TECHNICAL REPORT

ISO/TR 11773

First edition
2013-02-15

Global distribution of reference materials

Distribution générale des matériaux de référence

Reference number
ISO/TR 11773:2013(E)

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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.

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is entirely informative in nature and does not have to be reviewed until the data it provides are considered to be no longer valid or useful.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

country, it gives notice of any restrictions on that product. This database works with a correlation list for all products which are listed on any current EU list based on the customs tariff numbers.

4.1.3.4 Trade embargos can cause delays in shipment or even prevent the RM distribution. For example, even in case of clearly non-critical materials, customs may ask for declarations that the material could not be used for nuclear purposes. Likewise, shipment of fertilizer CRMs is often difficult to countries where the application of such fertilizers is banned.

4.1.3.5 When the reference materials to be exported are of US origin, they may fall under the US Re-Export Law and the US Commerce Control List if your product is subject to being re-export licensed (see links to US NRC: http://www.nrc.gov/materials/miau/general-use.html and to "Don't let this happen to you" http://www.bis.doc.gov/enforcement/dontletthishappen2u.pdf).

4.1.3.6 Correspondence from Brazil to ISO/REMCO indicated that problems in the importation of all reference materials have been experienced. This is supported by information from courier services used to distribute laboratory intercomparison samples (see 4.2).

4.1.3.7 Sometimes US customs require FDA registration of the producer, before CRMs of food origin (e.g. milk powder) can enter the US. Without registration, goods may be returned.[4)]

4.1.3.8 CRMs of animal origin may fall under the EU legislation of animal by-products (Regulation 1069/2009/EC).

4.1.4 Administrative and documentation issues

4.1.4.1 Administrative requirements on transport documents vary from country to country.

4.1.4.2 Safety Data Sheets (SDS), certificates of health and certificates of origin should be readily available.

4.1.4.3 To know in advance which documents the importer may need to import the reference materials, one can use the so-called "MARKET ACCESS DATA BASE" on the internet http://madb.europa.eu/mkaccdb2/indexPubli.htm. By entering the first four digits of the customs tariff code and the import country, the exporter can get an idea which certificates or licenses the importer may need for the products to be exported.

4.1.4.4 If the RMP can understand German, one may use the "K&M Konsulats- und Mustervorschriften". This is either a CD-ROM or a book which is published every two years and shows, for every country of the world, the procedure and documents which are needed for a successful export to that country. This helps prevent problems with import customs authorities.

4.1.4.5 Customs may ask for additional information on what the material looks like, how it is closed, etc. The nature of the questions is unpredictable.

4.1.4.6 It may be advantageous to obtain and keep the status as 'customs approved special facility', such as Approved Exporter or Authorized Economic Operator (AEO: http://ec.europa.eu/taxation_customs/customs/policy_issues/customs_security/aeo/index_en.htm).

4.1.4.7 One may use the electronic custom tariff database "EZT Online" or "TARIC". http://ec.europa.eu/taxation_customs/dds2/taric/taric_consultation.jsp?Taric=&Lang=en&Screen=0&Description=&Area=&redirectionDate=20100909&Level=&LangDescr=en&Expand=false&SimDate=20100909. It gives notice of any restrictions on that product (i.e. export license is needed for that product as it is mentioned

4) See http://www.fda.gov/forindustry/fdabasicsforindustry/ucm237623.htm

on the dual-use goods list of the European Union). This database works with a correlation list for all products which are listed on any current EU lists based on the custom tariff numbers.

But if one uses, for this database, the customs tariff number 38220000 also for a product which is mentioned in the dual-use-goods list http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:134:0001:0269:en:PDF, one has to give the customs authorities notice via the AES/ATLAS (Automated Export System) that either the product is really subject to being export licensed (in that case a special code and the number of the export license has to be entered) or the product to be exported has only the same customs tariff number, but is in fact not mentioned specially on that list (another code has to be entered to confirm this). This prevents in the very beginning delays in export customs clearance.

Moreover, one has always to confirm in the AES process that those products are not listed on the list of products destroying the ozone layer (EU Law 1005/2009: http://ec.europa.eu/clima/policies/ozone/index_en.htm).

