PRODUCT CERTIFICATION REGULATION

RG-01i V22

Responsible	Version of the document	In force since
Certification Coordinator	22	May 4th 2020

Changes to the document	
Cause of change	**Change made on V21 (may 4th, 2020)**
Change in organizational structure General document review	• The responsibility of the certification director is changed to the certification coordinator. • In numeral 5.3.4 literal G, is clarified that test witnessing is required for the client's non-accredited laboratory according to procedure PR-09 • In definitions, a definition of a type test is added
Cause of change	**Change made on V20 (September 20th, 2019)**
External Audit	• External Observer is defined and consequences are clarified in case of not accepting the participation of external observers. (6.1.2 numeral 3) • Causes of reduction are added by change in the normative referents. (5.4 E) • FRG-02-05 contract is eliminated and definition of commercial proposal to contract is extended. Numerals 12 are added. Confidential information, numerals 5.4 of trademark use and 5.8 Notification of changes by contract elimination are completed, definitions are added • Conditions to deny certification are reviewed because they do not have authorization to use the brand. (5.4 Literal F) It is clarified that the transfer of the certificate does not imply modification of the certificate. (6.1.1 numeral 6) The marketer's obligation to submit the manufacturer's declaration on the changes made to the certification is added (6.1.2 numeral 29)
Cause of change	**Change made on V19 (June 30th, 2019)**
Internal Audit	• In 5.3.4 Complaints and claims assessment is included for schemes 1a and 1b. Brand use evaluation is eliminated in diagrams 1a and 1b. • Duties of the clients were documented in the FRG-02-05 was included in this document for greater clarity. • Rate information is entered and the way how QCERT obtains the resources to operate in 6.1.2. • Duties are entered before the expiration of ISO 9001 and to replace the units that are taken from the market for evaluation or to assume the cost in 6.1.2

	• In section 5.3.4 Evaluation of the QMS, was modified the conditions to accept the Iso 9001 Certificate. • In section 5.3.4, section H, was included the conditions to accept test report and was clarified that the review of the test reports on several times could generate additional costs. • In section 6.1.1 the right to give the certificate and the terms for doing it were included. • PR-12 Appeals was included. • In numeral 10 was included the condition to be registered as manufacturer or importer in the Superintendence of Industry and Commerce – SIC to emit the certificate with reglementary scope • in section 5.3.1, section G was clarified the methodology for the evaluation of non-accredited laboratories. • In Numeral 5.7 was defined that the surveillance must be completed at the expiration of the annuity and that the validity and surveillance may change according to the provisions of the technical regulation.

Made by	**Reviewed by**	**Approved by**
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Contenido

1. OBJECT

Establish guidelines for the granting, maintenance, renewal, amendment, withdrawal or suspension of certification of products and the commitments made by both the certification body and the client during the term of certification.

2. SCOPE

This regulation establishes the conditions governing the provision of product certification, defines the duties, rights and obligations of both client and agency QCERT for the following schemes of certification:

- Scheme 1a.
- Scheme 1b.
- Scheme 5.

3. REFERENCES

This regulation is based on the requirements of the NTC-ISO-IEC 17065 and NTC-ISO-IEC 17067 and it is part of the contractual requirements that must be signed by the Holder of the certification and QCERT.

RG-02, Implementing Regulation
RG-03, Certification Committee Regulation.
RG-04, Regulations governing use of a mark of QCERT.
NTC-ISO-IEC 17065: 2013 Conformity assessment. Requirements for bodies certifying products, processes and services.
NTC-ISO-IEC 17000:2005 Conformity assessment. Vocabulary and general principles.
NTC-ISO-IEC 17007, Conformity assessment. Guidance for drafting regulatory documents suitable for conformity assessment.
NTC-ISO-IEC 17067: 2013 Conformity assessment. Basics for certification products and guidelines for product certification schemes.
NTC/ISO/IEC 17020, Conformity assessment. Requirements for the operation of various types of bodies performing inspection.
NTC/ISO/IEC 17021, Conformity assessment. Requirements for bodies providing audit and certification of management systems.
ISO/IEC 17025 Conformity assessment. General requirements for the competence of testing and calibration laboratories.

GTC 19011 Guidelines for auditing management systems.

