

	<b>COOMET informational material</b>	<b>COOMET I/RM/1:2001</b>
	<b>Normative documents regulating the questions of RMs production and use</b>	
<i>Approved at the 12 Meeting of COOMET Committee Meeting (Havana, Cuba, May 6 – 7, 2002)</i>		

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## FOREWORD

The present overview information has been prepared in the framework of cooperation within COOMET in the subject-field “Development and use of reference materials of composition and properties of substances and materials”, project 185/RU/99; the author is Russia.

The overview is prepared based on the informational materials received from Contact Persons of COOMET member-countries, including: Republic of Belarus, Germany, Republic of Kazakhstan, Ukraine and the country-author of the project – the Russian Federation.

The work on the project was done in two stages:

- preparation of preliminary informational overview and circulating it among COOMET member-countries for comments and proposals;
- preparation of the final draft overview taking into consideration comments and additional materials received from COOMET contact-persons.

After preliminary draft overview had been circulated, the Project Coordinator received additional information from Ukraine, Germany and R. of Kazakhstan which submitted information at the first stage of work.

Unfortunately, the information was missing from other countries cooperating in this subject-field both at the first and at the second stages of the work and was not, therefore, reflected in the text, since the author didn't find it possible to search the access to the stocks of national normative documents (ND) on his own and analyze them.

But it doesn't rule out the possibility of preparing an annex to the present text, providing, that the meeting of COOMET experts, when discussing the results of work within the subject-field in point, finds it possible and feasible.

In supplementary information received from Germany, Mr. H. Klich expressed his concern about insufficient reflection of ISO/REMCO documents in the overview and recommended to list them in the annex to the document. In the present version this recommendation was taken into account. Supplementary information from Ukraine and R. of Kazakhstan was also included in the final draft.

Hereinafter in the text the acronyms of the following international and regional organizations are used:

International Organization for Standardization – ISO

International Organization of Legal Metrology – OIML

International Atomic Energy Agency – IAEA

International Union of Pure and Applied Chemistry – IUPAC

World Health Organization – WHO

European Cooperation of National Metrological Institutions – EUROMET

Euro-Asian Cooperation of National Metrological Institutions – COOMET

Euro-Asian Council for Standardization, Metrology and Certification – EASC.

## 1. INTRODUCTION

The history of regulating requirements for reference materials of composition and properties of substances and materials (RM) in the form of official normative documents (standards, guides, rules) is not very long.

We can assume with high probability, that the USSR State Standard 14263-69 “GSI. General Requirements for Reference Materials of Substances and Materials” adopted in February 1969, was the first official normative document in the world practice.

At the same time the use of substances and materials called now “reference materials” has deeper traditions dating back to the first years of the last century.

But it was only in 1970s that reference materials began to receive increasing attention of official metrological services due to their extremely important role in ensuring the uniformity of measurements and due to widening the competence of metrological services as regards new kinds and fields of measurements including various methods of quantitative chemical analyses in metallurgy, geology, production of foodstuffs, environmental protection, etc.

At the same 1070s reference materials evoked interest of authoritative international organizations, such as, ISO and OIML in the framework of which special working bodies were established to take up this problem: in 1973 International Working Group (REMPA) was set up in ISO, in 1975 it was transformed into ISO Council Committee on reference materials (ISO/REMCO); in the same 1975 in OIML Pilot Secretariat SP 27 “General Principles for the use of Reference materials in Legal Metrology”, transformed in 1995 into Subcommittee SC 3 “Reference Materials” within Technical Committee TC 3 “Metrological Control” was created.

It is a common knowledge, that provisions and rules in the field of metrological activity are traditionally regulated by normative documents and so is the outcome of work of international organizations usually embodied in guides, recommendations and other international documents.

That is why, beginning with 70s in natural agreement with the logical course of things, the developments of both national and international normative documents are being continually undertaken in the province of RM production and application, which forms the normative foundation for practical organization of works.

It should be noted, that after the first above-mentioned international bodies concerned with RMs in ISO and OIML were officially established, the works on these problems were included in the scope of many other international and regional organizations, including: IAEA, IUPAC, WHO, EUROMET, EASC, COOMET, etc.

