Brazilian Federal Public Service

MINISTRY OF DEVELOPMENT, INDUSTRY, AND INTERNATIONAL TRADE

BRAZILIAN NATIONAL INSTITUTE OF METROLOGY, QUALITY AND TECHNOLOGY – INMETRO

Ordinance no. 118, of March 6th, 2015

THE PRESIDENT OF THE BRAZILIAN NATIONAL INSTITUTE OF METROLOGY, QUALITY, AND TECHNOLOGY – INMETRO, in the exercise of the powers vested by Article 4, paragraph 3, of Law no. 5,966, of December 11th, 1973; by Article 3, subsection I and IV, of Law 9,933, of December 20th, 1999; by Article 18, subsection V, of the Internal Structural Statute of the Autarky, approved by Decree no. 6,275, of November 28th, 2007;

Considering clause *f* of item 4.2 of the Term of Reference of the Brazilian Compliance Evaluation System (SBAC), approved by Conmetro Resolution no. 04, of December 2nd, 2002, which confers to Inmetro the competence to establish guidelines and criteria for the process of compliance evaluation;

Considering the increasing demand for establishing Compliance Evaluation Programs and the need to rethink and streamline the form to meet them;

Considering the need to ensure greater standardization and conciseness in establishing the Compliance Evaluation Programs;

Considering the importance of continuous improvement of the macro process of Assisted Implementation of Compliance Evaluation Programs;

Considering the existence of requirements for compliance evaluation which are common to any objects subjected to the evaluation process;

Considering the existence of general requirements for each of the different mechanism of compliance evaluation clarifies the interpretation of Compliance Evaluation Programs;

Considering that the General Requirements for Product Certification are intended to establish common devices to all Compliance Evaluation Programs that adopt the mechanism of certification;

Considering that the General Requirements for Product Certification are complemented by the Requirements for Compliance Evaluation, specific of each object eligible for certification;

Considering the need to improve the General Requirements of Product Certification, hereby resolves to lay down the following provisions:

Article 1. To approve the improvement of **General Requirements for Product Certification (RGCP)**, available on the website *www.inmetro.gov.br* or on the following address:

Instituto Nacional de Metrologia, Qualidade e Tecnologia – Inmetro
Divisão de Regulamentação Técnica e Programas de Avaliação da

Article 2. To ratify that the Public Consultation, which collected contributions from society in general for the creation of the herein approved General Requirements, has been published by Inmetro Ordinance no. 544, of November 18th, 2013, on the Brazilian Official Gazette on November 20th, 2013, section 01, page 97.

Article 3. To ratify that the Requirements for Compliance Evaluation to be created for each object shall only contain the specific requirements, complementary to General Requirements for Product Certification, while respecting the specificities of the object to be certified.

Paragraph 1. The Requirements for Compliance Evaluation shall define the following items:

I – Objective (specific to certification program);
II – Acronyms (only those which do not appear in this document);
III – Reference and complementary documents (only those which do not appear in this document);
IV – Definitions (only those which do not appear in this document);
V – Mechanism of Compliance Evaluation;
VI – Compliance Evaluation Stages (which shall contain, if applicable, at least the following items, complementing the RGCP):

- Definition of Certification Model(s) used;
- Initial Evaluation;
  - Application for certification;
  - Analysis of Application and Compliance of Documents;
  - Initial Audit of Quality Management System and Evaluation of Production Process (when applicable);
  - Initial Test Planning (when applicable);
  - Treatment of non-compliances in the stage of Initial Evaluation ;
  - Issuance of the Certificate of Compliance;
- Evaluation of the Maintenance of Quality Management System and Evaluation of Production Process (when applicable);
  - Maintenance Audit (when applicable);
  - Maintenance Test Planning (when applicable);
  - Treatment of non-compliances in the stage of Evaluation of the Maintenance;
  - Confirmation of Maintenance;
- Evaluation of the Recertification (when applicable);
- Special Cases;

VII – Treatment of Complaints;
VIII – Activities performed by the OCP accredited by a MLA member of IAF;
IX – Transfer of Certification;
X – Termination of the Certification;
XI – Compliance Identification Mark;
XII – Authorization to Use the Compliance Identification Mark;
XIII – Responsibility and Duties;

XIV – Market Surveillance;
XV – Penalties; and
XVI – Complaints.

Paragraph 2. In exceptional cases, the provisions of the herein approved Requirements may be changed, observing the specificities of the object to be evaluated, through the Requirements for Compliance Evaluation created for each object to be certified.

Paragraph 3. In cases of conditions of the previous paragraph, these conditions shall be clearly defined in Requirements for Compliance Evaluation.

Article 4. To ratify that the Compliance Evaluation Programs which do not use the RGCP shall be gradually adjusted to the same as the programs are improved.

Article 5. To determine that all product certification processes which have already adopted the RGCP shall be adjusted by the OCP from the maintenance or recertification following the publication of this Ordinance, provided that the maintenance or recertification do not occur within less than six (6) months, when they still meet the previous version of RGCP.

Article 6. To revoke the Inmetro Ordinance no. 361 of September 6th, 2011, published on the Brazilian Official Gazette on September 9th, 2011, section 01, page 76, within six (6) months after the publication of this Ordinance.

Article 7. This Ordinance shall come into force on the date of its publication on the Brazilian Official Gazette.

JOÃO ALZIRO HERZ DA JORNADA

President

INMETRO	**GENERAL REQUIREMENTS FOR PRODUCT CERTIFICATION**

1. OBJECTIVE

This document establishes the General Requirements for Product Certification common for all Compliance Evaluation Programs that use the Mechanism of Product Certification. The particularities of each Compliance Evaluation Programs shall be described in the Requirements for Compliance Evaluation, created for each product to be certified, which further specify the material, considering the specificities of the same.

1.1 The term "product" in this RGCP shall be applied to product, service or process.

2. ACRONYMS

ABNT	Brazilian Association of Technical Standards
Cgcre	General Coordination for Accreditation
Conmetro	Brazilian National Board of Metrology, Standardization and Industrial Quality
Dipac	Division of Technical Regulation and Compliance Evaluation Programs
Dconf	Compliance Evaluation Board of Directors
DOU	Brazilian Official Gazette
DPDC	Department of Consumer Protection and Defense
IAAC	Interamerican Accreditation Cooperation
IAF	International Accreditation Forum
IEC	International Electrotechnical Comission
ILAC	International Laboratory Accreditation Cooperation
INI	Inmetro Normative Instruction
Inmetro	Brazilian National Institute of Metrology, Quality and Technology
ISO	International Organization for Standardization
MLA	Multilateral Recognition Arrangement
MoU	Memorandum of Understanding
NBR	Registered Brazilian Standards
OCP	Product Certification Body Accredited by Inmetro
OCS	Quality Management System Certification Body
PAC	Compliance Evaluation Program
RAC	Requirements for Compliance Evaluation
RGCP	General Requirements for Product Certification
RTQ	Quality Technical Requirements
SBAC	Brazilian Compliance Evaluation System
Senacon	Brazilian National Consumer Secretariat
SGQ	Quality Management System

3. DOCUMENTS

3.1 REFERENCE DOCUMENTS

Law no. 8,078/1990	Makes provisions on the consumer protection and makes other arrangements.
Law no. 9,933/1999	Makes provisions on the competences of Conmetro and Inmetro, establishes the Metrological Service Tax, and makes other arrangements
ABNT NBR ISO 9001 standard	Quality management systems - Requirements
ABNT NBR ISO/IEC 17000 standard	Conformity Assessment – Vocabulary and General Principles
ABNT NBR ISO/IEC 17025 standard	General requirements for the Competence of Testing and Calibration Laboratories
ISO IEC 17067:2013	Conformity assessment – Fundamentals of product certification and guidelines for product certification schemes

3.2 COMPLEMENTARY DOCUMENTS

Inmetro Ordinance no. 274/2014 and its substitutes	Approves the Regulations for the Use of Brands, Symbols, Marks and Labels of Inmetro.
Inmetro Ordinance no. 453/2013 and its substitutes	Approves the Inmetro Vocabulary of Compliance Evaluation with terms and definitions commonly used by the Inmetro Board of Directors of Compliance Evaluation.
Ministry of Justice Ordinance no. 487/2012	Regulates the procedure of calling consumers or recall products and services that are considered harmful or dangerous after their introduction to the consumer market.

4. DEFINITIONS

The definitions in Inmetro Ordinance approving the Inmetro Vocabulary of Compliance Evaluation shall be applied in PACs established by Inmetro that use the mechanism of certification. Specific definitions used in each PAC shall be described in the specific RAC of the object.

5. MECHANISM OF COMPLIANCE EVALUATION

The Mechanism of Compliance Evaluation used in this document is the Certification.

6. STAGES OF THE COMPLIANCE EVALUATION

The process of Compliance Evaluation consists of several stages. Each stage shall follow a sequence of procedures, in accordance with the Certification Model(s) adopted.

6.1. Definition of Certification Model(s) used

The Certification Models shall be explained in the specific RAC of the object under evaluation, among those defined in Inmetro Vocabulary of Compliance Evaluation.

The specific RAC may address more than one Certification Model.

6.1.1 Stages of the Certification Models

Each model consists of a sequence of stages described in Table 1. These stages shall be addressed in the RAC, each model separately, when the specific RAC addresses more than one Certification Model.

Table 1: Stages of Certification Models

STAGES OF PRODUCT CERTIFICATION PROCESS		MODELS						
		1a	1b	2	3	4	5	6
Initial Evaluation	Application for Certification	X	X	X	X	X	X	X
	Analysis of Application and Compliance of Documents	X	X	X	X	X	X	X
	Initial Audit of Quality Management System and Evaluation of Production Process						X	X
	Initial Test Planning	X	X	X	X	X	X	
	Issuance of the Certificate of Compliance	X	X	X	X	X	X	X
Evaluation of the Maintenance	Maintenance Audit of Quality Management System and Evaluation of Production Process						X	X
	Maintenance Test Planning			X	X	X	X	
	Confirmation of Maintenance			X	X	X	X	X
Evaluation of the Recertification	Evaluation of the Recertification			X	X	X	X	X

6.2 Initial Evaluation

The stages of the process intended to certificate the compliance of the object shall be described in this item.

6.2.1.1 The certification shall be exclusively requested by the Supplier, and shall follow the provisions of this RGCP and specific RAC of the object to be evaluated.

