



apcer 

**GENERAL REGULATION
FOR PRODUCT,
PROCESSES AND
SERVICES CERTIFICATION** 



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1. FOREWORD

- 1.1. APCER develops the activity of product, processes and services certification according to the applicable accreditation standards and international guides.
- 1.2. APCER has in its organizational structure an Advisory Committee, advisory body of the Administration Board, which includes members from all parties significantly interested in the development of policies and principles related to the operation of the certification system. The mission of the Advisory Committee is to safeguard the impartiality of the certification activities.
- 1.3. APCER is a body partner of IQNet (*The International Certification Network*), an international network of certification bodies.
- 1.4. APCER may use the services of APCER group companies for the provision of certification services described in this regulation, keeping in either case the existing contractual position.

2. SCOPE

- 2.1. The present regulation provides all conditions to ensure that APCER services are credible, trustworthy, and impartial and have added value. It contains the general contractual requirements in force between APCER and its clients for product, process and service certification, herein referred to as product certification, and establishes the conditions for granting, maintaining, renewing, extending, reducing, suspending and withdrawing the certification and the right to use the certification marks and licences.
- 2.2. The present Regulation has Amendments providing certain conditions applicable to some products, processes and services, hereby called Special Requirements.
- 2.3. The application to APCER for product certification implies acceptance, by the candidate Organization, of the dispositions contained in this Regulation, REG002, and applicable Special Requirements.

3. NOTICE OF CHANGES

- 3.1. APCER reserves the right to amend this document whenever the circumstances so determine it, particularly, if there are changes in the requirements defined by the accreditation bodies, changes in the standards or other applicable normative documents.
- 3.2. Any changes made to this document shall be communicated to Client Organizations, who should comply with the certification requirements and adequately implement eventual changes.
- 3.3. When justified, these changes may lead to an audit.

4. DEFINITIONS AND REFERENCES

4.1. For the purposes of this document the definitions given in the standards ISO/IEC 17000, ISO/IEC 17007, ISO/IEC 17020, ISO/IEC 17021, ISO/IEC 17065, ISO/IEC 17067, all in force, shall apply.

4.2. To facilitate the reading and comprehension of this document, the following definitions are transcribed:

4.2.1. Scope of certification – Identification of:

- The products, processes and services for which the certification is granted,
- The applicable certification scheme, and
- The standards and other normative documents, including their date of publication, which is judged that the products, processes or services comply.

4.2.2. Evaluation - Combination of the selection and determination functions of conformity assessment activities.

4.2.3. Certification - Attesting of the third part, relative to products, processes, systems or people.

Note: attesting is the equivalent to emitting proof, based on a decision that is subsequent to analysis, that the compliance with specific requirements has been demonstrated.

4.2.4. Product, process or service certification - Means of guaranteeing the conformity of these items with rules and other reference documents applicable. In the present document, the term "Product" is used in broad sense and includes processes and services. The global objective of the certification of products, processes and services is to establish trust with all stakeholders that a product, process or service fulfills the specified requirements.

4.2.5. Certification cycle - Period of time, from the certification granting until the end of the certificate validity, during which the certification body performs a set of assessment activities to verify the compliance with the requirements by the certifying Organization. At the end of the certification cycle, a new cycle may be initiated.

4.2.6. Client - Organization or person responsible to a certification body for ensuring that certification requirements, including product requirements, are fulfilled.

Note: in this Regulation, the word Organization, which can be candidate or certified, is used instead of client.

4.2.7. Internal Control - Tests and other controlled activities under responsibility of the Organization, performed by the latter or by a hired laboratory. These tests are given in the Organization quality control plan.

4.2.8. External control - Certification process testing under the responsibility of APCER, performed in an approved laboratory. May include the concession test or certification renewal and surveillance tests.

4.2.9. Declaration of compliance - Attestation, hereinafter called certificate of conformity.

- 4.2.10. Scheme owner** - Person or organization responsible for developing and maintaining a specific certification scheme.
- 4.2.11. Certification scheme** - Certification system related to specified products, to which the same specified requirements, specific rules and procedures apply.
- 4.2.12. Product** - Result of a process, which can be a service, software, hardware or processed materials.
- 4.2.13. Certification requirement** – Specified requirements, including product requirements, which are fulfilled by the client as a condition of establishing or maintaining certification.
- 4.2.14. Product requirement** – Requirement that relates directly to a product, specified in standards or in other normative documents identified by the certification scheme.
- 4.2.15. Process** – Set of interrelated or interacting activities which transform inputs into outputs.
- 4.2.16. Service** – Service result of at least one activity necessarily performed at the interface between the supplier and the customer, which is generally intangible.
- 4.3. Audit Findings** - Except as otherwise specified in the amendment to this Regulation, the following finding definitions apply :
- 4.3.1. Non-conformity (NC)** - Non fulfillment of a requirement.
- 4.3.2. Major non-conformity (NCM)** - Absence, total shortage, systematic breach of a requirement, or a situation that raises reasonable doubts regarding compliance, security and legal compliance of the product.
- 4.3.3. Opportunities for Improvement (OM)** - Findings that can identify potential areas for improvement, but that did not include specific recommendations or solutions. These findings do not call into question the ability to ensure compliance with the specified requirements.