It should be pointed out, that the leading role among international organizations belongs to ISO/REMCO which, apart from the development of ND, plays a certain international coordinating role,

primarily, by preparation of general ND, the provisions of which are used as basic principles in the development of normative documents by both national metrological bodies and international organizations.

Annex 1 lists ISO/REMCO Guides, directly relating to RM development, certification, application and presentation of RM documentation.

It is quite natural, that ISO/REMCO normative documents do not completely settle the problem of regulating the process of RM production and use are not able to take a full account of national practice in this field of activity, which is specified and developed in national (and regional) normative documents.

So, such state of affairs may be considered quite natural, when in the presence of international ND, the national ND, including those similar to the international ones, are being developed.

Besides, as far as the author of the present overview knows, many countries of the Eastern Europe, including the Russian federation, establish the order for use of international standards, stipulating certain formal and legal procedures.

Only after these procedures are fulfilled and provided that international or regional standard corresponds to a sufficient extent to the national practice (which is not always the case), it may be used as a national standard with this or that mandatory fulfillment of the requirements thereof.

On the other hand, when developing draft national standards the agreement of their provisions relating to the object of standardization, with international ND is analyzed and certain measures are taken to eliminate contradictions. Unfortunately, this analysis and assessment of compatibility are reflected only in the documents accompanying the development of a standard, but not in the text of the document itself (by references or citing), which sometimes may produce an impression of ignoring international ND.

These explanations should be taken into account when considering the information provided in the overview.

It should be also noted, that the practice of RM production and application revealed that the requirements of normative documents formulated at the general, so to say, conceptual level (inherent in international ND) are sometimes misinterpreted by specialists and fail to answer all the questions, so they need to be explained and detailed, which is the reason and grounds for the development of supplementary normative documents, mainly of methodical nature.

Due to the fact, that RMs as a kind of measuring means are the object of metrological supervision, great importance is attached to the matters of uniform preparation and contents of RM documentation, reflection of essential elements in the working documents on RMs, including the information about RM producers and suppliers, the bodies which approved or recognized the RM type, etc.

All the requirements of like kind are, as a rule, reflected in national ND for RMs.

But these requirements may be subject to harmonization or unification beginning with regional metrological organizations with gradual extension of such unification to the international scale.

This approach may appear to serve as a landmark in selecting the object of standardization or normative regulation within COOMET.

The author would like to note, that the works on reference materials in the framework of EASC may serve an example of rather profound intergovernmental unification of normative requirements for RMs where alongside with standards, establishing general principles and requirements, a number of ND regulating various additional aspects of RM metrological certification, examination of technical documents, etc. has been adopted.

## **2. NATIONAL LEGISLATIVE ACTS, ESTABLISHING NORMS AND RULES RELATING TO REFERENCE MATERIALS**

According to modern definition the notion “normative document” is generic and may cover various kinds of documents, including those establishing juridical (legal) norms and requirements. Such an approach gives grounds to classify the documents of the highest legal status (laws adopted by national legislative bodies, documents approved by governmental acts or other bodies of the state administration) among normative documents. As it is known, a number of metrological rules is regulated at the legal level, being the juridical foundation of their application everywhere.

The works relating to RM development and use found their reflection in the national legislation of a number of the countries (Russia, Ukraine, R.of Kazakhstan), which forms an important legal foundation in the organization of works in this province. Table 1 gives brief explanations to the provisions of corresponding laws in relevance to the subject under discussion.

The presence of provisions relating to RMs is the basis for setting up organizational frameworks, working bodies to establish the order of works, normative basis, etc., which may be considered a favorable factor contributing to the general organization of works.

In particular, based on the National Law, Cabinet of Ministers of Ukraine approved “Regulations of the State Service of Reference Materials of Composition and Properties of Substances and Materials” (1998), Gosstandart of Ukraine approved “Regulations of a Parent Body of the State Service of Reference Materials” (1999).

