

# IMPLEMENTING ISO/IEC 17025:2005



## A PRACTICAL GUIDE

BOB MEHTA

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# Implementing Isoiec 17025 2005 A Practical Guide

**Food and Agriculture Organization of  
the United Nations**



## **Implementing Isoiec 17025 2005 A Practical Guide:**

*Implementing ISO/IEC 17025:2005* Bhavan "Bob" Mehta, 2013-04-16 The purpose of this book is to demystify the requirements delineated within ISO IEC 17025 2005 while providing a road map for organizations that wish to receive maintain accreditation for their laboratories AS9100 ISO 9001 and ISO 13485 are standards that support the development and implementation of effective approaches to quality management and are recognized blueprints for the establishment of a quality management system QMS for diverse industries Although similar to these recognized QMS standards ISO IEC 17025 serves a unique purpose laboratory accreditation It is not unusual for laboratories to retain dual certification to ISO 9001 and ISO IEC 17025

*Practical Process Validation* Mark Allen Durivage, Bob (Bhavan) Mehta, 2016-07-11 For the past decade process validation issues ranked within the top six of Food and Drug Administration FDA form 483 observation findings issued each year This poses a substantial problem for the medical device industry and is the reason why the authors wanted to write this book The authors will share their collective knowledge to help organizations improve patient safety and increase profitability while maintaining a state of compliance with regulations and standards The intent of this book is to provide manufacturing quality professionals working in virtually any industry a quick convenient and comprehensive guide to properly conduct process validations that meet regulatory and certification requirements It will aid quality technicians engineers managers and others that need to plan conduct and monitor validation activities

*The Certified Pharmaceutical GMP Professional Handbook* Mark Allen Durivage, 2016-05-23 The purpose of this handbook is to assist individuals for the Certified Pharmaceutical Good Manufacturing Practices Professional CPGP examination and provide a reference for the practitioner The second edition reflects the Body of Knowledge which was updated in 2015 This edition has also incorporated additional information including updated references The updates reflect the current trends and expectations of the evolving pharmaceutical industry driven by consumer expectations and regulatory oversight This handbook covers compliance with good manufacturing practices GMPs as regulated and guided by national and international agencies for the pharmaceutical industry It covers finished human and veterinary drugs and biologics and combination devices as well as their component raw materials including active pharmaceutical ingredients APIs and excipients and packaging and labeling operations

**How to Establish a Document Control System for Compliance with ISO 9001:2015, ISO 13485:2016, and FDA Requirements** Stephanie L. Skipper, 2015-10-12 This book explains the requirements for compliance with FDA regulations and ISO standards 9001 13485 for documented information controls and presents a methodology for compliance The document control system DCS or documented information control system DICS is the foundation of a quality management system It is the first quality system element that must be implemented because the establishment and control of documented processes and information in a quality controlled environment is dependent on the ability to proactively manage access to documents and the movement of documents through the document life cycle A well developed document control system

benefits business by Improving knowledge retention and knowledge transfer within and across business units Improving access to knowledge based information Improving employee performance by providing standardized processes and communicating clear expectations Improving customer communication and satisfaction by providing documented information from which common understanding can be achieved Providing traceability of activities and documentation throughout the organization Improving organization of and access to documents and data Sample documents are included in the appendixes of this book to help clarify explanations This book provides a process based approach that can be used for controlling all forms of documented information that are required to be managed under the quality management system African swine fever prevention, detection and control in resource-limited settings Food and Agriculture Organization of the United Nations, 2023-09-19 This booklet provides guidance on prevention detection and control of African swine fever ASF in resource limited settings It is designed primarily for places where ASF is endemic with few or no prospects of eliminating the disease and places at high risk of incursion The guide is divided into five sections The first covers key aspects of the disease that can be exploited when developing prevention and control programmes even when resources are limited The next three sections provide suggestions on simple low cost measures for ASF prevention early warning and detection and control that have been shown to work in these settings The last section considers ways that communities can work together to manage ASF as well as the role of public private partnerships in this process Animal health is not just the responsibility of government veterinary services or individual producers It also involves local communities feed suppliers pig traders and processors and animal health workers at community level By working together with the help of the knowledge contained in this guide we can ensure that the devastation caused by ASF can be minimized even in places where resources to prevent and control the disease are scarce **Recommendations for the surveillance of influenza A(H5N1) in cattle** El Masry, I.; Delgado, A.H.; Silva, G.O.D.; Dhingra, M.; Lyons, N.A., 2024-11-27 As influenza A H5N1 of clade 2.3.4.4b continues to spread from wild birds to poultry and to both terrestrial and marine mammals the recent cases in cattle highlight the critical importance of being prepared for and responding rapidly to spillover events and of planning for early detection and response at the country level especially in countries of low and middle income These recommendations from the Food and Agriculture Organization of the United Nations FAO aim to support countries in enhancing influenza A H5N1 surveillance in cattle populations with broader application to other farmed mammals to inform risk assessment and evidence based disease control measures Integrated surveillance strategies can leverage existing programmes for avian influenza and other cattle diseases enabling countries to enhance monitoring capabilities while maintaining cost efficiency With regard to preparing effectively FAO recommends a combination of different surveillance methods including risk based surveillance strategies tailored to individual country contexts Adopting these recommendations will strengthen early detection efforts support evidence based decision making and help implement targeted risk mitigation measures to protect both livestock and public health

