



GUIDE 35

**Certification of reference
materials —
General and statistical principles**

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M Mark



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Certification of reference materials International Organization for Standardization. Certification Committee, 1989

Measurement Uncertainty in Chemical Analysis Paul De Bièvre, 2003-01-17 It is now becoming recognized in the measurement community that it is as important to communicate the uncertainty related to a specific measurement as it is to report the measurement itself Without knowing the uncertainty it is impossible for the users of the result to know what confidence can be placed in it it is also impossible to assess the comparability of different measurements of the same parameter This volume collects 20 outstanding papers on the topic mostly published from 1999 2002 in the journal Accreditation and Quality Assurance They provide the rationale for why it is important to evaluate and report the uncertainty of a result in a consistent manner They also describe the concept of uncertainty the methodology for evaluating uncertainty and the advantages of using suitable reference materials Finally the benefits to both the analytical laboratory and the user of the results are considered

Handbook of Isolation and Characterization of Impurities in Pharmaceuticals Satinder Ahuja, Karen Mills Alsante, 2003-07-18 The United States Food and Drug Administration FDA and other regulatory bodies around the world require that impurities in drug substance and drug product levels recommended by the International Conference on Harmonisation ICH be isolated and characterized Identifying process related impurities and degradation products also helps us to understand the production of impurities and assists in defining degradation mechanisms When this process is performed at an early stage there is ample time to address various aspects of drug development to prevent or control the production of impurities and degradation products well before the regulatory filing and thus assure production of a high quality drug product This book therefore has been designed to meet the need for a reference text on the complex process of isolation and characterization of process related synthesis and formulation impurities and degradation products to meet critical regulatory requirements Its objective is to provide guidance on isolating and characterizing impurities of pharmaceuticals such as drug candidates drug substances and drug products The book outlines impurity identification processes and will be a key resource document for impurity analysis isolation synthesis and characterization Provides valuable information on isolation and characterization of impurities Gives a regulatory perspective on the subject Describes various considerations involved in meeting regulatory requirements Discusses various sources of impurities and degradation products

Reference Materials in Analytical Chemistry A. Zschunke, 2013-06-29 Analytical chemistry is increasingly becoming an important basis for decision making in science economy trade health care environmental and consumer protection sports and jurisdiction In all spheres analytical results need to fulfill a purpose This means being accurate to a specified extent according to the required level of uncertainty as well as being comparable depending on the range of validity In many cases this range is global Reference materials are important tools for meeting these demands Driving forces behind the increasing diversification of reference materials also include the rapid development of analytical chemistry the

development of new methods and applications and the inclusion of new analytes matrices and materials The growing need for reference materials is giving rise to an increasing demand for information orientation and stimulation Laboratory staff have questions on calibration validation home made reference materials and certified reference materials This book is a handbook for analytical chemists and technical personnel in analytical laboratories where it should become a standard reference work Berlin February 2000 A Zschunke Contents 1 Introduction Adolf Zschunke 1 1 Analytical Thinking 1 1 2 Demands on Analytical Chemistry 5 1 3 Measures Designed to Build Confidence 6 1 4 References 7 2 Classification of Reference Materials Werner Hiisselbarth 2 1 Definitions 10 2 2 Physical Character 12 2 3 Supplied Property 15 2 4 Metrological Qualification 16 2 5 Preparation Method 18 2 6 Intended Use 20 2 7 References

Reference Materials for Chemical Analysis Markus Stoeppler, Wayne R. Wolf, Peter J. Jenks, 2008-07-11 There are many academic references describing how RMs are made but few that explain why they are used how they should be used and what happens when they are not properly used In order to fill this gap the editors have taken the contributions of more than thirty RM practitioners to produce a highly readable text organized in nine chapters Starting with an introduction to historical theoretical and technical requirements the book goes on to examine all aspects of RM production from planning preparation through analysis to certification reviews recent development areas RMs for life analysis and some important general application fields considers the proper usage of RMs gives advice on availability and sources of information and lastly looks at future trends and needs for RMs This book is intended to be a single point of information that both guides the reader through the use of RMs and serves as a primary reference source It should be on the reading list of anyone working in an analytical laboratory and be found on the library shelf of all analytical chemical laboratories

ISO 9000 Quality Management, 2001 **Applications of Reference Materials in Analytical Chemistry** Peter Roper, 2001 Reference materials play an important role in analytical chemistry where they are used by analysts for a variety of purposes including checking and calibrating instruments validating methods and estimating the uncertainty of analytical measurements checking laboratory and analyst performance and internal quality control This book provides guidance and information for the users of certified reference materials CRMs explaining how they can best be used to achieve valid analytical measurements and improve quality in the analytical laboratory General information on CRMs and how they are produced sets the scene for readers The statistics relating to CRM use are then explained in an easy to understand manner and this is followed by sections covering the main uses of CRMs Detailed worked examples are used throughout Structured and comprehensive in coverage this book will be welcomed by all users of certified reference materials

Annual Book of ASTM Standards ASTM International, American Society for Testing and Materials, 2003 **BSI Catalogue**, 1995 *Wastewater Quality Monitoring and Treatment* Philippe Quevauviller, Olivier Thomas, André Van Der Beken, 2006 The issue of water quality monitoring is becoming a huge area as the EU requirements for cleaner water increase On line monitoring involves measuring a body of water constantly and in situ as opposed to

analysing samples in the lab Currently filling the gap in the market Wastewater Quality Monitoring On line Methods provides information on how to produce the best analyses of wastewater in order to meet the above mentioned requirements This reference will prove invaluable to all local water companies industrial companies producing wastewater as well as environment agencies and researchers

The Use of Matrix Reference Materials in Environmental Analytical Processes M. Parkany,Aleš Fajgelj,1999 The 14 papers continue a campaign to standardize terminology symbols and test methods among chemical laboratories in different countries and different industries They focus on how to apply matrix reference materials in environmental analysis presenting worked examples of selected materials Among them are method validation quality assurance quality control and quantifying uncertainty They include reference materials certified for trace elements radionuclides and organic microconstituents Distributed in the US by Springer Verlag for about 20 more than the British price Annotation copyrighted by Book News Inc Portland OR

Biocompatibility Julian H. Braybrook,1997-08-04 This book presents both an overview and forward assessment of medical device materials and test methods Highlighting the complex problem of host responses and related issues which may restrict the accuracy and reliability of existing test methodology the book provides an unbiased appraisal of the requirements for biocompatibility and the approaches that have been developed to evaluate it

Quality Assurance Principles for Analytical Laboratories Frederick M. Garfield,1991 Quality assurance planning statistical applications and control charts Personnel considerations Management of equipment and supplies Sample and record handling Sampling and sample analysis Proficiency and check samples Audit procedures Design and safety of facilities Laboratory accreditation

ISO Catalogue International Organization for Standardization,1997

Biological Evaluation of Medical Devices International Organization for Standardization,2000

American National Standard for Calibration ,1997-10

Catálogo de normas técnicas ISO para PETROECUADOR sectores de calidad y medio ambiente, 2003 ,2003

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