Federal Public Service
MINISTRY OF THE DEVELOPMENT, INDUSTRY AND FOREIGN TRADE
NATIONAL INSTITUTE OF METROLOGY, QUALITY AND TECHNOLOGY-**INMETRO**

Ordinance Nº 118 – 06 March 2015

THE PRESIDENT-IN-POWER OF THE NATIONAL INSTITUTE OF METROLOGY, QUALITY AND TECHNOLOGY - INMETRO, in the exercise of his powers, as granted in Paragraph 3 of Article 4 of Law Nº 5.966, 11 December 1973, Items I and IV of Article 3 of Law Nº 9.933, 20 December 1999, and item V of Article 18 of the Administrative Structure of the Autarchy, as approved by Decree Nº. 6275, 28 November 2007;

Whereas line *f* of item 4.2 of the Brazilian System of Reference Terms of Conformity Assessment, approved by Resolution Conmetro No 04 of 2 December 2002, which grants Inmetro the competence to establish guidelines and criteria for the activity conformity assessment;

Whereas the growing demand for the establishment of conformity assessment programs and the need to rethink and streamline the way to meet them;

Whereas the need to provide more standardization and concision in establishing Conformity Assessment Programs;

Whereas the importance of continuous improvement of the macro process of Assisted Deployment Conformity Assessment Programs;

Whereas the existence of Conformity Assessment Requirements that are common to any object subjected to the evaluation process;

Whereas the existence of general requirements for each of the different mechanisms of conformity assessment clarifies the interpretation of conformity assessment programs;

Whereas the General Requirements of Product Certification aim to establish the common devices to all Conformity Assessment Programs that adopt the certification mechanism;

Whereas the General Requirements of Product Certification are complemented by the Conformity Assessment Requirements specific to each eligible for certification purposes;

Whereas the need to improve the General Requirements of Product Certification, resolves to enact the following provisions:

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

Instituto Nacional de Metrologia, Qualidade e Tecnologia – Inmetro
Divisão de Regulamentação Técnica e Programas de Avaliação da Conformidade – Dipac
Rua da Estrela nº 67 – 3º andar – Rio Comprido
20251-900 - Rio de Janeiro/RJ

Article 2 Assure that the Public Consultation, which collected contributions of society in general for the preparation of General Requirements approved herein, was released by Ordinance Inmetro N°. 544, of 18 November 2013, published in the *Official Gazette* of 20 November 2013, section 01, page 97.

Article 3 Assure that the Conformity Assessment Requirements to be prepared for each object must contain only the specific requirements, complementary to General Requirements for product certification, respecting the specificities of the object under certification.

Paragraph 1. The Conformity Assessment Requirements shall define the following items:

I - Purpose (specific certification program);
II - Acronyms (only those that do not appear in this document);
III - Reference documents and complementary (only those who do not appear in this document);
IV - Definitions (only those that do not appear in this document);
V - Conformity Assessment Mechanism;
VI - Conformity Assessment Steps (which shall include, where applicable, at least the following items, complementing the RGCP):

- Definition (s) Model (s) used Certification (s);
- Initial Evaluation;
  - Certification Request;
  - Analysis of the Application and Compliance Documentation;
  - Initial Audit Quality Management System and Evaluation of the Production Process (where applicable);
  - Initial Testing Plan (if applicable);
  - Treatment of non-conformities in the Initial Evaluation step;
  - Issuance of the Certificate of Compliance;
- Quality Management System Maintenance and Evaluation of the Production Process (where applicable);
  - Maintenance Audit (if applicable);
  - Maintenance Testing Plan (if applicable);
  - Treatment of non-conformities in the Maintenance Assessment stage;
  - Confirmation of maintenance;
- Recertification Assessment (if applicable);
- Special Cases;

VII – Handling Complaints;
VIII - Activities performed by OCP accredited by the IAF MLA member;
IX - Transfer of Certification;
X - Certification of Termination;
XI - Conformity Identification Mark;
XII - Authorization for Use of Conformity Identification Mark;
XIII - Responsibilities and Obligations;
XIV - Monitoring the Market;
XV - Penalties; and
XVI - Complaints.

Paragraph 2. Exceptionally, the provisions contained in the now approved requirements may be amended, in compliance with the specifics of the object to be assessed by means of Conformity Assessment Requirements prepared for each object to be certified.

Paragraph In cases when the conditions of the preceding paragraph occur, these must be clearly defined in the Conformity Assessment Requirements.

Article 4 Assure that conformity assessment programs that do not use the RGCP will be gradually adapted to the extent that even through improvement.

Article 5 Determine that all processes of certification of products that already adopt RGCP must be suited by OCP from the maintenance or recertification following the publication of this Ordinance, provided they do not occur in less than 6 (six) months, when will still be able to meet the earlier version of RGCP.

Article 6. Revoke Inmetro Ordinance Nº 361 of 06 September 2011, published in Official Gazette of 09 September 2011, section 01, page 76, within 6 (six) months after the publication of this Ordinance.

Article 7. This Ordinance shall go into force on the date of its publication in the *Official Gazette*.

JOÃO ALZIRO HERZ DA JORNADA
President

GENERAL REQUIREMENTS OF CERTIFICATION OF PRODUCTS

1 OBJECTIVE

This document sets out the General requirements for certification of Products common to all conformity assessment Programs that use the product certification Mechanism. The particularities of each conformity assessment Programs are expressed in conformity assessment Requirements drawn up for each product to be certified, which will detail the subject, considering the specificities of the same.

1.1 The term "product" in this RGCP applies to product, service, or process.

2 ACRONYMS

ABNT	Brazilian Association of Technical Standards
Cgcre	General Accreditation Coordination
Conmetro	National Council of Metrology, Normalization and Industrial and Quality
Dipac	Technical Regulation Division and Conformity Assessment Programs
Dconf	Conformity Assessment Management
DOU	Official Gazette
DPDC	Department of Protection and Defense of the Consumer
IAAC	*Interamerican Accreditation Cooperation*
IAF	*International Accreditation Forum*
IEC	*International Electrotechnical Commission*
ILAC	*International Laboratory Accreditation Cooperation*
INI	Inmetro Normative Instruction
Inmetro	National Institute of Metrology, Quality and Technology
ISO	*International Organization for Standardization*
MLA	*Multilateral Recognition Arrangement*
MoU	Memorandum of Understanding
NBR	Brazilian Standard
OCP	Product Certification Body
OCS	Quality Management System Certifying Body
PAC	Conformity Assessment Program
RAC	Conformity Assessment Requirements
RGCP	General Requirements of Certification of Products
RTQ	Technical Quality Regulation
SBAC	Brazilian System of Conformity Assessment
Senacon	National Consumer Secretary
SGQ	Quality Management System

3 DOCUMENTS

3.1 REFERENCE DOCUMENTS

Lei nº 8078/1990	Regulates the protection to consumer and gives other provisions.
Lei nº 9933/1999	Regulates competences of Conmetro and Inmetro, defines the Metrologic Services Fees, and gives other provisions.

Standard ABNT NBR ISO 9001	Quality Management Systems – Requirements.
Standard ABNT NBR ISO/IEC 17000	Conformity Assessment – Vocabulary and General Principles.
Standard ABNT NBR ISO/IEC 17025	General Requirements for Competence of the Test and Calibration Laboratory.
ISO IEC 17067:2013	*Conformity assessment – Fundamentals of product certification and guidelines for product certification schemes*

3.2 ADDITIONAL DOCUMENTS

Inmetro Ordinance No. 274/2014 and replacements	Approves the Regulation for Use of Marks, Symbols, Seals and Inmetro's Labels.
Inmetro Ordinance No. 453/2013 and replacements	Approves Inmetro's vocabulary of Conformity Assessment with terms and definitions.
Ministry of Justice Ordinance No. 487/2012	Disciplines the consumer calling procedure or recall of products and services that, further to their launch into the market, are considered harmful or dangerous.

4 DEFINITIONS

The PAC established by Inmetro which use the mechanism of certification are applied the definitions in the gatehouse Inmetro approving the Inmetro Vocabulary of conformity assessment. Specific definitions used in each PAC shall be described in specific RAC for the object.

5 CONFORMITY ASSESSMENT MECHANISM

The conformity assessment mechanism treated herein is the certification.

6 PHASES OF THE CONFORMITY ASSESSMENT

The conformity assessment process consists of several steps. Each step will obey a sequence of procedures, according to the model (s) adopted certification (s).

6.1 Definition of the Certification Models used

The Certification Models will be set out in specific RAC for the object under evaluation, among those that are defined in the Inmetro vocabulary of Conformity Assessment.

The specific RAC can comprise more than one Certification Model.

6.1.1 Phases of the Certification Models

Each model is composed of a sequence of steps outlined in Table 1. These steps must be included in RAC, separately for each model, when the specific RAC comprises more than one certification Model.

Table 1: Phases of the Certification Models

PHASES OF THE PROCESS OF CERTIFICATION OF PRODUCT		**MODELS**						
		1a	**1b**	**2**	**3**	**4**	**5**	**6**
Initial Evaluation	Request for Certification	X	X	X	X	X	X	X
	Analysis of the Request and Documentation Conformity	X	X	X	X	X	X	X
	Initial Audit of the Quality Management System and Evaluation of the Productive Process						X	X
	Initial Test Plan	X	X	X	X	X	X	
	Issuance of the Certificate of Conformity	X	X	X	X	X	X	X
Maintenance Evaluation	Maintenance Audit of the Quality Management System & Evaluation of Productive Process						X	X
	Maintenance Test Plan			X	X	X	X	
	Maintenance Confirmation			X	X	X	X	X
Recertification Evaluation	Recertification Evaluation			X	X	X	X	X

6.2 Initial Assessment

In this item are described the process steps aimed the attestation of the conformity of the object.

6.2.1 Request for Certification

6.2.1.1 The certification must be requested exclusively by the supplier and shall follow established in this RGCP and in the RAC specific to the object to be measured.

