PD ISO/TR 11773:2013

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TECHNICAL REPORT

ISO/TR 11773

First edition
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ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
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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is entirely informative in nature and does not have to be reviewed until the data it provides are considered to be no longer valid or useful.

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

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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 low[1)],

— the volume of RMs containing flammable and/or toxic solvents is generally small, mostly less than 30 ml[2)],

— 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 obeyed[3)].

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.

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TECHNICAL REPORT **ISO/TR 11773:2013(E)**

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1 Scope

This Technical Report contains an inventory of problems and recommendations related to the transport, import and export of non-nuclear, non-radioactive reference materials, specifically for the packaging, labelling, and documenting of the shipments in order to comply with legal requirements. It does not explain detailed rules such as for labelling according to the Globally Harmonized System (GHS).

2 Abbreviated terms

ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
AES	Automated Export System
ATCC	American Type Culture Collection
CITES	Convention of International Trade in Endangered Species of Wild Fauna and Flora
CRM	Certified Reference Material
ECHA	European Chemicals Agency
FAPAS	Food Analysis Performance Assessment Scheme
GHS	Globally Harmonized System
IATA	International Air Transport Association
ICAO	International Civil Aviation Organization
LQ	Limited Quantity
RM	Reference Material
RMP	Reference Material Producer
SDS	Safety Data Sheet
TSCA	Toxic Substances Control Act
UNECE	United Nations Economic Commission for Europe

3 Custom regulations

3.1 On 1 January 2002, a general customs tariff number 3822.00 was introduced for "certified reference materials". This was generally considered as an important step in the facilitation of the global use of CRMs. However, experiences in recent years have shown that this number and its meaning are still not fully known by producers, distributors and users, and that some confusion still exists on the correct interpretation of both the text of customs tariff number 3822.00 itself and of the explanatory notes published by the World Customs Organization related to it.

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