6.2.1.2 The beginning of the certification process shall be subject to a formal request from the certification applicant, which shall be submitted directly to one of the Product Certification Bodies, of choice, accredited and/or appointed by Inmetro. The body shall be legally established in the country for the product evaluation. The request shall be accompanied by the submission of documentation, and shall meet the following requirements:

a) List of model(s) object of certification, referring its/their technical description(s) and including the list of all commercialized brands, in case of certification by model.

b) List of model(s) that compose the family object of certification, following the rules of family formation laid down in the specific RAC, referring its/their technical description(s) and including the list of all commercialized brands, in case of certification by family.

c) List of scope(s) of service for which the certification has been requested, in case of certification of service;

d) Photographic documentation of the object: external and internal photos of all sides, detailing the labels, logos, warnings, inputs, outputs, activation buttons, when applicable;

e) Descriptive memorial addressing the object design in its constructive and functional details, and the list of its critical components including its manufacturers and possible existing

certifications, translated into Portuguese, which are in a different language other than English or Spanish.

f) User manual with instructions written in Portuguese;

g) Packaging drawing or final artwork (primary, secondary and/or tertiary), when applicable (when there is packaging);

h) Option for the Certification Model, among those mentioned in the specific RAC of the object;

i) Information of company name, address and CNPJ of the certification applicant;

j) Contact person, phone number and email address of the certification applicant;

k) Identification of the manufacturer with full address, including the manufacturing site(s) to be certified, based in another country, when applicable;

l) Information of outsourced activities/processes that may affect the compliance of the product object of certification;

m) Documentation evidencing the compliance with the item 7 of this document (Treatment of Complaints) for all commercialized brands;

n) Documents of the Manufacturer Quality Management System, applicable to the object to be certified, in the case of certification by the models 5 and 6, as set forth in Tables 2 and 3 of item 6.2.3.1, even if these may necessarily be audited by the OCP, as set forth herein;

o) Valid certificate issued based on the ISO 9001 standard or ABNT NBR ISO 9001 standard in force, covering the production process of the object of certification, if any;

p) Identification of the batch of certification, in the case of Model 1b, including quantities and of the model(s) manufacturing batch(es) to be certified.

q) Import license, or, in the absence thereof, Import Declaration, in the case of Model 1b when referring to imported products;

r) Other documents required for the application process, described in the specific RAC.

Note 1: Should the brand(s) mentioned in a) and b) be not owned by the certification applicant, the applicant shall have an authorization for the use of the brand(s). The OCP shall be responsible to verify the legal qualification of the authorization instrument and the protocol of incorporation of the owner(s) of the brand(s).

Note 2: The photos mentioned in d) shall have a minimum resolution of 800 x 600 dpi.

Note 3: The OCP shall be responsible to evaluate the list of critical components mentioned in e), and may include others.

Note 4: User manual, mentioned in f), is the information about the product concerning: assembly instruction, installation, disassembly, uninstalling, handling, operation, cleaning, maintenance, warnings and other relevant information for the user.

6.2.1.3 Should the user manual is not applicable due to product characteristics, the OCP shall validate and record this information in the certification process.

6.2.1.4 Should the certification applicant be an integrator, packager and/or distributor which performs changes in the packaging of an already certified product or modifies the presentation form for marketing the product compared to the original certification process, the application for certification shall follow the requirements set forth in Annex B of this RGCP.

6.2.2 Analysis of Application and Compliance of Documents

6.2.2.1 The OCP, upon receiving the specified documentation, shall open a procedure to grant the Certificate of Compliance and perform an analysis in the relevance of the request as well as a compliance evaluation of the documentation submitted by the certification applicant.

6.2.2.2 Should any non-compliance be identified in the documentation received, this shall be formally submitted to the certification applicant for its correction and duly formalization at the OCP, in order to evidence the implementation of the same for new analysis.

6.2.2.3 Should any of the documents mentioned in 6.2.1 not be submitted in its definitive form by the certification applicant, upon delivery of the documentation. Provided that this event does not interfere in other stages of the process of initial evaluation, this event shall be explained by the OCP and the conclusion of certification shall only take place after all documents are in their final form and duly approved by the OCP.

6.2.3 Initial Audit of Quality Management System and Evaluation of Production Process

The audit of QMS shall be performed whenever the chosen certification model requires, regardless of the manufacturer or service provider has a certified Quality Management System based on the ISO 9001 standard or ABNT NBR ISO 9001 standard in force.

In accordance with the adopted model, the OCP shall evaluate the documents and records of QMS, and performs audit in the facilities of the service provider or manufacturing site, in order to verify the compliance of the production process, including installations and personnel training. The audit of QMS shall pursue the objective evidence that the production process is effectively systemized and monitored, providing evidences of compliance with the product requirements set forth in the RAC. Therefore, the requirements of QMS are complementary to the requirements defined in the specific RAC of the object.

Compliance records in compliance with these requirements shall be obtained consistently.

The date of visit for the audit shall be scheduled in agreement with the Certification applicant.

6.2.3.1 The evaluation of QMS shall be performed by the OCP based on the scope of the certification process and in compliance with the requirements of the ISO 9001 standard or ABNT NBR ISO 9001 standard in force, with the minimum requirements established in the following Tables 2 and 3:

Table 2: Minimum requirements for verification of QMS for manufacturers or service providers with valid certification in ISO 9001 standard or ABNT NBR ISO 9001 standard.

QMS REQUIREMENTS	ISO 9001 standard or ABNT NBR ISO 9001 standard
Control of records	4.2.4
Planning of product realization	7.1
Customer communication	7.2.3
Purchasing process	7.4.1

Verification of purchased product	7.4.3
Control of production and service provision	7.5.1
Identification and traceability	7.5.3
Customer property	7.5.4
Preservation of product	7.5.5
Control of monitoring and measuring devices	7.6
Monitoring and measurement of processes	8.2.3
Monitoring and measurement of product	8.2.4
Control of nonconforming product	8.3
Corrective Action	8.5.2

Table 3: Minimum requirements for verification of QMS for manufacturers or service providers without valid certification in ISO 9001 standard or ABNT NBR ISO 9001 standard.

QMS REQUIREMENTS	**ISO 9001 standard or ABNT NBR ISO 9001 standard**
Control of documents	4.2.3
Control of records	4.2.4
Management review	5.6.1/ 5.6.2/ 5.6.3
Competence, awareness and training	6.2.2
Infrastructure	6.3
Planning of product realization	7.1
Customer communication	7.2.3
Purchasing process	7.4.1
Verification of purchased product	7.4.3
Control of production and service provision	7.5.1
Validation of processes for production and service provision	7.5.2
Identification and traceability	7.5.3
Customer property	7.5.4
Preservation of product	7.5.5
Control of monitoring and measuring devices	7.6
Customer satisfaction	8.2.1
Internal Audit	8.2.2
Monitoring and measurement of processes	8.2.3
Monitoring and measurement of product	8.2.4
Control of nonconforming product	8.3
Analysis of data	8.4 (b), (c), (d)
Corrective Action	8.5.2

6.2.3.2 Despite with the submission of a valid certificate, in accordance with the ISO 9001 standard or ABNT NBR ISO 9001 standard in force, issued by an OCS accredited by the Inmetro or MLA member body of IAF, for the scope of its accreditation, the OCP shall proceed to the initial audit of the QMS in the manufacturing site or service provider site during the stage of initial evaluation, according to the Table 2 of this RGCP, in order to verify the compliance of the production process.

Note: The certificates issued by a foreign OCP shall be accompanied by a sworn translation in Portuguese, when these have been issued in a different language other than English or Spanish. The other documents regarding the Management System, which are in a different language other than English or Spanish, shall be translated into Portuguese.

6.2.3.3 During the audit, the certification applicant shall provide to OCP all documents corresponding to the certification of the Quality Management System based on the ISO 9001 standard or ABNT NBR ISO 9001 standard in force and submit the records of the production process which shall be clearly stated the identification of the object of certification. The OCP shall analyze the relevant documentation to ensure that the requirements described in Table 2, of item 6.2.3.1 have been met.

6.2.3.4 The OCP, after the audit, shall issue a report, recording the result of the same, in accordance with this RGCP and the specific RAC of the object.

6.2.3.5 The audit report shall be signed by at least the audit team, and a copy shall be available to the certification applicant.

6.2.3.6 Any change in the manufacturing process shall be informed to the OCP and may require another audit, if it affects the compliance of the product.

6.2.3.7 In case of certification based on prototypes, the OCP, during the audit, shall ensure that the product manufactured in scale corresponds to a tested prototype.

6.2.4 Initial Test Planning

The initial tests shall certify that the object of compliance evaluation meets the requirements defined in normative grounds.

The OCP shall be responsible to prepare the test planning which shall contain, at least, the initial tests to be performed, the clear definition of test methods, number of samples and the acceptance/rejection criteria for these tests. In case of certification by family, the test planning shall also be prepared in order to cover, at least, the models that contain the largest number of pre-established requirements by the normative grounds of reference. The OCP shall perform the critical analysis of the laboratory test reports, comparing them with the test planning previously established.

The OCP shall require that laboratory test reports inform the performed measurement uncertainties.

Test reports issued before the beginning of the certification process shall not be accepted, unless clearly defined in the specific RAC of the object.

Any change of critical component(s) shall be informed to the OCP and shall lead to the performance of new tests.

6.2.4.1 Definition of Tests to be performed

The tests, their methods and acceptance/rejection criteria shall be defined in the specific RAC of the object and shall be performed in accordance with the pre-established requirements by the normative grounds.

The test report shall contain the complete identification of the object model to be certified, so the test report be clearly traced to the collected sample.

The OCP shall be responsible to evaluate whether the data in the descriptive memorial and product design or specification are in accordance with the technical identification of the model in the presented test report.

6.2.4.2 Definition of Sampling

The OCP is the responsible to select and seal the samples of the object to be certified. The collection of samples to be sent to the laboratory shall be agreed between the Certification applicant and the OCP. The quantity of samples, acceptance/rejection criteria and exceptional cases shall be addressed on the specific RAC of the object. The Table 4 gives an applicable example of collection of samples for Models 1a, 2, 3, 4 and 5.

The OCP, when collecting and sealing samples, shall write a report of sampling, detailing the data, local, storage conditions, sample identification (model/brand, production batch and date of manufacture, quantities sampled, etc.)

Note 1: The Sampling Plan shall not be applied when the specific RAC of the object allows the acceptance of reports before the beginning of the certification.

Note 2: When applicable, additional pieces, components or parts of the products complementary to the sample(s) shall be sealed, identified and sent to the laboratory with the product.

Note 3: In case of certification model 1b, the selection and seal of samples shall take place in national territory.