6.2.1.2 The beginning of the certification process is conditioned to a formal manifestation of the Supplier requesting certification, which must be made directly to one of the Accredited Product Certification Bodies and/or designated by Inmetro, as its discretion, legally established in the country, for the product under evaluation, together with the delivery of documentation, in compliance with the following requirements:

a) List of models subject of certification, when the certification is by model, making reference to its technical description(s) and including the list of all traded brands.

b) List of model(s) comprising the Family under certification, complying with the rules of formation of family, as set in the specific RAC, when the certification is per family, making reference of its technical description(s) and including the list of all traded brands;

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

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

e) Descriptive Memorial contemplating the object of the project in its constructive and functional details, and the relationship of its critical components, including its suppliers and possible existing certifications, translated into Portuguese, when in language other than English or Spanish;

f) User manual with instructions in Portuguese language;

g) Drawing or artwork of packaging (primary, secondary and / or tertiary), where applicable (existing packaging);

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

"i) Information of the name, address and CNPJ of the Supplier requesting the certification, as well as presentation of the Articles of Incorporation, or any other constituent instrument that proves his condition of Supplier." (N.R.)

j) Contact person, telephone and email address of the requesting certification Supplier;

k) Manufacturer identification with full address, including the manufacturing units to be certified, based in another country, where applicable;

l) Activity Information / outsourced processes that may affect the conformity of the certification object product;

m) Documentation showing compliance with item 7 of this document (Complaints Handling) for all brands marketed, at all locations belonging to the requestor of the certification or directly outsourced by him, where the Claim Handling activity occurs." (N.R.)

n) Documents relating to the management system manufacturer Quality, applicable to the object to be certified in the case of certification by models 5 and 6, as provided in tables 2 and 3, item 6.2.3.1, even though they necessarily come to be audited by the OCP, as provided herein;

o) Valid certificate issued based on the current edition of Standard ISO 9001 or ISO 9001 standard, covering the certification object of the production process, if any;

p) Certificate lot identification in case the model 1b, including amounts and lot(s) for the manufacture of model(s) for certification.

q) Import License, or, failing that, the Import Declaration, in the case of Model 1b when imported goods;

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

"s) Documentation proving classification as micro and small company – MPE of the manufacturer, requestor of the certification, when applicable."

Note 1: In case the marks referred to in a) and b) are not property of the Supplier requesting the certification, it must have authorization for their use (s). It is for the OCP verify the legal qualification of the authorization tool and the constitutive act (s) of owner (s) make (s).

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

Note 3: It is for the OCP evaluate the relationship of the considered critical components mentioned in e), which may include others.

Note 4: The term User Manual, mentioned in f), the product information relating to: assembly instructions, installation, dismantling, removal, handling, operation, cleaning, conservation, warnings and other information relevant to the user.

"Note 5: The documentation referred to in line "m" shall be exempt from presentation in case the OCP decides for conducting the audit in the Note of subsection 7.3."

6.2.1.3 When, due to product characteristics, the user manual does not apply, the OCP must validate and record this information in the certification process.

6.2.1.4 If the certification applicant Provider is an integrator, packer and / or distributor make changes in the product box already certified or modify the presentation for marketing the product in relation to the original certification process, the certification request must follow the requirements set out in Annex B of this RGCP.

6.2.2 Analysis of the Application and Compliance Documentation

6.2.2.1 The OCP receives the specified documentation, to open a procedure for granting the Certificate and conduct an analysis of the relevance of the request, as well as an assessment of the conformity of the documentation forwarded by the applicant certification Supplier.

6.2.2.2 If any non-compliance is found in the documentation as received, this must be formally sent to the certification applicant Supplier for correction and due formalization by the OCP, aiming to highlight its implementation for further examination.

6.2.2.3 In case any of the documents referred to in 6.2.1 is not provided in its final form by the Supplier requesting the certification, by the time of the presentation of the documentation, and since this fact does not interfere in the other phases of the Initial Evaluation Process, this fact must be made explicit by the OCP and the completion of the certificate will only occur when all the documents are in their final form and duly approved by the OCP.

6.2.3 Initial Audit Quality Management System and Productive Process Evaluation

The audit of the QMS must be performed whenever the certification model chosen so defined, regardless of the manufacturer or service provider to possess Quality Management System certificate based on the current edition of ISO 9001 or ISO 9001 standard.

According to the adopted model, the OCP evaluates the documents and records of the QMS, and performs an audit on the premises of the service provider or the plant in order to check the conformity of the production process, including facilities and staff training. The audit of the QMS must seek objective evidence that the production process is systematic and monitored effectively, providing evidence of compliance with product requirements of RAC. Thus, the QMS requirements are complementary to the requirements of specific RAC object.

Compliance records in meeting these requirements shall be obtained consistently.

The date of visit for the audit must be scheduled in agreement with the Supplier requesting certification.

6.2.3.1 The evaluation of the QMS is made by OCP based on completeness of the certification process and according to the current edition of the requirements of ISO 9001 or ISO 9001 standard, with the minimum requirements defined in Tables 2 and 3 following:

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

QMS REQUIREMENTS	ISO 9001 or ABNT NBR ISO 9001 Standard
Records control	4.2.4
Planning the product realization	7.1
Communication with the client	7.2.3
Purchasing process	7.4.1
Verification of purchased product	7.4.3
Production control and service providing	7.5.1
Identification and traceability	7.5.3
Client ownership	7.5.4
Product preservation	7.5.5
Monitoring and measuring equipment control	7.6
Monitoring and measuring processes	8.2.3
Monitoring and measuring the product	8.2.4
Control of no conform product	8.3
Corrective action	8.5.2

Table 3: Minimum verification requirements of the QMS for manufacturers and service providers without certification in Standard ISO 9001 or Standard ABNT NBR ISO 9001

QMS REQUIREMENTS	ISO 9001 or ABNT NBR ISO 9001 Standard
Document control	4.2.3
Records control	4.2.4
Critical analysis by the Management	5.6.1. / 5.6.2 / 5.6.3
Competence, training and awareness	6.2.2
Infrastructure	6.3
Planning the product realization	7.1
Communication with the client	7.2.3
Purchasing process	7.4.1
Verification of purchasing process	7.4.3
Production control and service providing	7.5.1
Validation of production processes and service providing	7.5.2
Identification and traceability	7.5.3
Client ownership	7.5.4
Product preservation	7.5.5
Monitoring and measuring equipment control	7.6
Client satisfaction	8.2.1
Internal audit	8.2.2
Monitoring and measuring processes	8.2.3
Monitoring and measuring products	8.2.4
Control of non-conform product	8.3
Data analysis	8.4 (b), (c), (d)
Corrective action	8.5.2

"Note: The QMS audit shall be made based on the current edition in force of Standard ISO 9001 or Standard ABNT NBR 9001, complying with the transition period set by the IAF."

6.2.3.2 Even by the presentation of a valid certificate, according to the current edition of Standard ISO 9001 or ISO 9001 Standard, issued by an OCS accredited by Inmetro or IAF MLA member, for the scope of respective accreditation, the OCP shall proceed with the initial audit of the QMS in the manufacturing unit or service provider during the initial evaluation phase, according to Table 2 of this RGCP, with the objective of checking conformity of the productive process.

Note: Certificates issued by a foreign OCS must be followed by a sworn translation in Portuguese, when they are issued in language other than English or Spanish. The other documents related to the management system, which are in a different language other than English or Spanish, must be translated into Portuguese.

6.2.3.3 During the audit, the certification applicant Supplier shall make available to the OCP all documents related to the Quality Management System certification based on current edition of ISO 9001 or ISO Standard 9001 and present the records production process where clearly marked identification of the certification object. The OCP shall analyze the documentation to ensure that the requirements outlined in Table 2, item 6.2.3.1 are met.

6.2.3.4 The OCP, after the audit, must issue a report, recording the result of the same, with reference to this RGCP and the specific RAC object.

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

6.2.3.6 Any change in the production process must be reported to the OCP and may involve, if impact on product conformity, a new audit.

6.2.3.7 In the case of certification based on prototypes, it is for the OCP, during the audit, ensure that the product produced in scale corresponds to the tested prototype.

6.2.4 Initial Testing Plan

The initial tests must show that the conformity assessment of the object meets the requirements defined in normative basis.

The OCP is responsible for preparing the test plan shall include at least the initial tests to be performed, a clear definition of test methods, number of samples and the criteria of acceptance / rejection for these tests. In the case of certification by family, the test plan must also be developed to cover at least the models that contain the largest number of pre-established by normative baseline requirements. It is for the OCP carry out a critical analysis of laboratory test reports, confronting them with the prescribed test plan.

The OCP shall require that the test reports laboratories report the measurement uncertainties practiced.

Not issued test reports will be accepted before the start of the certification process, unless clearly defined in specific RAC object.

Any change in the critical components must be reported to the OCP and shall lead to new tests.

6.2.4.1 Definition of tests to be made

The tests, its methods and acceptance / rejection criteria must be defined in specific RAC object and must be carried out according to pre-established by normative basis requirements.

Must appear in the test report of the body to complete identification of the object model to be certified so that the test report is clearly traced to the collected sample.

The OCP is responsible for assessing whether the data in descriptive text and design or product specification are in conformity with the technical identification of the model presented in the test report.

6.2.4.2 Definition of Sampling

The OCP is responsible for selecting and seal samples of the object to be certified. The collection of samples for dispatch to the laboratory must be agreed between the Supplier requesting certification Supplier requesting certification and the OCP. The number of samples, acceptance / rejection criteria and exceptional cases must be included in the RAC specific for the object. Table 4 presents an example of sample withdrawal applicable to Models 1a, 2, 3, 4 and 5.

When performing the check and seal the samples, the OCP shall prepare a sampling report, detailing the date, location, storage conditions, sample identification (model / brand, production batch and date of manufacture, quantities sampled, etc.).

Note 1: Sampling Plan does not apply when the specific RAC for the object allow the acceptance of previous reports to the beginning of certification.

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

"Note 3: In the case of certification model 1b, the selection and the seal of the samples must take place in the national territory. Counterproof and witness samples do not apply in this case." (N.R.)

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

		SAMPLE SIZE			
TESTS	**NORMATIVE BASE**	**PROOF**	**COUNTER PROOF**	**CONTROL**	**ACCEPTANCE/REJECTION CRITERIA**
(test name)	(item corresponding to the normative base)	(quantity of units of the product)	(quantity of units of the product)	(quantity of units of the product)	(criteria for acceptance/rejection of the sample)

Note: The tests of samples of counterproof control and must necessarily be performed in the same laboratory where the test was carried out sample test.

6.2.4.2.1 If there is approval of proof testing, the sample is considered approved. If non-compliance is found in the sample test, the test(s) must be repeated in counterproof and control samples.

a) If a non-compliance is found in the counterproof, the sample is regarded as having failed;

b) If the counterproof does not show non-compliance, the control sample is then tested;

c) If the control test presents non-compliance, the sample is regarded as having failed;

d) If the control test does not show non-compliance, the sample is considered approved.

Note: It is for the specific object RAC define the need to repeat all the tests prescribed in the rules of the samples of counterproof and control.

6.2.4.2.2 At the discretion of the certification applicant Supplier by formalizing the OCP, samples of counterproof control and need not necessarily be tested. In this case, there can be no disagreement on results obtained in the sample test.

6.2.4.2.3 Prototypes can be sent directly to the laboratory. In this case, the initial sample consists only by proof of product, paying the counterproof and control.

6.2.4.2.4 It is for the OCP ensure that the tested prototype is the product that will be produced in scale. If the OCP finds any discrepancy between the tested prototype and the product produced in scale, or even, the object design, if deemed relevant, shall conduct new tests, according to the test plan, on new samples.

