

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,		

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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 criterion 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

Guidelines for Laboratory Quality Managers Saverio Mannino,2022-11-22 This useful and extensive set of guidelines is designed to assist food control laboratories in gaining accreditation from an internationally recognized external body providing all of the necessary information and practices in an easy to read step by step fashion Authored by an experienced consultant for laboratory accreditation in many different countries with this text food control lab owners now have all of the up to date information they need to gain accreditation in a single source Guidelines for Laboratory Quality Managers covers the essentials for quality management in the food control laboratory from testing processes to current quality management systems The ISO standards for accreditation are extensively explored including managerial requirements organizational aspects complaint handling procedures internal audits and sampling An entire section is dedicated to the implementation of managerial and technical requirements from quality control to program monitoring and evaluation Analysis selection preparation and validation is covered extensively and an entire section is dedicated to basic statistics from data presentation to distribution Each section comes with helpful tips for lab managers plus definitions and terms Comprehensive easy to use and up to date Guidelines for Laboratory Quality Managers is the guide for accreditation for food control laboratories

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

Federal Register ,2013-06 Meat & Poultry ,2007-07 **Morbidity and Mortality Weekly Report** ,2012 **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

OIML Bulletin ,2008 **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

Encyclopedia of Food Microbiology Carl A. Batt, 2014-04-02 Written by the world's leading scientists and spanning over 400 articles in three volumes the *Encyclopedia of Food Microbiology* Second Edition is a complete highly structured guide to current knowledge in the field Fully revised and updated this encyclopedia reflects the key advances in the field since the first edition was published in 1999 The articles in this key work heavily illustrated and fully revised since the first edition in 1999 highlight advances in areas such as genomics and food safety to bring users up to date on microorganisms in foods Topics such as DNA sequencing and E coli are particularly well covered With lists of further reading to help users explore topics in depth this resource will enrich scientists at every level in academia and industry providing fundamental information as well as explaining state of the art scientific discoveries This book is designed to allow disparate approaches from farmers to processors to food handlers and consumers and interests to access accurate and objective information about the microbiology of foods Microbiology impacts the safe presentation of food From harvest and storage to determination of shelf life to presentation and consumption This work highlights the risks of microbial contamination and is an invaluable go to guide for anyone working in Food Health and Safety Has a two fold industry appeal 1 those developing new functional food products and 2 to all corporations concerned about the potential hazards of microbes in their food products *Quality Today*, 2000 *Consultants and Consulting Organizations Directory*, 2006 *Symposium Record*, 2003 **World Trade Report**, 2005 *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

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