In the Russian Federation the following procedural documents have been also prepared and adopted: “Provision Regulations of a Parent Body of the State Service of Reference Materials of Composition and Properties of Substances and Materials” (approved by Gosstandart of Russia in 1998); in the same year methodical document “GSI.The Bodies of State Service of Reference Materials of Composition and Properties of Substances and Materials. General Requirements” (MI 2471-98) was adopted, on the basis of which a network of competent organizations is being established in the branches of industry.

Table 1

Country	Law, date of adoption and implementation	Contents of the law provisions
Russia	“On the ensuring the uniformity of measurements”, April 1993	<p>Clause 12, sub-clause 5 establish the national State Service for reference materials of composition and properties of substances and materials for interregional and interbranch coordination of works on the development and introduction of RMs aimed at the ensuring the uniformity of measurements based on RM use.</p> <p>Clause 12, sub-clause 7 envisages approval of SSRM Regulations by RF government</p>
Ukraine	“On metrology and metrological activity”, February 1998	<p>Clause 12 establishes State Service for reference materials of composition and properties;</p> <p>As per cl. 12, sub-clause 9 of SSRM Regulations is subject to approval by Ukranian Cabinet of Ministers.</p> <p>Clause 29 includes metrological examination of technical documents including those on RM in the province of metrological control</p>
Kazakhstan	“On the ensuring the uniformity of measurements”, June 2000	<p>Clause 15, sub-clause 3 establish the national State Service for reference materials of composition and properties of substances and materials (SSRM)</p> <p>Clause 18 points out the necessity of licensing organizations for RM issue and use.</p> <p>Clause 25 envisages state metrological supervision over RM issue and use.</p>

It should be noted, that national laws, establishing general system of state administration of metrological activity, define separate works and production and economical areas subject to state metrological control and supervision. It is just for this province of state metrological supervision that

mandatory requirements are legislatively established for measurement instruments, measurement procedures, etc. Given in Table 1 the law provisions are related to RMs intended for use in this field.

It should be also noted, that a considerable part of metrological and measurement works on their national scale are not subject to the state metrological control.

Regulation of the order of works, rules and requirements within this second field falls into the province of the branches of national economy and subjects of economical activity, which are given the opportunity to define on their own the extent of mandatory application of national and international standards and to set terms in specific agreements and contracts with partners.

### **3. REGIONAL NORMATIVE DOCUMENTS USED IN COOMET MEMBER-COUNTRIES IN THE WORKS ON THE RM PROBLEM**

Distinguishing feature of the countries' cooperation in regional organizations is that it results in the developments of specific RMs and in the necessity to settle the questions of their mutual recognition since they may be the object of mutual supplies in the countries for the intended use in practical measurements.

That is why, adoption of documents defining the subject-matter of cooperation and establishing procedural order of works and the form of their finalizing is usually the initial procedural stage of cooperation in regional organizations.

It should be noted once again, that underlying ISO/REMCO documents are taken into consideration in the development of regional normative documents, in particular, within the "Reference Materials" subject-field.

When preparing the present overview, the use was made of the information concerning the documents developed by 3 regional organizations: COOMET, Standards, Measurement and Testing Programme of European Commission and EASC. The titles of the documents, adopted by these organizations are given in table 2.

Special commentary should be given to the European Commission Doc. BCR/01/97. This rather comprehensive (about 60 pages) document contains a highly detailed list of recommendations covering the whole cycle of works on RM production beginning with technical and commercial grounds for RM development, including all technological stages of RM manufacturing and investigation, homogeneity and stability tests, guidelines for RM metrological certification and requirements for presentation of BCR documents.

In other words, this document regulates the whole set of works containing the sections, on which, for example in EASC, separate documents have been adopted (in particular, GOST 8.351, GOST 8.532, RMG 17-96 and GOST 8.315, the latter establishing general conceptual provisions and the sequence of RM development, certification, validation, issue and use).

For rough comparison the contents of Doc. BCR/01/97 and GOST 8.315 (with short explanation of its sections) is given in annexes B and C to this document. The basic principles of both documents are sufficiently well compatible.

At the same time there is a certain distinction between these documents consisting in the nature of their requirements.