6.2.4.3 Definition of a Laboratory

6.2.4.3.1 The OCP shall hire test laboratories taking into account the priority defined below:

1 Laboratory designated by Inmetro;
2 Third party laboratory, domestic or overseas, accredited by Inmetro/Cgcre or signatory of ILAC or IAAC mutual recognition agreements, integrally in the tests of the RAC specific of the object;
3 First party laboratory, domestic or overseas, accredited by Inmetro/Cgcre or signatory of the ILAC or IAAC mutual recognition agreements, integrally in the tests of the RAC specific of the object;
4 Third party laboratory, domestic or overseas, accredited by Inmetro/Cgcre or signatory of the ILAC or IAAC mutual recognition agreements, partially (above 70% of the total) of tests prescribed in the RAC specific of the object;
5 First party laboratory, domestic or overseas, accredited by Inmetro/Cgcre or signatory of the ILAC or IAAC mutual recognition agreements, partially (above 70% of the total) of tests prescribed in the RAC specific of the object;
6 Third party laboratory, domestic or overseas, accredited by Inmetro/Cgcre or signatory of the ILAC or IAAC mutual recognition agreements, partially (above 70% of the total) of tests prescribed in the RAC specific of the object or accredited in the same class of test and area of activity(ies) of the test(s) of the specific RAC, however for a different object;
7 First party laboratory, domestic or overseas, accredited by Inmetro/Cgcre or signatory of the ILAC or IAAC mutual recognition agreements, partially (above 70% of the total) of tests prescribed in the RAC specific of the object or accredited in the same class of test and area of activity(ies) of the test(s) of the specific RAC, however for a different object;
8 Third party laboratory, domestic or overseas, accredited by Inmetro/Cgcre or signatory of the ILAC or IAAC mutual recognition agreements, in another scope;
9 First party laboratory, domestic or overseas, accredited by Inmetro/Cgcre or signatory of the ILAC or IAAC mutual recognition agreements, in another scope;
10 Third party laboratory, domestic or overseas, non-accredited;
11 First party laboratory, domestic or overseas, non-accredited.

Note 1: The laboratory designation will happen, in exceptional form, from criteria defined by Inmetro, by publication of a specific Ordinance in the Official Journal.

Note 2: The third party laboratory accredited in part of the tests of the RAC specific of the object may, when authorized by Inmetro/Cgcre, subcontract accredited third party laboratory (ies) partly or entirely of the RAC tests specific of the object to make the test(s) for which it is not accredited. In this condition, it shall be regarded in the same selection position as the third party laboratory accredited by Inmetro/Cgcre or signatory of ILAC or IAAC mutual recognition agreements, in the totality of the tests of the RAC specific of the object. The test report shall be issued in whole by the laboratory that applied for the subcontract and shall contain the identification of the tests and respective subcontracted laboratory(ies). In this case, the Certification Body, in the condition of responsible for the certification process, shall analyze and approve the use of the subcontracted laboratory." (N.R.)

6.2.4.3.2 To use effect of that order of priority, it must be considered any of the following cases:

a) Laboratory defined in previous priority does not exist;
b) When the laboratory defined in the previous priority does not make available the test budget in a maximum of ten (10) working days from the request made by the OCP or cannot answer in a maximum of thirty (30) calendar days from the date of acceptance by the OCP, the deadline for the start of the

tests described in the Conformity Assessment Requirements (CAR) or cannot run them in a maximum of one and a half the regular time of the tests described in the normative base;
c) When the OCP show that the price of testing, plus the cost of evaluation / monitoring by the OCP, compared with earlier priority is defined in at least less than 50%.

Note 1: The OCP must register through supporting documents, updated a every maintenance/recertification, the reasons that led you to select the adopted laboratory, per model or certified family. When the cost credit from 6.2.4.3.2 c) is used for selection of the first party laboratory, a spreadsheet of the internal costs (calculation memorial) that result from the price charged for each test shall be presented." (N.R.)

Note 2: Depending on the specifics of the product at the time of preparation of specific RAC or its implementation phase, Inmetro may authorize, by Ordinance, the use of first party laboratories accredited alternatively to accredited third party.

Note 3: In case there is only a third party laboratory accredited to the specific scope abroad, but there first part fully accredited laboratory in the specific scope in the country, it can be used.

Note 4: When under specific RAC object conducting toxicity tests, the OCP may alternatively accreditation, select laboratory test with recognition by Inmetro / Cgcre the Principles of Good Laboratory Practice GLP-under the System Organization Data Mutual Acceptance for Economic Cooperation and Development - OECD.

6.2.4.3.3 For laboratory use accredited by a signatory to the ILAC Mutual Recognition Agreements or IAAC, is OCP's responsibility to observe and document the equivalence of the method and test parameters.

6.2.4.3.4 In all cases of 1st party laboratory use accredited in the specific scope, in whole or in part, the OCP must monitor and record the execution of all the tests. This monitoring consists of, at least, by the steps of selecting and preparing the samples and making the subsequent results.

6.2.4.3.5 In all cases of 1st party laboratory use or 3rd party accredited for another scope test, the OCP must, after acknowledge and document the training and infrastructure (including equipment) laboratory, monitor and record the execution of all tests. This monitoring consists of, at least, by the steps of selecting and preparing the samples, the start of testing and subsequent decision results.

6.2.4.3.6 In any laboratory use cases of non-accredited 1st or 3rd part, the OCP must, after assess and record all the requirements detailed in Appendix A of this document, monitor and record the execution of all stages of all the tests. The evaluation by the OCP must be done by professional OCP having training record, at least 16 hours / class, in standard ISO IEC 17025 current, and formal proof of experience and specific technical knowledge on the appropriate tests to be evaluated.

6.2.4.3.7 The definition of the laboratory must be taken in agreement between the OCP and the Supplier requesting certification, provided you adhere to the provisions in 6.2.4.3.

6.2.5 Treatment of non-conformities in the Initial Assessment stage

6.2.5.1 If any non-compliance identified in the Initial Assessment stage, the certification applicant Supplier shall send to the OCP, within a period of sixty (60) calendar days, evidence of implementation of corrective actions for the non-compliance (s) found (s).

6.2.5.2 The review of the causes of non-compliance, as well as the proposal of corrective actions, are the responsibility of the applicant certification Supplier.

6.2.5.3 If the certification applicant Supplier fails to meet the deadline, the certification process must be canceled or interrupted, and may be restarted if there is interest of the Supplier requesting certification and OCP.

6.2.5.4 New terms can be agreed, as long as formally required by the certification applicant Supplier, justified and considered the relevance by OCP. These periods also apply to non-compliance or disputes identified in the application review.

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

6.2.5.6 It is OCP criterion the need to conduct a new audit of the QMS and / or new tests to verify the implementation of corrective actions.

6.2.5.7 The certification applicant Supplier shall identify and segregate the product (s) (s) not as (s) in separate areas, so there is no possibility of mixing with the product as and send to the market and must keep record of this action.

6.2.5.8 The objective evidence of the treatment of non-compliance is a requirement for the issuance of the Certificate.

6.2.6 Certificate Issuance

6.2.6.1 Critical Analysis and Certification Decision

6.2.6.1.1 The OCP must designate at least one person to critically analyze the information and results of evaluation. The review must be performed by person (s) not involved (s) in the evaluation process.

6.2.6.1.2 The review shall include all the information about the documentation, audits, test results and treatment noncompliance.

6.2.6.1.3 Recommendations for certification based on critical analysis must be documented.

6.2.6.1.4 The OCP is responsible for decisions regarding the certification.

6.2.6.1.5 The certification decision will be made by a person or group of persons not involved in the evaluation process.

6.2.6.1.6 The OCP shall notify the certification applicant Supplier case decides not to grant certification, reporting the reasons for the decision.

6.2.6.1.7 In the case of OCP choose to use a Certification Commission, there must be formal rules for the appointment, terms of reference and operation thereof.

6.2.6.1.7.1 Certification Fees must be free of any interests, commercial, financial and other pressures which might influence their decisions.

6.2.6.1.7.2 It is for the OCP appointment and exclusion of members of the Certification Committee.

6.2.6.2 Certificate Issuance
Once the requirements in this RGCP and specific RAC for the object are fulfilled, the OCP issues a unique Certificate, with different numbering system for each model or family, subject of the request.

6.2.6.2.1 Where certification is per family, the certificate shall list all models covered by the family.

6.2.6.2.2 If required more than one page to the certificate, all pages must be numbered with reference to its own number and the total number of pages, must appear on each page the certificate number and date of issue. The home page must tell how many pages make up the full certificate. In this case, the certificate shall include the words "valid Certificate accompanied only of the N 01 pages" (mention in pages and order the certificate).

6.2.6.3 Conformity Certificate

The Conformity Certificate has validity defined in specific RAC and must contain the following, in the case of certification according to Models 2, 3, 4, 5 and 6: "The validity of this Certificate is linked to carrying out assessments of maintenance and treatment of possible non-compliance in accordance with the OCP guidelines laid down in specific RAC. To check the current condition of regularity of this Certificate must be obtained from the product database and Certificate Services Inmetro ".

6.2.6.3.1 The Certificate, as a formal instrument issued by OCP, must contain at least:

a) Numbering of the certificate of conformity;
b) Corporate name, National Register of Legal Entities (CNPJ), full address and, where applicable, brand name of the certification applicant Provider (certificate holder);
c) Business name, full address and, where applicable, trade name of the manufacturer;
d) Name, address, accreditation registration number and signature of the responsible for the OCP;
e) Date of issue and expiration date (except Model 1a and 1b) of the Certificate;
f) Certification model adopted;
g) Identification of the certified product model, the certification by case model, including the list of all marketed brands;
h) Identification certified product family and all relevant models in the case of certification by family, including the list of all marketed brands;
i) Identification of the lot (s) of manufacture (obligatory certification if the Model 1b);
j) Scope of service in the case-service certification;
k) Ordinance of the RAC based on which the certificate was issued (certification scope) and its (their) complementary ordinances, if any;
l) Barcode of the models provided in g) or h), and all the versions, when it exists in the GTIN Standard – *Global Trade Item Number*;
m) Number and, issuance date of the test report(s), as well as the identification of the issuing laboratory;" (N.R.)
n) Date of the audit, applicable for Models 5:06.

Note 1: A license is required for each family certified in the case of certification for family or for each certificate type in the case of certification by model.

Note 2: Any additional items required for the issuance of the Certificate of Conformity must be listed in the specific RAC.

"Note 3: For purposes of the provisions of paragraph k), it shall be considered the complementary ordinance(s) that alter the RAC requirements and call for adequacy of scope with Inmetro/Cgcre."

6.3 Maintenance Assessment

Following the granting of the Certificate, the control of the certification is done by the OCP, to see if the technical and organizational conditions that gave rise to the initial grant certification are still met.

The maintenance assessment must be programmed by the OCP according to periodicity and the criteria in specific RAC for the object in question. The limits must be counted from the date of issue of certificate. All steps must be completed by the deadlines established in specific RAC for the object.

Note 1: The frequency of maintenance and maintenance test audits can be fixed or variable, as defined in the RAC.