Table 4: Presentation model for sample sizes required for initial tests

		SIZE OF THE SAMPLE			
TESTS	**NORMATIVE GROUNDS**	**PROOF**	**COUNTER PROOF**	**WITNESS**	**ACCEPTANCE/ REJECTION CRITERIA**
(test denomination)	(corresponding item of normative grounds)	(quantity of product units)	(quantity of product units)	(quantity of product units)	(criteria for acceptance/ rejection of the sample)

Note: The sample tests of counterproof and witness shall, necessarily, be performed in the same laboratory where the test of the proof sample has been performed.

6.2.4.2.1 Should proof tests be approved, the sample is approved. Should non-compliance be detected in the proof sample, the test(s) shall be repeated in the counterproof and witness samples.

a) Should non-compliance be detected in the counterproof sample, the sample is rejected;

b) Should the counterproof sample does not have non-compliance, the witness sample shall be tested;
c) Should the witness sample has non-compliance, the sample is rejected;
d) Should the witness sample does not have non-compliance, the sample is approved.

Note: The specific RAC of the object shall determine the need to repeat all tests laid down in normative grounds on counterproof and witness samples.

6.2.4.2.2 At the discretion of the certification applicant, through the formalization of the OCP, counterproof and witness samples shall not necessarily have to be tested. In such case, there shall not be contestation of the results obtained in the proof sample.

6.2.4.2.3 Prototypes may be sent directly to the laboratory. In this case, the initial sample shall only be consisted of the proof of the product, dismissing the counterproof and witness samples.

6.2.4.2.4 The OCP shall ensure that the tested prototype be the product which will be produced in scale. Should the OCP finds any discrepancy between the tested prototype and the product produced in scale, or, the object design, if deemed appropriate, shall lead to the performance of new tests, according to the test planning, in new samples.

6.2.4.3 Definition of Laboratory

6.2.4.3.1 The OCP shall adopt test laboratories considering the priority order defined as follows:

1st Laboratory appointed by Inmetro;
2nd Third-party laboratory, national or foreign, fully accredited by Inmetro/Cgcre or signatory of mutual recognition agreements ILAC or IAAC, in the specific scope;
3rd First-party laboratory, national or foreign, fully accredited by Inmetro/Cgcre or signatory of mutual recognition agreements ILAC or IAAC, in the specific scope;
4th Third-party laboratory, national or foreign, partially accredited by Inmetro/Cgcre or signatory of mutual recognition agreements ILAC or IAAC, (over 70% of the tests required in the normative grounds) in the specific scope;
5th First-party laboratory, national or foreign, partially accredited by Inmetro/Cgcre or signatory of mutual recognition agreements ILAC or IAAC, (over 70% of the tests required in the normative grounds) in the specific scope;
6th Third-party laboratory, national or foreign, accredited by Inmetro/Cgcre or signatory of mutual recognition agreements ILAC or IAAC, in another scope, in the same area of activity and test class of the specific scope;
7th First-party laboratory, national or foreign, accredited by Inmetro/Cgcre or signatory of mutual recognition agreements ILAC or IAAC, in another scope, in the same area of activity and test class of the specific scope;
8th Third-party laboratory, national or foreign, accredited by Inmetro/Cgcre or signatory of mutual recognition agreements ILAC or IAAC, in another scope;
9th First-party laboratory, national or foreign, accredited by Inmetro/Cgcre or signatory of mutual recognition agreements ILAC or IAAC, in another scope;
10th Third-party laboratory, national or foreign, non-accredited;
11th First-party laboratory, national or foreign, non-accredited.

6.2.4.3.2 For the purpose of use of the mentioned priority order, any of the following cases shall be considered:

a) Absence of the laboratory defined in the previous priority;
b) When the laboratory defined in the previous priority does not provide the budget of tests in, a maximum of, ten (10) business days of the application made by the OCP, or may not meet, at a maximum of, thirty (30) consecutive days counted from the date of acceptance by the OCP, the deadline for the beginning of the tests set forth in the Requirements of Compliance Evaluation (RAC), or may not perform the tests in, a maximum of, one and a half the regular time of the tests set forth in the normative grounds;
c) When the OCP shows that the price of the performed tests, plus the costs of evaluation/monitoring by the OCP, compared with the determined prices in the previous priority is, at least, lower than 50%.

Note 1: The OCP shall record, through supporting documents, the reasons to select the adopted laboratory.

Note 2: Depending on the product's characteristics, at the time of the creation of the specific RAC or its implementation stage, the Inmetro may authorize, through Ordinance, the use of accredited first-party laboratories, alternatively to the accredited third-party laboratories.

Note 3: In case of existing only third-party laboratory accredited in the specific scope abroad, although having first-party laboratory accredited in the specific scope in the country, the latter may be used.

Note 4: When provided in the specific RAC of the object the performance of toxicity tests, the OCP may select, alternatively to accreditation, a test laboratory with recognition by Inmetro/Cgcre of the Principle of Good Laboratory Practices – BPL, under the Data Mutual Acceptance System of the Organization of Economic Co-operation and Development – OECD.

6.2.4.3.3 The OCP shall be responsible to observe and document the equivalence of the method and parameters of test in the case of use of laboratory accredited by signatory of mutual recognition agreements ILAC or IAAC.

6.2.4.3.4 In any case of the full or partial use of first-party laboratory accredited in the specific scope, the OCP shall monitor and record the performance of all tests. This monitoring consists of, at least, following up the stages of selection and preparation of samples and the subsequent collection of results.

6.2.4.3.5 In any case of the use of first or third-party laboratory accredited to another scope of test, the OCP shall monitor and record the performance of all tests after acknowledging and recording the training and infrastructure (including equipment). This monitoring consists of, at least, following up the stages of selection and preparation of samples, beginning of tests and subsequent collection of results.

6.2.4.3.6 In any case of the use of non-accredited first or third-party laboratory, the OCP shall monitor and record the performance of all stages of all tests after evaluating and recording the requirements listed in Annex A of this document. The evaluation performed by the OCP shall

be carried out by an OCP's personnel member with a training certificate of at least 16 hours/class and issued according to ABNT NBR ISO IEC 17025 standard in force, besides having formal proof of experience and specific technical knowledge as to the tests to be performed.

6.2.4.3.7 The definition of laboratory shall be made in agreement between the OCP and the certification applicant in accordance with the item 6.2.4.3.

6.2.5 Treatment of non-compliances in the stage of Initial Evaluation

6.2.5.1 Should any non-compliance be identified in the stage of Initial Evaluation, the certification applicant shall submit to OCP, within a maximum period of sixty (60) consecutive days, the evidence of the implementation of corrective actions to the non-compliance(s) found.

6.2.5.2 The certification applicant shall be responsible for the critical analysis of the causes of non-compliances and proposition of corrective actions.

6.2.5.3 Should the certification applicant fails to meet the deadline, the certification process shall be cancelled or interrupted. The process may be restarted if the OCP and certification applicant have been interested.

6.2.5.4 New deadlines may be agreed, provided they have been formally requested and justified by the certification applicant, and have had their relevance evaluated by the OCP. These deadlines shall be also applicable to the non-compliances or pending items identified in the analysis of the request.

6.2.5.5 The OCP shall evaluate the effectiveness of the implemented corrective actions, accepting them or not.

6.2.5.6 The need of a new audit of QMS and/or performance of new tests to verify the implementation of corrective actions is at the OCP's discretion.

6.2.5.7 The certification applicant shall identify and segregate the nonconforming product in separate areas, in order not to be possible to mix them with conforming products and ship to the market, and shall keep a record of that action.

6.2.5.8 The objective evidence of the treatment of non-compliances is required to issue the Certificate of Compliance.

6.2.6 Issuance of the Certificate of Compliance

6.2.6.1 Critical Analysis and Decision of Certification

6.2.6.1.1 The OCP shall designate at least one person to critically analyze the information and results related to the evaluation. The critical analysis shall be performed by person/people not involved in the evaluation process.

6.2.6.1.2 The critical analysis shall include all information about the documentation, audits, test results and treatment of non-compliances.

6.2.6.1.3 The recommendations for the Certification based on the critical analysis shall be documented.

6.2.6.1.4 The OCP shall be responsible for the decisions on Certification.

6.2.6.1.5 The Decision of Certification shall be performed by a person or a group of people not involved in the evaluation process.

6.2.6.1.6 The OCP shall notify the certification applicant if decided not to grant the Certification, reporting the reasons for decision.

6.2.6.1.7 Formal rules for the appointment, terms of reference and operation of the same shall be created in case the OCP chooses to use a Committee for Certification.

6.2.6.1.7.1 The Committees for the Certification shall be free of any interests, commercial, financial and other pressures that may influence their decisions.

6.2.6.1.7.2 The OCP shall appoint and exclude members of the Committees for Certification.

6.2.6.2 Issuance of the Certificate

After the requirements of this RGCP and the specific RAC of the object have been met, the OCP issues an exclusive Certificate of Compliance, with distinct numeration for each model or family, object of the application.

6.2.6.2.1 Should the certification be by family, the certificate shall list all models covered by the family.

6.2.6.2.2 Should more than one page be needed to the certificate, all pages shall be numbered with reference to their own number and the total number of pages. Each page shall contain the certificate number and date of issue. The initial page shall inform the quantity of pages of the complete certificate. In this case, the certificate shall contain the words "Certificate of Compliance valid only with the pages 01 to N." (mention the first and last page of the certificate.)

6.2.6.3 Certificate of Compliance

The Certificate of Compliance has its validity laid down in the specific RAC, and shall contain the following wording when the certification has been granted according to the Models 2, 3, 4, 5 and 6: "*A validade deste Certificado de Conformidade está atrelada à realização das avaliações de manutenção e tratamento de possíveis não conformidades de acordo com as orientações do OCP previstas no RAC específico. Para verificação da condição atualizada de regularidade deste Certificado de Conformidade deve ser consultado o banco de dados de produtos e serviços certificados do Inmetro*". ("The validity of this Certificate of Compliance depends on the performance of evaluations of maintenance and on the treatment of possible non-compliances, according to the orientations provided by the OCP covered by the specific RAC. The product database and Inmetro certified services shall be consulted to verify the updated condition of regularity of this Certificate of Compliance".)

