

General requirements for the competence of testing and calibration laboratories

1 Scope

This document specifies the general requirements for the competence, impartiality and consistent operation of laboratories.

This document is applicable to all organizations performing laboratory activities, regardless of the number of personnel.

Laboratory customers, regulatory authorities, organizations and schemes using peer-assessment, accreditation bodies, and others use this document in confirming or recognizing the competence of laboratories.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO/IEC Guide 99¹⁾, *International vocabulary of metrology — Basic and general concepts and associated terms (VIM)*

ISO/IEC 17000, *Conformity assessment — Vocabulary and general principles*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO/IEC Guide 99 and ISO/IEC 17000 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <http://www.electropedia.org/>

3.1

impartiality

presence of objectivity

Note 1 to entry: Objectivity means that conflicts of interest do not exist, or are resolved so as not to adversely influence subsequent activities of the *laboratory* (3.6).

Note 2 to entry: Other terms that are useful in conveying the element of impartiality include "independence", "freedom from conflict of interests", "freedom from bias", "lack of prejudice", "neutrality", "fairness", "open-mindedness", "even-handedness", "detachment", "balance".

[SOURCE: ISO/IEC 17021-1:2015, 3.2, modified — The words "the certification body" have been replaced by "the laboratory" in Note 1 to entry.]

1) Also known as JCGM 200.

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Michael Seilmaier



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Validierung in der Analytik Stavros Kromidas, 2012-07-18 Die Validierung von Methoden und Geräten ist eine elementare Aufgabe in jedem analytischen Labor. Erstmals liegt mit diesem Band der Reihe eine praktische Einführung für den Anwender vor. In didaktisch bewährter Form werden die einzelnen Validierungsparameter ausführlich erklärt, kommentiert und ihre Verknüpfung erläutert. Der Leser wird sukzessiv durch die Validierungsschritte geführt von der Fragestellung bis zur Bewertung der Ergebnisse und Plausibilitätsbetrachtung. Er erhält konkrete Hilfestellung in Form von Fallbeispielen, Checklisten und Diagrammen sowie durch Antworten auf typische Fragen und Hinweise zur Vermeidung typischer Fehler. Ergänzend dazu enthält das Buch ein Glossar und einen Anhang mit nützlichen weiterführenden Informationen. Es ist der Begleiter für alle Anwender, die validieren müssen. Aus Rezensionen bereits erschienener Bände: Das sehr empfehlenswerte Werk ist didaktisch geschickt formuliert und illustriert. Es setzt die bewährte Reihe zur Praxis der instrumentellen Analytik fort und sollte in keiner einschlägigen Fachbibliothek fehlen. Die Pharmazeutische Industrie. Besonders lehrreich für den Anfänger ist die Vielzahl von praktischen Beispielen. Die Nahrung Handbook of Digital Forensics of Multimedia Data and Devices, Enhanced E-Book Anthony T. S. Ho, Shujun Li, 2016-05-20 Digital forensics and multimedia forensics are rapidly growing disciplines whereby electronic information is extracted and interpreted for use in a court of law. These two fields are finding increasing importance in law enforcement and the investigation of cybercrime as the ubiquity of personal computing and the internet becomes ever more apparent. Digital forensics involves investigating computer systems and digital artefacts in general while multimedia forensics is a sub topic of digital forensics focusing on evidence extracted from both normal computer systems and special multimedia devices such as digital cameras. This book focuses on the interface between digital forensics and multimedia forensics bringing two closely related fields of forensic expertise together to identify and understand the current state of the art in digital forensic investigation. Both fields are expertly attended to by contributions from researchers and forensic practitioners specializing in diverse topics such as forensic authentication, forensic triage, forensic photogrammetry, biometric forensics, multimedia device identification and image forgery detection among many others. Key features: Brings digital and multimedia forensics together with contributions from academia, law enforcement and the digital forensics industry for extensive coverage of all the major aspects of digital forensics of multimedia data and devices. Provides comprehensive and authoritative coverage of digital forensics of multimedia data and devices. Offers not only explanations of techniques but also real world and simulated case studies to illustrate how digital and multimedia forensics techniques work. Includes a companion website hosting continually updated supplementary materials ranging from extended and updated coverage of standards to best practice guides, test datasets and more case studies. *Quality Issues in Clinical Genetic Services* Ulf Kristoffersson, Jörg Schmidtke, J. J. Cassiman, 2010-06-25 Initially genetic disorders were all considered as rare diseases. At present in the mid of 2009 the OMIM catalogue contains information on more than 12 000

