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**General requirements for the programme
of reference material certification
in serial production**

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General requirements for the programme of reference material certification in serial production

01-Scope

This International Document sets out ~~the general~~ requirements for the development of documented procedure, describing programme of reference material (RM) certification, covering the description of specific procedures for the determination assessment of metrological characteristics homogeneity, stability, characterization, assignment of property values and their associated uncertainties, certification of reference materials of the same type, released in series as by the producer of certified reference materials (CRMs), used in metrological activities, covered, in conformity with national laws, by state metrological control and supervision ~~(SMCS)~~, exercised by national services of legal metrology.

Note:

In this document the term "reference material" is used as a generic term, to which certified reference material also belongs - the reference material, characterized by a metrologically valid procedure for one or more specified properties, accompanied by a RM certificate that provides the value of the specified property, its associated uncertainty and a statement of metrological traceability [A.2, A.5].

It is recommended, that the principles, set out in this International Document be implemented by ~~(C)RM~~ producers in the development and release of ~~RMs and CRMs~~, used in the fields of for the purposes of legal metrological control and supervision (LMCS), in the activities of national services of legal metrology and accreditation bodies, in the development of OIML publications.

This International Document has been developed taking into consideration the general concepts, expressed in ISO/REMCO and OIML international publications concerning the development, release and use of ~~RMs and CRMs~~. Account has also been taken of the concepts of OIML publications, establishing the use of reference materials in fields, covered by metrological control, exercised by national services of legal metrology [A.1].

This International Document ~~is also based rests upon on~~ ISO/REMCO Guides 30-35 (see Annex A) and supplements these Guides as concerns the requirements for documented procedures of (C)RM producers² by which documentation on RM certification, to be taken into consideration in the determination of metrological characteristics and the certification of released ~~lots~~ batches or units of ~~(C)RMs of~~ the same CRM type, produced in series and intended for the use in the field of LMCS are periodically carried out during a long period of time.

It recommended, that producers of CRMs, released in series and intended for use in the field of LMCS, follow the requirements of ISO Guides 30-35 (see Annex A) and OIML D 18 (A.1).

When determining characteristics of non-certified reference materials, to be used in the field of LMCS in the absence of corresponding CRMs or, e.g. accepted for use in pharmacopoeia documents, the recommendations, set out in this document or ISO Guides 30-35 (see Annex A) should be followed as far as possible.

12 General concepts

CRMs are widely used in metrological activities, related to the fields, covered by LMCS, e.g., for the verification, ~~as measurement standards of units for the~~ calibration of measurement instruments, validation and control of measurement procedures, etc. General principles of CRM use in the fields, covered by metrological control and supervision, exercised by national services of legal metrology, are set out in OIML D 18 [A.1].

Uninterrupted release of interchangeable ~~(C)RMs~~ of the given type, used in the field of LMCS from batch to batch or from unit to unit of proper quality during a long period of time can be ensured by the CRM producer ~~of (C)RMs~~, provided, that he has documented procedures (technological documentation, as described in subclause 4.4 [A.1]), clearly and in detail describing the range, sequence and specific work operations on the production and certification of ~~the (C)RMs and RM certification.~~

Note:

(C)RMs, produced in compliance with the same technical documentation, from the same or similar in composition material, having the same ~~metrological characteristics~~ property to be certified, intended use, ~~established statement of~~ metrological traceability of the certified value, the same or similar property value and accuracy are referred to as ~~(C)RMs~~ of one and the same type.

The important step in ~~(C)RM release~~ the production of any CRM type is the determination of their metrological characteristics (determination assessment of (C)RM homogeneity, and and stability, (C)RM characterization, assignment of based on the research of CRM candidate (C)RM material (hereinafter referred to as (C)RM material), calculation of RM certified property-values and their associated uncertainties), and RM certification of reference materials.

The programme of certification of series produced CRMs (hereinafter referred to as certification programme) is ~~T~~ technological documentation, describing the range, and the sequence of works on the determination of metrological characteristics of RMs of the same given CRM type. Certification is the programme of RM certification, which includes specific operations and procedures and relates to the documentation of (C)RM producer's quality management systems, [A.65].

Note:

CRM producer's certification programme as a document, which is the part of the technical documentation for CRMs, intended for use in the field of LMCS, is envisaged under subclause 4 of OIML D 18 [A.1]. The requirement to document programmes, procedures, instructions and other documents is provided under subclause 4.3.1 of ISO Guide 34 [A.5].

~~The definition of the term “certification of RM” is given in subclause 4.1 [A.2], procedure for RM certification is described in clause 11 [A.7].~~

General requirements for the competence of RM producers and requirements for RM certification are established in ISO Guide 34 [A.5] and ISO Guide 35 [A.6] respectively.

This International Document specifies the minimum requirements for the programme of the document - certification programme, used in the production of CRMs, intended for use in the field of LMCS ~~released in series~~. The concepts of this International Document may be extended in national regulatory documents taking into account specific features and practical work experience in various countries.

~~ISO/REMCO Guides 34-35 may serve as a useful guidance in resolving this question (see Annex A).~~

23 Terminology

The terminology used in this Document is in line with:

- The *International vocabulary of metrology – Basic and general concepts and associated terms* (VIM) [A.87];
- The *International vocabulary of terms in legal metrology* (VIML) [A.98];
- ISO Guides 304-35 (subclauses A.2 –A.76 of Annex A).

4. Some peculiarities of reference material serial production

4.1 Serial production of a specific CRM type envisages periodic release of the CRM in batches or in units. The frequency and the volume of re-occurring CRM batches or units are established by a CRM producer, who, when planning production, specifies the relevant information in technical documentation on CRM type. Serial production of CRMs is carried out according to one and the same documented procedures, describing in detail technical and operating requirements subject to the provisions of ISO Guide 34 [A.5].

4.2 In the process of serial production of CRMs, intended for use in the field of LMCS, the producer should follow the provisions of OIML D 18 and ISO Guides 30-35 (see Annex A).