5. CERTIFICATION SCHEME

5.1 PRODUCT REQUIREMENTS

- 5.1.1** The product, process or service certification is supported on requirements related directly to the product, process or service and usually specified in standards, regulations, technical specifications or other publicly available documents.
- 5.1.2** Where product requirements are not specified, APCER may submit a tender for its development, to be validated by a Technical Commission, together with the certification requirements.

5.2 SCHEME REQUIREMENTS

- 5.2.1** APCER provides product certification according to ISO/IEC 17065, and develops the respective certification schemes, following the guidelines for certification schemes of development as defined in ISO/IEC 17067, presented below.
- 5.2.2** Where applicable, the guidelines of ISO/IEC 17067 are supplemented or replaced by the certification scheme rules defined by the scheme owner or applicable certification scheme standards.
- 5.2.3** The specific requirements for each certification scheme are set out in the respective Special Requirements.
- 5.2.4** The declaration of compliance with standards or other applicable reference documents is made in the form of a certificate of compliance, which may include assignment of the right to use of certification marks or licenses.

5.3 TECHNICAL COMMITTEE

- 5.3.1** Where applicable, the scheme or product certification requirements can be validated by a Technical Committee comprising representative elements of the various stakeholders in the certification, in particular, representatives of producers, knowledge centers, suppliers, customers, consumers and representatives of the certifying entity, among others, so that no interest predominates.
- 5.3.2** The technical committees have the following scope of intervention and powers:
- Prepare technical specifications or certification schemes;
 - Validate in whole or in part, technical specifications or certification schemes;
 - Review and update specifications or certification schemes.
- 5.3.3** Any interested party that integrates the Committee may identify the need to update or change an existing product.

5.4 TYPES OF CERTIFICATION SCHEMES

- 5.4.1** APCER develops and documents the certification schemes of products, processes and services following the guidelines of ISO/IEC 17067, establishing different types of product certification schemes to which different rules and procedures of conformity assessment apply. They are briefly discussed below.
- 5.4.2** The scheme type 1a is the initial evaluation of one or more samples of the product, representing subsequent production items. There are no control activities after the issuance of the certificate of conformity, and later produced items are not covered by that certificate. It is often called the prototype certification or design examination.

- 5.4.3** The scheme type 1b involves the certification of a whole batch of products, following selection and determination as specified in the scheme. There are no control activities after the issuance of the compliance certificate. There is the possibility to affix conformity marking for all the constituent items of the batch, often being designated certification per batch.
- 5.4.4** In scheme type 2, the product is certified as a result of an initial assessment to one or more samples of the product, being regularly subjected to assessment activities. It involves periodically taking samples of the product from the market and subjecting them to determination activities to check that items produced subsequent to the initial attestation fulfil the specified requirements
- 5.4.5** In scheme type 3, the product and the production process are initially evaluated, being regularly submitted to determination activities involving the regular taking of sample of the product from the point of production, to verify compliance with the specified requirements. It also includes periodic assessment of the production process.
- 5.4.6** The scheme type 4 allows the combination of types 2 and 3, with the product being collected periodically from the market or from the production site.
- 5.4.7** The scheme type 5 is intended to carry out the evaluation of the product, the production process, the management system, and the impact of the supply chain on the product. The surveillance part of this scheme allows for the choice between periodically taking samples of the product either from the point of production, or from the market, or from both, and subjecting them to determination activities to check that items produced subsequent to the initial attestation fulfil the specified requirements. The surveillance includes periodic assessment of the production process, or audit of the management system, or both.
- 5.4.8** The scheme type 6 is applicable to services or processes. The assessment of a service activity includes the evaluation of intangible elements such as the effectiveness of an organization's procedures, and the evaluation of tangible elements such as inspection activities. The evaluation activities of a process may include tests and inspection of samples resulting from this process. For services and processes, follow-up activities include periodic audits to the management system and periodic evaluation of the service or process.
- 5.4.9** The development by APCER of other certification schemes satisfying different rules and activities is possible.
- 5.4.10** Certification schemes provided by APCER are described in the respective Special requirements.
- 5.4.11** Certification schemes of type 2, 3, 4, 5 and 6, and any other enabling product marking, involve the client's commitment to maintain compliance with the applicable requirements.

6. GRANTING CERTIFICATION

6.1. GENERAL

- 6.1.1. APCER provides impartial and non-discriminatory certification services, and any organization regardless of its status, size or area of activity may apply to certification.
- 6.1.2. APCER reserves the right not to provide services or maintain contractual relationships with organizations, or issue or maintain the certificate of conformity of an organization, when there are reasons stated that they can have a negative image on the reputation of APCER. Organizations that are dedicated to illegal activities or present a repetitive history of noncompliance with certification requirement for products or other similar matters are included in these circumstances, among others.
- 6.1.3. The period during which the certification is granted, as well as the evaluation activities and monitoring to verify the maintenance of the conditions which led to certification, are set out in the respective Special Requirements.

