



BSI Standards Publication

**Reference materials —
Establishing and expressing
metrological traceability of
quantity values assigned to
reference materials**

National foreword

This Published Document is the UK implementation of ISO/TR 16476:2016.

The UK participation in its preparation was entrusted to Technical Committee RMI/1, Reference Materials.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

© The British Standards Institution 2016.

Published by BSI Standards Limited 2016

ISBN 978 0 580 79297 7

ICS 71.040.30

Compliance with a British Standard cannot confer immunity from legal obligations.

This Published Document was published under the authority of the Standards Policy and Strategy Committee on 30 June 2016.

Amendments/corrigenda issued since publication

Date	Text affected
------	---------------

TECHNICAL
REPORT

ISO/TR
16476

First edition
2016-06-01

**Reference materials — Establishing
and expressing metrological
traceability of quantity values
assigned to reference materials**

*Matériaux de référence — Etablissement et expression de la
traçabilité métrologique des valeurs assignées à des matériaux de
référence*



Reference number
ISO/TR 16476:2016(E)



COPYRIGHT PROTECTED DOCUMENT

© ISO 2016. Published in Switzerland

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
Ch. de Blandonnet 8 • CP 401
CH-1214 Vernier, Geneva, Switzerland
Tel. +41 22 749 01 11
Fax +41 22 749 09 47
copyright@iso.org
www.iso.org

Contents

Page

Foreword	iv
Introduction	v
1 Scope	1
2 The VIM definition of metrological traceability	1
3 Challenges arising from the definition of metrological traceability	7
3.1 Conventions.....	2
3.2 (C)RM as the carrier of traceable values.....	3
3.3 Implicit traceability to the unit of the measurement scale.....	4
3.4 Traceability networks.....	5
3.5 Properties expressed in units of measurement scales other than the SI.....	5
3.6 Properties other than quantitative.....	6
3.7 Summary of an ISO/REMCO event on metrological traceability.....	6
4 Approaches to metrological traceability of (C)RM	7
4.1 General.....	7
4.2 Approach A.....	7
4.3 Approach B.....	8
5 Establishing traceability of (C)RM property values (Approach B)	9
5.1 Principles.....	9
5.2 Traceability pathways.....	10
5.3 Steps in establishing traceability.....	10
5.3.1 General.....	10
5.3.2 Combining results.....	11
5.4 Summary.....	12
6 Reporting traceability	12
6.1 Inquiry.....	12
6.2 Results of the inquiry.....	12
6.3 Requirements.....	13
6.4 Formats.....	14
6.5 Further recommendations.....	16
Annex A (informative) Worked out example	17
Annex B (informative) Catalogue of analytes and measurement areas covered by WHO	19
Annex C (informative) Example for method-independent, SI traceable values obtained by inter-laboratory comparison	21
Bibliography	22

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

ISO/TR 16476 was prepared by the ISO Committee on Reference Materials (ISO/REMCO).

Introduction

Reference materials (RM), in particular when certified (CRM), are a major tool for assuring the quality and reliability of results obtained in measurement and testing. CRM property values, in particular used for assessing the trueness of a measurement procedure as implemented in a laboratory, also establish traceability of the measurement result. Which reference the property values assigned to (C)RM should be traceable to, and how this traceability should be established, demonstrated, and reported on certificates is, therefore, a question of primary importance, mainly for RM producers. However, users of (C)RMs should also know what the endpoint of their traceability chain is, in particular for all purposes of cross-border acceptance of measurement results.

It was therefore considered necessary to conduct a study into existing principles for, and requirements to, the traceability of (C)RM, in particular with a specific view to the current definition of metrological traceability given by the Vocabulary of International Metrology (VIM), edition 3, 2007.

Reference materials — Establishing and expressing metrological traceability of quantity values assigned to reference materials

1 Scope

This Technical Report investigates, discusses, and specifies further, the general principles of establishing traceability of measurement results laid down in the Joint BIPM, OIML, ILAC and ISO Declaration on Metrological Traceability [1], in particular for values assigned to (certified) reference materials. The document covers the following topics:

- a study into existing principles for, and requirements to, the traceability of the value assigned to the property of a (C)RM, with a specific view to the current definition of metrological traceability given by the 2007 edition of the VIM (published also as JCGM 200:2008[2] and ISO/IEC Guide 99:2007[21]);
- the development of a sensible, widely applicable approach to the understanding of the traceability of a value assigned to (C)RM property;
- recommendations on how traceability should be established, demonstrated, and reported on certificates and other documents accompanying (C)RM.

The developed approach is exemplified for measurement procedures not covered earlier by other guidance documents on the topic.

2 The VIM definition of metrological traceability

The recent edition of the VIM[2],[21] defines *metrological traceability* (term 2.41) as

property of a measurement result whereby the result can be related to a reference through a documented unbroken chain of calibrations, each contributing to the measurement uncertainty	
NOTE 1	For this definition a 'reference' can be a definition of a measurement unit through its practical realization, or a measurement procedure including the measurement unit for a non-ordinal quantity, or a measurement standard.
NOTE 2	Metrological traceability requires an established calibration hierarchy.
NOTE 3	Specification of the reference must include the time at which this reference was used in establishing the calibration hierarchy, along with any other relevant metrological information about the reference, such as when the first calibration in the calibration hierarchy was performed.
NOTE 4	For measurements with more than one input quantity in the measurement model, each of the input quantity values should itself be metrologically traceable and the calibration hierarchy involved may form a branched structure or a network. The effort involved in establishing metrological traceability for each input quantity value should be commensurate with its relative contribution to the measurement result.
NOTE 5	Metrological traceability of a measurement result does not ensure that the measurement uncertainty is adequate for a given purpose or that there is an absence of mistakes.