**Genomic characterization of animal genetic resources** Food and Agriculture Organization of the United Nations, Ajmone-Marsan, P., Boettcher, P. J., Ginja, C., Kantanen J., Lenstra, J. A., 2023-01-12 Molecular biotechnologies have developed rapidly and substantially since the release of these previous guidelines. The livestock sector has been an active participant in the so-called genomic revolution. Advancements in the sequencing of genomes and related genotyping methods have created opportunities for gathering much more information on the molecular level than ever possible at a faster rate and for exponentially decreased costs. Scientists and other livestock stakeholders in countries with highly developed economies have been among the main beneficiaries of this revolution. However, the greatly decreased costs of genomic applications have also created opportunities in countries with developing and transitional economies. In many instances, the lack of awareness of these opportunities and in the technical capacity for the full application of genomic tools may represent a greater obstacle to their utilization than the expenses involved. The development of these guidelines and the subsequent application of the information contained herein may help to bridge this gap, bringing new opportunities to light and transferring knowledge that can be used to increase the genetic characterization of AnGR and subsequently improve the sustainable use and conservation of livestock genetic diversity.

**Implementing ISO/IEC 17025:2017, Second Edition** Bob Mehta, 2019-02-21 The focus of this book is to demystify the requirements delineated within ISO/IEC 17025:2017 while providing a road map for organizations wishing to receive accreditation for their laboratories. AS9100, ISO 9001:2015 and ISO 13485:2016 are standards that have been created to support the development and implementation of effective approaches to quality management and are recognized blueprints for the establishment of a quality management system (QMS) for many diverse industries. Similar to these recognized QMS standards, ISO/IEC 17025:2017 for laboratory accreditation serves a unique purpose. It is not unusual for laboratories to retain dual certification in ISO 9001:2015 and ISO/IEC 17025:2017. However, ISO/IEC 17025:2017 contains requirements specific to the laboratory environment that are not addressed by ISO 9001:2015. This book highlights those differences between ISO 9001:2015 and ISO/IEC 17025:2017 while providing practical insight and tools needed for laboratories wishing to achieve or sustain accreditation to ISO/IEC 17025:2017. For those currently or formerly accredited to the 2005 version of ISO/IEC 17025, an appendix outlines the changes between the 2005 and 2017 versions of the standard.

**The ASQ Certified Pharmaceutical GMP Professional Handbook** Mark Allen Durivage, 2024-09-30 The ASQ Certified Pharmaceutical GMP Professional Handbook assists candidates preparing for the Certified Pharmaceutical Good Manufacturing Practices Professional (CPGP) examination and serves as a handy reference guide for practitioners in the field. This handbook covers compliance with good manufacturing practices (GMPs) as regulated and guided by national and international agencies for the pharmaceutical industry.