Note 2: The variable frequency allows increasing the spacing of the time interval between the audit and / or maintenance tests. The increased spacing relates solely to the failure to identify non-compliance. If found non-compliance, the spacing is reduced, then restarting new cycle. The opposite occurs when they are not identified nonconformities. The RAC defines whether or not of the variable frequency.

Note 3: The presence of non-compliance with treatment not later entails the application of the increase in the time interval spacing between two maintenance, planned maintenance with variable frequency.

It is for the OCP formally request the certificate holder to report any change in design, descriptive text or production process.

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

"For the cases in which the same holder of the certificate wishes to certify a new family (in the case of certification per family) or a new model (in the case of certification model), the OCP must conduct a new certification process starting from 6.2. The QMS audit can be exempted, at the OCP criterion, in case new families or models to be included come from the same productive process already audited previously to certify other families or models from the same manufacturing unit. In this case, the OCP shall report the reason for exempting the QMS audit, by documenting the correspondence of the requirements previously audited in the same productive process." (N.R.)

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

6.3.1.1 The OCP must be programmed to perform periodic maintenance audit in the production process of the manufacturer or service provider covering at least the following steps:

a) verification of the original of the documentation in item 6.2.1, particularly as their availability, organization and retrieval, and
b) analysis of records, especially those related to compliance with the requirements in Tables 2 and 3.

6.3.1.2 The date of the visit to the audit of maintenance must be scheduled in agreement with the requesting Provider certification. However, if explicitly defined by Inmetro / Dconf, the OCP must conduct the audit of maintenance or extraordinary audits without notice.

"6.3.1.3 In case the supplier holder of the certification presents a QMS certificate within its validity time the OCP can, under its analysis and responsibility, decide for not assessing the QMS provided in this RGCP during the maintenance assessment phase. The Certificate must have been issued by an OAC accredited by Inmetro or IAF MLA member for the accreditation scope and according to the ISO 9001 Standard edition (and their translations) in force or ABNT NBR 9001 Standard, complying with the transition period set out by the IAF. The certification shall be valid for the productive process at the manufacturing unit of the object for certification. In this case, the supplier must make available to the OCP all documents corresponding to this certification and present the productive process records showing clearly the identification of the certification object. The OCP shall analyze the relevant documentation to assure that the requirements described in Table 2 of subsection 6.2.3.1 have been met for the QMS.

6.3.1.3.1 It is responsibility of the supplier to assure that the Quality Management System, certified based on the current edition of ISO 9001 Standard (and its translations) or ANBT NBR ISO 9001 Standard is executed and applied considering conformity with the Conformity Assessment Requirements specific of the object."

6.3.2 Maintenance Testing Plan

Maintenance tests must prove maintaining compliance after the initial evaluation with the requirements laid down in specific RAC for the object.
Just as in the Initial Assessment, the OCP is responsible for preparing the Test Plan, which must contain at least maintenance tests, test methods, sampling, acceptance / rejection criteria and frequency, according to the provisions of specific RAC for the object.
The OCP shall require that the test reports laboratories report the measurement uncertainties practiced.
The Test Plan must be planned so that, over the maintenance, there is rotation of family models, when the certification is for family.

6.3.2.1 Definition of tests to be performed

The tests shall be in accordance with the criteria set out in subsection 6.2.4.1 of this document.

6.3.2.2 Format of maintaining sample

The criteria set out in subsection 6.2.4.2 of this document must be fulfilled.

"**6.3.2.2.1** For certification models 2, 4 and 5, at the sample collection/purchase phase, both for domestic products and imported products, to carry out the maintenance tests, the OCP must necessarily collect/purchase them commercially.

6.3.2.2.1.1 The shipping are of the manufacturing unit or distribution centers can be considered as trade, provided the product is already in the final sale packaging to the consumer, in conditions of having the Nota Fiscal issued.

6.3.2.2.1.1.1 The shipping area collection are of the manufacturing unit or distribution centers can only be made by the OCP without previous notice, and cannot be made during the audit period in the case of Certification Model 5." (N.R.)

6.3.2.2.2 The collection to perform the maintenance tests must be performed by the OCP in samples which have been manufactured from the date of issue and the first assessment of maintenance. After the collection must occur in samples of the product produced in the interval between two sequential maintenance or between the last maintenance and recertification.

6.3.2.3 Defining the laboratory
The guidelines described in subsection 6.2.4.3 of this document must be fulfilled.

6.3.3 Handling non-conformities in the Maintenance Assessment phase

6.3.3.1 If any non-compliance identified during the evaluation of maintenance, it is for the holder of the certificate to critical analysis of the causes of non-conformities and to propose corrective actions.

6.3.3.2 The certificate holder must send the OCP, within a maximum of fifteen (15) calendar days, the corrective action plan, which must have sixty (60) calendar days as deadline for evidence of implementation of corrective actions.

6.3.3.3 The certificate holder must take immediate control actions in the factory to prevent the model / fail family (a) the maintenance test is sent to the market.

6.3.3.4 The OCP evaluate the effectiveness of the corrective actions proposed in the plan, and whether they have been implemented.

6.3.3.5 It is up to the OCP review the need to conduct a new audit to verify the implementation of corrective actions and / or new tests.

6.3.3.6 Failure to submit the corrective action plan within the period specified in 6.3.3.2 or identification of any non-compliance without evidence of treatment, result in the immediate suspension of the Certificate for the model / family not to comply. The OCP shall notify the holder of the certificate in writing stating that you can only resume the certification process when non-conformities found are settled.

6.3.3.6.1 In the case of certification by model, if no evidence of compliance may compromise other models already certified, suspension of accreditation can be extended to these models, the discretion of the OCP.

6.3.3.6.2 In the case of certification by family, if not evidenced in accordance of the family models, the suspension of the certification applies to all models that make up the family and may be extended to other families at the discretion of OCP.

6.3.3.7 The certificate holder shall submit the corrective action plan within 15 (fifteen) days from the suspension of its certification. The certification back in force when corrective actions are deemed effective by the OCP. The effectiveness of corrective actions must be confirmed by testing, audit and / or document analysis, at the discretion of the OCP.

6.3.3.8 New terms can be agreed provided that formally requested by the certificate holder, justified, and assessed the relevance for the OCP.

6.3.3.9 If the certificate holder does not meet the deadlines, and since that has not been agreed new period, the certification will be canceled.

6.3.3.10 If the certificate holder's refusal to implement corrective actions, the OCP must cancel the Certificate for the model (s) / family (s) of product (s) certificate (s) and communicate formally Inmetro.

"6.3.3.11 In the event the product cannot be collected as determined in subsection **6.3.2.2.1**, the certificate shall be canceled." (N.R.)"

6.3.3.12 In the event of non-compliant products that may jeopardize the risk to health or user`s safety, the OCP shall suspend the Certificate of Conformity, regardless of the timeframes estimated for proposition of corrective actions by the supplier holder of the certification, the time required for correction of the productive process, respected the limit of validity of the certificate." (N.R.)

6.3.4 Confirmation of Maintenance

The OCP shall issue the confirmation of maintenance after the review, including information on the documentation, audits, testing, treatment non-compliance, monitoring the market and handling of complaints, observing the relevant requirements of subsection 6.2.6, that maintaining compliance with the requirements has been demonstrated.

Met the requirements in this RGCP and specific RAC for the product, the OCP issues the document entitled "Confirmation of Maintenance", formalizing that certification is maintained.

6.3.4.1 Confirmation of maintenance, as a formal instrument issued by OCP, must contain at least:

a) Reference to the conformity certificate being maintained;
b) Corporate name, National Register of Legal Entities (CNPJ), full address and, where applicable, brand name of the certificate holder;
c) Name, address, accreditation registration number and signature of the responsible for the OCP;
d) Date of issue of the Maintenance Confirmation;
e) Certification model adopted;
f) Identification of the model certificate, the certification by case model, including the list of all marketed brands;
g) Identification certified family and all relevant models in the case of certification by family, including the list of all marketed brands;
h) Scope of service in the case-service certification;
i) RAC Ordinance based on which the certificate was issued (certification scope) and its complementary ordinances, if any;
j) Barcode number of the models provided in f) or g), and all the versions, when existing in GTIN standard – *Global Trade Item Number*;
k) Number and date of issuance of the maintenance test report(s), as well as identification of the issuing laboratory;" (N.R.)
l) Date of the audit, applicable for Models 5 and 6;

m) Date of next maintenance assessment in the case of maintenance assessment with variable frequency, dependent on whether or not they non-conformities in auditing and testing according to the specific RAC object.

"Note: For effect of the provision in paragraph k), it shall be considered the complementary ordinance(s) that alter the RAC requirements and request adequacy of scope with Inmetro/Cgcre."

6.4 Evaluation Recertification

The recertification assessment must be scheduled by the OCP, according to the criteria established in Section 6.2 of this document and the specific RAC object.

"The recertification assessment must be scheduled by the OCP, in accordance with the criteria set out in subsection 6.2 of this document and in the RAC specific to the object, except for the Treatment of No Conformities which must follow the provisions in 6.3." (N.R.)

In the case of specific RAC include evaluation of maintenance with variable frequency; the OCP must as recertification, to continue the spacing practiced from the last assessment carried out, depending on the existence or not of a non-compliance.

The collection for the tests must be performed by the OCP in samples that have been made between the last maintenance date and the date of recertification.

The OCP, after the review, including information on the documentation, audits, testing, treatment non-compliance, monitoring the market and handling of complaints, decides for recertification.

Met the requirements in this RGCP and specific RAC for the product, the OCP issues the new Compliance Certificate.

A certificate with different numbering shall be issued by the OCP for each model or for each family, each recertification.

Note: Any additional items required for the issue of the new Certificate of are described in the specific RAC for the object.

6.5 Special Cases

6.5.1 The product certification subject to multiple certification (hybrid product) must consider all use of functions subject to compulsory certification, i.e., all functions subject to certification must be certified (initial assessment, maintenance and recertification) concurrently, even that certification carried out in separate processes. If the certification process is conducted by a single OCP, it must be accredited for both certification subject scopes.

"**6.5.1** Certification of products subject to multiple certification (hybrid product) shall take into account all functions of use subject to compulsory certification, that is, all functions subject to certification shall be certified (initial assessment, maintenance and recertification) simultaneously, even if they are conducted at different certification processes. In case the certification process is conducted by a sole OCP, it must be accredited for both scopes subject to certification. Tests and test methods common to both regulations can be made at the same time." (N.R.)

The hybrid product shall bear only a Conformity Identification Mark.

Note: For purposes of this RGCP, hybrid product is characterized as a single product, not being able to uncouple, designed to perform the function of two or more products subject to compulsory certification.

6.5.2 If, after the granting of the license, is published processing order of the Conformity Assessment Requirements with current RAC revocation forecast, the OCP must lead a new certification process.

6.5.2.1 The new certification process, based on the new published requirements, must be initiated and completed by the 6.2 final date for suitability for manufacture and importation, defined by the new Ordinance.