If GOST 8.315 contains sufficiently clear and unambiguous provisions and requirements (which is established by general rules for drafting standards), then in Doc BCR/01/97 separate requirements are accompanied by methodical explanations (often very detailed), which is pointed out by the authors in the introduction to the document. Thus, in the introductory part of the document it is noted, that the document is called neither "rules" nor "requirements", because no detailed single set of rules can cover all particular cases encountered in all fields of measurement and testing. However, the document contains a number of clear guidelines and requirements to be observed.

Nearly the same difficulties were encountered by the authors of EASC regional standards, whose separate provisions are also recommendations.



Table 2

Regional organization	Codes and titles of documents	Notes
1	2	3
<p>COOMET</p> <p>European Commission (SMT Programme)</p> <p>EASC</p>	<ol style="list-style-type: none"> <li>1. Memorandum of understanding on development and use of reference materials of composition and properties of substances and materials within COOMET – COOMET D/RM/6-98</li> <li>2. Procedure for joint development, recognition and registration of reference materials within COOMET – COOMET R/RM/7-98</li> <li>3. Contents and rules of drawing up documents for RMs developed within COOMET – COOMET R/RM/8-98</li> <li>4. Register of reference materials of composition and properties of substances and materials developed within COOMET – COOMET R/RM/9-98</li> <li>5. Guidelines for the production and certification of BCR reference materials – Doc.BCR/01/97 Part A. Recommendations to proposers of reference material projects Part B. Guidelines and requirements for the implementation of reference material projects. Part C. Instruction for the preparation of BCR certification reports.</li> <li>6. Agreement of the development and use of reference materials of composition and properties of substances and materials within the Commonwealth of Independent States, 1992.</li> <li>7. Regulations of the intergovernmental reference materials –PMG 16-96.</li> <li>8. The order of planning works on a cooperation in the field of production and application of RMs for composition and properties of substances and materials – RMG 17-96</li> <li>9. Register of intergovernmental RMs. Basic principles – PMG 26-98.</li> </ol>	<p>“D” and “R” mean “document” and “recommendation” respectively.</p> <p>The document is a new version of the document adopted in 1993.</p> <p>“PMG” and “RMG” mean “rules” and “recommendations” respectively. The requirements of rules are mandatory.</p>

1	2	3
	<p>10. The order and contents of works in conducting metrological examination of documents for intergovernmental RMs – RMG 27-29</p> <p>Intergovernmental (regional) standards adopted by EASC</p> <p>11. GOST 8.315-97 “GSI. Reference materials of composition and properties of substances and materials.</p> <p>12. GOST 8.531-85 “GSI. Homogeneity of reference materials of composition of disperse materials. Measurement procedure.</p> <p>13. GOST 532-85 “GSI. Reference materials of composition and properties. Procedure for interlaboratory certification.</p>	<p>Under revision</p> <p>-“-</p>



There is another important circumstance to be mentioned. Provisions of regional normative documents, listed in table 2 are, undoubtedly, used as guidelines in the work of the organizations concerned.

But at the same time a number of regional ND is used in the countries as national ND.

Thus, adopted in Germany is “Guidelines for the production and certification of BAM reference materials” which is a version of the document BCR/01/07, adjusted to the purposes of BAM being actually identical in the structure and in the contents to the latter (with the exception of section 7, items 7.1; 7.2 and section 13, items 13.1; 13.2, part B) and supplemented by Appendix A “Nicht-statistische Überprüfung von vermeintlichen Ausreißern bei chemischen Analysen”. Besides, small additions specifying the provisions of the document BCR/01/97, are included in a number of its items. As for EASC documents, they are used as national ones in several countries, which is demonstrated in table 3.

Table 3

Designation of regional ND	The use of ND as national documents			
	R. of Belarus	R. of Kazakhstan	Russia	Ukraine
GOST 8.315-97	-	+	+	+
GOST 8.531-85	+	+	+	+
GOST 8.532-85	+	+	+	+
RMG 27-99	-	-	+	+

Note: Full titles of documents are given in table 2.

Active use of EASC regional normative documents as national ones by CIS member-countries is explained, first, by their long , close cooperation in the framework of a single country – the USSR and, second, by the fact, that in intergovernmental standards the opinions of the countries concerned are taken into consideration to a rather full extent.