4. GLOSSARY

In order to facilitate the comprehension of the terms related through the present document and its annexes, some definitions are given below:

Accreditation body: Body with authority that grants accreditation.
Appeal: Requirement made by the provider of the evaluation object Application provider object to the conformity assessment body conformity assessment or accreditation body, to reconsider the decision I make in relation to the object.
Attestation: Issuing a statement, based on a decision made after the review, it has been shown that the specified requirements are met.
Assessment Program: A set of one or more evaluations planned for a period of time determined and directed towards a specific purpose**.**
Audit/ Evaluation: Systematic, independent and documented process for obtaining records, statements of fact or other relevant information in order to be objectively evaluated to determine the compliance with the requirements to be fulfilled.
Body conformity assessment: Services company that performs conformity assessment.
Certification: Attestation third party on products, processes, systems or persons.
Certification Committee: Person assigned for QCERT to make the decision on certification and who has not been involved in the evaluation process, this person is part of a professionals and qualified group for the review and attestation.
Competence: Personal attributes and demonstrated ability to apply knowledge and skills.
Complaint: An expression of dissatisfaction, other than appeal, filed by a person or organization to a conformity assessment body or accreditation body, relating to the activities of that agency, for which a response is expected.
Commercial Proposal: Document that is understood as a contract, which describes the request for products to be certified, the value for the service, the applicable standard, regulation or reference and the type of certification requested (among others). When this proposal is mentioned, it will be understood that it also refers to the follow-up or renewal notices**.**
Confidential information: Information communicated by any of the Parties in any form or medium including verbally, electronically, visually, in writing or in any other way, identified as confidential and / or property of the Party that discloses it.
Contract: Understand any commercial proposal accepted by the client, tacitly or expressly.
Conformity Assessment: Demonstration that specified the achievement of the requirements relating to a product, process, system, person or body.
Conformity assessment schemes: On specific objects of conformity assessment, which the same specified requirements, rules and procedures apply.
Corrective actions: Actions which aims to eliminate the cause of a detected nonconformity and prevent recurrence.
Evaluation criteria: Set of policies, procedures or requirements. The evaluation criteria are used as a reference in order to compare the evidence of the assessment.
Evaluation team: Two or more evaluators conducting an evaluation. One of the evaluators of the evaluation team is going to be designated as the same leader. The evaluation team includes training evaluators.
Evaluation *in situ:* Evaluation made in the applicant or/and manufacturer installations.
Evaluator: Person with the competence to conduct an assessment.

Evidence of evaluation: Records, statements of fact or other information that is relevant to the evaluation criteria and is verifiable. Evidence can be qualitative or quantitative.
Format: Document used to record the data required by the QMS.
Findings: The results of the evaluation of the evidence gathered against the evaluation criteria. The evaluation findings can indicate either conformity or nonconformity with the evaluation criteria as opportunities for improvement.
Format: Document used to record the data required by the QMS.
Inspection: Examination of the design of a product, process or installation and determination of it conformity with specific requirements or on the basis of professional judgment, with general requirements.
Monitoring/Follow-Up: A systematic repetition of conformity evaluation activities in order to keep the validity of the conformity declaration.
Multilateral agreement: Agreement between two or more parties under which each party recognizes or accepts the results of conformity assessment of other parties. **Scheme Type 1a:** In this scheme one or more product samples are subjected to determination activities. A certificate of conformity it is issued or other declaration of conformity for the product type, whose characteristics are defined in the certificate or in a document referred to in the certificate. The subsequent production elements are not covered by the attestation of conformity of the certification body**.**
Scheme Type 1b: This type of scheme involves the certification of an entire product batch, immediately after the selection and determination as specified in the scheme. The proportion that it is to be tested, may include all units in the lot (test 100%), would be based, for example in the homogeneity of the items in the lot and implementation of the sampling plan, where suitable. If the result, revision and definition are positive, all items in the lot can be described as certificates and may carry the conformity mark.
Scheme Type 5: The monitoring part of this scheme allows the choice between making periodic sample of the product from either the point of production, market, or both and submission to the determination activities to verify that the elements subsequently produced the initial attestation meeting the specified requirements. Monitoring includes periodic evaluation of the production process, the audit management system, or both. The extent to which the four run surveillance activities may vary for a given situation, as defined in the scheme. If monitoring includes the audit management system, it will be necessary an initial audit of the management system.
Scope of the attestation: Extension or characteristics of conformity assessment objects covered by attestation.
Technical Standard: Document, established by consensus and approved by a recognized body that provides for common and repeated use, rules, guidelines or characteristics for activities and their results, aimed at achieving the optimum degree of order in a given context. Technical standards should be based on the consolidated results of science, technology and expertise and its objectives should be the optimum benefits for the community.
Procedure: Specified way to carry out an activity or process.
Product: Result of a process.
QCERT: Quality Certification. Conformity Assessment body, which resources come from private capital and the fulfilment and supply of product certification services.
Quality Management System: Rules, procedures and management for carrying out conformity assessment.
Review: Verification of the suitability, adequacy and effectiveness of selection and determination activities, and the results of these activities, with regard to compliance with specified requirements, related to an object of conformity assessment.
Requirement specified: Need or expectation established.