6.5.2.2 Upon completion of the new certification procedure, the OCP shall issue a new certificate with a new numbering.

"**6.5.2** If, after granting the certificate, an ordinance improving the Conformity Assessment Requirements is published, with provision to revoke the current RAC, the OCP shall carry out a new certification process, with issuance of a new certificate. The certificates issued after the publication of the improvement ordinance, still with basis on the current RAC, shall have their validity tied to the 1st. adequacy time informed in the latest published ordinance.

6.5.2.1 The new certification process, based on the new published Requirements, must start from 6.2 and completed by the time of adequacy estimated for manufacturing and importation, as defined in the new Ordinance.
6.5.2.2 After completing the new certification process, the OCP shall issue a new certificate, with a new numbering." (N.R.)

7 HANDLING CLAIMS

The complaints handling described in this document applies to the requesting Supplier certification and the OCP.

7.1 The complaints-handling process must include:

a) A system for handling complaints, signed by the formally designated to do so, to show that the certification of the applicant and the OCP Supplier:

- They value and provide effective treatment to claims filed;
- Know and undertake to comply with and be subject to the penalties provided for in the laws, specifically in Law No. 8078/1990;
- Critically analyze the results and take appropriate action in the light of complaints received;
- Define responsibilities for dealing with complaints;
- Undertake to respond to Inmetro any complaint within fifteen (15) calendar days;
- Undertake to respond to the complainant regarding the receipt, processing and completion of the claim, according to the deadlines established internally.

b) A system for handling complaints containing the records of each of the treatment given and the current stage;
c) The formal indication of a person or team, properly trained and freedom to pursue complaints;
d) Telephone number or other means of meeting the claims and complaints registration form, including code or protocol number provided to the consumer to follow.

7.2 The certification applicant Supplier and the OCP must also carry out annually a critical analysis of complaints and evidence of implementation of the corresponding corrective actions, as well as opportunities for improvement, recording their results.

7.3 The OCP must audit all places where Complaint Handling activity is carried out in order to verify compliance with previously established requirements, whatever the certification model adopted, the initial assessments, maintenance and recertification, if any.

"**7.3** Mandatorily, whichever the model of certification implemented, the OCP must audit all locations (belonging to the applicant to the certification or directly outsourced by him), where the activity of

Handling Complaints is performed, for verification of compliance to the requirements previously set, during the initial assessments, maintenance and recertification, if any.

7.3.1 For the cases when the applicant to the certification proves his status of micro and small company – MPE, audit is optional, being made at the discretion of the OCP." (N.R.)

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

8.1 The conformity assessment activities, carried out by a body accredited by the IAF MLA member, may be accepted, subject to observance of all the following conditions:

a) It shall be an MoU with a Brazilian OCP accredited by Inmetro / Cgcre;

b) It shall be accredited by the same international rules adopted by Inmetro, or accredited by a signatory to the IAF MLA for the same scope or equivalent;
c) The activities of the OCP must be equivalent to those regulated by Inmetro;
d) No restriction shall exist by the Regulatory Authority for certification submitted object.

8.2 MoU will be subject to verification in the periodic accreditation reviews conducted by Inmetro / Cgcre and must include at least the following conditions:

a) The parties must agree to keep the signatories informed about changing conditions of its accreditation in the country of origin;
b) The parties shall agree which certification process documents issued in language other than English or Spanish, must be accompanied by a sworn translation into Portuguese;
c) Parties must make clear the activities that are covered by the MoU, such as audit, test plan, evaluation of test reports, audit report evaluation.

8.3 The Office legally established in the country and accredited by Inmetro / Cgcre will be responsible for judging and issuing the certificate in accordance with the Brazilian regulations, assuming all responsibility for the activities carried out abroad and resulting from this issue, as if it had conducted itself.

8.4 Foreign certification bodies accredited by INMETRO / Cgcre the specific scope could lead certification processes in specific RAC scope for the object, provided they are legally established in Brazil. In this case, all the certification process documentation must be available in Brazil and in Portuguese, observing the exceptions provided in 6.2.1.2 "and" and subsection 6.2.3.2 of the note.

"**8.4.1** Foreign Body means a Body legally established in Brazil, accredited by Inmetro/Cgcre in the specific scope, one whose personnel has technical skill, located in Brazil, having physical structure in the national territory, with easy access to the certification process and that complies with the legal requirements of the documentation required by Brazil to start a company, such as CNPJ and Articles of Incorporation and Bylaws."

9 CERTIFICATION OF TRANSFER

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

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

9.3 Each OCP must be included in contracts with their clients the availability to provide the necessary information to other OCP, upon transfer of a certificate issued by him, still valid, and considering the provisions in 9.1 of this RGCP.

9.4 A qualified person OCP receiver must perform a critical analysis of the new client certification process. This review shall be conducted by examining the documents / records and / or performing visit to the manufacturer or provider of the service, and be duly registered. The review must cover at least the following:

a) Process steps carried out so far and the situation in the certification of the current process step;
b) Test reports;
c) Test plan performed, correlating with family or model;
d) Reason for the request for transfer;
e) Validity of the certificate with respect to the authenticity and duration, covering the scope of the transfer object;

f) Certification of validity and non-compliance pending correction(s). This verification must preferably be made together with the emitter OCP, except that it has terminated its work;
g) Report (s) of the last audit (certification, maintenance and recertification) and (s) extraordinary (s), and any non-compliance has not remedied;
h) Claim(s) / appeal (s) received and action(s) taken;
i) The current stage of certification.

9.5 The certificates suspended, canceled or expired expiration date cannot be accepted for transfer purposes.

9.6 If in the previous critical analysis no outstanding compliance or potential risks are identified, or when there are doubts about the adequacy of existing certification, the receiver must OCP, depending on the extent of the doubt:

a) Do not accept the transfer process and start a new certification process; or
b) Accept the transfer process after the disclosure, through audit or test, that the original certification can be maintained.

The decision as to required actions depend on the nature and extent of non-conformities found and must be recorded and explained to the certificate holder.

9.7 If in the previous critical analysis are not identified no outstanding compliance or potential risks, the receiver must accept the OCP certification transfer.

9.8 Heeded the transfer, the OCP receiver issue a new certificate, dated the end of the review and the remaining period of validity from the original certificate, and considering all the items listed in 6.2.6 of this RGCP.

"**9.8.1** The new issued certificate of conformity must also mention that it refers to the transfer process of certification, showing the issuing Body, number of transferred certificate and date of transfer.

9.8.2 The issuing OCP shall only cancel the Certificate of Conformity when the receiving OCP issues a new Certificate of Conformity with the remaining validity."

9.9 The next evaluation of maintenance or recertification must take place according to the criteria in specific RAC for the object and must be achieved within the deadlines specified in the certification process conducted by the issuer original OCP.

9.10 OCP receiver must keep all documentation and all records concerning secure transfer during the time specified in its quality management system.

10 CLOSING THE CERTIFICATION
The closure of the certification will give up in the event of closure of manufacture / import of the products or service delivery activities, compulsory licenses, or certificate holder's option in the case of voluntary certification.

The OCP must ensure that objects certified before this Decision are in accordance with the specific RAC for the object.

10.1 The OCP must schedule an extraordinary audit to verify and record the following requirements:
a) Date of manufacture and size of the last batches of the certificate object;
b) Material available in stock;
c) Amount of finished product in stock and forecast for this lot will be distributed;

d) Compliance with the requirements in the specific RAC for the object since the last follow-up audit;
e) Routine tests carried out in recent batches produced;
f) Stock acquired stamps.

"**10.1.1** In case of imported product, the closing audit shall be made at the applicant's facilities to verify the following: date of last importation and size of the last imported lots; quantity of finished products in stock (at the requestor of the certification and/or importer) and estimated date for distribution of this lot; fulfillment of the RAC requirements specific for the object since the last follow-up audit; routine tests made by the manufacturer on the last lots produced."

10.2 When deemed necessary, the OCP can also program the sampling and testing to assess the conformity of products in stock.

"**10.2.1** In the case of imported products, if no importation occurred between the period from the initial certification and the closing request, evidenced in the audit of 10.1.1, it is not applicable to make tests for verification of conformity of the products in stock at the importer."

10.3 If the results of these tests presents any are found, the OCP before considering the ending process, requests the certificate holder indicated treatment, defining the provisions and implementation deadlines.

10.4 In the event of non-compliant products on the market before considering the ending process, and depending on the commitment that the unidentified compliance may require the use of the product must be considered by the OCP the need for withdrawal from the market of the product, getting the certificate holder responsible for this action.

"**10.4** In case of no conformities in the market, before considering the process closed, and, depending of the consequences the no conformity may impose on the use of the product, the OCP must inform Inmetro about cancelling the certificate with the recommendation to remove the product from the market." (N.R.)

10.5 From the compulsory certification of closure, the product may no longer be manufactured or imported, and strictly permitted the distribution and sale of inventory produced within the validity of certification. Similarly, the closure of compulsory certification service, implies impediment to the provision of services.

10.6 On completion of the above steps, the OCP must cancel the certificate, updating the product database and certificate services provided by Inmetro, and notify the closure Inmetro / Dconf through the document issued contemplating the information specified in subclause 10.1.

10.7 If the certificate holder does not allow the OCP meet the requirements 10.1 to 10.5 above, the OCP must cancel the certificate, updating the product database and certificate services provided by Inmetro, and notify the closure Inmetro / Dconf, justifying the impediment mentioned above.

11 CONFORMITY IDENTIFICATION SEAL

The Conformity Identification Mark aims to identify the certification object was submitted to the conformity assessment process and meets the requirements in this document and in its respective RAC.

11.1 The model, characteristics, traceability and ways to affix the Conformity Identification Mark will be defined in specific RAC object, subject to the provisions contained in Inmetro No 274/2014.

11.2 The Conformity Identification Mark can be printed on the Certificate, marked or affixed to the product and / or printed or attached to the packaging, according to the specific RAC object.

11.3 In the case of imported products, except those certified by Model 1b, the Conformity Identification Mark shall be marked or affixed to the product and / or printed or attached to the packaging, according to the specific RAC object before the entry of even in the country.

12 AUTHORIZATION FOR USE OF CONFORMITY IDENTIFICATION SEAL

The authorization to use the Conformity Identification Seal is awarded upon completion of all requirements in this document and in the specific RAC object.

12.1 To certified product likely to object registration authorization to use the Conformity Identification Mark and marketing the product or service delivery, are conditioned to obtain the object registration.

12.2 In all other cases the authorization is granted when the product complies with the criteria set forth herein and in the specific RAC object being exempted from Registration by Inmetro.

12.3 The authorization for both products eligible for registration or not, will have its validity linked to the validity of certification and provided not suspended or canceled.

12.4 References for features not included in the referenced normative base, constant use of or information to the user instructions, cannot be associated to the Authorization for Use of Conformity Identification Seal or induce the user to believe that such features are covered by the process of Certification.