6.2.6.3.1 The Certificate of Compliance, as a formal instrument issued by the OCP, shall contain at least:

a) Numbering of Certificate of Compliance;
b) Company name, Brazilian Registry of Legal Entities (CNPJ), full address and, when applicable, commercial name of the certification applicant (certificate holder);
c) Company name, full address and, when applicable, commercial name of the manufacturer;
d) Name, address, accreditation record number and signature of the responsible for the OCP;
e) Date of issue and expiration date (except Model 1a and 1b) of the Certificate of Compliance;
f) Certification Model adopted;
g) Identification of the certified product model, in case of certification by model, including the list of all commercialized brands;
h) Identification of the certified product family and all covered models, in case of certification by family, including the list of all commercialized brands;
i) Identification of the manufacturing batch(es) (required in case of certification by the Model 1b);
j) Scopes of service, in case of service certification;
k) RAC Ordinance under which the certificate has been issued (certification scope);
l) Bar code of the models covered in g) or h), if any;
m) Number, date and identification of the issuing laboratory of test report(s);
n) Date of the performance of audit, applicable to Models 5 and 6.

Note 1: A certificate shall be issued for each certified family, in case of certification by family, or for each certified model, in case of certification by model.

Note 2: Any additional item required for the issuance of the Certificate of Compliance shall be listed in the specific RAC.

6.3 Evaluation of the Maintenance

After the granting of the Certificate of Compliance, the control of the certification shall be performed by the OCP to verify if the technical and organizational conditions that led to the initial grant of certification are being met.

The Evaluation of the maintenance shall be schedule by the OCP, according to the periodicity and the criteria set forth in the specific RAC of the object in question. The deadlines shall be counted from the date of issue of the certificate. All stages shall be completed by the deadlines established in the specific RAC of the object.

Note 1: The periodicity of the maintenance audit and the maintenance tests may be fixed or variable, as set forth in the RAC.

Note 2: The variable frequency allows the increase in the time interval between the audits and/or the maintenance tests. The increase in the time interval is uniquely related to the non-identification of non-compliances. Should non-compliance be found, the spacing shall be

reduced, restarting a new cycle. The opposite occurs when non-compliances have not been identified. The RAC defines the application or not of the variable frequency.

Note 3: The presence of non-compliances with subsequent treatment does not lead to the application of increase in time interval between two maintenances, established in the maintenance with variable frequency.

The OCP shall formally request to the certificate holder the information of any change in the design, descriptive memorial or production process.

In case of certification by family, a new model may be included in the certified family, at any time, in the same certificate, keeping the original validity of the issued certificate. The issued certificate shall contain the information of the date of inclusion of the new model(s).

The OCP shall perform a new certification process starting from the item 6.2 in cases in that the same certificate holder wants to certify a new family (in case of certification by family) or a new model (in case of certification by model).

6.3.1 Maintenance Audit of Quality Management System and Evaluation of Production Process

6.3.1.1 The OCP shall schedule the periodical performance of maintenance audit in the production process of the manufacturer or service provider covering at least the following stages:

a) verification of the original documentation mentioned in item 6.2.1, in particular regarding the availability, organization and retrieval;
b) analysis of records, especially those associated to the compliance with the fulfillment of the requirements in the Tables 2 and 3.

6.3.1.2 The visit date for the audit shall be scheduled in agreement with the certification applicant. However, the OCP shall perform the maintenance audit or special audits without notice if explicitly determined by Inmetro/Dconf.

6.3.2 Maintenance Test Planning

The maintenance tests shall prove the maintenance of compliance, after the initial evaluation, with the requirements laid down in the specific RAC of the object.

Similarly to the Initial Evaluation, the OCP shall be the responsible to prepare the Test Planning, which shall contain, at least, the maintenance tests, test method, sampling, acceptance/rejection criteria and periodicity, in accordance with the specific RAC of the object.

The OCP shall require that laboratory test reports inform the performed measurement uncertainties.

The Test Planning shall be planned in a way that there has rotation of the models of family throughout the maintenances, in case of certification by family.

6.3.2.1 Definition of Tests to be performed

The tests shall be in accordance with the criteria set forth in subitem 6.2.4.1 of this document.

6.3.2.2 Definition of sampling of maintenance

The criteria set forth in subitem 6.2.4.2 of this document shall be observed.

6.3.2.2.1 The OCP shall collect/buy the samples in the market for the certification models 2, 4 and 5 at the stage of collection/purchase of samples of both national and imported products for the performance of maintenance tests. In each new round of tests, the samples shall be collected/purchased in different points of sale. Should the certification holder proves, through invoice, that the product, national or foreign-made, not an off-the-shelf product, the shipment of the production process or distribution centers may be considered as collection points by the OCP.

Note 1: For off-the-shelf products, the lack of these products in the consumer point of sale shall result in the cancellation of the Certificate of Compliance of the model or family.

Note 2: For off-the-shelf products, the shipping area of the manufacturing site may not be considered as trade, despite the product invoice has been already issued.

6.3.2.2.2 The collection for performance of maintenance tests shall be carried out by the OCP in samples which have been manufactured between the date of issue of the certificate and the first evaluation of the maintenance. Then, the collection shall be carried out in samples of the product manufactured in the interval between two sequential maintenances or between the last maintenance and the recertification.

6.3.2.3 Definition of Laboratory

The criteria set forth in subitem 6.2.4.3 of this document shall be observed.

6.3.3 Treatment of non-compliances in the stage of Evaluation of the Maintenance

6.3.3.1 Should any non-compliance be identified in the evaluation of the maintenance, the certificate holder shall perform for the critical analysis of the causes of non-compliances and proposition of corrective actions.

6.3.3.2 The certificate holder shall submit to OCP, within a maximum period of fifteen (15) consecutive days, the plan of corrective actions, which shall have a maximum period of sixty (60) consecutive days, to evidence of the implementation of corrective actions.

6.3.3.3 The certificate holder shall take immediate control actions, in the factory, to prevent the model/family which failed the maintenance test from entering the market.

6.3.3.4 The OCP shall evaluate the effectiveness of the corrective actions proposed in the planning and whether the same have been implemented.

6.3.3.5 The need of a new audit to verify the implementation of corrective actions and/or performance of new tests is at the OCP's discretion.

6.3.3.6 The failure to submit the corrective action plan within the deadline specified in 6.3.3.2 or the identification of any non-compliance, with no evidence of treatment, shall result in the immediate suspension of the Certificate of Compliance for the nonconforming model/family. The OCP shall notify the certificate holder in writing, stating that the certification process shall only resume if the non-compliances identified have been solved.

6.3.3.6.1 In case of certification by model, should the evidenced non-compliance be threatening other models already certified, the suspension of the certification may cover these models, at the OCP's discretion.

6.3.3.6.2 In case of certification by family, should any non-compliance be evidenced in one of the family models, the suspension of the certification shall be applied to all models of this family and may cover other families, at the OCP's discretion.

6.3.3.7 The certificate holder shall submit the corrective action plan within up to fifteen (15) consecutive days counted from the date of the suspension of its certification. The certification comes back into force when the corrective actions are deemed effective by the OCP by the performance of tests, audit and/or document analysis, at the OCP's discretion.

6.3.3.8 New deadlines may be agreed, provided they have been formally requested and justified by the certificate holder, and have had their relevance evaluated by the OCP.

6.3.3.9 Should the certificate holder fails to meet the deadline, provided that a new deadline has not been set, the certification shall be cancelled.

6.3.3.10 Should the certificate holder refuses to implement the corrective actions, the OCP shall cancel its Certificate of Compliance for the model(s)/family(ies) of the certified product(s) and shall formally communicate it to Inmetro.

6.3.3.11 Should the product may not be collected as set forth in the specific RAC of the object, its certificate shall be cancelled.

6.3.3.12 Should nonconforming products be found in the market and considering the risk their use may pose, the OCP shall formally communicate to Inmetro and shall recommend to the certificate holder the need to withdraw the product from the market, being the certificate holder responsible for this action.

6.3.4 Confirmation of Maintenance

The OCP shall issue the confirmation of maintenance after the performance of critical analysis, including information on the documentation, audits, tests, treatment of non-compliances, market surveillance and treatment of complaints, observing the relevant requirements of subitem 6.2.6, that the maintenance of compliance with the requirements has been evidenced.

After the requirements of this RGCP and the specific RAC of the product have been met, the OCP shall issue the document entitled "Confirmation of Maintenance", formalizing the certification is maintained.

6.3.4.1 The Confirmation of Maintenance, as a formal instrument issued by the OCP, shall contain at least:

a) Reference to the certificate of compliance that has been maintained;

b) Company name, Brazilian Registry of Legal Entities (CNPJ), full address and, when applicable, commercial name of the certificate holder;

c) Name, address, accreditation record number and signature of the responsible for the OCP;

d) Date of issue of the Confirmation of Maintenance;

e) Certification model adopted;

f) Identification of the certified model, in case of certification by model, including the list of all commercialized brands;

g) Identification of the certified family and all covered models, in case of certification by family, including the list of all commercialized brands;

h) Scopes of service, in case of service certification;

i) RAC Ordinance under which the certificate has been issued (certification scope);

j) Bar code of the models covered in f) or g), if any;

k) Number, date of the maintenance test report(s) issued by the laboratory;

l) Date of the performance of audit, applicable to Models 5 and 6;

m) Date of the next evaluation of the maintenance, in case of evaluation of the maintenance with variable periodicity, depending whether or not non-compliances have been detected in the audit and in tests performed in accordance with the specific RAC of the object.

6.4 Evaluation of the Recertification

The evaluation of the recertification shall be scheduled by the OCP, in accordance with the criteria established in item 6.2 of this document and the specific RAC of the object.

In case of the specific RAC includes the evaluation of the maintenance with variable frequency, the OCP shall continue the time interval used from the last evaluation performed, depending or not of the existence of non-compliances, in the recertification.

The collection for the performance of the tests shall be carried out by the OCP in samples that have been manufactured between the date of the last maintenance and the date of the recertification.

The OCP shall decide to grant the recertification after the critical analysis that includes the information about the documentation, audits, tests, treatment of non-compliances, market surveillance and treatment of complaints.

After the requirements of this RGCP and the specific RAC of the product have been met, the OCP shall issue the new Certificate of Compliance.

The OCP shall issue a certificate with distinct numeration for each model or family in each recertification.

Note: Any additional item required for the issuance of the new Certificate of Compliance shall be described in the specific RAC of the object.

6.5 Special Cases

6.5.1 The product certification subject to multiple certification (hybrid product) shall consider all functions of use subject to compulsory certification, i.e. all functions subject to certification shall be concurrently certificated (initial evaluation, maintenance and recertification), even if different certification processes have been performed. Should the certification process be performed by a single OCP, the same shall be accredited for both scopes subject to certification.