6.2. PRE-AUDIT

- 6.2.1. Where applicable, the Organization may request a pre-audit or it may be proposed by APCER.
- 6.2.2. The pre-audit is an audit of reduced time and sampling, which aims to analyze the dispositions documented by the organization and to confirm the scope of certification, briefly review the degree of compliance with the applicable requirements, collect information for proper planning of evaluation of later activities and inform the Organization on the state of preparedness for the audit of certification.
- 6.2.3. The completion of the pre-audit and the respective date are agreed with the applicant Organization. Information on the audit team and on the audit plan is sent to the Organization.
- 6.2.4. The pre-audit results in a report, which can be left at the Organization or be sent later.

6.3. APPLICATION

- 6.3.1. The certification process begins with the application by the Organization for certification of products, processes or services certification provided by APCER. To this end, APCER provides an application form that can be obtained from its services or through the website www.apcergroup.com.
- 6.3.2. The contracting of the service must be signed by authorized representatives of the candidate Organization to certification, that is, people with ability to legally bind the organization and assume for it legal commitments.

- 6.3.3.** When applying for certification, the Organization shall have implemented the requirements according to the standard to which requests the certification and there shall be evidence of this implementation.
- 6.3.4.** When the candidate Organization for certification includes more than one legal entity, only one stands out as a candidate for certification and as the certificate holder, contracting the service with APCER, according to the provisions in 6.3.2.
- 6.3.5.** The candidate Organization undertakes to provide APCER with information and documentation related to the product to be certified, considered relevant, as defined in the application documents.

6.4. APPLICATION REVIEW

- 6.4.1.** APCER reviews the application and communicates its result to the Organization.
- 6.4.2.** APCER reserves the right not to accept an application for certification of a product, process or service for which it has not yet been developed the respective certification scheme, when there are no defined product requirements, or in which it has no previous experience.
- 6.4.3.** APCER reserves the right not to accept an application if it concludes that the candidate Organization do not have the conditions to comply with this Regulation, with the applicable Special Requirements and the requirements of the reference standard, namely:
 - a)** If information on the candidate Organization and the product is not sufficient to conduct the certification process;
 - b)** If any understanding of difference between the candidate Organization and APCER is not resolved, including the agreement on the standards or other normative documents;
 - c)** If the desired scope of certification is not defined;
 - d)** If the means are not available to perform all assessment activities;
 - e)** If it is not possible to have the technical skills required for certification activities.
- 6.4.4.** In these cases, APCER communicates the reasons for non-acceptance and the Organization may, in cases a) to d), redesign the application no later than six months after the date of receipt of the written communication, without incurring additional costs.
- 6.4.5.** APCER reserves the right to terminate the certification process if, within one year after acceptance of the application, the certification audit was not performed for reasons beyond APCER's control.
- 6.4.6.** APCER reserves the right to terminate the certification process if, within two years of the date of the process acceptance, the Organization has not yet been certified for reasons attributable to it.
- 6.4.7.** The termination of the process is communicated by APCER in writing to the Organization, unless this is not possible, due to changes in contact information not communicated by the Organization.

6.5. INTERNAL CONTROL

- 6.5.1** Where appropriate and in accordance with the rules set out in the respective Special Requirements, APCER may ask the candidate or certified organization to deliver product test reports resulting from the internal control performed by the Organization, in different phases of the cycle certification.
- 6.5.2** The following conditions, subject to supplement and adequacy in the respective Special Requirements, shall be verified:
- The execution of the tests shall be performed according to standards or other specified requirements;
 - The tests shall be carried out in laboratories approved by APCER for its performance in accordance with the standards and specified requirements;
 - The tests shall be completed within the time limits eventually set out;
 - Test report shall be submitted in models approved by APCER, where applicable.
- 6.5.3** The candidate or certified Organization shall guarantee that the tested products, which originated the reports submitted to APCER, were produced in the normal course of the production process and are not the result of a procedure carried out under special conditions.
- 6.5.4** The Organization shall establish and maintain records that demonstrate that the products were tested. These records shall indicate clearly whether the product meets or does not meet the defined acceptance criteria.

6.6. EXTERNAL CONTROL

- 6.6.1** Where appropriate and in accordance with the rules, procedures and deadlines set out in the respective Special Requirements, APCER may proceed with the selection and collection of samples and with the completion of product testing for the purpose of external control in different stages of the certification cycle.
- 6.6.2** The test results are sent directly to APCER.

6.7. APPROVED LABORATORIES

- 6.7.1** The requirements for selection and approval of laboratories are established in the respective Special Requirements.
- 6.7.2** In the laboratory's qualification process, APCER ensures the compliance with the defined rules, including those related to independence and confidentiality.
- 6.7.3** The list of contracted laboratories approved for each product is available in the respective Special Requirements.

- 6.7.4** When requesting certification, the Organization allows the use of laboratories that are approved and contracted by APCER.
- 6.7.5** In case of substantiated objection, APCER can propose another approved laboratory, when feasible. APCER reserves the right to not complete the service in the absence of a sustained consent or other situation that compromises the execution of the assessment activities.
- 6.7.6** APCER reserves the right to be present during the execution of the tests, in the eventual selection or collection of samples when this is done by a contracted laboratory, to verify the conditions in which these activities are completed, respective records and files.

