Contents of RM documents and Label as per ISO Guide 31:2015

Mandatory information for CRM and RM

1. Title of the document - There should be a distinct title, such as 'Product information sheet' or 'Reference material certificate'.

- ✓'Certificate' or 'Certificate of Analysis' has often been used for the title of a document.
- ✓It is good practice that the user of a CRM checks, even if the title of the document includes the word 'certificate', whether mandatory information from this Guide is present in the document thus fulfilling the requirement of a CRM.
- ✓Examples of other terms used for the product information sheet are material information sheet, analysis report, statement to users, information leaflet, etc.; and those for the reference material certificate are certificate of analysis, certificate, etc

Mandatory information for CRM and RM

2. Unique identifier of the RM

Every RM and its related RM document shall carry a unique identifier by which it is uniquely distinguishable from the document of any other RM issued by the same or any other producer.

- ✓A unique combination of a product code and a batch number is one example.
- ✓The code number makes it easy to distinguish an RM from any other RM, e.g. NMIJ CRM 7305, ERM-AC110, NIST SRM 41.
- ✓In addition, the batch number will help prevent confusion that may arise when a laboratory has material from more than one batch in use at the same time. Some producers incorporate the batch number in the alphanumeric code for the material, e.g. NMIJ CRM 7305-a.

Mandatory information for CRM and RM

3. Name of the RM

- ✓ The name of the RM shall be stated. As far as possible, the name should describe the type of RM in sufficient detail to distinguish it from other similar materials. Thus, the name of the rock or ore, followed by its origin or a compositional characteristic, gives more individuality to geological materials; e.g. "Syenite (Phalaborwa)" or "Nepheline syenite".
- ✓ For trace analysis of pollutants in natural matrices, it is important to state the nature of the matrix.

Mandatory information for CRM and RM

4. Name and contact details of the RM producer

The name and contact details of the RM producer shall be stated. Examples of the contact details are full postal address, telephone number, fax number, e-mail address and website.

Mandatory information for CRM and RM

5. Intended use

The main intended use of an RM shall be stated. When the properties provided are independent of a particular analytical or measurement procedure, this statement is not intended to restrict the use for other purposes. The RM document shall provide sufficient information to the users so that they are able to decide whether or not the respective RM meets their requirements (e.g. matrix type, measurand, quantity level, etc.).

- ✓ Intended use of an RM other than CRM
- ✓ Intended use for a CRM

Mandatory information for CRM and RM

5. Intended use – continued –

Examples of intended use of an RM other than a CRM are:

- ✓to demonstrate control of a measurement process within a laboratory over a period of time;
- ✓to check instrument performance;
- ✓repeatability and reproducibility studies – repeated use over an extended period of time, instruments, operators, etc., to estimate long-term reproducibility or robustness of a measurement process or laboratory;
- ✓to confirm the degree of equivalence of measurement results from two or more laboratories (e.g. provider and user), where the materials are inherently stable;
- ✓to check operator variability;
- ✓to investigate the impact of any changes to the environmental conditions (e.g. temperature, humidity).

Mandatory information for CRM and RM

5. Intended use – continued -

Examples of intended use for a CRM are:

- ✓the realization of a fixed point of an (international) measurement scale;
- ✓the calibration of instruments or measurement systems
- ✓the transfer of property values among different materials;
- ✓the validation of analytical methods, in particular regarding trueness;
- ✓the determination of the recovery factor of matrix separation operations such as extraction.

Mandatory information for CRM and RM

6. Minimum sample size

Whenever applicable, the minimum sample size of the RM to be used shall be stated based on the degree of the RM homogeneity, or other methods such as stability, characterisation, and interlaboratory characterisation studies.

This should be accompanied by a statement that the property value and its associated uncertainty are only guaranteed if the minimum sample size is respected.

✓Applicable to RM and CRM.

Mandatory information for CRM and RM

7. Period of validity

A period of validity (or expiry date) shall be stated. The fitness for purpose of the material cannot be guaranteed beyond the period of validity (or expiry date).

✓Period of validity is the shelf life of the RM or CRM

Mandatory information for CRM and RM

8. Commutability

Where commutability information is required the RM producer shall provide sufficient information for the user to judge whether the material is appropriate for its particular use without further qualification, or whether additional qualification by the user is required before use.

✓Applicable to clinical RMs.

Mandatory information for CRM and RM

9. Storage information

The conditions for storage (e.g. temperature, exposure to light) of the RM in order to maintain the validity of the RM document, shall be stated.

Mandatory information for CRM and RM

10. Instructions for handling and use - Instructions for the handling and use of the RM shall be stated. Examples:

- ✓appropriate instructions to ensure homogenization of the container contents before use;
- ✓prescribed instructions for the opening of the container;
- ✓the exact conditions for the drying of the material and/or the dry mass correction;
- ✓where necessary, instructions for further particle size reduction;
- ✓appropriate instructions for the reconstitution of a solid RM to prepare a solution;
- ✓appropriate mathematical expression for the calculation of the value of the property at the time of use, e.g. in the case of materials which are inherently unstable, such as radioactive substances

Mandatory information for CRM and RM

11 Page number

An RM document shall include the page number and the total number of pages.