The hybrid product shall have only one Compliance Identification Mark.

Note: For the purpose of this RGCP, product hybrid shall be characterized as a single product, not unattachable, designed to perform the function of two or more product subject to compulsory certification.

6.5.2 Should an Ordinance of improvement of the Requirements of Compliance Evaluation be published after the granting of the certificate, with the possibility of revocation of the RAC in force, the OCP shall perform a new certification process.

6.5.2.1 The new certification process, based on the new requirements published, shall be initiated from the item 6.2 and completed until the period of adjustment intended for manufacturing and import, determined in the new Ordinance.

6.5.2.2 The OCP shall issue a new certificate with new numeration after the conclusion of a new certification process.

7 TREATMENT OF COMPLAINTS

The treatment of complaints described in this document shall be applied to the Certification applicant and the OCP.

7.1 The process of treatment of complaints shall address:

a) A system for the treatment of complaints, signed by the responsible formally assigned to do so, which evidences that the Certification applicant and the OCP:

- Appraise and effectively treat the complaints submitted;
- Acknowledge and make the commitment to obey and to be subject to penalties provided in laws, specifically Law no. 8,078/1990;
- Critically analyzes the results and take proper actions according to the complaints received;
- Define the responsibilities as to the treatment of complaints;
- Make the commitment to respond to Inmetro any complaint within fifteen (15) consecutive days;
- Make the commitment to respond to the complainer as to the receipt of the complaint, its treatment and conclusion, according to internally established deadlines.

b) A system to treat complaints containing the record of each complaint, its treatment, and current stage;

c) A person or team formally assigned, duly and freely capable of treating complaints; and;

d) A complaint record form and telephone number or other ways to receive complaints, including code or protocol number provided for the consumer to follow up.

7.2 The Certification applicant and the OCP shall still perform a yearly critical analysis of the complaints received and of the evidence of the implementation of their respective corrective actions, as well as their opportunities of improvement.

7.3 The OCP shall audit all sites where the activity of Treatment of Complaints has been carried out, to verify the compliance with the previously established requirements, regardless of the certification model adopted in the initial evaluations of maintenance and recertification, if any;

8 ACTIVITIES PERFORMED BY THE OCP ACCREDITED BY A MLA MEMBER OF IAF

8.1 Compliance evaluation activities, performed by a body accredited by a MLA member of IAF, may be accepted, if all the following conditions are observed:

a) The body shall have a MoU with a Brazilian OCP accredited by Inmetro/Cgcre;

b) The body shall be accredited according to the same international rules adopted by Inmetro, i.e., accredited by a MLA signatory member of IAF, for the same or equivalent scope;

c) The activities performed by the OCP shall be equivalent to those regulated by Inmetro;

d) There is no restriction from the Regulatory Authority of the object subject to certification.

8.2 The MoU shall be verified by Cgcre/Inmetro during periodic accreditation assessments and shall meet the following minimal requirements:

a) The parties shall agree to keep the undersigned informed about any modification in their accreditation status in their country of origin;

b) The parties shall agree which documents of the certification process, issued in a language other than English or Spanish, shall be enclosed with its sworn translation into Portuguese;

c) The parties shall define the activities within the scope of the MoU, such as audit, test planning, test and audit report evaluation.

8.3 The body legally established in the country and accredited by Inmetro/Cgcre shall be responsible for the judgment and issuance of the certificate in compliance with the Brazilian regulations, assuming all responsibilities for the activities carried out abroad and resulting from this issue, as if the body had carried out them.

8.4 Foreign bodies accredited by Inmetro/Cgcre in the specific scope may perform certification processes in the scope of the specific RAC of the object, provided that they are legally established in Brazil. In this case, the entire documentation of the certification process

shall be available in Brazil and written in Portuguese, observing the exceptions laid down in the subitem 6.2.1.2 ‘e’ and the note of subitem 6.2.3.2.

9 TRANSFER OF CERTIFICATION

9.1 The transfer of valid certificates, issued in accordance with the specific RAC, from an issuer OCP to a receiver OCP, shall be admitted and may be motivated by the issuer OCP or by the certificate holder.

9.2. The receiver OCP shall be legally established in the country and accredited by Inmetro/Cgrcre.

9.3 Each OCP shall include in the contracts with their customers the availability to provide the necessary information to another OCP, upon the transfer of a valid certificate issued by them, and considering the provisions of item 9.1 of this RGCP.

9.4 A qualified person of the receiver OCP shall perform a critical analysis of the certification process of the new customer. This critical analysis shall be performed through the examination of documentation/records and/or visit the manufacturer or service provider, and be duly recorded. The critical analysis shall cover, at least, the following aspects:

- **a)** The stages of process performed to date and the situation on the stage of the current certification process;
- **b)** Test reports;
- **c)** Test planning performed, correlating with family or model;
- **d)** Reasons for the transfer request;
- **e)** Validity of the certificate regarding the authenticity and the duration, covering the scope object of the transfer;
- **f)** Validity of the certification and situation of non-compliance(s) pending correction(s). This verification shall preferably be performed along with the issuer OCP, unless the OCP has terminated its activities;
- **g)** Report(s) of the last audit (certification, maintenance and recertification) and special audit(s), and any non-compliance still not solved;
- **h)** Received complaint(s)/appeal(s) and action(s) taken;
- **i)** Current stage of certification.

9.5 The certificates suspended, canceled or with expired date of validity shall not be accepted for transfer purposes.

9.6 Should pending non-conformities or potential risks be identified in the previous critical analysis, or when there are doubts on adjustment of the existing certification, the receiver OCP shall, depending on the extent of the doubt:

- **a)** Not accept the transfer process and start a new certification process; or,
- **b)** Accept the transfer process after evidencing, through audit or test, that the original certification may be maintained.

9.7 Should pending non-conformities or potential risks be not identified in the previous critical analysis, the receiver OCP shall accept the transfer of certification.

9.8 After the transfer has been accepted, the receiver OCP shall issue a new certificate, dated from the completion of the critical analysis and with the remaining expiration date compared to the original certificate, and considering all items set forth in 6.2.6 of this RGCP.

9.9 The next evaluation of the maintenance or the recertification shall be performed in accordance with the criteria established in the specific RAC of the object, and shall be carried out within the deadline specified in the original certification process performed by the issuer OCP.

9.10 The receiver OCP shall maintain all documentation and all records related to the transfer of certification, during the period determined in its quality management system.

10 TERMINATION OF THE CERTIFICATION

The certification shall be terminated when the manufacture/import of products or service provision activities, compulsory certificated, be canceled or the certificate holder's choice in case of voluntary certifications.

The OCP shall ensure that the objects certified before this decision shall be in compliance with the specific RAC of the object.

10.1 The OCP shall schedule a special audit to verify and record the following requirements:

- **a)** Date of manufacture and size of the last batches of the certified object;
- **b)** Material available in stock;
- **c)** Amount of stocked finished products and the estimated time for the distribution of this batch;
- **d)** Compliance with the requirements provided in the specific RAC of the object since the previous maintenance audit;
- **e)** Routine tests performed in the last produced batches;
- **f)** Stock of purchased marks.

10.2 When applicable, the OCP may also schedule a sample collection and the performance of tests to evaluate the conformity of the products in stock.

10.3 Should the result of these tests identify any non-compliance, the OCP shall require the certificate holder to treat it, establishing the requirements and their implementation deadlines before considering the process terminated.

10.4 Should non-conforming products be found in the market, before considering the process terminated and depending on the risk their use may pose, the need to withdraw such product from the market shall be considered by the OCP, being the certificate holder responsible for this action.

10.5 After the termination of the compulsory certification, the product may no longer be produced or imported, being strictly permitted the distribution and commercialization of the stock produced within the validity of the certification. Similarly, the termination of the compulsory certification of service leads to the hindrance of service provision.

10.6 After the stages above have been completed, the OCP shall cancel the certificate, update the database of the certified products and services made available by Inmetro, and notify the termination to Inmetro/Dconf, through the issuance of a document addressing the information set forth in subitem 10.1.

10.7 Should the certificate holder does not allow the OCP to meet the requirements 10.1 to 10.5 above, the OCP shall cancel the certificate, update the data database of the certified products and services made available by Inmetro, and notify the termination to Inmetro/Dconf, justifying the hindrance mentioned above.

11 COMPLIANCE IDENTIFICATION MARK

The Compliance Identification Mark aims to identify that the object of the certification has been subject to the process of compliance evaluation and meet the requirements set forth in this document and in its RAC.

11.1 The model, the characteristics, the traceability and the ways to affix the Compliance Identification Mark shall be determined in the specific RAC of the object, complying to the provisions of Ordinance Inmetro no. 274/2014.

11.2 The Compliance Identification Mark may be printed on the Certificate of Compliance, marked or affixed to the product and/or printed or affixed to the packaging, in accordance with the specific RAC of the object.

11.3 In case of imported products, except those certified by Model 1b, the Compliance Identification Mark shall be marked or affixed to the product and/or printed or affixed to the packaging, in accordance with the specific RAC of the object, before entering the country.

12 AUTHORIZATION TO USE THE COMPLIANCE IDENTIFICATION MARK

The authorization to use the Compliance Identification Mark shall be granted upon the completion of all requirements in this document and in the specific RAC of the object.

12.1 For certified product eligible of Object Registration, the authorization to use the Compliance Identification Mark and the commercialization of the product or service provision shall be subject to obtain the Object Registration.

12.2 In other cases, the authorization shall be granted when the product complies with the criteria set forth in this document and in the specific RAC of the object, dismissing the Registration by Inmetro.

12.3 The authorization, for product eligible or not for registration, will have its validity connected to the validity of the certification and condition of non-suspended or canceled.

12.4 The references about the characteristics not included in the mentioned normative grounds, contained in the instructions for use or information to the user, may not be associated to the Authorization to Use the Compliance Identification Mark or induce the user to believe that such characteristics are covered by the certification process.

13 RESPONSIBILITIES AND DUTIES

13.1 Duties of the Certificate Holder

13.1.1 To only provide the services or to produce, import and commercialize the products object of certification, in compliance with the specific RAC of the object, that is evidenced by the Certificate of Compliance.

13.1.2 To accept all conditions established in this document, in the specific RAC of the object in question, in legal provisions, and in contracts, regarding the authorization, regardless of their transcription.

13.1.3 To apply the Compliance Identification Mark to all certified products, according to the criteria established in this document and in the specific RAC of the object.

13.1.4 To accept the decisions made by the OCP with regard to the certification, appealing to Inmetro, in cases of complaints or appeals, via Inmetro Ombudsman agency.

