



## **GUIDE 35**

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

# Iso Guide 35 1989

**Daniel F McAuley**



## **Iso Guide 35 1989:**

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

*Measurement Uncertainty in Chemical Analysis* Paul De Bièvre, Helmut Günzler, 2013-06-29 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 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

**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

**Wastewater Quality Monitoring and Treatment** Philippe Quevauviller, Olivier Thomas, Andre Van Der Beken, 2007-01-11 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

*Measurement Uncertainties* S. V. Gupta, 2012-01-13 This book fulfills the global need to evaluate measurement results along with the associated uncertainty In the book together with the details of uncertainty calculations for many physical parameters probability distributions and their properties are discussed Definitions of various terms are given and will help the practicing metrologists to grasp the subject The book helps to establish international standards for the evaluation of the quality of raw data obtained from various laboratories for interpreting the results of various national metrology institutes in an international inter comparisons For the routine calibration of instruments a new idea for the use of pooled variance is

introduced The uncertainty calculations are explained for i independent linear inputs ii non linear inputs and iii correlated inputs The merits and limitations of the Guide to the Expression of Uncertainty in Measurement GUM are discussed Monte Carlo methods for the derivation of the output distribution from the input distributions are introduced The Bayesian alternative for calculation of expanded uncertainty is included A large number of numerical examples is included

*Differential Scanning Calorimetry* Günther Höhne, Wolfgang F. Hemminger, H.-J. Flammersheim, 2013-03-09 In this updated and fully revised second edition the authors provide the newcomer and the experienced practitioner with a balanced and comprehensive insight into all important methods and aspects of Differential Scanning Calorimetry DSC including a sound presentation of the theoretical basis of DSC thermal analysis and temperature modulated DSC TMDCS Emphasis is placed on modern evaluation techniques instrumentation the underlying measurement principles metrologically correct calibrations factors influencing the measurement process and on the exact interpretation of the results The information enables the research scientist the analyst and experienced laboratory staff to choose the most suitable equipment to apply DSC methods successfully to interpret the measurement curve and thus to measure key properties precisely In addition the new edition includes improved instrumental techniques such as Tzerotm and StepScantm new evaluation techniques more applications and the latest references

**Standard and Reference Materials for Environmental Science**, 1995

**Traceability in Chemical Measurement** Paul De Bièvre, Helmut Günzler, 2005-12-06 Metrological traceability of chemical measurement results means the establishment of a relation to metrological stated references through an unbroken chain of comparisons This volume collects 56 outstanding papers on the topic mostly published in the period 2000 2003 in the journal Accreditation and Quality Assurance They provide the latest understanding and possibly the rationale why it is important to integrate the concept of metrological traceability including suitable measurement standards such as certified reference materials into the standard measurement procedures of every analytical laboratory In addition this anthology considers the benefits to both the analytical laboratory and the user of the measurement results

**Standardization of**

**Diagnostic Markers** P. E. Barker, 2006 Provides information on Standard Reference Material SRM and their use This book addresses standards and technology in areas such as nanotechnology and early cancer detection HER2 testing of breast cancer gene expression and serum proteomics for early cancer detection It tells how standards arise in response to clinical needs and more

**Quality Assurance Principles for Analytical Laboratories** Frederick M. Garfield, Eugene Klesta, Jerry Hirsch, 2000

**Advanced Mathematical And Computational Tools In Metrology Vii** Patrizia Ciarlini, Eduarda Filipe, Alistair B Forbes, Franco Pavese, Christophe Perruchet, Bernd R L Siebert, 2006-03-06 This volume collects the refereed contributions based on the presentations made at the Seventh Workshop on Advanced Mathematical and Computational Tools in Metrology a forum for metrologists mathematicians and software engineers that will encourage a more effective synthesis of skills capabilities and resources The volume contains articles by world renowned metrologists and

mathematicians involved in measurement science and together with the six previous volumes in this series constitutes an authoritative source of the mathematical statistical and software tools necessary in modern metrology      **Plastics**

**Additives** J.C.J. Bart, 2006-03-15 Cover to cover reading of *Plastics Additives Advanced Industrial Analysis* is recommended for both professional analysts and plastics technologists Professor Bart's prose style is easy to read A professional background in analytical chemistry is not assumed Particularly valuable is the trove of good advice as to which approach might be best in a given situation Every department with a serious interest in additive property relations should invest in a copy *PMAD Newsletter* This industrially relevant and up to date resource deals with all established and emerging analytical methods for in polymer additive analysis of plastics formulations Quality assurance and industrial troubleshooting all benefit from direct analysis modes *Plastics Additives* comprises detailed coverage of solid state spectroscopy thermal analysis and pyrolysis laser techniques surface studies and microanalysis along with process analytics quantitative analysis and modern method development and validation applied to additives in polymers The book is organised for quick and easy reference and is extensively illustrated with over 200 figures 300 flow diagrams and tables to facilitate rapid understanding of this topic and it contains 4000 references Emphasis is on understanding principles and characteristics and industrial applicability

*NIST Handbook*, 1989      *Chemical calibration* C. Douglas Faison, 1999      *National Voluntary Laboratory Accreditation Program* C. Douglas Faison, 1999      **Laboratory Auditing for Quality and Regulatory Compliance** Donald C.

Singer, Raluca-Ioana Stefan, Jacobus F. van Staden, 2005-07-25 Identifying current tools techniques and approaches for the evaluation of laboratory operations this reference reviews the latest regulatory standards and auditing practices to test laboratory safety quality and performance      **Applications of Reference Materials in Analytical Chemistry** Ron

Walker, Peter Bedson, Richard Lawn, Vicki J Barwick, Shaun Burke, Peter Roper, 2007-10-31 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      *BSI Catalogue*, 1995

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