
Global distribution of reference materials

Distribution générale des matériaux de référence



Reference number
ISO/TR 11773:2013(E)

AVA Documents
Document Sharing Hub
© ISO 2013



COPYRIGHT PROTECTED DOCUMENT

© ISO 2013

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
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

Published in Switzerland

Contents

	Page
Foreword	iv
Introduction	v
1 Scope	1
2 Abbreviated terms	1
3 Custom regulations	1
4 Critical issues for RM transportation	2
4.1 Observations and recommendations.....	2
4.2 Case study.....	5
5 Other aspects for RM distribution	6
6 Conclusions	7
Annex A (informative) Further sources of information	8
Bibliography	9

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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

In exceptional circumstances, when a technical committee has collected data of a different kind from that which is normally published as an International Standard ("state of the art", for example), it may decide by a simple majority vote of its participating members to publish a Technical Report. A Technical Report is entirely informative in nature and does not have to be reviewed until the data it provides are considered to be no longer valid or useful.

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.

ISO/TR 11773 was prepared by the ISO Committee on Reference Materials (ISO REMCO).

Introduction

In discussions within ISO/REMCO and with its stakeholders, both reference material producers (RMPs) and reference material users (laboratories in universities and research institutes; regulators and control agencies; industrial laboratories; proficiency testing providers; metrology, standardization and accreditation bodies) complain about problems with the free circulation of reference materials (RMs). Their worldwide availability is hindered as a consequence of obstacles related to their transport, export and/or import in certain countries. This concerns certified reference materials (CRMs), which are qualified and accompanied by special certificates stating information on certified characteristics of the material,^{[1][2]} and non-certified RMs used for proficiency testing or other interlaboratory comparisons and collaborative studies, respectively. The underlying reason for this is that RMs are mostly treated and legislated by authorities as bulk amounts of their matrix substance (human, animal or plant material, chemical substance, explosive, drug, etc.) and not as a (sometimes legally) mandatory tool needed to perform correct measurements, which are frequently the basis for regulatory or other society-relevant decisions. Thereby, it is often ignored that

- the content of potentially toxic material present in the RM is often insignificantly low¹⁾,
- the volume of RMs containing flammable and/or toxic solvents is generally small, mostly less than 30 ml²⁾,
- RMs of biological origin (plant, animal, human) are neither entering the food chain, nor are they used in clinical treatments,
- RMs are exclusively used for measurement or testing purposes, and therefore the issue that they may contain pathogens or not is of limited concern when appropriate laboratory precautions are obeyed³⁾.

Moreover, inconsistencies in legal restrictions may make the use of certain extremely important CRMs very difficult or even impossible. For instance, some important ATCC (American Type Culture Collection) CRMs for mammalian cell lines are regulated by the “Convention of International Trade in Endangered Species of Wild Fauna and Flora” (CITES), despite the fact they are cultivated by means of cell culture media and therefore play no role at all in the protection of animals.

1) RMs classified as hazardous materials such as narcotic drugs, explosives, poisons and other dangerous substances only contain amounts of substances or solutions of them in concentrations which are such that these substances can neither be considered as dangerous nor they can be misused as narcotic drugs, explosives or poisons. In case of the latter it has to be checked if the chemicals or biological materials are considered as dual-use goods for which additional import/export regulations apply. The dual-use regulation does not provide any exemption for most listed materials, even not for very small quantities.

2) Many RMs consist of mg-level, µg-level or even lower amounts of substances in solution. For instance, it was possible in Germany to make an additional decree to ADR, the “Gefahrgut-Ausnahmeverordnung” (Hazardous material exception decree) with exceptions e.g. for materials of the ADR-classes 3 (Flammable liquid materials), 6.1 (Toxic materials) and 8 (Corrosive materials) up to 5 kg or 5 l.

3) Biological CRMs are generally processed in a form which is inappropriate for consumption.