**Practical Attribute and Variable Measurement Systems Analysis (MSA)** Mark Allen Durivage, 2015-07-27 This book is a result of 30 years of quality-related work experience written to aid quality technicians and engineers. It provides the quality professional working in virtually

any industry a quick convenient and comprehensive guide to properly conducting measurement systems analysis MSA The intent of this book is to provide background and examples on the application of gage R the simple answers are profit public health and safety Companies that are shipping product that is out of specification can be subjected to expensive litigation especially in the aviation pharmaceutical and medical device industries This book will be a useful reference when preparing for and taking many of the ASQ quality certification examinations including the Certified Quality Technician CQT Certified Calibration Technician CCT Certified Quality Inspector CQI Certified Six Sigma Green Belt CSSGB Certified Quality Engineer CQE Certified Six Sigma Black Belt CSSBB and Certified Reliability Engineer CRE Best Practice Guide on Sampling and Monitoring of Metals in Drinking Water Adam Postawa, 2012-01-15 Part of Metals and Related Substances in Drinking Water Set buy all five books together to save over 30% There is increasing concern regarding the presence of metals particularly heavy metals in drinking water In addition to the well known toxic effects of lead which are discussed at length in the Best Practice Guide on the Control of Lead in Drinking Water in this series of Guides the latest WHO guide values for maximum mean concentrations of arsenic nickel and others in drinking water have been lowered compared to previous versions European Union USA and National standards for drinking water have followed the trend based largely on the same toxicological information There is currently growing interest in the presence of hexavalent chromium in drinking water following its finding in some drinking waters in the USA above the national upper limit for total chromium and research suggesting that this limit needs to be considerably lowered Some metals particularly iron and manganese are associated with the production of discoloured dirty water in distribution systems and are therefore very important to the production of water with acceptable aesthetic qualities Others iron and aluminium are key to the treatment of raw waters to drinking water standards In most cases it is not possible to continuously monitor waters for metals and suitable sampling programmes must be designed and carried out to give results representative of the true water quality The Best Practice Guide on Sampling and Monitoring of Metals in Drinking Water gives guidance on the design and quality control of sampling programmes for metals in Raw waters in the water treatment works in the drinking water distribution system and at the consumers tap It also gives guidance on the analytical methods that can be used for the analysis of metals and quality control of those methods Sampling programmes on the same water will vary according to the purpose for which they are carried out and the statistical techniques used to determine and design the different types of programme are outlined Finally some case studies of optimisation of sampling are set out Best Practice Guide on Sampling and Monitoring of Metals in Drinking Water is a valuable text for scientists engineers and quality managers working in drinking water supply laboratory managers and scientists who carry out sampling and analysis and water industry consultants It is also an excellent resource for post graduate and research workers in the field of drinking water Editor Dr Adam Postawa AGH University Krakow Poland

*Carcass management guidelines* Miller, L.P., Miknis, R.A. and Flory, G.A., 2020-12-28 Animal disease outbreaks pose

many challenges for response authorities that can impact livelihoods food security and the environment Proper disposal of animal carcasses that die or are culled during the outbreak is a key component of a successful response to a disease outbreak because it helps prevent or mitigate the further spread of pathogens and in case of zoonotic disease to further protect human health The practical guidelines presented hereby provide carcass and related waste management considerations and recommended procedures for use by Veterinary Services and other official response authorities when developing animal disease outbreak containment and eradication plans The guidelines apply to animal disease outbreaks of varying sizes whether the outbreak is isolated to a single premise or spans a region to cover numerous premises However they are focused on small to medium sized holdings in countries without access to engineered landfills rendering plants or controlled incinerators The guidelines are written in the spirit of keep it simple and doable considering the limited human and financial resources that many countries are constrained with Its presentation and practical approach ensure that countries will find it very useful for their emergency operation procedures toolbox Further the guidelines directly contribute to the one health approach by protecting the health of animals humans and the environment Technical guidelines on rapid risk assessment for animal health threats Food and Agriculture Organization of the United Nations ,2021-03-23 The occurrence and spread of an animal health threat can be prevented when a timely assessment of the risk is carried out to inform prevention response and control measures These technical guidelines on rapid risk assessment RRA are designed as a simple and practical tool to be used by veterinary services to build risk assessment capacities and assist decision makers in conducting qualitative RRA on the emergence occurrence and or spread of animal health threats Using available evidence data and information a multidisciplinary team can conduct an RRA in a short time within two weeks The publication provides a simple and flexible methodology for conducting a RRA when facing a disease event Eight steps in the RRA process are described and detailed examples are provided The final outcomes of the RRA provide robust evidence and guidance for decision makers in designing timely prevention control and eradication measures that contribute to sustainable livelihoods animal health public health and enhanced food security **A Practical Guide To The Forensic Examination Of Hair** James R. Robertson,Elizabeth Brooks,2021-10-21 A Practical Guide to the Forensic Examination of Hair From Crime Scene to Court presents current best practices and methodologies for forensic microscopists and trace evidence analysts in addition to lawyers and judges to detail the utilisation of hair evidence in court cases The 30 year evolution and development of forensic DNA analysis has placed very heavy focus on its value in identifying the source of biological materials in other evidence In addition to some recent controversies over the reliability of hair evidence and analysis the question arises what to do with hairs and hair evidence presented in court cases The reality is that this is a fairly common form of evidence present at and relevant in many types of crime scenes and scenarios Are we to simply ignore hairs as an evidence type This book outlines the case for hair evidence s continued relevance as a valuable biological source that can contribute to assisting in answering questions of