6.8. TESTING ANALYSIS RESULTS

- 6.8.1** When the results of the testing reveal nonconformities with the applicable requirements defined for the certification of the product, APCER requests a corrective action plan to the Organization.
- 6.8.2** The corrective action plan presented by the Organization shall identify for each non-conformity the investigation of the cause, the planned actions, deadlines for implementation and those responsible for them.
- 6.8.3** The Organization shall send the corrective action plan within 30 days of notification from APCER.
- 6.8.4** The Organization shall inform APCER of the closing of corrective actions, so that APCER can plan and collect new samples of the product In order to repeat the tests.
- 6.8.5** APCER reserves the right to request supplementary testing considered relevant.

6.9. TREATMENT OF NON-CONFORMING PRODUCTS

- 6.9.1** When testing results performed by APCER or by the Organization reveal that the product does not comply with the specified applicable requirements, the Organization shall initiate appropriate actions for their treatment and to prevent the delivery of nonconforming product.
- 6.9.2** Products or batches of non-conforming products shall be identified and segregated.
- 6.9.3** If products have already been shipped to a customer, a notification process shall be triggered. The records resulting from the notification process of the Organization shall be maintained.
- 6.9.4** When applicable, communication actions or recall of products shall be initiated, and APCER shall be informed of their occurrence.
- 6.9.5** If a nonconforming product has been corrected, assessment activities or tests shall be repeated and records maintained.
- 6.9.6** Additional dispositions defined in the respective Special Requirements or certification schemes shall be followed.

6.10. AUDIT TEAM

- 6.10.1** When an audit is set, APCER communicates in writing the establishment of the appointed Audit Team (AT), requesting its acceptance to the Organization.
- 6.10.2** The audit team includes a lead auditor and one or more auditors, including technical experts. The size and composition of the audit team depends of various factors, including the requested scope of certification.
- 6.10.3** The Organization can object to any particular appointed auditor. For that, the Organization shall fundament in writing its reasons, in a 5 days period after receiving the communication. After that time, if the Organization does not oppose, the AT is considered accepted.
- 6.10.4** If APCER considers valid the reasons presented by the Organization, other auditor is appointed. If the objections raised by the Organization prevent the audit conduction by qualified auditors, APCER reserves the right to cancel the certification process for non-feasibility.
- 6.10.5** The candidate Organization expressly recognizes the independence of the AT and undertakes to refrain from any deals with the AT or entities related to it, which can compromise its independence, including the request for advice or other, two years before and two years after the service, as agreed between the APCER and the Audit Team.
- 6.10.6** The lead auditor is responsible for coordinating the audit and for communication between the Audit Team and the Organization, in particular in defining the audit dates and sending the audit plan, drawn up based on the analysis of the submitted documentation.
- 6.10.7** Observers may be included in the audit team, without additional costs for the Organization, but do not participate in the audit. The observers can be:
- APCER's auditors in a qualification process;
 - APCER's auditors that are "Supervisors" included in the auditors' supervision process, this is, in situ evaluation of auditors' performance;
 - Auditors of the accreditation bodies, regulators or schema owners, as part of accreditation, notification and recognition procedures of APCER.
- 6.10.8** APCER communicates beforehand the participation of any observing element in the audit.
- 6.10.9** The organization must be available to the Audit Team during the audit and contribute to it, informing about all the facts relevant to the assessment of the product.
- 6.11 INITIAL AUDIT** The certification audit aims to determine if the organization meets all the established requirements.

- 6.11.2** Whenever a failure to meet the defined product requirements is verified during an audit, APCER assesses whether the organization has implemented actions for the treatment of non-conforming products.
- 6.11.3** According to the applicable conformity assessment scheme, the audit shall be held within four months after the date of the decision of acceptance of the application process, except in duly justified cases.
- 6.11.4** Depending on the applicable certification scheme, the certification audit may take place in a single moment or in two phases, as described in the respective Schedule.

6.12 AUDIT REPORT

- 6.12.1** The audit results in a report, owned by APCER, and prepared by the Audit Team.
- 6.12.2** The findings recorded in the audit report are classified as defined in 4.3.
- 6.12.3** The audit report is presented at the audit closing meeting and one copy of the report is delivered to the Organization.
- 6.12.4** Any diverging opinions regarding the audit findings or conclusions that cannot be solved and clarified at the closing meeting are recorded in the audit report and submitted to APCER for review and decision.
- 6.12.5** The audit report is approved by APCER and can be subject to changes as result of additional clarifications requested to the Audit Team.
- 6.12.6** The Organization submits to APCER a corrective action plan until 30 days after the conclusion of the audit, identifying for each nonconformity and major nonconformity a root cause analyses, correction and corrective action taken or planned to be taken, the deadline and the person responsible for it.
- 6.12.7** There is no need for an answer to the audit report when there aren't recorded any NC, MNC or other findings that required additional clarification.
- 6.12.8** The Organization shall submit to APCER evidence of the implementation of corrections and corrective actions of MNC, NC or other findings and response to any clarifications requested.
- 6.12.9** For MNC, evidence of proper implementation of proposed corrective actions and the evaluation of their effectiveness must be submitted.
- 6.12.10** Unless otherwise specified in the Special Requirements, the corrective actions to NC and MNC shall be implemented by the Organization within 6 months following the last day of the audit. In exceptional situations, the Organization can propose a new deadline, presenting the reasons to APCER, to whom the analysis and decision on the matter is trusted.