As it was pointed out at the beginning of this chapter, development of specific RMs, which may be subject to mutual supplies is the key (if not crucial) task of cooperation.

The fact of RM official recognition by competent bodies (representatives) of the countries is of primary importance for their free use in cooperating countries. This circumstance is reflected in underlying documents of COOMET, EASC and in a less explicit manner, in the Guidelines of the European Commission (see table 2, documents under numbers 2,5,7). Besides, EASC Intergovernmental Standard GOST 8.315 establishes unified forms of the documents for such RMs (description, specification and label) for convenience of their further use and control.

Similar requirements are, in fact, established by COOMET documents (document No.3 in table 2) as well as by “part C” of the Guidelines of European Commission, which points out the same logical approach to the settlement of this question.

#### **4. NATIONAL NORMATIVE DOCUMENTS USED IN PRACTICAL WORKS ON THE PRODUCTION AND USE OF REFERENCE MATERIALS**

As it was stated above, provisions and requirements of underlying standards need, as a rule, further explanations as applied to the development of specific RM types in view of a great number of RMs and astonishing variety of metrological and technical problems arising in the course of RM development.

All the questions of like kind are subject to regulating in normative ND having, in their majority, the status of recommendations.

RM producers express their interest in such ND and readily use them in practical works.

Subject to regulation in national ND are also procedural and legal questions of RM production and registration, rules of metrological supervision exercised by national metrological services.

The author of the present overview received the information on the national normative documents from R. of Belarus, Russia and Ukraine<sup>1</sup>.

The list of national ND of these countries is given below. This list should be regarded as a supplement to underlying documents listed in table 3.

### **Republic of Belarus**

1. STB 8005-94, *Reference materials. Basic principles.*

Note: This standard is currently under revision with a view of bringing it in compliance with GOST 8.315.

2. MI 1709-87, *Methodical guidelines. Homogeneity of reference materials of solids for spectral analysis.*
3. MI 1952-88, *Stability of reference materials of composition of substances and materials. Assessment procedure.*
4. MI 2258-93, *Reference materials. Evaluation of metrological characteristics with the use of measurement standards and reference devices.*

### **Russian Federation**

#### a) Procedural- and- legal ND

1. PR 50.2.020-98, *GSI. The order of keeping the National Register of the approved types of reference materials.*
2. PR 50.2.021-98, *GSI. Licensing procedure for production and sale of certified reference materials.*
3. R 50.2.005-2000, *GSI. Metrological Supervision over RM issue and use. Contents of inspection procedures.*

#### b) Methodical documents of general nature.

4. MI 1952-88, *GSI. Stability of reference materials of composition of substances and materials. Assessment procedure.*
5. MI 2258-93, *GSI. Reference materials. Evaluation of metrological characteristics with the use of measurement standards and reference devices.*
6. MI 2281-94, *GSI. Sets of reference materials of composition of substances and materials. Intercomparison procedure.*
7. MI 2255-95, *GSI. Calibration characteristics of means for measuring composition and properties of substances and materials. Methods of plotting with the use of reference materials.*
8. MI 1992-98, *GSI. Metrological certification of reference materials of composition of substances by preparation procedure. Basic principles.*
9. MI 2574-2000, *GSI. Reference materials for composition of pure organic substances. Methods of certification. General Principles.*
10. MI 2608-2000, *GSI. Contents and preparation of technical documentation for branch and in-plant reference materials. General requirements.*
11. MI 2589-2000, *GSI. General methodical recommendations on the implementation of GOST 8.315 in the development and use of reference materials.*

Note: Documents in the rank of the rules of metrology (PR) are mandatory; all the others are of a recommendation character.

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<sup>1</sup> In the information received from Kazakhstan it was only mentioned that provisions of general standards are specified at the level of in-plant standards.