13.1.5 To facilitate to the OCP or to the hired party, with proof of this condition, the activities of inspection and follow up, as well as the performance of tests and other certification activities defined in this document and in the specific RAC of the object.

13.1.6 To maintain the technical-organizational conditions that resulted in obtaining the Certificate of Compliance, reporting, previously to OCP, any changes that it is intending to make in the product for which the certification has been granted.

13.1.7 To immediately communicate to the OCP the definite interruption of the service provision or the manufacture or importation of the certified product.

13.1.8 To use different codes (brand name) for a certified and a non-certified product.

13.1.9 To submit to Inmetro any publishing material that displays the Compliance Identification Mark in order to be authorized.

13.1.10 Certificate holders have technical, civil, and criminal liabilities for the certified products, as well as for all documents referring to the certification, not being possible to transfer such liabilities.

13.1.11 The certificate holder shall compensate to OCP the costs of the actions of market surveillance determined by Inmetro, as set forth in item 14 of this RGCP.

13.1.12 When announcing the recall of certified products with non-compliances, this shall be in accordance with the rules of the Ordinance MJ487/2012.

13.1.13 To report to Anvisa, within 48 hours, when identifying the certificated object distributed on the market has non-compliances, which put the health or the safety of the consumer at risk, in order that Inmetro shall request to Senacon/DPDC of the Ministry of Justice the withdrawal of the product from the market and the recall, and shall arrange the removal of

the product from the market and give a final destination to it, in compliance with the legislation in force.

13.1.14 To respond the notifications of Inmetro, within the deadlines, that request clarifications related to the processes of investigation of non-compliances identified in the certified object.

13.1.15 To request to Inmetro the Object Registrations, if the legislation requires, providing all information demanded in the registration process.

13.1.16 To provide to Inmetro all required information, regarding the certification process of the product object to the RAC, submitting supporting documents, when necessary and requested.

13.1.17 To submit to OCP the process which will be used to publish the information, in a systematized way, to all its customers on the period of adjustment intended for the market to provide its products without the Compliance Identification Mark, for the duration of this period.

13.1.18 The certificate holder shall consider the deadlines provided by the OCP, test laboratory and Inmetro to timely submit the Evaluations of the Maintenance and Recertification.

13.1.19 The certificate holder shall inform to OCP, at any time, any changes in the design, descriptive memorial or production process of the certified object.

13.1.20 In case of cancellation of the issuer OCP of the certificate, the certificate holder shall migrate to other OCP no later than the deadline for the performance of the next maintenance or recertification, whichever comes first.

13.2 Duties of the OCP

13.2.1 To have trained personnel, maintaining the record of the qualification and training action, in order to be able to competently perform all certification process set forth in the specific RAC of the object.

13.2.2 To perform the product certification in compliance with the requirements set forth in this document and in the specific RAC of the object, mandatorily settling all questions with Inmetro.

13.2.3 To feed and keep updating, within five (5) business days, the database of the products and certified services provided by Inmetro, with the information concerning the certificate, including the issuance, adjustment of scope, suspension and cancellation.

13.2.4 In addition to item 13.2.3, to notify within five (5) business days to Inmetro/Dconf, in case of suspension or cancellation of the certification, through physical or electronic means. For cases of products regulated by another Regulatory Authority associated to certification process coordinated by Inmetro, this notification shall be also submitted to the same.

13.2.5 To submit to Inmetro/Cgcre for analysis and approval of the use, the Memorandum of Understanding within the scope of this document and the specific RAC, established with other certification bodies.

13.2.6 To select, in agreement with the certification applicant, the laboratory to be used in the certification process, based on the requirements set forth in this document and in the specific RAC of the object.

13.2.7 To collect samples in the market, at any time and hour by determination of Inmetro before duly substantiated suspicions or complaints, for the performance of tests established in the specific RAC of the object in accordance with the provided sampling criteria, bearing the costs related to the collection and testing, observing the provisions of item 14 of this RGCP.

13.2.8 To have a Treatment of Complaints System in accordance with the Chapter 7 of this RGCP.

13.2.9 To have no pending with Inmetro.

13.2.10 To immediately report to Inmetro, within 48 hours, any information about the recall, although preliminary i.e. in the investigation stage, provided by companies that have their certified object.

13.2.11 To report to Inmetro/Cgcre the existence of non-compliance identified during the audit of QMS performed in the manufacturer holder of ABNT NBR ISO 9001 or ISO 9001 certificate.

13.2.12 To formally report to its customers holders of the Authorization to Use the Compliance Identification Mark the changes in technical standards and documents issued or acknowledged by Inmetro that may interfere in the requirements of this document.

13.2.13 The OCP shall be exclusively responsible for the interpretation of the results contained in the test reports issued by the laboratories, and shall not accept that the laboratory does this.

13.2.14 To require the laboratories to inform the measurement uncertainties inherent to performed tests.

13.2.15 Should the OCP has its accreditation withdrawn, it shall:

a) Immediately report to its customers its condition and instruct them in the transition process for another OCP with active accreditation, pointing out that the certificates already issued will be valid until the expiration of the maintenance or renovation deadlines, whichever comes first.
b) Provide to Inmetro/Dconf, when requested, all records and information related to the certification processes performed by it.
c) Provide to its customers all records, certificates, reports and other documents related to its/their certification process(es) to subsidize them when contracting other accredited OCP to the continuation of its certification;

d) Inform to Inmetro/Dconf all actions performed during the process of migration of the certificate holder companies in order to prevent damages to the suppliers and the consumers;

e) Facilitate the migration of the certification process to other OCP chosen by the certification holder.

13.2.16 The cancelled OCP shall not perform the activities of maintenance or renewal of the certificates issued for the Compliance Evaluation Programs established by Inmetro.

13.2.17 The suspended OCP shall inform such condition to its customers and, while in this condition, shall not perform any activity of initial granting of certification nor grant recertification or scope extensions to certifications in force. During the period of suspension, the OCP shall perform all activities related to the maintenance of the certificates in force, should there is no expansion in the scope of these.

14 MARKET SURVEILLANCE

The certified objects shall be subject to the market surveillance through the Inspection, Verification of Compliance, Technical Inspection, among others.

14.1 The certificate holder shall be responsible to restore the samples of the certified object taken from the market by Inmetro or its delegate bodies, for the purpose of market surveillance.

14.2 The certificate holder, which has the certified object subject to market surveillance, shall provide to Inmetro and the OCP, when requested or notified administratively, all information on the certification process and the internal process control of production quality, within five (5) business days.

14.3 Should Inmetro identify non-conformities in the market surveillance actions, it shall notify the certificate holder and the OCP, establishing the necessity of actions and deadlines.

14.4 The non-conformities identified by the market surveillance may lead to apply the penalties laid down in the item 15 of this RGCP.

14.5 Should any non-compliance found be considered by Inmetro as systemic or as a potential risk to health and safety of the consumer or environment, the Inmetro shall determine the withdrawal of the product from the market.

14.6 Should any non-compliance found be considered by Inmetro as systemic or as a potential risk to health and safety of the consumer or environment, the Inmetro shall critically analyze each case and may decide to report the fact to Senacon/DPDC of the Ministry of Justice. Then, the Senacon/DPDC will analyze the need of recall by the certificate holder.

14.7 The OCP shall receive the samples collected by Inmetro in the market, at any time and hour, to perform tests established in the specific RAC of the object in accordance with the provided sampling criteria, when determined by Inmetro in case of duly substantiated complaint. The OCP shall submit the samples to the accredited laboratory, determined in agreement with Inmetro, bearing the costs related to the testing, and, at the end of these, the

OCP shall send the test reports to Inmetro. The Inmetro may determine that its technicians shall follow up the performed tests.

14.8 The collection of samples may, exceptionally, be conducted by the OCP, when determined by Inmetro. The OCP shall deliver the samples to the laboratory. In this case, the OCP shall be responsible for the cost of the collection of samples and shipping to the laboratory, besides the cost of testing.

15 PENALTIES

Failure to observe the instructions provided in the Ordinances, in this document and in the specific RAC will result in the imposition of penalties of warning, suspension and cancellation of the Certification, on the respective offenders.

16 COMPLAINTS

The Inmetro Ombudsman agency receives complaints and suggestions through the following means:

- Email: ouvidoria@inmetro.gov.br
- Phone number: 0800 285 18 18
- Website: www.inmetro.gov.br/ouvidoria
- Mailing address:

Ouvidoria - Instituto Nacional de Metrologia, Qualidade e Tecnologia (Inmetro)
Rua Santa Alexandrina, 416 – térreo
Rio Comprido - Rio de Janeiro – RJ
CEP: 20261-232

ANNEX A – REQUIREMENTS FOR THE EVALUATION OF LABORATORIES NON-ACCREDITED BY PRODUCT CERTIFICATION BODIES

1 NON-DISCLOSURE

Laboratories shall have documented and implemented procedures for preserving the non-disclosure and the integrity of information, considering at least the following:

a) Access to files, including those computerized;
b) Restricted access to the laboratory;
c) Personnel's acknowledgment about the non-disclosure of information.

2 ORGANIZATION

2.1 Laboratories shall designate individuals to sign test reports and have full technical responsibility for their contents.

2.2 Laboratories shall have a technical manager and a deputy (regardless of its denomination) with full responsibility for technical operations.

2.3 Should the laboratory be of first party, the responsibilities of the key-personnel involved or that has influence on tests shall be defined in order to identify potential conflicts of interest.

2.3.1 The organizational structure shall be such that the departments with potential conflict of interest, such as production, marketing, or finance, may not negatively influence the compliance of the laboratory with the herein requirements.

3 MANAGEMENT SYSTEM

3.1 All the necessary documents for the correct performance of the laboratory's activities shall be uniquely identified and contain their date of issue, revision number, and authorization of their issue.

3.2 All documents required for the correct performance of the laboratory's activities shall be updated and accessible to its personnel.

3.3 Laboratories shall document the attributions and responsibilities of their technical manager and technical personnel involved in the performance of tests, considering at least the responsibilities as to the following:

a) performance of tests;
b) planning of tests, evaluation of results, and preparation of test reports;
c) modification, development, characterization, and validation of new testing methods;
d) management activities.

3.4 Laboratories shall identify the authorized undersigned (when applicable).

3.5 Laboratories shall have documented and implemented procedures for the traceability of measurements.

3.6 Laboratories shall have formalized the scope of their services and provisions to ensure adequate resources, facilities and personnel.