13 RESPONSIBILITIES AND LIABILITIES

13.1 Certificate Holder Obligations

13.1.1 Only provide the services or produce, import and market the object of certification products, which comply with the specific RAC object, which is evidenced by Certificate.

13.1.2 To comply with all the conditions set out in this document, the specific RAC for the object in question, the legal provisions and the contractual provisions relating to authorization, regardless of their transcription.

13.1.3 Apply the Conformity Identification Seal on all certified products, according to the criteria set forth herein and in the specific RAC for the object.

13.1.4 Comply with the relevant decisions taken by the Certification OCP, using the Inmetro, in cases of complaints and appeals via Ombudsman Inmetro.

13.1.5 To facilitate the OCP or its contractor, upon proof of this condition, the auditing and monitoring work, as well as testing and certification of other activities contained in this document and in the specific RAC for the object.

13.1.6 Keep the technical and organizational conditions that formed the basis for obtaining the certificate of conformity, informing, prior to the OCP, any changes you wish to make the product to which license was granted.

13.1.7 Report immediately to the OCP in the event of termination, definitely, the service is provided or the manufacture or import of the certified product.

13.1.8 Not to use the same encoding (trade name) to a certified product and a non-certified product.

13.1.9 Submit to Inmetro for authorization, all publicity material in which appears Conformity Identification Mark.

13.1.10 The certificate holder has technical, civil and criminal liability relating to certificates objects as well as to all documents related to certification, with no transfer hypothesis of this responsibility.

13/01/11 The certificate holder must reimburse the OCP the costs of follow-up actions on the market determined by Inmetro, as provided in Section 14 of this RGCP.

13/01/12 In announcing the recall of certified products with non-compliance, do it according to the rules of the MJ487 / 2012 Ordinance.

13.1.13 Inform Inmetro, within 48 hours, whenever the certified object launched in the market is found with non-conformities that put in risk the health and safety of consumers and the environment, so that Inmetro can request the Ministry of Justice Senacon / DPDC to withdraw such product from the market and proceed with a *recall*. After withdrawing the product from the market, a final destination must be given to it, in compliance with current legislation.

13.1.14 Reply notifications Inmetro, within the deadlines, requesting clarification related to non-compliance of research processes identified in the certificate object.

13.1.15 Request from Inmetro Registration of the object, in cases where the regulations, providing all the information required in the Registration process.

13.1.16 Provide Inmetro all information requested by this, for the RAC object product certification process, forwarding when necessary and requested, supporting documents.

13.1.17 Submit to the OCP process you will use to display the information in systematic manner to all its customers, about the period of adjustment intended for trading make their products without the Conformity Identification Seal for the duration of this period.

13.1.18 The certificate holder must consider the deadlines given by the OCP, the laboratory tests and the Inmetro to get timely with Reviews Maintenance and Recertification.

13.1.19 The certificate holder must inform the OCP, at any time, any change in design, descriptive text or production certificate process object.

13.1.20 The certificate holder, in case of cancellation of the issuer of the same OCP, must migrate to another OCP no later than the deadline for completion of the next maintenance or recertification, whichever occurs first.

"**13.1.21** Proceed with the return of the Conformity Identification Seal with sequential numbering to Inmetro/Dconf Pre-Market Control Coordination in up to ten (10) days, in case of cancellation of the certification."

13.2 OCP Obligations

13.2.1 Having trained staff, keeping track of qualification and training activities in order to be able to conduct the entire certification process provided for in specific RAC object.

13.2.2 Performing a product certification according to the requirements set forth herein and in the specific RAC for the object, must settling doubts with Inmetro.

13.2.3 Feed and update within five (5) working days, the product database and certificate services provided by Inmetro, with the information on the certificate, including issuing, adequacy of scope, suspension and cancellation.

13.2.4 In addition to item 13.2.3 notify within 5 (five) working days to Inmetro / Dconf in the case of suspension or withdrawal of certification, by physical or electronic means. For cases of products regulated by another Authority Regulatory associated with certification processes coordinated by Inmetro, this notification shall also be forwarded to it.

"13.2.4 Notify, in up to five (5) workdays, Inmetro/Dconf, the cases of suspension or cancellation of the certification, exclusively by electronic means, e-mail address regobjeto@inmetro.gov.br, for the cases of object subject to Registration of Objects with Inmetro, or e-mail address divec@inmetro.gov.br, for the cases of objects not subject to Registration of Objects with Inmetro. When the communication of suspension or cancellation is relative to object whose Conformity Assessment Requirements were defined by Inmetro by delegation of another regulation body, sending of the communication to Inmetro/Dconf must be followed by evidence that the regulating body was also informed.

13.2.4.1 The communication of suspension or cancellation of certification must contain, at least:
a) number of the certificate of conformity the communication refers to;
b) identification of the Scope and Inmetro Ordinance of the RAC (compulsory or voluntary) based on which the certificate was issued;
c) occurrence (suspension or cancellation);
d) model (if certification per model) or family of product (if certification per family) comprised by the occurrence;
e) reason for the suspension or cancellation (inform the nature of the no conformity, identification of the failure test, identification of the compromised lot(s), as well as removal from the market);

e1) In cases of cancellation by transfer, inform the OCP the destination and date of the transfer;
e2) In cases of cancellation by cease of manufacturing or importation, inform the date of the last production or importation of the product;
e3) In cases of cancellation of the certification by abandonment/breach of contract, this condition must be expressly shown;
e4) In cases of revocation of suspension, which corrective action led to such revocation;
f) date of closing audit (in case of cancellation by closing);
g) date of suspension or cancellation or revocation of the suspension;
h) signature of the OCP signatory.

Note 1: An e-mail must be sent with the field "subject" filled in as follows:
Subject: "type of communication (cancellation or suspension)/Scope/Inmetro Ordinance of the RAC – Reason "

Note 2: The reason must be shown as described below: **Reason**	**Description**
I	Suspension or cancellation by failure in tests;

II	Suspension of cancellation by other types of no conformities not related to tests;
III	Suspension or cancellation or Cancellation by abandonment/breach of contract (no compliance of the maintenance or recertification phase);
IV	Cancellation per transfer of OCP;
V	Cancellation by request due to cease of manufacturing/importation;
VI	Cancellation for adequacy to new RAC (maturity of 1st timeline of adequacy)." (N.R.)

13.2.5 Submit to Inmetro / Cgcre, for review and approval of the use, the Memoranda of Understanding, the scope of this document and the specific RAC, established with other Certification Bodies.

13.2.6 Select, in agreement with the Supplier requesting certification, the laboratory to be used in the certification process, based on the requirements set forth herein and in the specific RAC for the object.

13.2.7 Collect at any time and date, as determined by the Inmetro, before suspicions or duly substantiated complaints, samples on the market for performing tests defined in the specific RAC for the object, following the intended sampling criteria, at their own expense regarding the collection and testing, as set forth in item 14 of the RGCP.

13.2.8 To have a Complaint Handling System as provided in Chapter 7 of this RGCP.

13.2.9 No outstanding issues with Inmetro.

13.2.10 Report immediately to Inmetro, within a maximum of 48 hours, any information about the recall, although preliminary, that is, in the research phase, provided by companies that have their certificate object.

13.2.11 Report Inmetro / Cgcre the existence of non-compliance detected during audit of the QMS held in certificate holder manufacturer ISO 9001 or ISO 9001.

13.2.12 Report formally holders clients of Authorization for the Use of the Conformance Identification Seal changes in technical standards and documents issued or recognized by Inmetro which may affect the requirements of this document.

13.2.13 The interpretation of our results in test reports issued by laboratories is the sole responsibility of OCP and must not accept that the lab to do.

13.2.14 Require laboratories to report the uncertainties inherent in the measurement tests.

13.2.15 If the OCP has its accreditation withdrawn, shall:

a) Immediately to your customers your condition and instruct them in the transition to another OCP who is active with his accreditation, pointing out that the certificates already issued will remain valid until the end of the maintenance periods or renewal, whichever comes first ;
b) Make available, on request, to Inmetro / Dconf all records and information relating to the certification procedures carried out by him;
c) Make available to its customers all records, certificates, reports and other documents related to is procedure (s) certification to subsidize them when contracting other OCP believed to continuity of its approval;
d) Report to Inmetro / Dconf all actions taken during the migration process of the companies holding licenses in order to avoid damage to suppliers and consumers;
e) Facilitate the migration of the certification process for other OCP defined by the holder of certification.

13.2.16 The OCP canceled cannot carry out maintenance activities or renewal of licenses for the Conformity Assessment Programs established by Inmetro.

13.2.17 The suspended OCP must report such condition to their customers and, while in this condition, you cannot perform any certification initial leasing activity nor grant recertification or scope extension for certifications in force. During the suspension period, the OCP must perform all the activities related to maintenance of the certificates in force, provided there is no extension of scope of these.

"13.2.18 In case of cancellation of the accreditation by Cgcre/Inmetro, the OCP shall cancel the certificates issued on the date of conclusion of the migration to the receiving OCP or, not having migration, on the date of maintenance or renewal of the issued certificate, whichever happens first, as well as updating the Prodcert System within five (5) days.

13.2.19 Make available, when requested, to Inmetro/Dconf all records and information relative to the certification processes carried out by the OCP, within maximum five (5) workdays.

13.2.20 Plan the maintenance and recertification activities so as to meet at any time the adequacy timelines given in the regulation and their updates."

14 MARKET FOLLOW-UP

Certificates objects are subjected to monitoring the market through the Inspection, Compliance Verification, Technical Surveillance, among other forms.

14.1 The certificate holder is responsible for restoring the samples of the certificate object withdrawn from the market by Inmetro or its delegated bodies, for follow-up in the market.

14.2 The certificate holder who has submitted the certificate object monitoring the market shall provide the Inmetro and the OCP, when requested or notified administratively, all information about the process of certification and the domestic process control of production quality, maximum period of five (5) workdays.

14.3 If Inmetro identify nonconformities in the follow-up actions on the market, notify the certificate holder and the OCP, establishing the need for action and timeline for the action.

14.4 Non-conformities identified by monitoring the market may lead to the penalties provided in section 15 of this RGCP.

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

14.7 Where determined by Inmetro, in duly substantiated complaint, the OCP must receive samples collected by Inmetro in the market, at any time and time for testing defined in specific RAC, following the planned sampling criteria. The OCP will send the samples to the accredited laboratory, defined together with Inmetro, bearing the costs of test and at the end of these, send to Inmetro test reports. Inmetro may determine that its technical accompanying tests.

14.8 The sampling may exceptionally and when defined by Inmetro be performed by the OCP, we will arrange to deliver them to the laboratory. In this case, the OCP will be responsible for the burden of collecting the samples and sent to the laboratory, in addition to the costs of testing.

15 PENALTIES

Failure to comply with the requirements included in the Regulations, this document and the specific RAC will cause the application to their offenders, the penalties of warning, suspension and cancellation of certification.