entries of which about 2500 are available for clinical testing based on the identification of the responsible gene defect. However altogether it has been estimated that about 8 percent of a population in the economically developed countries will during their lifetime suffer from a disease mainly as the result of their genetic constitution. Adding to that it is estimated that all diseases have a genetic component which will determine who will be at a higher than average risk for a certain disorder. Further it is postulated that in the near future this genetic profiling could become useful in selecting an appropriate therapy adapted to the genetic constitution of the person. Thus genetic disorders are not rare. Measuring quality of health care related processes became an issue in the 1990s mainly in laboratory medicine but also for hospitals and other health care systems. In many countries national authorities started to implement recommendations guidelines or legal procedures regulating quality of health care delivery. In laboratory medicine in parallel the use of accreditation as a method assuring high quality standards in testing came in use. With the increasing possibilities of performing molecular genetic testing genetic laboratories needed to become involved in this process. As many genetic disorders are rare most laboratories worldwide offered analysis for a specific set of disorders and therefore very early on a transborder flow of samples occurred. While international quality criteria ISO have been in existence for a number of years the regulation of quality issues still may differ between countries. Based on their personal experience in the varying fields of quality research and clinical implementation of quality criteria in genetic services the authors of this book share their experience and give examples of the implementation of quality issues in national quality systems worldwide. This book which is the result of the effort of many persons is destined to aid laboratory managers and counsellors health care managers and other stakeholders in national or international health care service to improve the services to the benefit of patients with suspected genetic disorders.

Quality Management in Forensic

Science Sean Doyle, 2018-11-20 Forensic science has been under scrutiny for some time since the release of the NAS report in 2009. The report cited the need for standardized practices and the accreditation of crime labs. No longer can the forensic community take the position that cross examination in a courtroom will expose weaknesses in methodology and execution. Quality Management in Forensic Science covers a wide spectrum of forensic disciplines relevant ISO and non ISO standards accreditation and quality management systems necessary in any forensic science laboratory. Written by a globally well respected forensic scientist with decades of experience in the forensic science laboratory and on the stand as an expert witness who is also a Fellow of both the Royal Society of Chemistry and the Chartered Society of Forensic Sciences. This book will be a must have resource for all forensic science stakeholders particularly law enforcement agents and lawyers less familiar with the impact of quality management on the reliability of scientific evidence. A comprehensive multidisciplinary reference of scientific practices for use in the forensic laboratory. Coverage from DNA to toxicology from trace evidence to crime scene and beyond. Extensive review of ISO and non ISO standards accreditation QMS and much more. Written by a foremost forensic scientist with decades of experience in the laboratory and as an expert witness.

Interlaboratory

Studies and Certified Reference Materials for Environmental Analysis E.A. Maier, Ph. Quevauviller, 1999-12-17 The participation in interlaboratory studies and the use of Certified Reference Materials CRMs are widely recognised tools for the verification of the accuracy of analytical measurements and they form an integral part of quality control systems used by many laboratories e.g. in accreditation schemes. As a response to the need to improve the quality of environmental analysis the European Commission has been active in the past fifteen years through BCR activity now renamed Standards Measurements and Testing Programme in the organisation of series of interlaboratory studies involving expert laboratories in various analytical fields inorganic trace organic and speciation analysis applied to a wide variety of environmental matrices. The BCR and its successor have the task of helping European laboratories to improve the quality of measurements in analytical sectors which are vital for the European Union: biomedical, agriculture, food, environment and industry; these are most often carried out in support of EC regulations, industrial needs, trade monitoring activities including environment, agriculture, health and safety and more generally when technical difficulties hamper a good comparability of data among EC laboratories. The collaborative projects carried out so far have placed the BCR in the position of second world CRM producer after NIST in the USA. *Interlaboratory Studies and Certification of Reference Materials for Environmental Analysis* gives an account of the importance of reference materials for the quality control of environmental analysis and describes in detail the procedures followed by BCR to prepare environmental reference materials including aspects related to sampling, stabilization, homogenisation, homogeneity and stability testing, establishment of reference or certified values and use of reference materials. Examples of environmental CRMs produced by BCR within the last 15 years are given which represent more than 70 CRMs covering different types of materials: plants, biological materials, waters, sediments, soils and sludges, coals, ash and dust materials, certified for a range of chemical parameters: major and trace elements, chemical species, PAHs, PCBs, pesticides and dioxins. The final section of the book describes how to organise improvement schemes for the evaluation method and/or laboratory performance. Examples of interlaboratory studies, learning scheme, proficiency testing and intercomparison in support to prenormative research are also given.