4.1.4.8 Certified Reference Materials have to be accompanied by the certificate.[1][2] Sometimes the certificate may be filed by customs together with all shipping documents and may not reach the CRM user.

4.1.4.9 In some cases, a pro-forma invoice is insufficient and final invoices must be attached to the packages.

4.1.4.10 Some countries require import licences; A TSCA (Toxic Substances Control Act) form needs to be provided for shipments into the USA.

4.1.4.11 Some countries require statements that the packages are free of wood.

4.1.4.12 Some materials require certificates of final use.

4.1.4.13 The challenge with the issues mentioned above lies in the fact that they keep changing. There is no systematic information flow from distribution service providers (couriers) to RMPs. The information is sometimes transmitted by customers, but mostly only experienced due to problems at customs.

4.2 Case study

4.2.1 General

As an illustration of distribution problems with reference materials, experiences collected in the course of dispatching samples for two international intercomparison studies are briefly described here.

4.2.2 Background

LGC (Teddington, UK) was the co-ordinating laboratory for two interlaboratory studies with a requirement that the respective samples be transported to the participating laboratories in frozen conditions. As all participants (apart from LGC) were from outside the UK, dry ice shipments were needed. The RMs for the studies had to be distributed to laboratories located in Europe, Asia, Australia, the South and North Americas. The participating laboratories were asked to provide as much information as possible before any samples were dispatched, to assist in the swift passage of samples through their respective customs organizations.

4.2.3 Dispatch observations

4.2.3.1 Samples were successfully sent to laboratories within the European Union without any problems.

4.2.3.2 Dispatch outside the EU was more complex. In total, five couriers were used to transport samples to eight countries.

The main issues were as follows:

— courier not willing to ship samples on dry ice;

— courier not offering a dry ice 'top up' service;

— courier requesting a health statement relating to the condition, exposure and treatment of one of the samples which was fresh fish;

— courier requesting an import permit from the destination laboratory;

— delays in customs waiting for additional documentation;

— inconsistency in documentation required between countries.

4.2.4 Summary

The RM transport delays were frustrating for both LGC and the participants. The first dispatch was attempted in April 2007 and the last sample was finally received by one of the participating laboratories in July 2007, which was after the original reporting dates for the intercomparison studies. The laboratories cannot plan their work (requiring specialized staff, instrumentation and work of many weeks) if they do not know when, and if, the intercomparison samples will be received.

It is obvious that different couriers have different modes of operation in the various countries and request significantly different levels of paperwork to accompany the samples. For the materials and countries involved in these two studies, the courier with the most comprehensive network of local agents was the most effective.

The need to ship and maintain these samples in a frozen state using dry ice further complicated the distribution – some airlines are willing to accept dry-ice shipments, while others are not. Couriers work with specific airlines and this impacts their ability to distribute such products. The costs of transporting frozen materials under dry ice are significant. There are then the additional costs of maintaining the dry ice top-up, if customs clearance is delayed. In addition, to obtain evidence that the samples have not defrosted, a temperature history of the consignment would be desirable. Again, this will add to the cost of distribution.

5 Other aspects for RM distribution

5.1 REACH is a European Community Regulation on chemicals and their safe use ((EC) No 1907/2006). It deals with the Registration, Evaluation, Authorization and Restriction of chemical substances. The law entered into force on 1st June 2007. The regulation aims to protect human health and the environment through the better and earlier identification of the intrinsic properties of chemical substances. Enterprises which manufacture in or import into the EU more than one tonne of a chemical substance per year will be required to register it in a central database administered by the new EU Chemicals Agency (ECHA).

There have been opinions that the introduction of REACH would have far-reaching impacts on producers and distributors of reference materials, especially for reference materials containing very toxic and/or bioaccumulative substances. As the regulation is very complex, the following clarification has been provided by the relevant services of the European Commission.

— Registration of chemicals is only necessary, if the yearly production exceeds 1 tonne per year. This tonnage limit is independent of the nature of the substance and is not influenced by toxicity, bioaccumulativeness, etc. Natural substances are also exempted from registration, if they are not dangerous and have not been chemically modified.