4.3 The determination of CRM characteristics in the framework of serial

production, namely, the assessment of homogeneity, stability, property value and its associated uncertainty, the assessment of commutability (if necessary), the calculation of the CRM certified value and its associated uncertainty and also monitoring of stability should be carried with each renewal issue of CRM batch or unit of the given type, which is a solid material, including suspensions and sediment, in conformity with ISO Guides 34, 35 [A.5, A.6] according to certification programme, developed for the given CRM type. For re-occurring batches or units of CRMs, which are solutions, gases or pure compounds it is allowed not to carry out homogeneity study in full, as stipulated by ISO Guide 35 [A.6], provided that the necessary work according to [A.6] was carried out for the first CRM batch or unit. In this case, when renewal CRM batches or units are produced applying the same procedures, that were used for the production and certification of the first CRM batch or unit, appropriate verification assessments are required to ensure that estimations of uncertainty due to inhomogeneity, obtained on the first batch or unit remain applicable also for the new CRM batch or unit with account of established acceptance criteria.

In the framework of serial production it is allowed not to carry out stability study in full, as stipulated by ISO Guide 35 [A.6], for renewal release of CRM batch or unit of the given type according to the same procedures, that were used in the production and certification of the first CRM batch or unit. In this case, appropriate verification assessments are sufficient to ensure that estimations of uncertainty due to instability, obtained on the first batch or unit remain applicable also for the new CRM batch or unit with account of established acceptance criteria. Monitoring of stability should be provided for all CRM batches or units of serial production in compliance with the requirements of ISO Guide 34[A.5].

Note:

The results of certification of the first and subsequent CRM batches or units of the given type, including the results of the assessment of homogeneity, stability, post-certification monitoring of stability, recertification, etc. should be documented by CRM producer in compliance with the requirements of ISO Guide 34[A.5].

Assumptions, provided under subclause 4.3, hold true, if no amendments were introduced in the documented procedures during the production and certification of re-occurring CRM batches or units, which, eventually could result in property values and estimated uncertainties, different from the planned ones for this CRM type.

4.4 In the long-term serial release of CRMs, the documentation may be amended due to:

a) the use of new candidate materials (e.g., materials from other producers, other deposits, etc.) for the production of this CRM;

b) procedures for CRM candidate material processing (subclause 5.8 of ISO Guide 34 [A.5]);

c) a new CRM container, made of material, different from container material, used for the first CRM batches or units;

d) the changes in CRM transportation conditions (e.g., temperature), when planning to ship it to other regions of the world; storage and application conditions;

Depending on the type of introduced or proposed amendments in CRM documentation within the works on the determination of characteristics of CRM subsequent batch or unit, the following work, set out in certification programme, should be carried out:

- when amendments are introduced according to a) and b), the assessment of homogeneity and stability of a new CRM batch or unit should be carried out in full in accordance with the requirements of ISO Guide 35 [A.6];

- when amendments are introduced according to c) and d), the assessment of stability of a new CRM batch or unit is carried out in full in accordance with the requirements of ISO Guide 35 [A.6];

Amendments, related to measurement methods and procedures, measurement instruments, CRMs, used in the determination of CRM characteristics, should satisfy the need to release the given CRM type with specified intended use, accuracy and metrological traceability.

4.5 In the framework of CRM serial production it is allowed to recertify the material according to sub-clause 6.7 [A.6] when the actual CRM property value deviates from the certified value, provided in the CRM certificate. In this case the work on the assessment of homogeneity and stability, characterization, assignment of certified property values and their associated uncertainties should be repeated in compliance with certification programme.

Note:

All CRMs, produced in series, should be accompanied by a certificate, corresponding to ISO Guide 31 [A.3], issued as a result of certification or recertification.

4.6 During the production of CRMs, intended for use in the field of LMCS, the following legal requirements should be observed:

- all measurements, stipulated by procedures, should be made in compliance with ISO/IEC 17025[A.10];

- measurement methods should be validated and comply with ISO/IEC 17025[A.10] and ISO Guide 34 [A.5];

- primary measurement standards, used for measurement (if necessary), should undergo regular comparison with primary measurement standards of other countries, subject to the infrastructure, established by the International Bureau of Weights and Measures and Regional Metrological Organizations. If there are no primary measurement standards in a particular field of measurement in CRM producer's country, national measurement standards, traceable to the implementation of the definition of the unit through a primary measurement

standard of another country should be used [A.10];

- to achieve metrological traceability of measurements, measurement standards (see above) and/or certified reference materials with established metrological traceability should be used, as far as possible;

- measurement instruments should be calibrated and verified and should ensure metrological traceability of measurement results to accepted reference.

- measurement should be made only by laboratories, competent in the relevant field of measurement.

Notes:

1. Additional requirements for measurement methods, measurement instruments and testing equipment are provided in ISO Guides 34 and 35 [A.5, A.6];

2. Requirements, set out in ISO 15189, may be used for tests in the field of medicine.

35 General requirements for the programme of reference material certification

35.1 The (C)RM producer develops the certification programme ~~of RM certification~~ to establish the amount, sequence of works, description of specific procedures, carried out when determining ~~metrological~~ characteristics of ~~released (C)RMs~~ of the given CRM type released in series with specified intended use, ~~and accuracy~~ and metrological traceability.

Notes:

1 ~~The Certification~~ programme ~~of RM certification~~ is an integral part of (C)RM producer's ~~technical~~ documentation for CRM release.

2 ~~The Certification~~ programme ~~of RM certification~~ may be issued as a separate document or as a section of CRM technical assignment, section or part of the document (specifications), which establishes the order of CRM serial production.

35.2 ~~The Certification~~ programme ~~of RM certification~~ is intended for use by the personnel of (C)RM producer, periodically performing specific work on the determination of CRM ~~metrological~~ characteristics in the release of new (C)RM batches or ~~specimens~~ units of the same CRM type with specified intended use.

Note:

The personnel of (C)RM producer, conducting the work on the determination of ~~metrological~~ characteristics of ~~RM~~ of the given CRM type should be made aware of the certification programme.

35.3 ~~The programme of RM eCertification~~ programme is developed prior to the work on the determination of ~~RM metrological~~ characteristics of re-occurring CRM batches or units based on:

- initial data (e.g., the intended use of the future (C)RM, planned limits range of the property values and their associated uncertainties, of its metrological

~~characteristics~~, planned conditions of transportation, ~~storage~~ and safety of the (C)RM, etc.);

- ~~the data, provided and contained~~ in (C)RM technical assignment (project);
- ~~the results of certification of the first CRM batch or unit, obtained during the development of the given CRM type.~~

3.5.4 ~~In~~ During the development of RM-certification programme, the requirements are established ~~to~~ for the ~~selected~~ procedure of the material : preparation prior to the determination of CRM characteristics.