## Ukraine

### a) procedural-and-legal ND

1. Regulations of the National Register of measuring devices approved for use in Ukraine (contains a section on reference materials).
2. The order of issue of measuring device pattern approval certificates, certificates of Conformity of measuring devices to the approved pattern and certificates of recognition of the approved pattern of measuring devices.
3. PMU 15-99, *Instruction on the procedure for accuracy control of measurement results in measurement laboratories.*

### b) methodical documents of general nature

4. MI 1992-89, *GSI. Reference materials prepared by mixing. Certification by preparation procedure.*
5. MI 1952-88, *GSI. Stability of reference materials of composition of substances and materials . Assessment procedure.*
6. MI 1709-87, *Methodical guidelines. Homogeneity of reference materials of composition of solids for spectral analysis. Assessment procedure.*

Besides the documents listed above, the use in practical works is made of a number of general metrological documents, establishing metrological terminology, the rules of processing measurement results, requirement for the contents of measurement procedures, the rules of verification of measuring devices , etc., which in view of their general nature are not mentioned here.

It is easy to make a conclusion from the titles of these documents about the subject they regulate. Any comments concerning their contents seem not to be feasible at the stage of preliminary analysis.

## 5. GENERAL CONCLUSIONS AND PROPOSALS

The study of the set of normative documents used by the countries cooperating in COOMET within the subject-field “Development and Use of Reference Materials of Composition and Properties of Substances and Materials” makes it possible to arrive at some general conclusions.

1. The works on the RM development and use in COOMET member-countries hold a prominent place among general metrological problems and in a number of the countries they are subject to legal regulation.

2. By the present moment underlying normative documents, both international, regional and national establishing sufficiently agreed common conception of reference materials and reflecting their role and place in the system of measurement assurance, have been developed and adopted.

ND of general nature, in principle, lack contradictions which would serve the grounds for their amendment and revision.

3. As a whole, the stock of ND directly relating to the subject-matter of cooperation within COOMET, numbers about 40 documents including more than 20 national ones, which is the evidence of active work of metrological bodies concerned with this problem.

4. In regional organizations primary emphasis is placed on the first stages of works on RM production: demonstration of the feasibility of the project, specification of technical requirements for RMs, organization of carrying out and completion of the works.

5. General analysis of the stock of national ND allows to reveal the coincidence of the scope and the subject-matter of a number of documents: in one way or another they regulate the most important stages of work in the RM production: homogeneity and stability testing, procedure for metrological certification of RMs, technique for comparison of RM metrological characteristics, which points out to the feasibility of their unification.

The listed above general conclusions make it possible to formulate some ideas relating to the improvement of normative foundation of cooperation within COOMET.

At present this normative foundation is in principle made up by 2 COOMET working documents (see Table 2, p.p.2 and 3), which regulate the order proper and technology of works. The task of agreement of technical requirements for RMs to be developed is delegated to cooperating partners as well as of agreement of certification programmes and procedures, the scope and nature of investigation of RM material properties, etc. ND to be appealed to by the partners in settling disputable questions are missing in COOMET. The availability of such documents would be useful to substantiate the point of view. These are documents specifying the requirements for RM certification programmes and procedures, methods of homogeneity and stability testing and probably procedures for RM comparison with similar RMs of, for example, cooperating or third countries.

To facilitate and speed up the adoption of COOMET ND of the kind, it would be feasible to use the already existing regional and national ND as the first drafts with further amendment (if any) and adoption as COOMET ND.

As an example GOST 8.531, GOST 8.532 being revised and RMG 27-99 , MI 1992-98 in force may be considered as the first drafts.

The possibility and feasibility of such works may be discussed at the meeting of COOMET contact-persons.

## ANNEX A

### LIST OF ISO/REMCO NORMATIVE DOCUMENTS

1. ISO Guide 30:1992, *Terms and definitions used in connection with reference materials.*
2. ISO Guide 31: 2000, *Contents of certificates of reference materials.*
3. ISO Guide 32: 1997, *Calibration in analytical chemistry and use of reference materials.*
4. ISO Guide 33:2000, *Uses of reference materials.*
5. ISO Guide 34: 2000, *Quality system guidelines for the production of reference materials.*
6. ISO Guide 35: 1987, *Certification of reference materials- General and statistical principles.*

# **ANNEX B**

## **GUIDELINES FOR THE PRODUCTION AND CERTIFICATION OF BCR REFERENCE MATERIALS**

### **CONTENTS**

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- 1.2 Important notes
- 1.3 Contact persons

