

Reference materials —

Part 5: Quality system guidelines for the production of reference materials

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Committees responsible for this Published Document

The preparation of this Published Document was entrusted to Technical Committee SS/6, Precision of test methods, upon which the following bodies were represented:

- British Gas plc
- Chemical Industries Association
- Consumers' Association
- GAMBICA (BEAMA Ltd.)
- Institute of Quality Assurance
- Laboratory of the Government Chemist
- Ministry of Agriculture, Fisheries and Food
- Ministry of Defence
- National Physical Laboratory
- Royal Society of Chemistry
- University of London

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National foreword

This Part of PD 6532 has been prepared under the direction of the Managements Systems Sector Board. It is identical with ISO Guide 34:1996 *Quality system guidelines for the production of reference materials* published by the International Organization for Standardization (ISO).

Five Parts of this Published Document have been published and these may be summarized as follows.

Part 1: Guide to terms and definitions used in connection with reference materials (identical with ISO Guide 30:1992). This Part recommends terms and the meanings that should be assigned to them, used in connection with reference materials. Particular attention is given to terms that are used in reference material certificates and corresponding certification reports.

Part 2: Guide to the contents of certificates of reference materials (identical with ISO Guide 31:1981). This Part provides guidance on the preparation to clear and concise certificates of reference materials that summarize the information needed by the user of the reference material. The information that should be provided on a certificate is listed under a series of headings. Each heading is further explained and examples are provided where necessary.

Part 3: Guide to the users of certified reference materials (identical with ISO Guide 33:1989). This Part provides guidance on the use of certified reference materials (CRMs). The proper uses, and potential misuses, of CRMs are explained. Recommendations are presented for the assessment of precision and trueness of a measurement process by the use of CRMs. The use of CRMs for the definition and realization of conventional measurement scales is discussed, including temperature, pH, octane number, soluble solids content (refractometric), turbidity, hardness and the Roga test for the classification of hard coals.

Part 4: Guide to general and statistical principles for the certification of reference materials (identical with ISO Guide 35:1989). This Part provides guidance on the concepts and practical aspects of the certification of reference materials. The roles of reference materials in quantitative measurements are described and important technical aspects of the certification of reference materials are considered, including the measurement uncertainty associated with certified values. Commonly used methods for the certification of reference materials are discussed.

Part 5: Quality system guidelines for the production of reference materials (identical to ISO Guide 34:1996). This part provides guidance to both reference material producers and accreditation authorities on the correct quality system procedures to adopt for the production of reference materials. It therefore provides a specific interpretation of the general requirements of ISO Guide 25 and the ISO 9000 series of standards. Compliance with the requirements of this Part of PD 6532 should ensure that reference materials are produced to an acceptable level of quality.

In particular, this Part of PD 6532 provides guidance on material preparation, including homogeneity and stability testing, traceability, validation and the various approaches to characterization and the certification of a material's property values.

Cross-references

The British Standards that implement international publications referred to in this document may be found in the BSI Catalogue under the section entitled "International Standards Correspondence Index".

Compliance with a British Standard does not of itself confer immunity from legal obligations.

Summary of pages

This document comprises a front cover, an inside front cover, pages i to iv, the ISO Guide 34 page, pages ii to iv, pages 1 to 12 and a back cover.

This standard has been updated (see copyright date) and may have had amendments incorporated. This will be indicated in the amendment table on the inside front cover.



GUIDE 34

Quality system guidelines for the production of reference materials

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Documents

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Descriptors: Reference materials, production, quality assurance, quality assurance systems, handbooks.