16 COMPLAINTS

Inmetro Ombudsman receives complaints, complaints and suggestions through the following channels:

- e-mail: ouvidoria@inmetro.gov.br
- telephone: 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

"16 DENOUNCES, COMPLAINTS AND SUGGESTIONS
Inmetro's Ombudsman receives denounces, complaints and suggestions through the following channels:
Website: www.inmetro.gov.br/ouvidoria
Phone number: 0800 285 18 18

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" (N.R.)

APPENDIX A - REQUIREMENTS FOR LABORATORIES EVALUATION NOT ACCREDITED BY PRODUCT CERTIFICATION BODIES

1 CONFIDENTIALITY

The laboratory must have documented procedures and implemented to preserve the protection of confidentiality and integrity of information, considering at least:

a) Access to files, including computerized;
b) Restricted access to the laboratory;
c) Knowledge of the laboratory staff about the confidentiality of information.

2 ORGANIZATION

2.1 The laboratory shall designate the signatory to sign the test reports and have full technical responsibility for their content.

2.2 The laboratory shall have a technical manager and a replacement (whatever the name) with overall responsibility for its technical operations.

2.3 When the laboratory is the first part, the responsibilities of the organization's key personnel who have involvement or influence on laboratory tests must be defined in order to identify potential conflicts of interest.

2.3.1 It must also, that the organizational arrangements are such that the departments that have potential conflicts of interest, such as production, commercial or financial marketing, do not adversely affect the laboratory's compliance with the requirements of this Annex.

3 MANAGEMENT SYSTEM

3.1 All documents necessary for the proper performance of laboratory activities must be identified unambiguously and bear the date of issue, the number of review and authorization to issue.

3.2 All documents necessary for the proper performance of laboratory activities, must be updated and accessible to its staff.

3.3 The laboratory shall document the duties and responsibilities of the technical manager and technical staff involved in the tests, considering at least the responsibilities as:

a) Implementation of the tests;
b) When planning the tests, evaluate the results and issue test reports;
c) Change, development, characterization and validation of new testing methods;
d) Management activities.

3.4 The laboratory must have the identification of authorized signatories (where this concept is appropriate).

3.5 The laboratory shall have documented and implemented procedures for obtaining the traceability of measurements.

3.6 The laboratory shall have formalized the scope of its services and provisions to ensure that own premises, staff and appropriate resources.

3.7 The laboratory shall have documented and implemented procedures for handling of test items.

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

3.9 The laboratory shall have documented and implemented procedures for feedback and corrective action whenever they are detected nonconformities in the trials.

3.10 The laboratory shall inform the measurement uncertainties inherent in the tests.

4 STAFF

4.1 The laboratory must have sufficient personnel with the necessary education, training, technical knowledge and experience for the designated functions.

4.2 The laboratory shall have procedures for the use of experts in the training process, establishing for it, the supervision of the same records and setting up mechanisms to ensure that their use does not harm the test results.

4.3 The laboratory shall have and maintain updated records of all professional staff involved in the tests. These records must have the date of approval, at least for:

a) Carry out the different types of sampling, where applicable;
b) To carry out the different types of tests;
c) To sign test reports;
d) Operate different types of equipment.

5 ROOMS AND ENVIRONMENTAL CONDITIONS

5.1 The laboratory accommodation, areas of testing, power supplies, lighting and ventilation must allow proper performance of the tests.

5.2 The laboratory shall have facilities with effective monitoring, control and record the environmental conditions where necessary.

5.3 The laboratory shall maintain an effective separation between neighboring areas, where there are incompatible activities.

5.4 The laboratory must have facilities to enable security for the tests, and the PPE inherent in the protection of their personnel.

6 EQUIPMENT AND REFERENCE MATERIALS

6.1 The laboratory must have all the equipment, including reference materials necessary for the proper performance of the tests.

6.2 Prior to testing, the laboratory must check if any item of equipment is presenting suspect results. If this occurs, the equipment must be taken out of operation, identified as disused, repaired and shown by calibration, verification or test, which came back to operate satisfactorily, before being put back into use.

6.3 Each equipment must be labeled, marked or identified to indicate the calibration status. This calibration status must indicate the last and the next calibration, visibly.

6.4 Each unit shall have a record indicating at least:

a) Name of the equipment;
b) Manufacturer's name, type identification, serial number or other unique identifier;
c) Receipt of Condition, as appropriate;
d) A copy of the manufacturer's instructions, as appropriate;
e) Dates and results of calibrations and / or verifications and date of the next calibration and / or verification;
f) Maintaining the details held and planned for the future;
g) History of each damage, modification or repair.

6.5 Each reference material must be labeled or identified to indicate certification or standardization. The label must contain at least:

a) Reference material name;
b) Responsible for certification or standardization (firm or individual);
c) Composition, where appropriate;
d) Expiration Date.

6.5.1 For the long-term reference materials, the laboratory must have a record containing the information specified in item 6.5.

7 TRACEABILITY OF MEASUREMENTS AND CALIBRATIONS

7.1 The laboratory shall have an established program for the calibration, verification and maintenance of their equipment in order to ensure the use of calibrated equipment and / or checked on the date of execution of the tests.

7.2 Reference standards of calibration certificates must be issued by:

a) National metrology laboratories mentioned in 7.2;
b) Calibration laboratories accredited by Inmetro / Cgcre;
c) Laboratories members of Metrology National Institutes of other countries, in the following cases:
- Where traceability is obtained directly from an institution holding the primary pattern associated magnitude, or;
- When the institution participate in interlab comparison programs, along with Inmetro / Cgcre, obtaining consistent results;
- Laboratories accredited by accreditation bodies of other countries, when there is mutual recognition agreement or cooperation between Inmetro / Cgcre and those bodies.

7.3 Certificates of measurement and testing of a test laboratory equipment must meet the requirements of the previous item.

7.4 The reference standards maintained by the laboratory must only be used for calibration, unless it can be shown that their performance as a reference standard is not invalidated.

8 CALIBRATION AND TEST METHOD

8.1 All instructions, standards and data relevant reference to the work of the laboratory, must be documented, kept up to date and readily available to laboratory personnel.

8.2 Laboratory may use documented procedures and appropriate statistical techniques, selection of samples, when performing the sampling as part of the assay.

8.3 The laboratory must submit the calculations and data transfers to appropriate checks.

8.4 The laboratory shall have procedures for security prevention of data from computer records.

9 HANDLING ITEMS

9.1 The laboratory shall identify uniquely the items to be tested, so there is no misunderstanding, at any time, for their identification.

9.2 The laboratory shall have documented procedures and appropriate facilities to avoid deterioration or damage to the test item during storage, handling and preparation of the test item.

10 RECORDS

10.1 The laboratory shall maintain a proper record system to their particular circumstances and must meet the applicable regulations as well as the record of all original observations, calculations and data arising, records and copies of test reports for a period of at least four years.

10.2 Changes and / or errors of records must be scratched, not removing or making illegible writing or previous note and the new annotation must be recorded next to the previous scratched, legibly, allowing unambiguous interpretation and contain the signing or initialling of charge.

10.3 The records of test data must contain at least:

a) Laboratory identification;
b) Identification of the sample;
c) Identification of the equipment used;
d) Relevant environmental conditions;
e) Measurement result and its uncertainty, where appropriate;
f) Date and signature of personnel performing the work.

10.4 All computer paper records or calculators, charts and other must be dated, initialed and attached to the records of the measurements.

10.5 All records (technical and quality) must be kept by the laboratory for safety and confidentiality purposes.

11 TEST REPORTS

11.1 The results of each test or series of tests carried out by the laboratory shall be reported accurately, clearly and objectively, unambiguously in a test report and must include all necessary information for the interpretation of test results, as required by the method used.

11.2 The laboratory must record all information necessary to repeat the test and these records must be available to the client.

11.3 All test report must include at least the following information:

a) Position;
b) Name and address of the laboratory;
c) unique identification of the report;
d) Name and address of the customer;
e) Description and identification without ambiguity of the tested item;
f) Characterization and condition of the test item;
g) Date of receipt of the item and date of the test;
h) Reference to sampling procedures as appropriate;
i) Any deviations, additions or exclusions from the test method and any other relevant information to a specific test, such as environmental conditions;
j) Measurements, checks and proceeds, supported by tables, graphs, diagrams and photographs;
k) Statement of estimated uncertainty of the test result (where relevant);
l) Signature, title or equivalent identification of staff responsible for report content and date of issue;
m) Where applicable, a statement that the results relate only to the items tested;
n) A statement that the report can only be reproduced in full and with the client's approval;
o) Item identification;
p) Reference to the specification of the standard used.

12 SUPPORT SERVICES AND EXTERNAL SUPPLIERS

12.1 The laboratory shall maintain records related to the acquisition of equipment, materials and services, including:

a) Specification of purchase;
b) Receipt inspection;
c) Calibration or verification;
d) Registration of suppliers.

ANNEX B - CRITERIA FOR CERTIFICATES OBJECTS JOINT CERTIFICATION (KIT) OR CERTIFICATION TRANSFER

1 OBJECTIVE

This Annex applies in the case of the integrator, packer and / or distributor to replace or make changes in the original packaging of the product already certified or to change the form of presentation for marketing the product in relation to the original certification process, using or taking advantage of the original product certification, for subsequent sale to the end consumer. This Annex shall not apply in the case of products already certified, which besides having changed the original packaging has been modified in its characteristics, a condition which entail as authorized by Inmetro, a new certification process.

Note 1: For text simplicity, integrators, packers and / or distributors them to arrange modifications for repackaging or training kits already certified in origin, are here called "packers".

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

2 DEFINITIONS

2.2.1 Training Kit

The training kit is characterized when the packer (transferee) integrates in the same package, two or more products already certified.

2.2.2 Fractionation

Operation characterized when the packer (transferee) performs a fractionation operation, from the bulk packing of the product, in addition to exhibiting packing return.

3 STEPS OF CONFORMITY ASSESSMENT

Packers that do not make any modification in original packaging already certified products, but that change the way of introduction to marketing the product in new packaging will be subject to certification considering all of the following except the Test Plan in this Annex.

Packers them to arrange changes in the original packaging of the product already certified, shall be subject to certification considering all the items described below. In this case, the final package must contain all the required markings in the specific RAC for the object.

For cases of integration of two or more certified products in the same package, the OCP responsible for certification transfer process must be accredited at least for the scope of the main product. In cases where the products are similar, so not getting clear the main product, the OCP responsible for certification transfer process must be accredited at least one of the scopes that are part of the *kit*.

For labeling purposes in packaging kits containing certified products that did not have its amended original packaging shall appear on the new packaging the expression: "CONTAINS REGISTERED PRODUCTS WITH INMETRO".