6.13 CERTIFICATION DECISION

- 6.13.1** The Audit Report, the Corrective Action Plan and respective evidences of implementation are assessed by APCER.
- 6.13.2** The decision over certification can be positive or negative.
- 6.13.3** A positive decision is made when:
- The corrective actions proposed by the Organization are considered adequate, prompt and implemented effectively (proved through a new audit or by other appropriate means of verification);
 - For major non conformities (MNC), evidences that the proposed actions had been implemented and an evaluation of the effectiveness has been made should be presented;
 - When applicable, the results of the product's testing comply with the applicable requirements, defined in standards or technical specification;
 - If any nonconformity in the product has been identified, the corrective actions proposed by the applicant organization are effective and ensure compliance with the requirements, confirmed by repeat testing.
- 6.13.4** The verification of the evidence of MNC corrective actions implementation can be of documental character or through conducting a follow-up audit.
- 6.13.5** In case of a negative certification decision, APCER substantiates the reasons for that and may propose a follow-up audit to be completed within one year.
- 6.13.6** The certification decision is communicated in writing to the Organization within one month from the date of receipt of all necessary information, except in duly justified cases.

6.14 CERTIFICATE, USE OF CERTIFICATION MARKS AND LICENSES

- 6.14.1** After a positive certification decision, APCER issues a Certificate and authorizes the certified Organization to use the certification marks, according to the procedure “General rules for using the certification mark” or other applicable trademark use documents, whose access is available from APCER or schema owner.
- 6.14.2** Each certificate has a validity period defined in the Special Requirements. Its validity and its scope can be confirmed through contact with APCER.
- 6.14.3** After the period of validity, the certificate will be renewed for a period similar to the first, where applicable.
- 6.14.4** Copies of certificates or other documents relating to the certification, provided by the Organization to third parties, shall be fully reproduced.
- 6.14.5** The Organization shall use the Certification Mark in accordance with the defined rules and shall make no reference to product certification that might damage the reputation and image of APCER.

- 6.14.6** The Organization shall not make any statement or claim related to certification of its product that can be considered misleading or unauthorized.
- 6.14.7** When the conformity assessment scheme entitles the use of Marks or licenses that are not APCER property, they must be used in accordance with the rules set by the owners of the marks.
- 6.14.8** In no circumstances, the certification mark shall be used outside the scope of certification identified in the Certificate.
- 6.14.9** APCER verifies the proper use of the certification marks and certificate in surveillance and recertification audits and monitoring actions during surveillance activities.
- 6.14.10** The misuse of Certification Marks by the Organization can be brought to the attention of APCER by an interested party.
- 6.14.11** The improper use of the Certification Mark or breach thereof expressed in the document "Rules for the Use of APCER Certification Mark" gives rise to the identification of non-conformity, and the Organization shall trigger the necessary actions for its correction.
- 6.14.12** The abusive use of the Certification Mark or the Certificate, by the certified Organization or third parties, gives the APCER the right to take, the actions he considers appropriate under the current legislation, including legal action.

7 SURVEILLANCE AND RECERTIFICATION

- 7.1** Where appropriate and in accordance with the dispositions of the Special Requirements of the certification scheme, a set of monitoring and control activities during the period of validity of the certificate is defined and carried out by APCER.
- 7.2** The purpose of the surveillance activities is to verify that the Organization maintains the conditions that led to the certification and ensures compliance of the requirements in order to maintain certification.
- 7.3** Control activities may include, among others, conducting periodic surveillance audits during the certification cycle, recertification audits at the end of the certification cycle, short-notice audits or unannounced audits, mystery visits, periodic sampling and testing of the product.
- 7.4** The Organization shall establish, in response to the audit report, a plan of corrective actions to be submitted to APCER within 30 days after the last day of the audit, identifying for each Non-Conformity (NC) or Major Non-conformity (MNC) the root cause analysis, correction and corrective action taken or planned, the defined deadline and responsible for them.
- 7.5** Unless otherwise specified in the Special Requirements, the corrective actions to NC and MNC shall be implemented by the Organization within 4 months following the last day of the audit. In exceptional situations, the Organization can propose a new deadline, presenting the reasons to APCER, who is responsible for the analysis and the decision on their acceptance.