~~the preparation of the RM material prior to the determination of RM metrological characteristics:~~

~~conducting preliminary research of the possibility to determine RM metrological characteristics (as appropriate).~~

In the certification programme ~~of RM~~ ~~certification~~ specific requirements are established for:

~~the number and the competence of laboratories, which will make measurements in the framework of the determination of RM metrological characteristics;~~

the preparation of CRM candidate material for carrying out the studies (if necessary);

- subcontractors, involved in the work (if necessary);

- the procedure for the determination of CRM metrological characteristics;

- the method (-s) of the establishment and demonstration of metrological traceability of CRM property values;

- the documents, issued as a result of the studies;

~~the time schedule for carrying out the work on the determination of RM metrological characteristics studies. ;~~

-- certification;

- the procedure of monitoring of CRM stability;

- recertification.

3.5.5 The section “The procedure for the determination of RM metrological characteristics” of certification programme describes:

- the procedure for the ~~determination~~ assessment of ~~RM material~~ homogeneity;

- the procedure for the ~~determination~~ assessment of ~~RM material~~ stability;

- the procedure for ~~the~~ characterization of RM material;

-- the procedure for the assessment of CRM commutability (if necessary);

- the procedure for testing with the purpose of the assessment of applicability of estimations of uncertainties due to inhomogeneity and instability, obtained for the first CRM batch or unit, for a new CRM batch or unit (if necessary);

- the algorithms of calculation of the CRM certified value and expanded uncertainty of the certified value

~~and~~ The section establishes the requirements for:

- the ~~applied~~ measurement procedures, measurement instruments, ~~(C)RMs~~, other equipment, used in the ~~determination of RM metrological characteristics study~~;
- the measurement standards ~~of units~~, ensuring the establishment of metrological traceability or (in their absence) ~~to~~ for the accepted references;
- the number of samples, the number of measurement results, needed for the ~~determination of RM homogeneity and stability, RM characterization, assessment of homogeneity and stability, characterization, monitoring of stability, assessment of CRM commutability (if necessary), testing for the purpose of the assessment of applicability of estimations of uncertainties due to inhomogeneity and instability~~ frequency of measurements;
- the conditions of carrying out experimental work;
- the algorithms of processing measurement results, obtained within the works on the determination of RM ~~metrological~~ characteristics;
- the algorithms for the calculation of the CRM certified value, its associated uncertainty ~~of the certified value~~ and its components;
- the form of reporting the obtained results.

Notes:

1. The Certification programme ~~of RM certification~~ may include the requirements for measurement conditions, the qualification of operators, in case there are special requirements, not specified in the applied procedures.

~~2. If necessary, the procedure for the determination of RM metrological characteristics may include the procedure for the research of RM commutability.~~

32. When describing specific requirements (subclauses 35.3, 35.4), it is recommended to follow provisions set forth in [A.65, A.76].

35.6 Recommendations on the structure and presentation of ~~RM~~ certification programme are given in Annex B.

35.7 The title page of ~~RM~~ certification programme ~~shall~~ should contain the date of its approval. The pages of the document shall be enumerated.

35.8 It is recommended ~~The programme of RM certification shall~~ to include the sheet of changes in certification programme, which, if required, may be subject to changes and additions over time.

35.9 The Certification programme ~~of certification of RMs~~, covering CRMs intended for the use in the field of SLMCS[A.1], is subject to metrological examination, which evaluates:

- the correct use of metrological terms and concepts, designations and symbols of the SI units;
- the completeness of ~~presentation of the procedures~~ for the ~~determination of RM material homogeneity, the procedure for RM material characterization, the~~

~~procedure for the determination (monitoring) assessment of homogeneity and stability, characterization, assessment of CRM commutability (if necessary), for monitoring of CRM material stability, sufficient to carry out the relevant work by the personnel of (C)RM producer;~~

- the conformity of selected measurement procedures, measurement instruments, measurement standards ~~of units~~ with the criteria, specified in [A.65], [A.76], [A.12] and this document;

- the conformity of requirements for the sub-contractors, ~~carrying out the work on the determination of the RM metrological characteristics~~, the requirements for laboratories, carrying out measurements, with the criteria, specified in [A.65], [A.76] and in this document;

- the validity of choice of the method of establishing (C)RM metrological traceability of CRM certified values, ~~including the account of taking into consideration the~~ provisions, set out in [A.65], [A.76], [A.109], [A.12];

- the conformity of the algorithms of the calculation of RM the certified value, ~~the its associated~~ uncertainty ~~of the certified value and its components~~ with the provisions, set out in [A.7] and in national regulatory documents.

Note:

Metrological examination of documentation is carried out in conformity with provisions, adopted in the countries.

Positive results of metrological examination are the basis for the decision, taken by CRM producer to approve RM certification programme.

35.10 The (C)RM producer may introduce amendments in ~~the RM~~ certification programme over time with ~~due~~ account of provisions [A.65].

Note:

When the amendments, introduced in ~~the certification~~ programme ~~of RM certification~~ are related to the amendment in the method of RM characterization, ~~the determination of RM certified value, and /or~~ measurement procedures, used in the ~~determination of RM metrological characteristics, the assessment of homogeneity and stability, characterization, monitoring of stability, assessment of CRM commutability (if necessary),~~ certification programme is subject to repeated metrological examination to verify the possibility of the release of (C)RM of the given CRM type with specified intended use, ~~and~~ accuracy and metrological traceability.