For kits containing certified products that has been modified original packaging the following options are considered:

a) There is clearly the main product: in this case must be on the new packaging Identification Mark of Conformity of the main product, with the number of registration kit.
b) There is no clarity of the main product: in this case must be on the new packaging of the product Conformity Identification Seal for which the OCP is accredited with the number of registration kit.
In both situations the OCP must also evaluate the item 7 of this RGCP - Complaints Handling.

3.1 Initial evaluation

3.1.1 Application Certification Transfer

The request to be sent to the OCP must be accompanied by the following documentation:

a) the packer unit address, requesting Supplier of certification;
b) National Register of Legal Entities - CNPJ, and the company's articles containing the object, the description of its activities;
c) Documentation to demonstrate compliance with item 7 of RGCP (Complaints Handling) for all brands marketed;
d) Product description fractionated or products provided in the kit;
e) Copy (s) certified (s) (s) Certificate (s) Product Compliance subjected to fractionation or products that make up the kit, within its validity;
f) Authorization particular certification transfer, signed by the holder (s) of the certificate (s) (s) of product (s) mentioned in e);
g) Photographic Documentation (s) product (s) listed in d): external and internal photos from all sides, detailing the labels, logos, warnings, inputs, outputs, drive buttons, where applicable;
h) Design or artwork of packaging (primary, secondary and / or tertiary);
i) User manual with instructions in Portuguese language, when;
j) Authorization for the use of (s) make (s), case packer is used of (s) make (s) the original certification.

Note: In the event of schedule in j), it will be the OCP verify the legal qualification of the authorization tool and the constitutive act (s) of owner (s) (s) make (s).

Note: When the user manual does not apply in the original certification, the OCP must validate and record this information in the certification process.

3.1.1.1 In the case of transfer of certification process for imported products, you must send a copy of the Import License (LI), along with the request of the certification transfer.

3.1.1.2 The documents listed in subsection 3.1.1 must have their authenticity confirmed by the OCP, with respect to the original documents.

3.1.2 Analysis of the Application and Compliance Documentation

3.1.2.1 The OCP before starting the certification transfer process, examine the request of the service viability, as well as verifying the submitted documentation. If the request is deemed unfeasible, the OCP must formally the reason for the impossibility of care and return all documentation submitted.

3.1.2.2 If any non-compliance identified in the documentation received, it must be treated as sub-item 6.2.2 of RGCP.

3.1.3 Initial Audit Management System

3.1.3.1 Upon review and approval of the application and documentation, the OCP, in agreement with the packer, certification transfer of the applicant, must schedule the completion of the initial audit the packer unit, evaluating complementary to the requirements of the Management System Quality repackaging applicable to processes in accordance with Table 1 below:

Table 1: QMS verification requirements for the packer based on the standard ISO 9001 or ISO 9001 Standard

QMS REQUIREMENTS	ISO 9001 Standard or ABNT NBR 9001
Purchasing process	7.4.1
Verification of purchased product	7.4.3
Identification and traceability	7.5.3
Product preservation	7.5.5
Control of non-conform product	8.3
Corrective action	8.5.2

Note: This review must take place regardless of the packer have certified quality management system.

3.1.3.2 If, during the audit, to be evaluated by the OCP the possibility that the original certified product may have their conformity affected by the repackaging process, the product must be tested in the items provided in the RAC object.

3.1.3.3 The OCP shall issue the audit report, recording the result of the same, with reference to this Annex. The audit report must be signed by the pack and the OCP. A copy of this report shall be made available to the packer.

3.1.4 Testing Plan Initial Package

The OCP must be responsible for preparing the Test Plan that must at least clearly define sampling, initial testing to be performed on the packaging of the product subject of transfer and acceptance / rejection criteria for these trials.

If evaluated by the OCP that certified original product had its conformity affected by the repackaging process, the test plan must include all tests required for the product in the RAC object.

3.1.4.1 Definition of the tests to be performed in Packaging

3.1.4.1.1 The tests on the packaging must be made based on the specific RAC.

3.1.4.1.2 The test laboratory must maintain evaluation of photographic record.

3.1.4.2 Defining the packaging sampling

3.1.4.2.1 For the certification of transfer, the OCP shall establish the procedure for the collection of samples (proof, counterproof and control), the object of packaging pass certification, in order to enable the tests laid down in specific RAC.

3.1.4.2.2 The OCP is responsible for the collection of samples for the tests, in accordance with its procedures.

3.1.4.2.3 The OCP must sample all models of packaging and forwarding them to the testing laboratory for analysis in accordance with the provisions of the RAC.

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

3.1.4.2.5 For the realization of tests and counterproof control, you must repeat the same sample quantity defined in 3.1.4.2.4.

3.1.4.3 Defining Laboratories for Packaging Testing
The test packaging shall be conducted in laboratories according to the requirements defined in this RGCP and specific RAC.

Note: If the evaluation of the proposed package in the RAC object, is limited to a visual assessment of it (check markings, instructions and manual), this may be executed by OCP.

3.1.4.4 Criteria of Acceptance and Rejection Packaging

3.1.4.4.1 All tested units must show compliance with the requirements of specific RAC for the object.

3.1.4.4.2 If there is approval of proof testing, the sample is considered approved. If non-compliance is found in the sample test, all tests shall be repeated in counterproof control and samples.

a) If found not to conform in counterproof, the sample is regarded as having failed;
b) If the counterproof not show non-compliance, the control sample to be tested;
c) If the control present non-compliance, the sample is regarded as having failed;
d) If the control does not show non-compliance, the sample is considered approved.

3.1.4.4.3 At the discretion of the certification applicant Supplier by formalizing the OCP, samples of counterproof control and need not necessarily be tested. In this case, there can be no disagreement on results obtained in the sample test.

3.1.4.4.4 In case of failure in the tests, the certification transfer process will be aborted.

3.1.5 Treatment of non-conformities in the Initial Assessment stage
If any non-compliance identified in the initial assessment stage, it must be treated as sub-item 6.2.5 of RGCP.

3.1.6 Certificate Issuance

3.1.6.1 Once all requirements in this Annex are met, the OCP issues the Certificate.

3.1.6.2 The Certificate, as a formal instrument issued by OCP, must contain at least:
a) Business name, full address, trade name and National Register of Legal Entities (CNPJ) certification of transfer of the object of the packer;
b) Date of issue and validity of the Certificate;
c) Name, accreditation registration number and signature of the responsible for the OCP;
d) Number(s) of the certificate(s), validity and OCP name of all certified products in the original process and included in the certification of transfer;
e) Model(s) of the product(s) that make up the kit or fractional packaging;
f) Number, date, and identification of the issuer of the packaging test report(s) issued by the laboratory.

Note: The Certificate must state, unequivocally, the operating unit of the packer which it applies.

Note: In the case of kit, the product description on the license must be preceded by the term Kit In the case of bulk to product fractionation, product description on the license must be preceded by the word *Fraction*.

"Note: The certificate must show, in highlighted letters, the phrase *Repasse de Certificação*." [Repass of Certification]

3.1.6.3 When the certificate issued is a result of the transfer of more than one original certification, its validity must be equal to the lesser validity from the licenses for products that make up the package for the ultimate purchaser. When the certificate is issued resulting from the transfer of only an original certification, its validity must be the remaining term of the original certificate.

3.1.6.4 The certificate must contain the following: "The validity of this certificate is linked to the performance of reviews of maintenance and treatment of possible non-compliance in accordance with the OCP guidelines".

"**3.1.6.5** For purposes of traceability, the mode of notating models on the issued certificate must allow identifying the model corresponding to the transferred certificate."

3.2 Assessment of Maintenance

3.2.1 Maintenance Planning Assessment

3.2.1.1 Following the granting of the Certificate, the OCP must plan audits and maintenance tests on the packaging, in order to ascertain whether the technical and organizational conditions that led to the certification of the original grant are being held.

3.2.1.2 The frequency of packer maintenance assessment shall be twelve (12) months.

3.2.1.3 OCP responsible for the transfer certification must monitor the duration of maintenance of each of the kit components, since the validity of the certificate kit maintenance will be dependent upon the certification of the validity of each of its components.

3.2.1.4 The OCP certifier shall request to each of the OCP responsible for certification of each of the products components in the kit or product with new packaging, which is reported in the suspension or cancellation of the original certificate, so that it can take arrangements about certification of the kit or product with new packaging. The opposite case is also applicable, i.e., a suspension, cancellation or *recall* action of the kit certificate shall be informed to all OCP of the original products.

3.2.2 Maintenance Audit

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

3.2.3 Maintenance Testing Plan Package

The OCP shall draw up the plan of maintenance tests of the package according to the provisions of subsection 3.1.4 of this Annex.

To achieve the maintenance tests, the OCP must necessarily collect them / buy them commercially, with each new round of tests, samples must be collected / purchased at different points of sale.

3.2.4 Treatment of non-conformities in the Maintenance Assessment stage

If any non-compliance is found in the maintenance assessment stage, it must be treated as sub-item 6.3.3 of RGCP.

3.2.5 Confirmation of Maintenance

The OCP shall issue the confirmation of maintenance after the review, including information about the documentation, audits, testing, treatment non-compliance, market surveillance and treatment of complaints, noting the relevant requirements of subsection 3.1.6 of this Annex, of that compliance with requirements has been evidenced.

The OCP shall request the original certification to the respective Confirmation(s) of Maintenance of each product subject to the division or the products that make up the kit.

Met the requirements in this Annex, the OCP issues the document entitled "Confirmation of Maintenance", formalizing that certification is maintained.

3.2.5.1 Confirmation of maintenance, as a formal instrument issued by OCP, must contain at least:

a) Business name, full address, trade name and National Register of Legal Entities (CNPJ) certification of transfer of the object of the packer;
b) Name, accreditation registration number and signature of the responsible for the OCP;
c) Number(s) of the certificate(s), the duration and the OCP of all certified products in the original process and included in the certification process transfer;
d) Type(s) of product (s) that make up the kit or fractional packaging;
e) Date of issue and validity of the Certificate;
f) Number, date, and identification of the issuer of the packaging test report(s) issued by the laboratory;
g) Issuance date of the Confirmation Maintenance.

Note: The Certificate of Conformity must indicate, in unambiguous manner, the unit of the packer it applies to.

Note: In the case of kit, the product description on the license must be preceded by the term Kit In the case of bulk to product fractionation, product description on the license must be preceded by the word Fraction.

3.3 Evaluation Recertification

The recertification assessment must be programmed by the OCP, according to the criteria established in Section 3.1 of this Annex.

3.3.1 Handling non-conformities in Recertification Assessment phase

If any non-compliance identified in the recertification evaluation stage, it must be treated as sub-item 6.3.3 of RGCP.

3.3.2 Confirmation of Recertification

Confirmation of recertification by the OCP is based on the decision after review, including information about the documentation, audits, testing, treatment noncompliance and treatment of complaints, noting that compliance with requirements has been demonstrated.

The requirements established by this Annex, the OCP issues the new Certificate.

A certificate with different numbering shall be issued to each recertification.

Note: any additional items required for the issue of a Certificate will be described in RAC.