- 7.6** Audit reports, test results and corrective action plans submitted by the Organization are analyzed by APCER, which takes a decision on the maintenance of the certificate.
- 7.7** Depending on the results, the decisions can be:
- 7.7.1** Maintenance of certification:
- No comments;
 - With increased frequency of audits or sampling and testing, or other changes of control activities;
- 7.7.2** Conducting additional controls, such as a follow-up audits to verify the implementation of remedial actions proposed or other additional activity control;
- 7.7.3** Application of one of the sanctions described in Chapter 9.
- 7.8** If APCER decides that a follow-up audit is needed to verify the effective closure of corrective actions, this usually occurs after a period of implementation of these actions, not replacing the audit from the certification cycle.
- 7.9** APCER reserves the right to apply immediate sanction in case it concludes, through examining the audit or test results report, that the conditions to maintain certification are not met, not waiting for the implementation of corrective actions.
- 7.10** APCER may suspend the certification if the certified organization does not present a response to the audit report within 30 days after the last audit day, nor evidence of the implementation of appropriate corrective actions in time.
- 7.11** Following the surveillance and recertification monitoring, APCER will communicate, in writing, the results of that evaluation.

8 SPECIAL AUDITS

8.1 EXTENSION AUDITS OF THE CERTIFICATION SCOPE

- 8.1.1** APCER considers extensions to the certificate all the applications of the certified Organization regarding the enlargement of the certification scope already granted, that is, new products or new sites.
- 8.1.2** Requests for certification scope extension are formalized by the certified Organization through a new application for certification following the dispositions of the correspondent section.
- 8.1.3** The extension audit can be conducted during a surveillance or recertification audit and it may be necessary to adjust the duration of that audit.

8.2 SHORT-NOTICE AUDITS

- 8.2.1** Short-notice audits can be carried out in the following situations:

- Investigation of complaints received by APCER on the activities or products covered by the scope of certification of the Certified Organization, that raise significant doubt about the effectiveness and conformity with the applicable requirements;
 - Decided by APCER following the analysis of the results of monitoring activities when they do show major non-conformities or a set of non-conformities that raise relevant reasonable doubt to compliance and safety of the product;
 - Changes in the Organization.
- 8.2.2** The audit team and dates are communicated in writing to the Organization within a maximum period of 10 days to its start.
- 8.2.3** The certified Organization has the obligation to pay all costs of the short-notice audits. The Organization is committed to ensure APCER free access to its facilities, reserving APCER the right to make unannounced visits, if circumstances so warrant.

9 SANCTIONS

9.1 GENERAL

- 9.1.1** The failure of the conditions established in this Regulation, as well as of the terms of the application form, by certified Organizations may be subject to sanctions, for which APCER shall consider the seriousness of the breach, persistence and repetition of the same.
- 9.1.2** When a noncompliance with the certification requirements are substantiated, applicable sanctions can be the maintenance of certification under specific conditions imposed by APCER, such as, for example, enhanced vigilance or additional actions, temporary suspension, reduction in the scope for removal of variants of non-compliant products, or the withdrawal of the conformity certificate.
- 9.1.3** The sanctions imposed are always communicated to the certified Organization in writing by registered letter with acknowledgment.
- 9.1.4** The implementation of a sanction does not give the Organization any right to reimbursement of the payments made until this date, nor does it relieve the Organization of the obligations resulting from the sanction.
- 9.1.5** The removal of sanctions may involve, as appropriate, audit activities, testing, decision, and reissue of the certificate, monitoring and information, which assess compliance with all the requirements of the reference standard. These activities do not a substitute audits in certification cycle.
- 9.1.6** In the event of the temporary suspension, reduction of the scope or withdrawal of the certificate, APCER makes any necessary changes to the certification formal documents, public information, and authorization for the use of trademarks, in order to ensure that it does not

provide any indication that the product continues to be certified. The Organization bears the cost of such changes.

9.2 TEMPORARY SUSPENSION OF THE CONFORMITY CERTIFICATE

9.2.1 The temporary suspension of the certificate applies whenever there is one or more of the following situations:

- Changes in the certified organization that raise reasonable doubts on the confidence of the system or product (security and compliance);
- Persistent or serious failures to fulfil the certification requirements revealed in the system or product;
- Major nonconformities whose corrective actions were not properly implemented within the agreed deadlines;
- Failure in implementing required corrective actions within the maximum deadlines established in the present Regulation or in the applicable Specific Requirements;
- Absence of response to the audit report through a corrective action plan, in the terms established in the present Regulation within the prescribed period;
- Not allowed by the certified Organization to perform the audits in the terms established in the present Regulation and the applicable Specific Requirements;
- Failure within time frame stipulated by APCER, of the implementation of the changes arising from the review of standards and / or other applicable reference documents;
- Failure to comply with financial obligations towards APCER by the certified Organization;
- Repeated absence of response to contacts;

9.2.2 The maximum period of suspension is six months, but the grounds for such suspension may impose a longer period. After this period, without changing the causes that motivated the suspension, the withdrawal of the product certification will take place, except in duly justified cases. The removal of the suspension to product certification will always be decided by the Decision Committee.

9.2.3 The temporary suspension of certification implies the prohibition of use of the certificate and the certification marks issued by APCER as well as any reference to the certified product.

9.2.4 The suspension is communicated to the client, together with the actions required for its termination and product certification replacement, according to the respective certification scheme.