Process and Chemical Engineering, 2002 **Cone Penetration Testing** 2022 Guido Gottardi, Laura Tonni, 2022-06-23 This volume contains the proceedings of the 5th International Symposium on Cone Penetration Testing CPT 22 held in Bologna, Italy, 8-10 June 2022. More than 500 authors (academics, researchers, practitioners and manufacturers) contributed to the peer-reviewed papers included in this book which includes three keynote lectures, four invited lectures and 169 technical papers. The contributions provide a full picture of the current knowledge and major trends in CPT research and development with respect to innovations in instrumentation, latest advances in data interpretation and emerging fields of CPT application. The paper topics encompass three well-established topic categories typically addressed in CPT events: Equipment and Procedures, Data Interpretation, Applications. Emphasis is placed on the use of statistical approaches and innovative numerical strategies for CPT data interpretation, liquefaction studies.

application of CPT to offshore engineering comparative studies between CPT and other in situ tests Cone Penetration Testing 2022 contains a wealth of information that could be useful for researchers practitioners and all those working in the broad and dynamic field of cone penetration testing **Forensic Toxicology** Susannah Davies,Atholl Johnston,David Holt,2019-03-15 New designer drugs access to databases and changing availability of samples for analysis have changed the face of modern forensic toxicology in recent years Forensic Toxicology Drug Use and Misuse brings together the latest information direct from experts in each sub field of the discipline providing a broad overview of current thinking and the most innovative approaches to case studies The text begins with an in depth discussion of pharmaco epidemiology including information on the value of nationwide databases in forensic toxicology The use and abuse of drugs in driving sport and the workplace are then discussed by industry experts who are conducting case work in their field Not only are new drug groups discussed NPS but also their constantly changing impact on drug legislation Synthetic cannabinoids khat and mephedrone are discussed in detail Following a section devoted to legislation and defence readers will find comprehensive chapters covering sample choice reflecting the increasing use of hair and oral fluid and also the less commonly used sweat and nail analysis New and old case examples are compared and contrasted in the final part of the book which will enable readers to understand how drugs impact on each other and how the interpretative outcome of a case are dependent on many aspects From use of pharmaceutical drugs in a clinical setting through smart drugs to new psychoactive drugs this book documents the wide range in which drugs today are abused This book will be an essential resource for postgraduate students in forensic toxicology and for researchers in forensic toxicology laboratories who need the latest data and knowledge *Trace Quantitative Analysis by Mass Spectrometry* Robert K. Boyd,Cecilia Basic,Robert A. Bethem,2011-08-24 This book provides a serious introduction to the subject of mass spectrometry providing the reader with the tools and information to be well prepared to perform such demanding work in a real life laboratory This essential tool bridges several subjects and many disciplines including pharmaceutical environmental and biomedical analysis that are utilizing mass spectrometry Covers all aspects of the use of mass spectrometry for quantitation purposes Written in textbook style to facilitate understanding of this topic Presents fundamentals and real world examples in a learning though doing style *A Textbook of In Vitro Fertilization and Assisted Reproduction* Peter R. Brinsden,2005-08-12 This major book known as The Bourn Hall Textbook evolved from teaching courses held at this prestigious Clinic one of the birthplaces of IVF and clinical reproductive medicine The content is comprehensive covering assessment of the infertile couple and both laboratory and clinical aspects of assisted reproductive technologies The emphasis throughout is on the practical management of patients undergoing assisted conception treatment The third edition is a complete update of the field including expanded sections on newer technologies such as GIFT and ICSI The book is authored largely by current or previous members of the Bourne Hall staff with additional material from leading international authorities The Bourn Hall Procedures Protocols and Information Sheets previously