Annex A: Bibliography

A.1	OIML International Document D 18, <i>The use of certified reference materials, in fields, covered by metrological control, covered by national services of legal metrology. Basic principles</i> , 2008
A.2	ISO Guide 30: 1992 <u>2015</u> , <u>Reference materials – Selected Terms and definitions</u> , used in connection with reference materials ISO Guide 30:1992 Amd. 1:2008, Revision of definitions for reference material and certified reference material
A.3	ISO Guide 31:2000, <i>Reference materials – content of certificates and labels</i>
A.4	ISO Guide 32:1997, Calibration in analytical chemistry and use of certified reference materials
A. 5 <u>4</u>	ISO Guide 33:2000 <u>15</u> , <u>Reference materials – Uses of Good practice in using certified</u> reference materials
A. 6 <u>5</u>	ISO Guide 34:2009, <i>General requirements for the competence of reference material producers</i>
A. 7 <u>6</u>	ISO Guide 35:2006, <i>Reference materials – general and statistical principles for certification</i>
A. 8 <u>7</u>	OIML V 2-200, <i>International Vocabulary of Metrology — Basic and General Concepts and Associated terms (VIM)</i> , 3 rd Edition. (Edition 2010 with minor Corrections), 2012
A. 9 <u>8</u>	OIML V 1, <i>International vocabulary of terms in legal metrology (VIML)</i> , 2013
A. 10 <u>9</u>	<i>Joint BIPM, OIML, ILAC and ISO Declaration on Metrological Traceability.</i> OIML Bulletin, Volume LIII, Number 1, January 2012.
A.1 <u>10</u>	ISO/IEC 17025:2005, General requirements for the competence of testing and calibration laboratories
A.11	<u>ISO/REMCO Position Paper, The need for assessment of commutability of reference materials, 2014</u>
A.12	<u>OIML D 1:2012, Considerations for a law on metrology.</u>

Annex B

(recommended)

B.1 Structure and content of reference material certification programme

B.1.1 The name of the document, establishing RM certification programme, is based on the area of its application.

Example:

“The programme of certification of a reference material for composition of diesel fuel of serial production”

B.1.2 ~~RM~~ eCertification programme includes the introductory part and the following sections:

- general concepts ([subclause B.1.4](#));
- preparation of [CRM candidate](#) material for ~~the work on the determination of RM metrological characteristics~~ [carrying out the studies \(as appropriate\) \(subclause B.1.5\)](#);
- subcontractors, ~~participating~~ [involved](#) in the work ~~on the determination of RM metrological characteristics~~ (as appropriate) ([subclause B.1.6](#));
- procedure for the determination of [CRM metrological characteristics](#) ([subclause B.1.7](#));
- [the method \(-s\)](#) of the establishment and demonstration of metrological traceability of [CRM property values](#) ([subclause B.1.8](#));
- ~~the form of reporting the documents issued as a results of the determination of RM metrological characteristics studies~~ ([subclause B.1.9](#));
- the time schedule for carrying out the work on the [studies](#) ~~determination of RM metrological characteristics~~ ([subclause B.1.10](#));
- ~~RM~~ certification ([subclause B.1.11](#));
- [the procedure of post-certification monitoring of CRM stability](#) ([subclause B.1.12](#));
- [recertification \(if necessary\)](#) ([subclause B.1.13](#)).

Note:

It is allowed to delete or supplement these sections taking into consideration [CRM](#) specific features and the data, established in the determination of ~~metrological~~ characteristics of the first ~~(C)~~RM batch or ~~specimen~~ [unit](#).

B.1.3 Introductory part establishes the intended use and scope of ~~RM~~ certification programme.

Introductory part is set out as follows: “This document establishes ~~RM~~ certification programme (the name of [CRM](#) is indicated), to be used in ~~(C)~~RM serial ~~issue~~ [production](#)”.

B.1.4 Section “General concepts” of ~~the certification~~ programme includes subsections, specified under subclauses B.1.4.1-.B.1.4.2.

B.1.4.1 Subsection “Information on CRM producer”

This subsection includes the name and the address of CRM producer.

B.1.4.2 Subsection “The names of the property to be certified, prescribed limits of property values ~~RM metrological characteristics to be determined~~”

This subsection includes: ~~lists the names of metrological characteristics to be determined and specifies the interval of permissible values of RM characteristics to be certified, namely:~~

- the name of ~~characteristic (-s)~~ the property to be certified,
- the range of permissible certified values and their associated uncertainties ~~of certified value (-s),~~
- other information (as appropriate).

Note:

This subsection may provide a reference to other documents of ~~(C)~~RM producer, in which this information is given.

B.1.5 Section “Preparation of CRM candidate material for ~~the work on the determination of RM metrological characteristics~~” carrying out the studies”

This section is prepared as appropriate. It includes the requirements for:

- the procedure for sampling CRM candidate material ~~to carry out the work on the determination of RM metrological characteristics~~ (as appropriate);
~~the procedure for conducting preliminary research of the possibility to determine RM metrological characteristics (as appropriate);~~
- the procedure for CRM candidate material preparation (as appropriate).

B.1.5.1 Subsection “The requirements for sampling CRM candidate material”, prepared as appropriate, includes the requirements for:

- qualification of the operator, conducting the sampling (e.g. the information on qualification of the operator, his education, the information ~~of~~ fn his skill upgrading and safety training, etc.);
- the period of time within which the sampling of ~~RM~~ material should be completed;
- the equipment, measurement instruments, used for ~~RM~~ material sampling (the name of equipment, measurement instruments, identification of documents, according to which they are issued, requirements for calibration and verification of measurement instruments ~~(if required)~~);
- the amount of CRM candidate material, sufficient for all kinds of measurements (e.g. mass and/or volume of material, etc.);
- the procedure ~~of~~ for material sampling (description of sampling procedure is should be provided);

- the container, into which the borrowed samples of ~~RM~~ material are placed (the name of container, material, the container is made of, capacity of the container (volume and/or mass);
- the marking identification and labelling C RM candidate material sample (the type of ~~marking labelling~~, the form of ~~marking labelling~~),
storage and transportation conditions (if required) of borrowed samples of CRM candidate material.

~~B.1.5.2 Subsection “Requirements for the procedure for conducting preliminary research of the possibility to determine RM metrological characteristics” is included in RM certification programme in cases where doubts arise in obtaining sufficiently homogeneous and stable RM and/or in the capability of selected laboratory (-s) to make measurements.~~

~~The subsection describes the concrete procedures, ensuring the work on defining the feasibility of experiments and the capability of laboratory (-s), involved in the experiment to make measurements.~~

B.1.5.32 The subsection “Requirements for ~~RM~~ material preparation procedure” is included in the certification programme ~~of RM certification~~ when the certified value of CRM is determined by preparation procedure.