identity and questions of what happened or the criminalistic potential of hairs The authors present a four level approach to the case management of recovered hairs This system which can be incorporated into contemporary forensic practice stresses the need for thorough and systematic recording of hairs and their microscopic features and on the need to focus on differences to effectively triage recovered hairs The approach focuses on the efficient and accurate selection of hairs for nuclear and mitochondrial DNA analysis while addressing the criminalistic potential of hairs Key Features Outlines the latest advances in the collection and forensic hair fibres and includes full colour illustrative figures throughout Covers the advances in DNA extraction and analysis of hair samples including nuclear and mt DNA testing Addresses all forensic aspects of hair evidence including recovery collection examination analysis testing and presentation of such results in court A Practical Guide to the Forensic Examination of Hair is a practical reference written for practitioners and promotes the need for quality assurance measures process standardization and proficiency testing to ensure the scientific reliability of hair examination The book discusses how to interpret and report on hair findings to impart to investigators and to the broader legal system the appropriate weight that should be attributed to hair findings It provides invaluable methodologies and guidelines that reinforce the ongoing value and validity of hair examinations

**Developing field epidemiology training for veterinarians** Food and Agriculture Organization of the United Nations,2021-11-29 Epidemiology workforce capacity development is a key part of strengthening Animal Health Systems The aim of a field epidemiology training programme is to improve the institutional capacity to detect prevent control and manage animal diseases that negatively impact animal and human health farmers livelihoods food security and trade These guidelines provide an eight step approach to develop competency based training programmes from assessment of the needs and readiness of a country or region to developing planning implementing and monitoring and assessment of the impact of field epidemiology training programs A set of core competencies developed by a participative and inclusive process for frontline and intermediate levels are provided to guide the development of curriculum and strategic plans to better achieve field epidemiology training programme sustainability These guidelines should assist in addressing the veterinary services and animal health systems needs and priorities including field epidemiology workforce capacity development

**Responsible use of antimicrobials in beekeeping** Food and Agriculture Organization of the United Nations,2021-10-13 These guidelines focus on responsible use of antimicrobials in sustainable apiculture Following a one health approach they aim to protect not only honey bees but even human health e g reducing the risks of residues in hive products and preventing development of antimicrobial resistance and the environment The best way to reach this goal is to prevent and to guarantee the early detection of clinical cases of the main honey bee diseases through the application of good beekeeping practices and biosecurity measures And when medicines are needed for the honey bees specific indication is provided to reduce their impact choosing medicines with a low environmental impact using them timely prudently and following the due instructions It is imperative to apply only those active ingredients that are



registered for the honey bees and that are ideally prescribed by a veterinarian Antibiotics should always be avoided as much as possible to reduce risks of residues in hive products and to prevent risks of antimicrobial resistance Prudent and limited use of antimicrobials in beekeeping benefits the quality of bee products and the safety of surrounding ecosystems while also slowing development of antimicrobial resistance which is a widespread issue affecting multiple sectors Finally in this document for the first time a progressive management pathway PMP has been devised for honey bees as well as surveys were created to assess current beekeeping practices and general awareness of topical issues such as AMR The overall aim of these guidelines is to provide information of current challenges within the sector and orientate towards sustainable production and honey bee colony health