12 Document version

The version of the RM document shall be clearly stated by, e.g. a unique version number or the approval date of the documentation.

Additional information for RM Certificate

A) Description of the material

A general description of the material shall be stated in an RM certificate that provides a more detailed explanation of the name.

For materials certified for their chemical composition, the main characteristics of the matrix, especially the presence or absence of interfering substances, may be of considerable importance in the selection of appropriate analytical methods.

Additional information for RM Certificate

A) Description of the material (continued)

Examples of matrix information:

- ✓alloys prepared from individual constituents;
- ✓rocks or waters obtained from natural sources;
- ✓products of animal or vegetable origin;
- ✓whether the analytes are spiked in or are naturally present.

The physical description of the material may also be given, where appropriate, e.g. sample size, particle size, dimensions of metal cylinders or discs, and the nature of the container in which it is supplied.

Additional information for RM Certificate

B) Property of interest, property value and associated uncertainty

An RM certificate shall contain a clear statement of the property(ies) of interest, its (their) property value(s) and associated uncertainty(ies). Certified values shall be clearly indicated as certified values and distinguished from any other values that may be provided in the RM certificate. The associated uncertainty(ies) of the property value(s) should be reported according to ISO/IEC Guide 98-3.

NOTE In some cases that are covered by specific legislation (e.g. most pharmacopoeia assay standards), the uncertainties of the assigned values are not stated since they are considered to be negligible in relation to the defined limits of the method-specific assays for which they are used.

Additional information for RM Certificate

C) Metrological traceability

An RM certificate shall contain a statement of metrological traceability. It shall include information about the measurement scale to which the certified value is traceable and should list the principle(s) of the measurement procedure(s) used for characterizing the material.

To summarize, the information on metrological traceability that shall be stated in the RM certificate is, therefore,

- ✓a clear specification of the measurand;
- ✓the measurement scale to which the property value is made traceable.

Additional information for RM Certificate

D) Measurement methods for method dependent measurands

When the definition of a measurand depends on the measurement method, information about the method used is essential. In such cases, the certificate shall give full details of the method used or a reference to a publication in which the method is fully described.

NOTE: The same principle applies in the case of qualitative properties.

Additional information for RM Certificate

E) Name and function of the RM producer's approving officer

The name and function of an officer representing the RM producer and accepting responsibility for the contents of the certificate shall be stated in an RM certificate.

NOTE : The name of the officer can be the name of the responsible organization.

Other useful information for RM Documents

(i) Measurement methods for method-independent measurands

When the measurand is not defined by the measurement method used, it may still be useful to include the following details:

- ✓ the measurement method(s)/technique(s) of characterization;
- ✓ the approach for characterization (e.g. single method, multiple methods, etc.);
- ✓ whenever applicable, the method used for sample handling/transformation.

Other useful information for RM Documents

(ii) Health and safety information

Whenever appropriate, the RM document should include health and safety information. A reference to the existence of a safety data sheet should also be stated because the safety data sheet is often taken away during the exporting and/or importing process.

Other useful information for RM Documents

(iii) Subcontractors

When an RM is produced under a sub-contract, the name and contribution of the subcontractor may be listed.

Where several laboratories or independent analysts have contributed to the characterization of an RM, their names may be listed, together with the methods they have used.

Other useful information for RM Documents

(iv) Indicative Values

The RM producer may include indicative values.

Examples :

- ✓ The approximate concentration of an analyte in a complex matrix that does not fulfil the criteria for a certified property value;
- ✓ individual results from each laboratory or analyst, where results from several laboratories or analysts were used to assign the property value(s).

Other useful information for RM Documents

(v) Legal Notice

A legal notice may be included.

(vi) Reference to a certification report

Many users of an RM will not require any information in addition to that contained in the RM document. However, additional information may be made available with an RM in the form of a production or certification report, obtainable on request or otherwise accessible to interested parties.

CONTENTS OF RM LABEL

The information provided on a label of an individual unit of an RM shall serve to

- ✓ uniquely identify the material and
- ✓ allow the identification of the appropriate product information sheet or RM certificate.
- ✓ Whenever applicable, health and safety information shall be included in compliance with relevant legislation or directives.

CONTENTS OF RM LABEL

- ✓Label of an RM shall be securely attached to the product container of an individual RM unit.
- ✓Label shall be designed to remain legible and intact under the defined storage and handling conditions within the period of validity.
- ✓The information supplied on the label of a unit of an RM shall be clear and concise.
- ✓The label and/or the container marking shall allow identification of the appropriate RM document, usually by the use of a unique product identifier.
- ✓Where space allows, it is advisable to include the name of the RM and the producer.

CONTENTS OF RM LABEL

- ✓It is advisable that neither (certified) property values nor indicative values are included on the label to prevent the use of the material without the information in the RM document having been studied.
- ✓The labels shall, where appropriate, comply with requirements related to health, safety and environmental regulations, e.g. show toxicity symbols, hazard and precautionary phrases.
- ✓If the material is classified as dangerous for transport or hazardous for use, the label shall contain mandatory information in accordance with the applicable regulations.
- ✓ The Safety Data Sheet contains more information than the label and forms the reference source for the management of hazardous chemicals in the workplace.