Subsection “Requirements for ~~RM~~ material preparation procedure” includes the information on ~~RM~~ material preparation procedure, providing the requirements for:

- the initial materials (substances), used for the preparation of CRM candidate material;
- the measurement instruments, used for the preparation of ~~RM~~ material;
- the qualification of personnel, engaged in the preparation of ~~RM~~ material;
- the environmental conditions, under which ~~RM~~ material is prepared;
- the ~~RM~~ material preparation procedure;
- the identification and labelling of ~~RM~~ material;
- the containers into which the prepared ~~RM~~ material is placed;
- the storage conditions for the prepared ~~RM~~ material.

B.1.6 Section “Subcontractors, participating involved ~~in the work on the determination of RM metrological characteristics~~”

This section is included when subcontractors are involved in the work on the determination of CRM metrological characteristics. It includes:

- the requirements for the competence of subcontractors and testing laboratories, involved in measurements and determination of CRM metrological characteristics taking into consideration recommendations [A.65], [A.76];
- the specific kind of work, performed by a subcontractor, the terms of interaction.

Note

It is possible to include other required information on legal entities, involved in the work, on laboratory accreditation.

B.1.7 Section “The procedure for the determination of ~~metrological~~ CRM characteristics ~~of reference material~~”

This section includes the requirements for the procedure for the determination of CRM metrological characteristics, ~~including the procedure for the determination of RM homogeneity, RM characterization, the determination of RM stability.~~ Recommended contents of the procedure ~~for the determination of RM metrological characteristics are~~ is described ~~in~~ under subclause B.2.

B.1.8 Section “The Mmethod(-s) of the establishment and demonstration of metrological traceability of CRM property values”

This section includes the information (e.g. the number, name, etc.) on national or international measurement standards of units or other accepted references, which ensure the obtaining measurement results with established metrological traceability of property values.

Note:

It is recommended to provide in this section the unit (-s), to which metrological traceability of property values is ensured and the scheme of the unit transfer in the determination of CRM certified value.

In case, when it is difficult to establish metrological traceability of property values, the information on the proposed procedure (-s), specified under ~~subclauses 5.12~~ [A.65] is provided.

B.1.9 Section “~~The form of reporting the results of the determination of RM metrological characteristics~~ documents, issued as a result of the studies”

This section provides ~~the form for reporting the established metrological characteristics, and also~~ the requirements for presentation of the documents, issued on the as a results of RM certification of the assessment of homogeneity and stability, characterization, monitoring of stability, assessment of CRM commutability (if necessary), testing for the purpose of the assessment of applicability of estimations of uncertainties due to inhomogeneity and instability, (including the report, protocols, etc.) taking into consideration the provisions, set out in [A.3, [A.65], [A.76].

B.1.10 Section “Time schedule for carrying out the work on the ~~studies determination of RM metrological characteristics~~” is reported as appropriate.

This section indicates the time schedule or frequency for carrying out the work on the ~~determination of RM metrological characteristics~~ studies of assessment of homogeneity and stability, characterization, monitoring of stability, assessment of

CRM commutability (if necessary), testing for the purpose of the assessment of applicability of estimations of uncertainties due to inhomogeneity and instability.

B.1.11 Section “~~RM~~eCertification”

This section describes the work on ~~RM~~-certification in conformity with clause 11 [A.76].

The CRM certificate, envisaged by [A.5] and [A.6] is issued in accordance with [A.3].

This section establishes the requirements for:

- qualification of personnel (e.g., profession, education, practical experience, position in the company), engaged in certification.
- the form of certificate for the given CRM type.

Note:

In certification programme the form of certificate for the given CRM type, released by CRM producer, may be provided as an example.

B.1.12 Section “Procedure for monitoring of CRM stability”

The evaluation of monitoring of CRM stability is carried out in accordance with subclause 8.4 [A.6]. The section includes subsections, specified under subclauses B.1.12.1- B.1.12.9.

B.1.12.1 Subsection “Information on the method, used in monitoring of CRM stability” is prepared with account of provisions, specified under subclause 8.4 [A.6] with an indication of methods, used in CRM stability monitoring:

- classical experiment;
- isochronous method.

B.1.12.2 Subsection “Reference material storage conditions and frequency of measurements during monitoring of CRM stability”

This subsection includes:

- CRM storage conditions, provided in CRM certificate (environmental conditions, humidity, lighting, etc.);
- the interval of time, at which the study within the framework of monitoring of CRM stability is carried out;
- the frequency of measuring CRM property value in monitoring of CRM stability by the method, selected under subclause B.1.12.

When selecting parameters, it is recommended to follow provisions, set out in [A.6].

B.1.12.3 Subsection “Measuring instruments, reference materials, chemical reagents, testing equipment etc., used for measurements during monitoring of CRM stability”

This subsection is prepared in the absence of the relevant information in documented measurement procedures, used during monitoring of CRM stability.

The subsection provides the list of measurement instruments, CRMs, supporting devices, materials, chemical reagents used for making measurements.

B.1.12.4 Subsection “Measurement procedure (-s), used during monitoring of CRM stability”

This subsection describes measurement procedure (-s), used during monitoring of CRM stability and makes references to the relevant documented procedure (-s).

B.1.12.5 Subsection “Preparation of CRM for measurements”

This subsection describes preparatory work, related to CRM preparation for measurements, to be carried out prior to measurements (if necessary).

B.1.12.6 Subsection “Execution of work”

This subsection presents the order of work, including:

- the list and sequence of operations;
- the number and frequency of measurements;
- the requirements for reporting intermediate and final measurement results (the number of significant figures, etc.,) etc.

Note:

This information is provided for each experiment, envisaged in the framework of stability monitoring.

B.1.12.7 Subsection “The form of reporting measurement results, obtained during monitoring of CRM stability”

This subsection includes the form of reporting measurement results, obtained during monitoring of CRM stability.

B.1.12.8 Subsection “The algorithm of processing measurement results with a view to estimate the uncertainty of stability due to instability”.

This subsection indicates:

- the algorithm of calculation of the standard uncertainty due to instability, obtained during monitoring of CRM stability;
- the criterion of CRM stability demonstration according to subclause 8.2.4 [A.6].

B.1.12.9 Subsection “The form of reporting results of monitoring of CRM stability”

This subsection includes the form of report, prepared as a result of CRM stability monitoring and the form of recommendation on further actions to be taken for the CRM according to [A.6].