3.7 Laboratories shall have documented and implemented procedures for the handling of testing items.

3.8 Laboratories shall have a list of reference standards and equipment used, including their respective identification.

3.9 Laboratories shall gave documented and implemented procedures for feedback and corrective actions when non-conformities are detected in tests.

3.10 Laboratories shall inform the measurement uncertainties inherent to performed tests.

4 PERSONNEL

4.1 Laboratories shall have enough personnel with the necessary level of education, training, technical knowledge and experience for the functions assigned.

4.2 Laboratories shall have procedures for the use of technicians still in training, record their supervision, and create mechanisms to ensure that they do not hinder test results.

4.3 Laboratories shall have and keep updated records of all technical personnel involved in the performance of tests. These records shall have date of authorization, at least, as to the following:

a) performance of different types of sampling, when applicable;
b) performance of different types of tests;
c) signature of test reports; and
d) operation of different types of equipment.

5 FACILITIES AND ENVIRONMENTAL CONDITIONS

5.1 The laboratory's facilities, testing areas, power sources, lights, and ventilation shall enable the adequate performance of tests.

5.2 Laboratories shall have facilities that effectively monitor, control, and record environmental conditions, when applicable.

5.3 Laboratories shall have effective divisions between bordering areas in case of incompatible activities.

5.4 Laboratories shall have facilities that are safe for testing, as well as the Individual Protection Equipment inherent to the protection of their personnel.

6 REFERENCE MATERIAL AND EQUIPMENT

6.1 Laboratories shall own all equipment, including the reference materials required for the correct performance of tests.

6.2 Before performing a test, laboratories shall verify if any piece of equipment has obtained suspicious results. Should this happen, the equipment shall be identified as out of operation/use, repaired and, before used again, it shall be proven by calibration, verification or tests that it may satisfactorily operate again.

6.3 All equipment shall be labeled, marked, or identified in order to indicate their calibration status, visibly displaying its last and next calibration.

6.4 Every equipment shall have a record that indicates at least the following information:

a) Name of the equipment;
b) Manufacturer's name, type identification, serial number, or other specific identification;
c) Condition of receipt, when applicable;
d) Copies of the manufacturer's instructions, when applicable;
e) Dates and results of last calibrations and/or verifications and date of the upcoming ones;
f) Details of maintenance (those performed and those planned for the future);
g) Damage, modification, and repair histories.

6.5 Each reference material shall be labeled or identified in order to indicate its certification or standardization. Labels shall contain at least the following information:

a) Name of the reference material;
b) Company or person responsible for the certification or standardization;
c) Composition, when applicable;
d) Date of expiration.

6.5.1 Laboratories shall have a record containing the information specified in item 6.5 for long-term reference materials.

7 TRACEABILITY OF MEASUREMENTS AND CALIBRATIONS

7.1 Laboratories shall have an established program for calibrating and verifying their equipment in order to ensure the use of only calibrated and/or verified equipment when performing tests.

7.2 Certificates of calibration according to the reference standards shall be issued by the following facilities:

a) National metrology laboratories mentioned in 7.2;
b) Calibration laboratories accredited by Inmetro/Cgcre;
c) Laboratories part of the National Metrology Institutes from other countries in the following cases:

- When traceability is directly obtained from an institutions that has the primary standard of associated unit, or;
- When the institution takes part in interlaboratory comparison programs, along with Inmetro/Cgcre, and obtains compatible results;
- When laboratories are accredited by Accreditation Bodies from other countries and there is a mutual acknowledgment or cooperation agreement between Inmetro/Cgcre and these bodies.

7.3 The certificates of the measuring and testing equipment of a testing laboratory shall comply with the requirements established in the item above.

7.4 Reference standards kept by laboratories shall be used solely for calibrations, unless it may be demonstrated that their performance as reference standard has not been invalidated.

8 CALIBRATION AND TESTING METHOD

8.1 Every reference data, standard, and instruction relevant to the work of the laboratory shall be documented, updated, and promptly available to personnel.

8.2 Laboratories shall have documented procedures and proper statistical techniques for sample collection when performing sampling as part of the test.

8.3 Laboratories shall subject calculus and data transfers to proper verifications.

8.4 Laboratories shall have procedures for securing data in computerized records.

9 HANDLING OF ITEMS

9.1 Laboratories shall uniquely identify the items to be tested, so they may never be misidentified.

9.2 Laboratories shall have documented procedures and adequate facilities to prevent deterioration or damage to testing items when storing, handling, and preparing them.

10 RECORDS

10.1 Laboratories shall comply with the applicable regulations and shall maintain a record system adequate to their particular circumstances. Records of all original notes, their calculus and data, and records and copies of test reports shall be kept for a minimal period of four years.

10.2 Modifications and/or mistakes on records shall be crossed out without removing or making the writing or previous note illegible. New notes shall be intelligibly recorded right next to that crossed out, they shall be followed by the signature or initials of the person in charge, and may not enable dubious interpretation.

10.3 Records of testing data shall contain at least the following information:

a) Identification of the laboratory;

b) Identification of the sample;
c) Identification of the equipment used;
d) Relevant environmental conditions;
e) Results of measurements and their uncertainties, when applicable;
f) Date and signature of personnel that performed the work.

10.4 All records that have been printed by a computer or calculator, graphics, and others shall be dated, signed, and attached to the records of measurements.

10.5 All technical and quality records shall be kept in the laboratory for safety and confidentiality.

11 TEST REPORTS

11.1 The results of each test or series of tests performed by the laboratory shall be accurately, clearly, objectively, and unambiguously provided in a test report and shall include all the information required for their interpretation according to the method used.

11.2 Laboratories shall record all information required for the repetition of the test. Such records shall be made available to the customer.

11.3 All test reports shall include at least the following information:

a) Title;
b) Name and address of the laboratory;
c) Unique identification of the report;
d) Name and address of the customer;
e) Unambiguous description and identification of the testing item;
f) Characterization and condition of the testing item;
g) Date the item had been received and date the test had been performed;
h) Reference to sampling procedures, when applicable;
i) Any deviation, inclusion, or exclusion to the testing method and any other relevant information to a specific test, such as environmental conditions;
j) Measurements, verifications, and results, supported by tables, graphics, diagrams, and pictures;
k) Estimated statement of uncertainty of test results, when applicable;
l) Signature, job position, or equivalent identification of the person responsible for the contents of the report and its date of issue;
m) Statement that the results refer solely to the tested items, when applicable;
n) Statement that the report may only be fully reproduced and under the customer's consent;
o) Identification of the item;
p) Reference to the specification of the standard used.

12 SUPPORTING SERVICES AND EXTERNAL SUPPLIES

12.1 Laboratories shall keep records of the acquisition of equipment, materials, and services, including the following:

a) Purchase specification;
b) Receipt inspection;
c) Calibration or Verification;
d) Registration of Suppliers.

ANNEX B – CRITERIA FOR CERTIFICATION OF SET OF CERTIFIED OBJECTS (KIT) OR CERTIFICATION TRANSFER

1 OBJECTIVE

This Annex shall be applied in case the integrator, packager and/or distributor performs changes in the packaging of an already certified product or modifies the presentation form for marketing the product compared to the original certification process, using or taking advantage of the product original certification, for the subsequent sale to the final consumer.

This Annex shall not be applied in case of products that have already been certified which have had their characteristics modified as well as the original packaging. This condition shall lead a new certification process, when authorized by Inmetro.

Note 1: To simplify the text, the integrators, packagers and/or distributors which perform changes in repackaging or creation of kits already certified in origin, shall be named as “packagers” herein.

Note 2: The certification transfer process shall be requested for each operating unit of the packager.

2 DEFINITIONS

2.2.1 Creation of Kit

The creation of kit shall be characterized when the packager (assignee) includestwo or more products already certified in the same packaging.

2.2.2 Fractionation

Operation characterized when the packager (assignee) performs a fractionation operation, from the bulk packaging of the product, as well as the change of display packaging.

3 STAGES OF COMPLIANCE EVALUATION

The packagers that do not modify the original packaging of products already certified, but modifies the presentation form for marketing the product in a new packaging shall be subject to certification considering all items below, except the Test Planning set forth herein.

The packagers that modify original packaging of products already certified shall be subject to certification considering all items described below. In this case, the final packaging shall contain all required markings set forth in the specific RAC of the object.

In cases of inclusion of two or more products already certified in the same packaging, the OCP responsible for the certification transfer process shall be accredited at least for the scope of the main product. In cases that the products are similar, thus, not being clear which is the main product, the OCP responsible for the certification transfer process shall be accredited in at least one of the scopes that are part of the kit.

For the purpose of marking on packaging of kits that contain certified products which have not had their original packaging modified, the new packaging shall contain the wording: “CONTÉM PRODUTOS REGISTRADOS NO INMETRO” (CONTAINS PRODUCTS REGISTERED IN INMETRO)

The following possibilities shall be considered for kits that contain certified products which have had their original packaging modified:

a) When the main product has been identified: in this case, the Compliance Identification Mark of the main product shall be affixed to the new packaging, with the Registration number of the kit.
b) When the main product has not been identified: in this case, the Compliance Identification Mark of the product for which the OCP is accredited shall be affixed to the new packaging, with the Registration number of the kit.

In both situations, the OCP shall also evaluate the item 7 of this RGCP – Treatment of Complaints.

3.1 Initial Evaluation

3.1.1 Application for Certification Transfer

The application to be submitted to the OCP shall be accompanied by the following documentation:

a) Address of the packager site, (certification applicant);
b) Brazilian Registry of Legal Entities – CNPJ, and the social contract of the company containing the description of its activities in the object;
c) Documentation that proves the compliance with the item 7 of RGCP (Treatment of Complaints) for all brands commercialized;
d) Description of the fractionated product or of the products included in the kit;
e) Authenticated copy (ies) of the Certificate(s) of Compliance of the product subject to fractionation or of the products included in the kit, within its expiration date;
f) Private authorization for certification transfer, signed by the certificate holder(s) of the product(s) mentioned in e);
g) Photographic documentation of the products listed in d): external and internal photos of all sides, detailing the labels, logos, warnings, inputs, outputs, activation buttons, when applicable;
h) Packaging drawing or final artwork (primary, secondary and/or tertiary);
i) User manual with instructions written in Portuguese;
j) Authorization to use the brand(s), if the packager used the brand(s) of the original certification.

Note: Upon the occurrence of item j), the OCP shall verify the legal qualification of the authorization instrument and the protocol of incorporation of the owner(s) of the brand(s).