#### **Part A Recommendations to -proposers of BCR certification projects**

#### **2. SPECIFICATION OF THE OBJECTIVES**

- 2.1 Definition of the needs (intended use; specifications; realistic cost)
- 2.2 Options available for certification of a quantity which is fully defined by a number and a unit
- 2.3 Certification of an "operationally defined" quantity or property (i.e. one whose definition implies the application of a standard procedure)
- 2.4 Notes

#### **3. PLANNING OF A FEASIBILITY STUDY**

- 3.1 Go / no-go decision points
- 3.2 Preliminary test batch
- 3.3 Stability testing
- 3.4 Preliminary intercomparison(s)
- 3.5 Alternatives routes in the workprogramme

#### **4. PLANNING OF THE PREPARATION OF THE MATERIAL**

- 4.1 Quantities
- 4.2 Method of preparation
- 4.3 Packaging: sealed containers
- 4.4 Indicators for improper handling
- 4.5 Labelling of "dangerous" materials
- 4.6 Requested information
- 4.7 Storage of samples for later reference

#### **5. PLANNING OF THE TESTING OF THE MATERIAL**

- 5.1 Homogeneity testing
- 5.2 Stability testing

#### **6. PLANNING OF THE CERTIFICATION EXERCISE AND RELATED TASKS**

- 6.1 The participants
- 6.2 Quality and traceability
- 6.3 The methods
- 6.4 Number of replicates per laboratory/method
- 6.5 Data evaluation; formal certification
- 6.6 Tasks related to storage and distribution

## Part B Guidelines for the implementation of BCR certification projects

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- 7.1 The material, its packaging, its stability
- 7.2 The intercomparison

### 8. PRODUCTION OF THE BATCH OF REFERENCE MATERIAL

- 8.1 Method of production
- 8.2 Packaging in units
- 8.3 Labelling and numbering

### 9. HOMOGENEITY TESTING

- 9.1 Selection of samples
- 9.2 Number of samples to be measured for the homogeneity test
- 9.3 Sample size
- 9.4 Nested design
- 9.5 Contribution to the uncertainty
- 9.6 Notes

### 10. STABILITY TESTING

- 10.1 Limited validity (expiry date) ?
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- 15.2 Table of contents

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- 15.5 List of the participating laboratories
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- 15.7 The preparation and packaging of the material
- 15.8 Homogeneity testing
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- 15.10 The certification measurements
- 15.11 Technical evaluation of the data
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- 15.13 References
- 15.14 The instructions for use
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## THE CERTIFICATES (a)

### 17. REFERENCE



**ANNEX 3**  
**THE CONTENTS OF INTERGOVERNMENTAL STANDARD**  
**GOST. 8315-97. REFERENCE MATERIALS OF COMPOSITION AND**  
**PROPERTIES OF SUBSTANCES AND MATERIALS. BASIC**  
**PRINCIPLES**

1. Scope  
(establishes general requirements for RM development, recognition, registration, release and use).
2. Normative references  
(lists ND referred to in GOST 8.315)
3. Definitions and abbreviations  
(contains more than 20 general terms and definitions)
4. General principles  
(establishes intended use of RMs, their kinds, (categories), requirements for metrological characteristics and validation).
5. The order of RM development  
(establishes the stages of RM development, general requirements for RM technical documents, methods of certification, metrological examination of RM documentation prior to their approval).
6. Approval, registration and release of reference materials.  
(establishes organizations, approving RM types and procedure for their approval, official registration of approved RMs, general requirements for organizations releasing RMs, documents accompanying supplies of each RM unit).
7. The use of reference materials  
(establishes general rules for the use and restrictions for the use of some RM categories).
8. Metrological control and supervision over RM release and use.  
(establishes the kinds and procedure of metrological control and supervision

Annex A. Approval procedure for foreign RMs

Annex B. The contents of technical assignment for the development of CRMs

Annex C. The form of certificate (of CRM type approval) with “CRM type description” attached.

Annex D. The form of CRM specification (passport) with “instruction for CRM use” attached.

Annex E. Information provided on CRM label (or marking).

Annex F. Extension procedure for certificates of CRM type approval.