published as an Appendix are now included on CD ROM for ease of adaptation for local use Analytical Methods for Drinking Water Philippe Quevauviller, K. Clive Thompson, 2005-12-13 Drinking water policies and research are intimately linked. It is thanks to the scientific progress made over the last 25 years in identifying and controlling toxic products in drinking water that regulations have developed in such a way that the protection of public health from waterborne diseases has drastically improved. The integration of research outputs into the policy making progress requires close cooperation among the scientific and policy communities which is not always straightforward. Exchanges among scientific and policy making communities are certainly representing key elements of progress for a better environmental protection. In this respect, analytical developments linked to drinking water are at the core of the science policy debate. This book, Analytical Methods for Drinking Water, Advances in Sampling and Analysis, reflects this awareness in joining recent analytical developments with policy considerations. A first chapter gives an overview of EU and US drinking water policies as well as on standardization. Analytical developments are described in depth in the second chapter focusing on bromate in drinking water. The third chapter deals with the development of a sampling protocol for lead in drinking water, thus mixing analytical development with standardization needs. Finally, the fourth chapter focuses on standardization aspects: pre-normative research related to materials in contact with drinking water. This book, written by experts in the field of drinking water policy and analysis, illustrates recent scientific advances in this area which have contributed to policy development and will be of direct use to policy makers, water scientists, researchers, and analytical laboratories. **Preclinical Development**

Handbook Shayne Cox Gad, 2008-03-21 A clear, straightforward resource to guide you through preclinical drug development. Following this book's step-by-step guidance, you can successfully initiate and complete critical phases of preclinical drug development. The book serves as a basic, comprehensive reference to prioritizing and optimizing leads, dose formulation, ADME, pharmacokinetics, modeling, and regulations. This authoritative, easy-to-use resource covers all the issues that need to be considered and provides detailed instructions for current methods and techniques. Each chapter is written by one or more leading experts in the field. These authors, representing the many disciplines involved in preclinical toxicology, screening, and testing, give you the tools needed to apply an effective multidisciplinary approach. The editor has carefully reviewed all the chapters to ensure that each one is thorough, accurate, and clear. Among the key topics covered are Modeling and informatics in drug design, Bioanalytical chemistry, Absorption of drugs after oral administration, Transporter interactions in the ADME pathway of drugs, Metabolism kinetics, Mechanisms and consequences of drug-drug interactions. Each chapter offers a full exploration of problems that may be encountered and their solutions. The authors also set forth the limitations of various methods and techniques used in determining the safety and efficacy of a drug during the preclinical stage. This publication should be readily accessible to all pharmaceutical scientists involved in preclinical testing, enabling them to perform and document preclinical safety tests to meet all FDA requirements before clinical trials may begin. Use of Ozone Depleting

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David Lilburn Watson,Andrew Jones,2023-11-09 Digital Forensic Processing and Procedures Meeting the Requirements of
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Pavell,2021-10-28 Revised to reflect significant advances in pharmaceutical production and regulatory expectations
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sterile products liquid chemical sterilization and medical device manufacture *Pemahmn & Penerapan ISO/IEC*
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Robertson,2019-07-11 The book provides a comprehensive approach to configuration management from a variety of product
development perspectives including embedded and IT It provides authoritative advice on how to extend products for a variety
of markets due to configuration options The book also describes the importance of configuration management to other parts
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contextual understanding of the theory practice and application of CM The book illustrates the interplay of configuration and
data management with all enterprise resources during each phase of a product lifecycle **Configuration Management**
Jon M. Quigley,Kim L. Robertson,2015-04-16 Configuration Management Theory Practice and Application details a
comprehensive approach to configuration management from a variety of product development perspectives including

embedded and IT It provides authoritative advice on how to extend products for a variety of markets due to configuration options The book also describes the importanc **Validation of Pharmaceutical Processes** James P. Agalloco, Frederick J. Carleton, 2007-09-25 Completely revised and updated to reflect the significant advances in pharmaceutical production and regulatory expectations this third edition of Validation of Pharmaceutical Processes examines and blueprints every step of the validation process needed to remain compliant and competitive The many chapters added to the prior compilation examine va

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