TECHNICAL REPORT

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Global distribution of reference materials

Distribution générale des matériaux de référence

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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is entirely informative in nature and does not have to be reviewed until the data it provides are considered to be no longer valid or useful.

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 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.

Global distribution of reference materials

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.

3.2 In the European Union, the customs aspects are further specified by the following.

For the purpose of heading 3822 of Commission Regulation (EC) No 2031/2001 of 6 August 2001 amending Annex I to Council Regulation (EEC) No 2658/87 on the tariff and statistical nomenclature and on the Common Customs Tariff, the expression "certified reference materials" means "reference materials which are accompanied by a certificate which indicates the values of the certified properties, the methods used to determine these values, and the degree of certainty associated with each value and which are suitable for analytical, calibrating or referencing purposes".

3.3 Moreover, it is specified that with the exception of the products in Chapter 28 or Chapter 29, for the classification of certified reference materials, heading 3822 shall take precedence over any other heading in the nomenclature.

3.4 In other words, a CRM is a well characterized and documented analysis or measurement sample in the form of:

— a pure substance (certified for its purity and/or contained impurities), or

— a standard solution of one or more pure substances (certified for its content), or

— a matrix material (transformed into a stabilized form) certified for major constituents and/or trace constituents, or

— a material, object or artefact certified for specific physical properties which is conceived to be used to calibrate, validate, control or monitor measurement procedures and/or processes.

3.5 According to information from the relevant services of the European Commission, the customs tariff number 3822.00 must be used for all CRMs corresponding to the above definition, but considering the exception mentioned in 3822.00 regarding products falling under Chapters 28 and 29. Consequently, CRMs which are pure (organic, inorganic, elemental) substances or solutions thereof, i.e. many CRMs being used as calibrants, belong to the exceptions to 3822.00.

3.6 Therefore, an important question to answer is how far the use of a (globally accepted) dedicated customs tariff number for CRMs has an impact on the transport, import, export regulations and restrictions at the global level. Can samples which are considered as a "CRM according to the customs definition"

— be imported into countries having a ban or imposing quarantine or sterilization treatments to food, feed, products of animal or plant origin, soils and sediments, waste, etc. as being clearly differentiated from the products targeted in the legislation?

— be exported freely without requiring specific licences from the receiving laboratory or country?

— be transported without considering the certified component always as a bulk amount of its constituents, and consequently as a transport of dangerous goods?

4 Critical issues for RM transportation

4.1 Observations and recommendations

4.1.1 Labelling

4.1.1.1 The UNECE GHS (Globally Harmonized System) rules for classification and labelling should be followed.

4.1.1.2 For the European Union, the classification, labelling and packaging of materials are defined in Regulation 1272/2008 EC.

4.1.1.3 The label on the material must be the same as what is mentioned on pro-forma invoices, SDS (safety data sheets), etc.

4.1.1.4 It is recommended not to list the certified analytes on the label, in order to avoid misunderstandings. A label "Milk powder" together with a product-specific CRM code should be sufficient, whereas a label "Dioxins in milk powder (high level)" asks for problems, even if the level of dioxins is below the legal limits for human consumption.

4.1.2 Transport issues

4.1.2.1 For transport by air, the IATA rules apply. They lay down, in detail, packaging requirements for dangerous goods. While the rules are clearly defined, a plethora of airline and country specific exceptions makes shipment a non-trivial task. For instance, different specialized packing may be required for corrosive materials such as acids.

4.1.2.2 Not all courier services allow transport of dangerous goods. This affects dry-ice transports, as dry ice is classified as dangerous goods. Moreover, prohibitive costs of some couriers do not allow door-to-door shipment, but only door-to-airport shipment.

4.1.2.3 Even if the concentrations of dangerous substances in reference materials are in most cases so small that nothing would happen during transport if the package was destroyed, they are sometimes declared as dangerous goods. Again appropriate labelling is crucial for the proper understanding by the carriers, etc. Fortunately, IATA/ICAO and ADR harmonized their regulations concerning limited/excepted quantities. For instance, in former times methanol was classified in the ADR more restrictively than in the IATA/ICAO. Now methanol with the UN Number 1230 is classified into the newly created harmonized class E2 which allows, on the road and in the air, the excepted/limited quantity of 30 g/30 ml for the inner packaging and 500 g/500 ml for the outer packaging.

4.1.2.4 Remote islands can cause delays in the shipment. For example, some islands off the coast of the British Isles or in Indonesia are only accessible by ferries, which do not run daily, delaying transport of potentially degradable material.

4.1.2.5 Shipments should be scheduled in a way that arrival of refrigerated materials on Fridays is avoided. This reduces the danger that materials remain at room temperature over the weekend.

4.1.2.6 Parcels for cooled transport should have a label "store at x °C" on the outside to facilitate rapid transfer to suitable storage conditions.

4.1.2.7 Some courier services refuse the acceptance of certain types of boxes.

4.1.3 Export/import issues

4.1.3.1 In some cases, a component of a RM (such as a molecular sequence) may be covered partially by intellectual property rights, preventing its import into specific countries.

4.1.3.2 Other materials may only be exported once, for instance because of security regulations. This limits the possibility for their redistribution. In addition, if the materials are processed in another country than the one where the RMP is located, transport to the storage may already constitute an import, which precludes further distribution.

4.1.3.3 To prevent problems with export customs authorities, one may use "EZT Online" or "TARIC" available under http://ec.europa.eu/taxation_customs/dds2/taric/taric_consultation.jsp .This is an electronic customs tariff. After entering the 8 first digits of the customs tariff number and the export