Note: When the user manual is not applicable in the original certification, the OCP shall validate and record this information in the certification transfer process.

3.1.1.1 In case of certification transfer process for imported products, a copy of the Import License (IL) shall be submitted along with the application for certification transfer.

3.1.1.2 The documents listed in subitem 3.1.1 shall have their authenticity confirmed by the OCP in relation to the original documents.

3.1.2 Analysis of the Application and the Compliance of the Documentation

3.1.2.1 The OCP shall analyze the viability of meeting the application and verify the submitted documentation before initiating the certification transfer process. Should the application be deemed impracticable, the OCP shall formally inform the reason for the service infeasibility and shall return all submitted documentation.

3.1.2.2 Should any non-compliance be identified in the documentation received, the non-compliance shall be treated in compliance with the subitem 6.2.2 of RGCP.

3.1.3 Initial Audit of the Management System

3.1.3.1 After analysis and approval of the application and documentation, the OCP shall schedule, in agreement with the packager applicant of certification transfer, the performance of the initial audit in the packager site, evaluating in a complementary form the requirements of Quality Management System applicable to the repackaging processes, in accordance with the Table 1, below:

Table 1: Requirements of QMS verification applicable to the packager based on the ISO 9001 or ABNT NBR ISO 9001 standard

QMS REQUIREMENTS	ISO 9001 or ABNT NBR ISO 9001
Purchasing process	7.4.1
Verification of purchased product	7.4.3
Identification and traceability	7.5.3
Preservation of product	7.5.5
Control of nonconforming product	8.3
Corrective Action	8.5.2

Note: This evaluation shall be performed regardless of the packager has a certified quality management system.

3.1.3.2 Should the possibility that the original certified product may have its compliance affected by the repackaging process be evaluated by the OCP during the audit, the product shall be tested in the items set forth in the RAC of the object.

3.1.3.3 The OCP shall issue the audit report, recording the result of the same, in accordance with this RAC. The audit report shall be signed by the packager and by the OCP. A copy of this report shall be available to the packager.

3.1.4 Initial Test Planning of the Packaging

The OCP shall be responsible to prepare the test planning which shall clearly determine, at least, the sampling, the initial tests to be performed in the packaging of the product object of transfer and the acceptance/rejection criteria for these tests.

Should the original certified product may have its compliance affected by the repackaging process be evaluated by the OCP, the test planning shall address all tests required for the product in the RAC of the object.

3.1.4.1 Definition of the Tests to be performed in the Packaging

3.1.4.1.1 The tests in the packaging shall be performed in accordance with the specific RAC.

3.1.4.1.2 The test laboratory shall maintain a photographic record of the evaluation.

3.1.4.2 Definition of Sampling of Packaging

3.1.4.2.1 For the certification transfer, the OCP shall establish the procedure for the collection of samples (proof, counterproof and witness) of the packaging object to certification transfer, in order to enable the performance of tests set forth in the specific RAC.

3.1.4.2.2 The OCP shall be responsible for the collection of samples to perform the tests, in accordance with its procedures.

3.1.4.2.3 The OCP shall test all models of packaging and submit them to the test laboratory for analysis in accordance with the RAC.

3.1.4.2.4 The sampling for proof tests shall have two (2) units of each model of packaging object to evaluation.

3.1.4.2.5 The same sample quantity, determined in 3.1.4.2.4, shall be used to perform the counterproof and witness tests.

3.1.4.3 Definition of Laboratories for Packaging Test

The packaging tests shall be performed in laboratories in compliance with the requirements set forth in this RGCP and in the specific RAC.

Note: Should the evaluation of packaging provided in the RAC of the object be limited to a visual evaluation of the same (verification of marks, instructions and manual), the evaluation may be performed by the OCP.

3.1.4.4 Acceptance/Rejection Criteria for Packaging

3.1.4.4.1 All tested units shall be in compliance with the requirements set forth in the specific RAC of the object.

3.1.4.4.2 Should proof tests be approved, the sample is approved. Should non-compliance be detected in the proof sample, all tests shall be repeated in the counterproof and witness samples.

a) Should non-compliance be detected in the counterproof sample, the sample is rejected;
b) Should the counterproof sample does not have non-compliance, the witness sample shall be tested;
c) Should the witness sample has non-compliance, the sample is rejected;
d) Should the witness sample does not have non-compliance, the sample is approved.

3.1.4.4.3 At the discretion of the certification applicant, through the formalization of the OCP, counterproof and witness samples shall not necessarily have to be tested. In such case, there shall not be contestation of the results obtained in the proof sample.

3.1.4.4.4 In case of failure in the tests, the certification transfer shall be cancelled.

3.1.5 Treatment of non-compliances in the stage of the Initial Evaluation

Should any non-compliance be identified in the stage of the initial evaluation, the non-compliance shall be treated in compliance with the subitem 6.2.5 of RGCP.

3.1.6 Issuance of Certificate of Compliance

3.1.6.1 After all requirements in this Annex be completed, the OCP shall issue the Certificate of Compliance.

3.1.6.2 The Certificate of Compliance, as a formal instrument issued by the OCP, shall contain at least:

a) Company name, full address, commercial name and Brazilian Registry of Legal Entities (CNPJ) of the packager of the object of certification transfer;
b) Date of issue and expiration date of the Certificate of Compliance;
c) Name, accreditation record number and signature of the responsible for the OCP;
d) Number(s) of Certificate(s), expiration date and the name of the OCP of all products certified in the original process and included in the certification transfer;
e) Model(s) of the product(s) that compose the kit or the fractioned packaging;
f) Number, date and identification of the issuer of test report(s) of the packaging shipped by the laboratory.

Note: The Certificate of Compliance shall state unequivocally the operating unit of the packager that the certificate shall be applied.

Note: In case of kit, the product description in the certificate shall be preceded by the term ‘Kit’. In case of fractionation of bulk product, the product description in the certificate shall be preceded by the term ‘Fraction’.

3.1.6.3 When the issued certificate be the result of the transfer of more than one original certification, its validity shall be equal to the shortest expiration date between the certificates of

the products that comprise the packaging intended for the final consumer. When the issued certificate be the result of the transfer of only one original certification, its validity shall be the remaining life of the original certificate.

3.1.6.4 The Certificate shall contain the following wording: “A validade deste Certificado está atrelada à realização de avaliações de manutenção e tratamento de possíveis não conformidades de acordo com as orientações do OCP”. (The validity of this Certificate depends on the performance of evaluations of maintenance and on the treatment of possible non-compliances, according to the orientations provided by the OCP).

3.2 Evaluation of the Maintenance

3.2.1 Planning of Evaluation of the Maintenance

3.2.1.1 After the granting of the Certificate of Compliance, the OCP shall plan the audits and the maintenance tests in the packaging, in order to verify if the technical and organizational conditions that led to the initial certification granting are being maintained.

3.2.1.2 The periodicity of evaluation of the packager maintenance shall be twelve (12) months.

3.2.1.3 The OCP responsible for the certification transfer shall monitor the validity of the maintenance of each kit component, as the validity of maintenance of the certified kit will be depending on the validity of certification of each component.

3.2.1.4 The OCP transfer certifier shall request to each OCP responsible for the certification of each product included in the kit or product with new packaging, the communication in case of suspension or cancellation of the original certificate, so the OCP transfer certifier may take appropriate actions regarding the certification of the kit or product with new packaging. The opposite case shall be also applicable, i.e. a suspension, action of recall or cancellation of the certificate of the kit shall be informed to all OCPs of the original products.

3.2.2 Maintenance Audit

The OCP shall schedule the maintenance audits in accordance with the subitem 3.1.3 of this Annex.

3.2.3 Packaging Maintenance Test Planning

The OCP shall prepare the packaging maintenance test planning in accordance with the subitem 3.1.4 of this Annex.

The OCP shall collect/buy the samples in the market for the performance of maintenance tests. In each new round of tests, the samples shall be collected/purchased in different points of sale.

3.2.4 Treatment of non-compliances in the stage of Evaluation of the Maintenance

Should any non-compliance be identified in the stage of evaluation of the maintenance, the non-compliance shall be treated in compliance with the subitem 6.3.3 of RGCP.

3.2.5 Confirmation of Maintenance

The OCP shall issue the confirmation of maintenance after the critical analysis, including the information about the documentation, audits, tests, treatment of non-compliances, market surveillance and treatment of complaints, observing the relevant requirements of subitem 3.1.6, that the compliance with the requirements has been evidenced.

The OCP shall request to the OCPs responsible for the original certification, the Confirmation(s) of Maintenance of each product subject to fractionation or products included in the kit.

After the requirements of this Annex have been met, the OCP shall issue the document entitled “Confirmation of Maintenance”, formalizing the certification is maintained.

3.2.5.1 The Confirmation of Maintenance, as a formal instrument issued by the OCP, shall contain at least:

a) Company name, full address, commercial name and Brazilian Registry of Legal Entities (CNPJ) of the packager of the object of certification transfer;
b) Name, accreditation record number and signature of the responsible for the OCP;
c) Number(s) of Certificate(s), expiration date and the name of the OCP of all products certified in the original process and included in the certification transfer;
d) Model(s) of the product(s) that compose the kit or the fractioned packaging;
e) Date of issue and expiration date of the Certificate of Compliance;
f) Number, date and identification of the issuer of test report(s) of the packaging shipped by the laboratory.
g) Date of issue of the Confirmation of Maintenance.

Note: The Certificate of Compliance shall state unequivocally the packager unit that the certificate shall be applied.

Note: In case of kit, the product description in the certificate shall be preceded by the term ‘Kit’. In case of fractionation of bulk product, the product description in the certificate shall be preceded by the term ‘Fraction’.

3.3 Evaluation of the Recertification

The evaluation of the recertification shall be scheduled by the OCP, in accordance with the criteria established in item 3.1 of this Annex.

3.3.1 Treatment of non-compliances in the stage of Evalutation of the Recertification

Should any non-compliance be identified in the stage of evaluation of the recertification, the non-compliance shall be treated in compliance with the subitem 6.3.3 of RGCP.

3.3.2 Confirmation of Recertification

The confirmation of recertification by the OCP shall be based on the decision after the critical analysis, including the information about the documentation, audits, tests, treatment of non-compliances and treatment of complaints, observing that the compliance with the requirements has been evidenced.

After the requirements set forth in Annex have been met, the OCP shall issue the new Certificate of Compliance.

The OCP shall issue a certificate with distinct numeration in each recertification.

Note: Note: Any additional item required for the issuance of the new Certificate of Compliance shall be described in the RAC.