B.1.13. Section “Recertification”

This section is prepared with account of provisions, set out under subclause 6.7 [A.6], if necessary. The section includes:

- the reasons for carrying out CRM recertification with account of provisions, set put under subclause 6.7 [A.6] (e.g. the change of the property value, identified as a result of monitoring of stability, etc.);

- the list of work to be carried out during CRM recertification, with an indication of certification programme sections, describing the procedures of the relevant work;

- the procedure of CRM preparation for reassessment of homogeneity, stability, recharacterization (e.g., opening the bottles, mixing the material, etc.) (if necessary).

In case of CRM recertification due to the need to reduce the uncertainty of the property value and clarify the certified value, to establish metrological traceability to a new unit of measurement (when new measurement standards and certified reference materials appear), it is necessary:

- to list the conditions, which will ensure the solution of the problem;

- to prepare and make appropriate amendments to certification programme in accordance with ISO Guide 34 [A.5].

B.2 The content of ~~the~~ certification programme section “Procedure for the determination of metrological CRM characteristics ~~of reference material~~”

B.2.1 The section “Procedure for the determination of metrological CRM characteristics ~~of reference material~~” of certification programme includes the following sections:

- procedure for the determination assessment of RM material homogeneity (subclause B.2.2);
- procedure for the determination assessment of RM material stability (subclause B.2.3);
- procedure for the characterization of RM material (subclause B.2.4);
- procedure for the assessment of CRM commutability (if necessary) (subclause B.2.5);
- the procedure of testing with the purpose of the assessment of the applicability of estimations of uncertainties due to inhomogeneity and instability, obtained for the first CRM batch or unit, to a new CRM batch or unit (if necessary) (subclause B.2.6);
- the algorithm of calculation of the certified value and expanded uncertainty of the CRM certified value (subclause B.2.7);

Notes:

1 It is allowed to delete or merge these sections or include additional sections taking into consideration C(RM) specific features.

2 It is allowed to issue the procedure for the determination assessment of RM material homogeneity, and the procedure for the determination assessment of RM stability and the procedure for RM characterization as separate documents.

B.2.2 The section “Procedure for the determination assessment of RM material homogeneity” includes subsections, described under subclauses B.2.2.1- B.2.2.8.

B.2.2.1 Subsection “~~Characteristics to be certified, according to~~ Properties, by which the determination assessment of homogeneity is carried out”

This subsection includes:

- the names of ~~characteristics to be certified, according to~~ the property, by which the determination assessment of homogeneity is carried out;
- the type of inhomogeneity (between-bottle, within-bottle), to be studied.

B.2.2.2 Subsection “Measurement instruments, reference materials, chemical reagents, testing equipment, etc., used for carrying out the work on the determination assessment of homogeneity”.

This section is prepared in the absence of appropriate information in documented measurement procedures, used in the determination of RM metrological characteristics homogeneity.

This subsection provides the list of measurement instruments, ~~(C)~~CRMs, support devices, materials, chemical reagents, used in measurements.

B.2.2.3 Subsection “Measurement conditions”

Subsection “Measurement conditions” establishes the requirements for the environment, accommodation and other factors, affecting measurements, CRM candidate material or provides reference to the measurement procedure (-s) in use.

B.2.2.4 Subsection “Preparation of CRM candidate material for measurements”

This subsection provides (as appropriate) the description of preparatory work, related to ~~RM~~ material preparation for measurements, carried out prior to measurements, namely:

- the information on the amount of borrowed samples of ~~RM~~ material for measurements, on the mass of samples;
- the information on the methods of preparation of RM material surface for measurements (for solid materials);
- the information on the ~~material~~ packaging material, in which ~~RM~~ the material is stored during the determination of CRM homogeneity, etc.;
- ~~–other information.~~

B.2.2.5 Subsection “Measurement procedure (-s), used in the ~~determination~~ assessment of ~~RM material~~ homogeneity”

This subsection describes the measurement procedure (-s), used in the ~~determination of~~ assessment of CRM homogeneity or provides reference to the appropriate documented measurement procedure (-s).

B.2.2.6 Subsection “~~Carrying out~~ Execution of work”

This subsection describes the procedure of work in the ~~determination~~ assessment of ~~RM~~ homogeneity:

- the list and sequence of operations, performed in the ~~determination~~ assessment of CRM homogeneity;
- the details of the part of CRM, within-bottle homogeneity of which is studied (e.g. disc diameter, cylinder height, etc., for solid material; the mass of the sample to be tested, the mass of the minimum representative sample for disperse material, etc.
- the number of measurements, the frequency of measurements for the ~~determination~~ assessment of within-bottle ~~in~~ homogeneity;
- the number of measurements, the frequency of measurements for the ~~determination~~ assessment of between-bottle ~~in~~ homogeneity;
- the requirements for reporting intermediate and final measurement results (the number of significant figures, etc.).

B.2.2.7 Subsection “Algorithm of the calculation of standard uncertainty due to reference material ~~in~~ homogeneity”

This subsection contains the algorithm of measurement results processing to calculate the value of the standard uncertainty due to ~~RM~~-inhomogeneity or the reference to the appropriate document, in which the algorithm is described.

B.2.2.78 Subsection “Additional information”

This subsection contains the requirements for the necessity of recording additional information, obtained from the results of the ~~determination~~-~~assessment~~ of ~~CRM~~ homogeneity, namely:

- minimum representative sample (for dispersed materials),
- details of the part of solid ~~CRM~~ material, in which the homogeneity study is carried out (for solid materials), for providing the relevant information in the report of RM certification and in CRM certificate.

~~—other information~~

~~for providing the relevant information in the report of RM certification and in CRM certificate.~~

B.2.2.89 It is recommended to include in the procedure for the ~~determination~~ assessment of ~~RM~~-homogeneity the following subsections:

- “Requirements for qualification of operators” containing the information about the level of skills (e.g. profession, education, experience, etc.) of the personnel, permitted to carry out the work;
- “Requirements for safety of work”, establishing the requirements, that will ensure labor safety ~~at work~~, compliance with the norms of workplace sanitation and environmental protection.

Note:

If the normative documents, regulating the requirements for safety, workplace sanitation and environmental protection are available, a reference to these documents is ~~provided~~ made in this subsection.

B.2.3 Section “Procedure for the ~~determination~~ assessment of ~~RM~~ stability”

Section “Procedure for the ~~determination~~ assessment of ~~RM~~ stability” includes subsections, specified under subclauses B.2.3.1 - B.2.3.12.