**Making way: developing national legal and policy frameworks for pastoral mobility** Food and Agriculture Organization of the United Nations, 2022-02-08 Mobility is a vital strategy employed by pastoralists to capitalize on the scarce availability of resources in variable environments making pastoralism economically feasible and environmentally sustainable Through mobility pastoralists can produce animal sourced products that provide food and income security to populations in the world's rangelands Such a practice also provides a range of benefits to the environment while fostering the capacity to adapt to changing social and natural environments With a few exceptions policies have largely not kept up with new scholarship and development discourse that acknowledges the importance of mobility to pastoralism There is a lag in and resistance to legislating in favor of mobility The overall objective of this handbook is to guide the development of legal and policy frameworks for securing mobility for various pastoral production systems and practices This handbook calls for the legal recognition and securing of pastoral mobility as a way of safeguarding and facilitating a continuous stream of economic and social benefits for pastoralists countries and the environment It facilitates a deeper understanding of pastoral mobility through examples and case studies drawn from various parts of the world and identifies considerations to be borne in mind when legislating for mobility

*Rift Valley fever action framework* Mariner, J.C., Raizman, E., Pittiglio, C., Bebay, C., Kivaria, F., Lubroth, J., Makonnen, Y., 2022-04-04 Rift Valley fever RVF is an arboviral disease affecting humans and livestock transmitted by mosquitoes It is endemic to large areas of Africa resulting in widespread abortion and neonatal mortality in livestock and severe complications in a small but significant percentage of human cases The range of RVF is largely determined by the distribution of suitable vector habitat and rainfall which changes over time and as a result of climate change In addition to which the movement of animals and animal products for trade may lead to the spread of RVF to previously non infected areas This RVF Action Framework is intended to provide decision makers with guidance on the best course of action to take in response to an RVF outbreak or the risk of an outbreak and help them develop a national action plan for this response A coordinated One Health approach that brings together the public animal and environmental health sectors is recommended as is a risk based approach that uses risk assessment and mapping to determine the appropriate measures to be taken and the locations where they are required A country's RVF response can

be best broken down into the four phases of the epidemiological cycle the inter epidemic pre epidemic epidemic and post epidemic periods Surveillance risk assessment and capacity building for instance are key during the inter epidemic period while the focus during the post epidemic period shifts to mitigating the disease s impact *Good beekeeping practices for sustainable apiculture* Food and Agriculture Organization of the United Nations, Apimondia, Chinese Academy of Agricultural Sciences, Istituto Zooprofilattico Sperimentale Lazio e Toscana, 2021-09-21 Bees provide a critical link in the maintenance of ecosystems pollination They play a major role in maintaining biodiversity ensuring the survival of many plants enhancing forest regeneration providing sustainability and adaptation to climate change and improving the quality and quantity of agricultural production systems In fact close to 75 percent of the world s crops that produce fruits and seeds for human consumption depend at least in part on pollinators for sustained production yield and quality Beekeeping also called apiculture refers to all activities concerned with the practical management of social bee species These guidelines aim to provide useful information and suggestions for a sustainable management of bees around the world which can then be applied to project development and implementation

**Best Practice Guide on the Control of Arsenic in Drinking Water** Prosun Bhattacharya, David Polya, Dragana Jovanovic, 2017-07-15 Arsenic in drinking water derived from groundwater is arguably the biggest environmental chemical human health risk known at the present time with well over 100 000 000 people around the world being exposed Monitoring the hazard assessing exposure and health risks and implementing effective remediation are therefore key tasks for organisations and individuals with responsibilities related to the supply of safe clean drinking water Best Practice Guide on the Control of Arsenic in Drinking Water covering aspects of hazard distribution exposure health impacts biomonitoring and remediation including social and economic issues is therefore a very timely contribution to disseminating useful knowledge in this area The volume contains 10 short reviews of key aspects of this issue supplemented by a further 14 case studies each of which focusses on a particular area or technological or other practice and written by leading experts in the field Detailed selective reference lists provide pointers to more detailed guidance on relevant practice The volume includes coverage of i arsenic hazard in groundwater and exposure routes to humans including case studies in USA SE Asia and UK ii health impacts arising from exposure to arsenic in drinking water and biomonitoring approaches iii developments in the nature of regulation of arsenic in drinking water iv sampling and monitoring of arsenic including novel methodologies v approaches to remediation particularly in the context of water safety planning and including case studies from the USA Italy Poland and Bangladesh and vi socio economic aspects of remediation including non market valuation methods and local community engagement

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