann,Alison Galloway,2019-07-26 A guide to the interface between forensic anthropology and the United States legal system Designed for forensic anthropologists at all levels of expertise Forensic Anthropology and the United States Judicial System offers a comprehensive examination of how to effectively present osteological analyses research and interpretations in the courtroom Written by noted experts the book contains an historical perspective of the topic a review of current legislation that affects expert testimony as well as vital information on courtroom procedure and judicial expectation of experts A comprehensive book Forensic Anthropology and the United States Judicial System explains how to prepare case reports and offers suggestions for getting ready for pre trial interviews The book also includes detailed information on affidavits fee structures and dealing with opposing experts This book is part of the popular Wiley American Association for Forensic Sciences series and Offers a unique volume that addresses the interface between forensic anthropology and the legal system Contains detailed guidelines for expert testimony by forensic anthropologists with all levels of experience from beginner to expert Includes information from the perspective of the Judiciary in terms of process and expectations of the Court Shows how to maintain independence from and collaborate with other experts Presents detailed explanations of current legislation impacting forensic science Forensic Anthropology and the United States Judicial System is an information filled guide for practitioners of the rapidly growing field that integrates forensic sciences and the judicial system

Textbook of Assisted Reproductive Techniques David. K Gardner,Ariel Weissman,Colin M. Howles,Zeev Shoham,2001-02-15 Textbook of Assisted Reproductive Technologies is a truly comprehensive manual for the whole team at the IVF clinic Information is presented in a highly visual manner allowing both methods and protocols to be consulted easily The text provides clinical and scientific teams with the A to Zs of setting up an

embryology laboratory gives research f *Federal Register* ,2013-06 **Meat & Poultry** ,2007-07 Computer Systems Validation Guy Wingate,2003-12-18 Both pervasive and ubiquitous computerized systems are now an integral component of every corporate strategy in pharmaceutical and healthcare companies However when technology is combined with high risk public safety projects or the production and control of life saving medicines or devices it is necessary to ensure that it is reliable quality The Feed Analysis Laboratory L. H. de Jonge,F. S. Jackson,2013 Animal feed impacts almost all sectors and services of the livestock sector This document presents a step wise process to guide the Laboratory Management starting from planning a feed analysis laboratory building and layout to hiring suitable staff choosing which methods to set up with appropriate equipment requirements This document will enable Member States to establish accredited laboratories and also help prepare the existing ones for the accreditation Quality of data on chemical composition and nutritive value will improve resulting in preparation of safe and quality animal diets imperative for increased sustainable livestock production

A Laboratory Quality Handbook of Best Practices Donald C. Singer,2001 Morbidity and Mortality Weekly Report ,2012 **Quality Today** ,2000 **Annals of Clinical Biochemistry** ,2000 *Materials Evaluation* ,2006 **Annual Book of ASTM Standards** ASTM International,American Society for Testing and Materials,2003 *Food and Environmental Protection Newsletter* ,1998 **Development of MS ISO/IEC 17025 Quality System (general Requirements for the Competence of Testing and Calibration Laboratories) for FKM Laboratory** Hon Chung Lew,2009 This report describe about the development of MS ISO IEC 17025 2005 quality manual and system procedure for FKM laboratory University Malaysia Pahang UMP This report consists of five chapters which are Introduction Literature Review Methodology Results and Conclusion The objectives of this project are study and identify the clauses of MS ISO IEC 17025 2005 and develop the quality manual and system procedure according to the standard requirement for FKM laboratory Studies and understanding the clauses is important before developing the quality manual and system procedure This standard is divided to two main requirements which are management requirement and technical requirement The management requirement of this standard is similar with the requirement of ISO 9001 The requirement of ISO 9001 was being studies A workshop of MS ISO IEC 17025 2005 was being attended to understand more clear on the clauses and some important information to develop the quality manual and system procedure After that one of the accredited MS ISO IEC 17025 laboratories has been chosen to visit It was also to understand more deep in developing the quality manual and system procedure and ensures that the quality manual and system procedure is developing in the right path The quality manual is developing as the policy and objective of the laboratory The system procedure will been develop as a procedure to achieve the objective of the quality manual The forms are creating as an evidence to support the requirements of the standard The quality manual had been developed from clause 4 9 to clause 4 15 which is clauses of management requirement of the standard The system procedure also had been developed for each of the clauses except the clause 4 10 improvement This

clause not required any system procedure because this clause had related with the entire clause to ensure that the quality management system is continual improve Some of the form had been created such as Non Conforming Investigation Form Corrective and Preventive Action Form The schedule for the internal audit and management review had been developed The audit checklist had been created for the auditor use during the audit process All the documents will be proposed to FKM laboratory for the accreditation of MS ISO IEC 17025 2005 In conclusion the objective of the project had been achieved where the entire related document had been developed ISO 17025:2017 Quality System Procedure Manual M. Naveed, Kranti Dharkar, Ramesh Lakhe, 2019-03-14 This book presents the Quality System Procedure for implementation of ISO 17025 2017 Lab Quality Management System Standard It covers all the mandatory procedures required by the standard and other relevant procedures Total 25 procedures are included in this book Each Procedure is formatted and the records related to it are specified Diagrams are included in the procedure to understand the clause requirements The organizations going for Lab Accreditation or wants improvement in the system will find this book useful for developing their own procedure manual which would suffice to the standard requirements *ISO 17025-2017 Sample Quality Manual for Testing Lab* M. NAVEED, Kranti DHARKAR, Ramesh LAKHE, 2018-12-17 This book is specially useful for the laboratories preparing Quality Manual as per ISO 17025 2017 Lab Quality Management System It includes the index release authorisation amendment sheet explanation of how lab complies with clause requirements references to procedures and records for each clause as an evidence The book is also useful to all the professionals associated with laboratory quality management as reference for preparing the lab for accreditation *Iso 17025 2017 Lab Quality Management System* Ramesh R Lakhe, Rakesh L Shrivastava, Prakash H Bhave, Sapan Kumar Ganguly, M M Naveed, 2018-12-30 Laboratory accreditation has assumed immense importance in recent years because of the need to assure the customer that the laboratory is capable of providing the valid test results reliably ISO 17025 2017 Lab Quality Management System has become part of the requirement of all the laboratories small to large Over the years ISO 17025 2017 Lab Quality Management System has evolved as per the laboratory and customer requirements and has become very important for improving laboratory systems and processes in order to sustain competitive advantages This book focuses on requirements and key features of ISO 17025 2017 Lab Quality Management System such as risk based thinking PDCA approach process management and continual improvement The readers would find it easier to understand the standard requirements and implement these in their work place

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