9.2.5 The revalidation of a suspended certificate implies the performance, as appropriate, of audit activities, testing, decision, certificate reissue, monitoring and information, to assess compliance

with all the requirements of the reference standard, and does not replace the certification cycle audits.

- 9.2.6** After the revalidation of the suspended certificate, and to the applicable extent, the certification cycle is recovered, the expiring date of the certificate is kept and is restored the authorization of the use of certification marks.
- 9.2.7** APCER may decide that the revalidation of the suspended certificate involves reducing the scope of certification, and the decision is communicated to the client and specified in the certification documentation and public information.
- 9.2.8** Information about the suspension of the certification, the revalidation of the certificate or reduction of scope is public.

9.3 SCOPE REDUCTION OR WITHDRAWAL OF THE CERTIFICATE

- 9.3.1** The scope reduction or withdrawal of the conformity certificate generally occurs when the problems that led to the temporary suspension are not resolved in the deadlines established by APCER.
- 9.3.2** The withdrawal of the certification happens due to the complete rupture of trust in the certified product or major violation of the REG002 dispositions, namely:
- Non-acceptance or non-implementation of changes to the certified product due to changes of standards or other applicable documents of product and certification requirements;
 - Non-compliance of deadlines set for implementation of actions in order to lift the suspension;
 - Non closing or ineffective closing of corrective actions for non-conformities identified, or other situation that configure the continued failure of the certification requirements;
 - Recidivism of non-conformities that previously led to a decision of suspension;
 - Cessation of the product manufacturing or availability of the service;
 - Improper or abusive use of certification marks;
 - Failure to meet the commitments of a financial nature.
- In the case of cancellation of the Certificate, the Organization shall return to APCER the original Certificate and any copies certified by APCER. The Organization may not use copies or reproductions thereof and must withdraw from its technical documentation and advertising any reference to certification or the Certification Mark granted by APCER, and withdraw from the product the Certified Product brand, since it is not a possible cause for annulment of the certification but a consequence.
- 9.3.3** In the case of cancellation of the certification, APCER proceeds to the cancellation of the Certificate and removes the reference to the certified product in any disclosure document APCER, and public information on the cancellation of certification.

- 9.3.4** In order to permit the disposal of products previously marked as "certified product" and not yet commercialized, APCER may grant, communicated in writing upon request of the Organization, deadlines for these to be marketed. Exceptions are all situations that put into question the safety of the consumer or user.
- 9.3.5** When the Organization, fails greatly, persistently or repeatedly in meeting the certification requirements, APCER can reduce the Organization's approval scope to delete the parts that do not meet the requirements, provided that the reduction is in accordance with the requirements of the reference standard.

10 VOLUNTARY SUSPENSION, REDUCTION OR WITHDRAWAL OF THE COMPLIANCE CERTIFICATE

- 10.1** The certified Organization may request a temporary suspension, a reduction of the scope or the withdrawal of the certificate.
- 10.2** The suspension or withdrawal requests shall be addressed to APCER by registered letter with acknowledgment of receipt, within a minimum of 60 days, except in force majeure cases, prior to the date of effect of the voluntary suspension or withdrawal.
- 11** In any case the suspension or withdrawal requests release the certified Organization from the obligation to proceed with the payments due to APCER and do not give the Organization the right to reimbursement of payments made by that date.
- 11.1** The voluntary suspension period is agreed between APCER and the Organization and determined by the motivations that led to the voluntary suspension.
- 11.2** Once the suspension, reduction of scope or withdrawal of the certificate is deferred by APCER, the dispositions defined for the subsequent actions in Section 9 are to be applied.

12 COMPLAINTS AND APPEALS

- 12.1** The Organization shall keep a record of all complaints received regarding compliance with product requirements covered by the certification. Records of complaints and documentation of actions taken must be available to APCER upon request. The Organization shall ensure that the AT has access to existing claims and the respective treatment.
- 12.2** The complaints addressed to APCER can be related to the service provided by APCER or complaints about Organizations certified by APCER.
- 12.3** The complaints and appeals are dealt according to procedures established for this purpose, which are publicly available.
- 12.4** Complaints received by APCER regarding organizations it has certified, under the scope of the respective certificates, are communicated to the certificate holders, investigated by APCER and may lead to additional actions.

- 12.5** The certified organization commits to promptly cooperate with APCER throughout the complaints research process eventually received about the organization, and any additional actions that APCER deems necessary.
- 12.6** APCER considers as an appeal any claim made by the certificate holder regarding the certification decision. The appeal must be submitted within 30 days of the decision's notification.
- 12.7** Appeals are assessed by the Appeals Committee of APCER, composed of independent elements of the case under review, with no appeal from the decisions of this Commission.
- 12.8** If the decision of the Appeals Committee is not favorable to the appellant, the cost of the appeal, any actions and travel expenses, will be charged to him.

13 POSTPONEMENTS

- 13.1** Postponements concerning the audit planning are not allowed, except in exceptional and duly justified cases.
- 13.2** Any postponement request that goes beyond the period between audits defined by APCER, or any unavailability of the Organization for planning and conducting the audit can lead to the decision of suspension of certification, as defined in point 8 of this Regulation.
- 13.3** The cancellation by the Organization of a scheduled audit, with 15 days or less from the planned date is subject to a penalty payment of 50% of the cost of that audit and charges that may occur with sampling, hiring tests or other.