B.2.3.1 Subsection “The list of factors, affecting ~~CRM~~ stability”

This subsection provides the list of factors, ~~affecting RM stability~~ (e.g. temperature, humidity, lighting, etc.), which may affecting ~~ing~~ ~~CRM~~ stability.

B.2.3.2 Subsection “Method of ~~reference material~~ stability study”

This subsection provides the information on the method, used to study ~~CRM~~ short-term and long-term stability in conformity with [A.76]:

- isochronous method (method of accelerated ageing),
- method of natural ageing.

B.2.3.3 Subsection “CRM S storage conditions ~~of reference material~~ and frequency of measurements in the ~~determination assessment~~ of ~~reference material~~ stability”

Subsection includes:

- CRM storage conditions
 - ~~environmental~~ conditions (temperature, humidity, lighting, etc.), under which CRM is stored, storage and transportation are planned within the experiment, corresponding to planned conditions of CRM storage and transportation,
 - material of container, in which CRM is stored during ~~RM~~ stability study;
- the frequency of measuring the property values ~~of RM characteristic to be certified in the determination of RM stability using the chosen~~ within the implementation of selected method of stability study.

When selecting parameters it is recommended to follow the provisions set out in [A.76].

B.2.3.4 Subsection “Measurement instruments, reference materials, chemical reagents, testing equipment, etc., used for carrying out the work on the ~~determination assessment~~ of stability”.

This subsection is prepared in the absence of appropriate information in documented measurement procedures, used for carrying out the work ~~in~~ on the ~~determination assessment~~ of ~~RM metrological characteristics~~ stability.

~~This subsection~~ It provides the requirements information, specified under subclause B.2.2.2.

B.2.3.5 Subsection “Measurement procedure (-s), used for carrying out the work ~~in~~ on the ~~determination assessment~~ of ~~reference material~~ stability”

This subsection describes the measurement procedure (-s), used ~~in the determination for carrying out the work on the assessment~~ of CRM stability or ~~provides~~ makes reference to the appropriate documented measurement procedure (-s).

B.2.3.6 Subsection “Preparation of CRM candidate material for measurements”

This subsection provides the description of preparatory work, related to CRM candidate material preparation for measurements, carried out prior to measurements.

B.2.3.7 Subsection “Execution of works”

This subsection describes the procedure of works in:

- defining CRM storage conditions,
- defining CRM transportation conditions,
- selecting of RM packaging material,

namely:

- the list and sequence of operations;
- the number of measurements, the frequency of measurements;
- the requirements for reporting intermediate and final measurement results (the number of significant figures, etc.).
- others.

Notes:

This information shall be provided for each experiment in the determination of

- short-term stability,
- long-term stability (when C(RM) transportation is planned).;
- CRM ~~material~~ stability after opening the package ing of ~~RM~~ (when CRM storage and use is allowed after opening the package ing).

B.2.3.8 Subsection “The form of reporting measurement results, obtained in the determination assessment of ~~reference material~~ stability”

This subsection provides the form of reporting measurement results, obtained in the determination assessment of CRM stability

B.2.3.9 Subsection “Algorithm of the calculation of standard uncertainty due to instability ~~of reference material~~”

This subsection provides the algorithm of the calculation of:

- standard uncertainty, characterizing CRM short-term and long-term instability;
- CRM life time

or the reference to the appropriate document, in which the algorithm of calculation is set out.

B.2.3.10 Subsection “The form of reporting the results of the determination assessment of ~~reference materials~~ stability”

This subsection provides:

- the form of reporting the standard uncertainty due to short-term and long-term stability, life time of CRM after its production;
- the information on how to achieve ~~the~~ CRM integrity ~~of reference material and immutability of its metrological characteristics~~:
 - - CRM storage conditions;
 - - CRM transportation conditions;
 - - CRM package ing (including package ing material), CRM shipping container, ensuring CRM stability under storage and transportation conditions during the validity period of ~~(C)RM~~ certificate and the period of ~~CRM~~ transportation;

- - possible restriction of CRM life time after opening the packageing , CRM storage conditions after opening the packageing.

~~B.2.3.11 Subsection “Monitoring of RM stability”~~

~~This subsection provides the information on the procedure of monitoring RM stability in conformity with provisions, set out in clause 8 [A.7].~~

B.2.3.12~~1~~ It is recommended to include in the procedure subsections “Requirements for qualification of operators” and “Requirements for safety of work”, specified under subclause B.2.2.8.

B.2.4 Section “~~The P~~procedure for ~~reference material~~ characterization” is prepared taking into consideration the recommendations, set out under subclauses B.2.4.1 – B.2.4.9.

B.2.4.1 Subsection “Method of ~~reference material~~ characterization”

This subsection provides the method of ~~reference material~~ characterization, selected in conformity with recommendations, specified in [A.5] and [A.76].

Note:

The content of the procedure ~~of the determination of RM certified value~~ for the characterization of reference material depends on the selected method of ~~RM~~ characterization.

B.2.4.2 Subsection “Information on measurement standards ~~of units~~, measurement instruments, reference materials, chemical reagents, testing equipment, etc., used in reference material characterization” is prepared in the absence of appropriate information in documented measurement procedures, used in RM characterization.

This subsection provides the information on measurement standards ~~of units~~, measurement instruments, ~~(C)RMs~~, testing equipment, and establishes the requirements for their ~~metrological~~ characteristics, calibration, and certification.

B.2.4.3 Subsection “Measurement procedure (-s), used in ~~the determination of the certified value of reference material characterization~~”

This subsection describes the procedure (-s), used in the determination of CRM characteristic to be certified property value or ~~provides~~ makes reference to the document (-s) in which it (they) is (are) established. This subsection provides the information on the units, to which the metrological traceability of measurement results is ensured in the realization of measurement procedure.

B.2.4.4 When CRM certified property value is determined using measurement standard ~~of unit~~, section “Procedure for ~~the determination of RM certified value~~ reference material characterization” shall additionally include:

- the information on the measurement standard ~~of unit~~;
- the information on measurement conditions;
- the information on the number of test results to be obtained when measurements are made using measurement standards;
- the form of reporting measurement results;
- ~~— the algorithm of the calculation of RM certified value and standard uncertainty due to RM characterization, taking into account the provisions, set out in [A.7].~~

B.2.4.5 When the ~~value of RM characteristic to be certified~~ CRM property value is determined from the results of interlaboratory ~~experiment~~ comparison, section “Procedure for ~~the determination of RM certified value~~ reference material characterization” shall additionally include subsection, specified under subclause B.2.4.5.1.