Regulatory bodies: The regulatory bodies for product certification services are the Accreditation of Colombia - ONAC and the Superintendence of Industry and Commerce - SIC.
Remove: Action to annul the declaration of conformity.
SGC: Refers to a Quality Management System (QMS).
Suspension: temporary invalidation of the declaration of conformity for all or part of the attestation specified range.
Type tests: They are considered in the first instance, those that are cited in the product standards as such, which define them as those that are carried out in the product design and development stage and it is not required to perform more than once, unless there are changes in its construction and/or design.
When the technical standard does not determine what the type tests are, QCERT will consider a type test to be one that meets one or more of the following conditions: a) the cost of the type test exceeds 50% of the total cost; b) the test execution time is greater than 15 days and c) the availability of the laboratory to execute the test is greater than 1 month, d) When the parameter evaluated by the test may be affected by the way the product is manufactured.

5. DESCRIPTION OF THE CERTIFICATION PROCESS

5.1 TYPES OF SCHEMES OF PRODUCT CERTIFICATION

The certification body QCERT responds to certification product requests in accordance with the guidelines established in this regulation. The product certification schemes are developed by defining specific activities for each of the applicable functions, which are described in the following table:

TABLE 1 PRODUCT CERTIFICATION SCHEME OFFERED BY QCERT SAS

Functions and activities of conformity assessment within product certification schemes		**Types of schemes**		
		1a	**1b**	**5**
I	**Selection** includes planning and preparation, specification requirements such regulatory documents, and sampling as applicable	X	X	X
II	**Determination** of characteristics, as applicable, by: a) Test b) Inspection c) Assessment Design d) Services Evaluation Process or e) Other activities of determination such as verification	X	X	X
III	**Review:** Review of the evidence of conformity obtained during the determining step to establish whether the requirements have been met.	X	X	X
IV	**Decision on certification** Granting, deny, maintenance, extension, reduction, suspension, withdrawal of certification.	X	X	X
V	**Attestation, License**			
	a) Issuance of a certificate of conformity or other declaration of conformity (attestation)	X	X	X
	b) Granting the right to use certificates or other conformity declarations	X	X	X
	c) Issuance of the certificate of conformity for a batch of products		X	
	d) Granting the right to use the marks of conformity (license) based on surveillance (VI) or a batch/sample certification.[1]	X	X	X
VI	**Monitoring,** as applicable			
	a) Test or inspection of samples from the open market			X
	b) Test or inspection of samples from a factory			X
	c) Management system audits combined with random inspections trials			X

Source: Modification from Table 1 NTC-ISO-IEC 17067: 2013.

[1] The use of QCERT brand is a requirement for all types of schemes. If the client uses brand must be according with the requirements of RG-04

5.2 APPLICATION FOR PRODUCT CERTIFICATION

To begin with the certification process QCERT must send the application form FRG-02-01, in order to be filled and sent back to QCERT by email along with the entire required documents. The client defines the scope of the certification, indicating the standard or regulation to certify. For voluntary field the client will select the version of the standard and always will be notified by QCERT if there is a more updated version of it; for regulatory field, the versions defined by the regulator will apply.

QCERT may use different means of collecting information, such as mail or interviews with the client to collect and clarify the information, in such a way that it is sufficient to evaluate the certification request.

5.3 CERTIFICATION PROCEDURE

5.3.1 VIABILITY OF THE PROCESS

Upon receipt of the completed form FR-02-01, the certification body proceeds with the respective feasibility analysis, for it uses the FRG-02-03 format in which it will assess the following aspects:

- That information about the customer and the product is sufficient to perform the certification process.
- That the scope of the certification request is defined.
- That means are provided for all evaluation activities in accordance with current regulations regarding accredited laboratories and non-accredited.
- That has the competence and ability to perform the certification activity, (evaluators, certification committee and internal staff with competence and scope to certify products).

Given the case that the requested information is not complete or not understood, QCERT will communicate with the client, in order to clarify the respective questions. Additionally, QCERT notifies the client when evidence in the application for certification refer to an outdated standard.