— Authorization to use or put a substance on the market is required for substances identified as substances of very high concern (SVHC) and included in Annex XIV of REACH. This Annex

will contain a list of substances subject to authorization. Carcinogenic, mutagenic, reprotoxic, bioaccumulative, persistent substances as well as endocrine disruptors are candidates for that list, but are not automatically included. Competent Authorities of the EU Member States or the ECHA, on a request by the European Commission, may suggest substances being classified as SVHC. If this suggestion is taken up, the substances are finally included in Annex XIV of the REACH regulation. The candidate list of substances for possible inclusion in Annex XIV is published and periodically updated by ECHA. The first candidate list was published on ECHA's website in October 2008. It is important to note that authorization for preparations containing an SVHC is only required if the mass fraction is above 0,1 %.

— Title VIII of REACH provides for possible restrictions on the manufacturing, placing on the market and use of certain dangerous substances (on their own, in preparations, or in articles). This is not a new feature of EU chemicals legislation. Annex XVII of REACH reflects the restrictions made already by Directive 76/769. EU Member States or the European Commission can propose more substances for inclusion in REACH Annex XVII when there is an unacceptable risk to human health or the environment arising from the manufacturing, use or placing on the market of substances, which needs to be addressed on a Community-wide basis.

5.2 In short, the impact on RMPs is as follows.

— No registration of reference materials under REACH is required for materials produced at less than 1 ton per year, regardless of the nature of the substance and/or certified parameters. The vast majority of reference materials will fall under this category.

— Reference material distributors will need to confirm whether their customers have the necessary authorization in the case of CRMs for SVHC. However, given the mass fraction limit of 0,1 %, this practically affects only pure substances and not even most of their solutions. In order to fulfil their obligation under REACH, RMPs need to follow the updates of Annex XIV of REACH.

— Reference Material producers will need authorization to handle SVHCs, if they are used in the production process, e.g. for spiking matrix materials or for the preparation of solutions.

5.3 Detailed information and guidance on REACH can be found on the ECHA website (http://www.echa.europa.eu/).

6 Conclusions

The introduction of the general customs tariff number 3822.00 has supported the global distribution of certified reference materials. But experience from recent years shows that this UN tariff code is not acknowledged by all customs worldwide. This corresponds with observations that the interpretation of transport and import/export rules varies not only from one customs station to another customs station within the same country, but even from individual to individual, thus creating additional uncertainty. Moreover, the administrative requirements including demanded documentation for RM transport vary from country to country. All these obstacles are even more difficult for non-certified reference materials, i.e. the samples which are usually distributed for interlaboratory comparisons such as proficiency testing.

It should be noted that reference materials are intended to be used by trained professionals under controlled conditions. They are used in small amounts, usually for enabling or checking measurements on similar materials in larger amounts at the same site. This should be taken into consideration in the development of international recommendations and their national or local implementation. Moreover, global regulatory labelling recommendations for small quantities would be useful to enable the availability of reference materials with adequate quality.

Annex A
(informative)

Further sources of information

EU list of dual-use goods:

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:134:0001:0269:en:PDF

EU Law 689/2008 Dangerous Chemicals:

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:204:0001:0035:EN:PDF

Further guidance on 'dangerous goods' transport:

http://www.icao.int/safety/DangerousGoods/Pages/default.aspx

IATA documents:

http://www.iata.org/Pages/default.aspx

http://www.iata.org/whatwedo/cargo/dgr/Pages/index.aspx

Shipper's declarations at:

http://www.iata.org/whatwedo/cargo/dgr/Pages/download.aspx

CFR forms required for US imports:

http://www.epa.gov/oppt/import-export/

GHS rules for labelling:

http://www.unece.org/trans/danger/publi/ghs/ghs_welcome_e.html

Bibliography

[1] ISO Guide 31:2000, *Reference materials — Contents of certificates and labels*

[2] ISO Guide 34:2009, *General requirements for the competence of reference material producers*

ICS 71.040.30

Price based on 9 pages