14 CONFIDENTIALITY

- 14.1** APCER controls access and manages as confidential all information, data and documents of the Organization obtained during the certification process, at all levels of its structure, including audit team composition, commissions and bodies or external people that act in the name of APCER. APCER also manages as confidential the information of the Organization from sources other than itself (e.g., entities presenting complaints, regulatory body).
- 14.2** APCER or its representatives can subscribe and accept additional requirements of confidentiality, on Organization's request.
- 14.3** If any additional requirements of confidentiality prevent the execution of conformity assessment or may not be ensured, APCER reserves the right not to provide the service.
- 14.4** There shall be no duty of confidentiality in the following cases:
- When the information received is in the public domain;
 - When the information is not confidential because it was publicly disclosed by the Organization;

- When it concerns the fulfilment of a legal obligation or binding orders issued by competent authorities, including courts or courts of arbitration.

14.5 APCER undertakes to inform in advance the Organization of the information to be made available to the public domain, in addition to that transmitted in this Regulation and in the applicable Special Requirements. When the disclosure of confidential information by APCER is required by law or authorized by contractual arrangements, the client organization or person concerned will be notified of the information provided, unless prohibited by law.

14.6 APCER reserves the right to provide confidential information to representatives and auditors of accreditation bodies, in order to provide documentary evidence of compliance with the standards and / or procedures of the certification activity, which are also subject to the duty of confidentiality, in cases involving the fulfilment of legal obligation or binding orders issued by competent authorities, courts, legal or arbitration, or administrative bodies or services.

15 INFORMATION

15.1 The updated information on the certificates of conformity issued, suspended or canceled is available on the APCER's website www.apcergroup.com.

15.2 This information includes the identification of the organization, the standard, the scope of certification and the geographical location (city and country) of the Organization, and may be supplemented by other information defined in the applicable Special Requirements.

15.3 The information concerning the withdrawn certificates is made available during a year, after the certificate is cancelled.

15.4 APCER, upon request of the Organization, confirms the validity and scope of a particular certification.

16 NOTIFICATION OF CHANGES BY THE ORGANIZATION

16.1 The certified Organization shall maintain compliance with the applicable requirements for the validity of the respective certificate of conformity.

16.2 The certified Organization agrees to inform APCER without delay, of any major changes that affect the ability to meet certification requirements, such as:

- The legal, commercial, organizational status or ownership, including changes of legal name or address;
- Organization and management such as key personnel and organizational structures related to the scope of certification;
- Relevant changes to the products and services included in the scope or method of production or supply thereof;

- Significant changes to the quality management system and procedures, where applicable;
- Changes of the persons designated to establish contact or in the form of contact with the APCER;
- Changes in the head office addresses and other permanent sites which may fall within the scope of approval.

16.3 When appropriate, these changes can imply conducting a special audit or another control action.

17 FINANCIAL OBLIGATIONS

17.1 The certification process involves the payment of the costs associated with the different assessment activities (application review, preliminary visit if applicable, and audit), which are invoiced when the services are provided, and are an obligation of the Organization, regardless of the results.

17.2 APCER reserves the right to not issue a certificate until the settlement of invoices concerning the assessment process.

17.3 APCER may, in any phase of the certification process, demand advance payments of the certification activities to be conducted.

17.4 APCER reserves the right to, at any stage of the certification process, to cancel the process and suspend or withdraw the certificate, when the financial obligations of the Organization to APCER are not settled in time, without prejudice to the use of the legal means at APCER disposal.

18 CERTIFICATE RECOGNITION AND TRANSFER

18.1 APCER accepts the transfer of certificates from other certification bodies accredited within the rules internationally set out for this purpose, and defined in the Special Requirements, where applicable.

19 RESPONSIBILITY

19.1 APCER is not responsible before third parties for any personal, material or intangible damage, resulting directly or indirectly from the activity of of the certified Organization.

19.2 The Certificate is issued according to methodologies internationally recognized and proves that the certified Organization has implemented the product requirements and the applicable certification scheme that has been found, based on the audit sampling and any subsequent information, to be in compliance with the established requirements in the applicable standard and that is capable of maintaining its performance. APCER is not responsible, in any case, for any actions or eventual mistakes of the certified Organization

- 19.3** Certification by APCER does not absolve in any case the Organization of the detention of warranties and liabilities relating thereto as the current legislation obliges, whatever product is certified. APCER is not responsible, in any case, for any noncompliance by the certified Organization of current legislation or noncompliance derived from the Organization's activity.
- 19.4** APCER is not responsible in the case a third party does not recognize or recognizes partly the certificate issued by APCER.
- 19.5** As a result of default or defective compliance of the contract that is celebrated with the Organization, it shall not be required from APCER a compensation superior to the costs of the respective services, except in situations of deceit or serious fault.
- 19.6** Except as established in the law as mandatory, APCER is not responsible for acts committed by the people used to fulfil the obligations under this contract, except in situations of deceit or serious fault.