Additionally, if QCERT do not have the competence or the scope for specific certification process, it must be declined and informed to the customer leaving the record in each request. If the client appeals that decision, *according to PR-12 Appeals*, QCERT will review the application again and inform the client the reasons why the assessment cannot be developed; if the appeal is in favor to the client, the certification body begins the certification process by sending the commercial proposal.

When QCERT certifies any product from a particular manufacturer, some activities can be skipped when they have been developed in advance; as long as the record is left in the **FRG-02-03** *Viability of the Process* explaining in which certificates were issued before or the omitted activities with its justification. If the client requests the justification for omitting certain activities, QCERT has to inform him through formal communication.

If the client presents test reports (see number 5.3.4 note 3), they will be reviewed in the viability process, to analyze if they could be used in the certification process. This review may have a cost related to the

documental analysis and will be informed to the customer before the beginning of the certification process. The above, does not imply that QCERT is obliged to accept the reports, carry out the certification process or that once the process has begun, additional tests may not be requested.

5.3.2 QUOTATION

If the results of the feasibility analysis are satisfactory, QCERT sends the applicant a commercial and technical proposal under the **FRG-02-04** code, according to application form in order to be accepted. The proposal is composed of:

- Annex 1. Acceptance of the commercial proposal.
- Annex 2. Definition of the activities during plan evaluation.

The commercial proposal is accepted by payment, email or by filling the Annex 1 **FRG-02-04**, which becomes the final agreement. Once the payment is received, QCERT proceed to program the evaluation.

5.3.3 THE ASSIGNMENT OF EVALUATION

QCERT has a procedure which explains how the selection is done and how the evaluator qualified for the different products identified within the scope of the accreditation.

The applicant and the evaluator are informed about the schedule of evaluation activities. After the evaluator is assigned, the applicant has the right to accept or reject the evaluator within five (5) business days. QCERT analyzes the reasons stated by the customer and communicate a decision. The justification will be evaluated with the following criteria:

- Inability to execute the evaluation that was not previously expressed by the evaluator.
- Difficulties in past evaluations.
- Incompatibilities in the implementation of the evaluation.

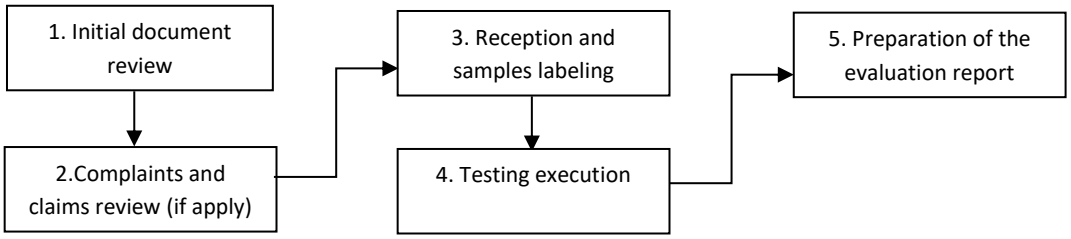
In case that QCERT has not received any type of communication during this period, the assignment will be considered approved. The evaluator will contact the applicant during a period of five (5) business days in order to set the evaluation date.

Instead, if the evaluator has reasons that could compromise the independence or impartiality, he must withdraw the assessment and QCERT must assign other evaluator, as described in the **RG-06** Regulation of the interested parties committee.

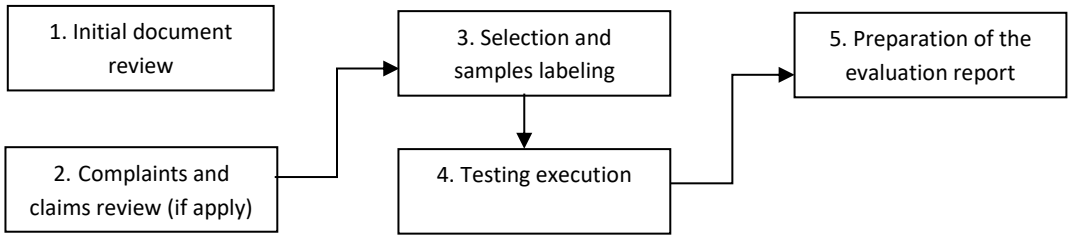
5.3.4 EXECUTION OF THE EVALUATION

The following evaluation stages are presented for the different accredited schemes of certification.