Note:

In case of reference material characterization based on the results of an interlaboratory ~~experiment~~ comparison, subsections, specified under subclauses B.2.4.2 – B.2.4.4 are included in section “Procedure for ~~the determination of RM certified value~~ reference material characterization” as appropriate.

B.2.4.5.1 Subsection “Information on the programme of interlaboratory ~~experiment~~ comparison”

Note:

It is recommended to prepare the programme of interlaboratory ~~experiment~~ comparison as a separate document.

The programme of interlaboratory experiment shall include:

- the information on CRM candidate material (~~the name of CRM candidate~~ material, the name of ~~characteristics to be certified~~ the property value to be measured, minimum representative sample, methods of sample storage, safety measures when working with samples, etc.) submitted to laboratories;
- the recommended measurement procedures (methods) to measure ~~the~~ property values ~~of RM characteristics to be certified~~ (as appropriate);
- the time schedule for carrying out the work, including the time for sample distribution and obtaining the protocols of measurement results;
- the requirements for the number of measurement results, obtained in laboratories;
- the requirements ~~for procedure for~~ CRM candidate material ~~sampling procedure~~, performed in laboratories (as appropriate);
- the requirements for measurement conditions to be provided by laboratories when carrying out experimental work;
- the requirements for metrological traceability of measurement results, obtained in each laboratory;

- the form of reporting ~~the property values of RM-certified characteristics~~ by laboratories.
- other requirements, specified in [A.76] (as appropriate).

~~B.2.4.7 Subsection “Processing of measurement results”~~

~~This subsection provides the information on the algorithms of calculation of RM certified value, standard uncertainty due to RM characterization taking into account the provisions, set out in [A.7].~~

~~B.2.4.8 Section “Algorithm of the calculation of the expanded uncertainty of RM certified value”~~

~~This section provides the algorithm of the calculation of the expanded uncertainty of RM certified value, including the uncertainty due to inhomogeneity, instability and due to RM characterization taking into account the provisions of [A.7].~~

B.2.4.96 It is recommended to include in the procedure the subsection “Requirements for qualification of operators”, “Requirements for safety of work”, specified under subclause B.2.2.8.

B.2.5 Section “Procedure for the assessment of CRM commutability”

This section is prepared with account of provisions, set out in [A.5], [A.11], if necessary. It includes:

- the information on routine samples, submitted for testing together with CRMs (the name, the information on the material of routine samples, etc.);

- the information on the reference measurement procedure “of a higher order” (the reference is made to the document, describing in detail measurement procedure with an indication of the used measurement standards, and/or measurement instruments, measurement procedure, measurement conditions, measurement result processing, etc.);

- the information on one or more routine measurement procedures “of a lower order” (the reference is made to the document, describing in detail measurement procedure with an indication of the used measurement instruments, measurement procedure, measurement conditions, measurement result processing, etc.);

-the information on the number of measurement results, to be obtained by measuring property values in routine samples and CRMs using reference measurement procedure “of a higher order” and one or more reference measurement procedures “of a lower order”;

- the form of reporting measurement results, obtained from measurements according to measurement procedures;

- the algorithm of processing results with the purpose of the assessment of CRM commutability with account of provisions, set out in [A.5], [A.11];

- the form of the report, prepared as a result of the determination of CRM commutability with an indication of measurement procedure, relative to which the

CRM is commutative, and the forms of reporting the results of commutability study in CRM certificate.

Note:

In the absence of reference measurement procedure “of a higher order”, the information of two or more measurement procedures, subject to harmonization, is provided instead.

B.2.6 Section “The procedure of testing with the purpose of the assessment of applicability of estimations of uncertainties due to inhomogeneity and instability, obtained for the first CRM batch or unit, to a new CRM batch or unit”

This section is prepared, as appropriate, with account of provisions, set out in [A.5] and under clause 3 of this document. The section includes:

- subsection “The procedure of testing with the purpose of the assessment of applicability of estimations of uncertainties due to inhomogeneity, obtained for the first CRM batch or unit, to a new CRM batch or unit”;

- subsection “The procedure of testing for the purpose of the assessment of applicability of estimations of uncertainties due to instability, obtained for the first CRM batch or unit, to a new CRM batch or unit”.

B.2.6.1 Section “The procedure of testing with the purpose of the assessment of applicability of estimations of uncertainties due to inhomogeneity, obtained for the first CRM batch or unit, to a new CRM batch or unit” includes:

- the information on estimations of uncertainties due to inhomogeneity, relative to CRM certified property for the first CRM batch or unit;

- criterion of applicability of estimations of uncertainties due to inhomogeneity, obtained for the first CRM batch or unit, to a new CRM batch or unit;

- the information on the measurement procedure, used for the measurement of property values in CRM candidate material of the subsequent CRM batch or unit (the reference is made to the document, describing in detail measurement procedure with an indication of the used measurement instruments, measurement procedure, measurement conditions, measurement result processing, etc.);

- the information on the number of measurement results, to be obtained by measuring property values in CRM candidate material of the subsequent CRM batch or unit; the requirements for the form of reporting measurement results;

- the algorithm of processing measurement results with the purpose of checking the applicability of estimation of uncertainties due to inhomogeneity, obtained relative to the certified property for the first CRM batch or unit, to a new CRM batch or unit with account of established acceptance criteria;;

- the form of the report, prepared as a result of the test with an indication of the form of recommendation on the use of obtained results.

2.6.2 Section “The procedure of the testing for the purpose of the assessment of applicability of estimations of uncertainties due to instability, obtained for the first CRM batch or unit, to a new CRM batch or unit” includes subsections, similar to those, specified under subclause 2.6.1, but applied to instability study.

B.2.7 Section “Algorithms of the calculation of the certified value and the expanded uncertainty of CRM certified value”

This section provides specific algorithm of the calculation of the certified value and the expanded uncertainty of the certified value, including the uncertainty due to inhomogeneity, instability and due to characterization taking into account the provisions of [A.5] and [A.6].