- **For schemes 1a**

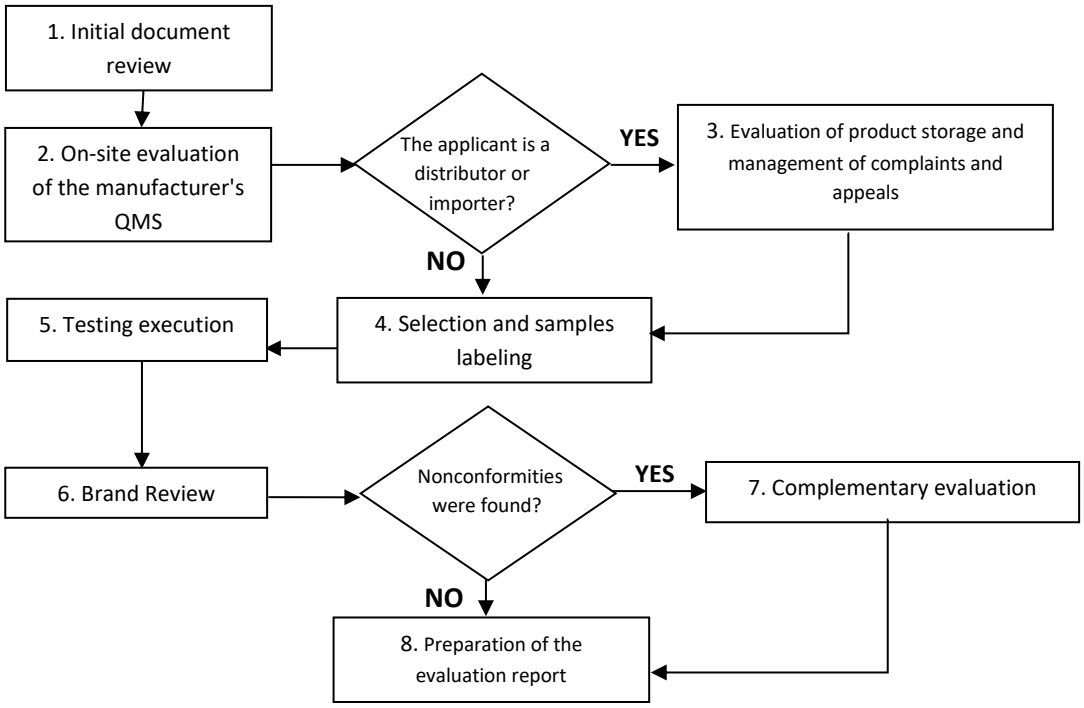


- **For schemes 1b**

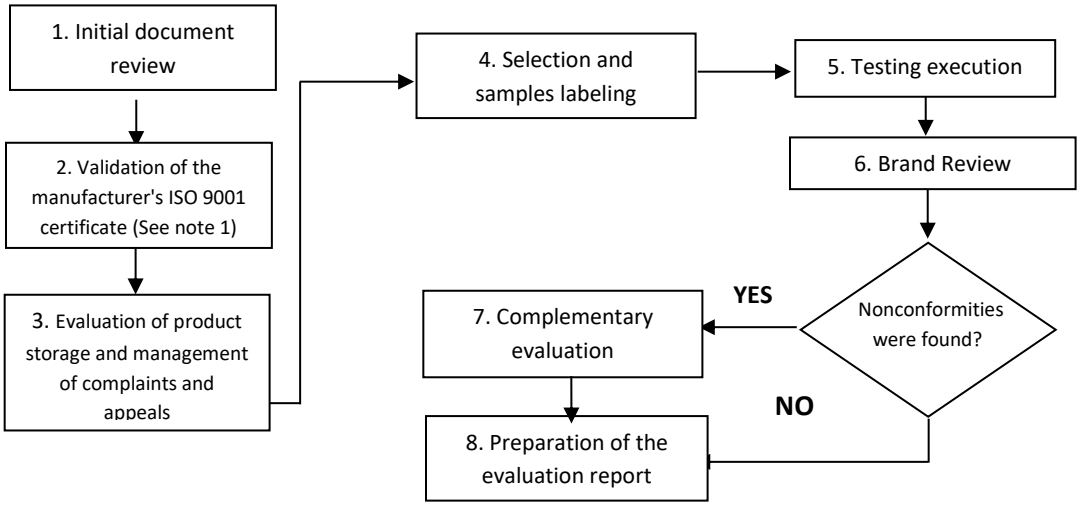


- **For scheme 5**

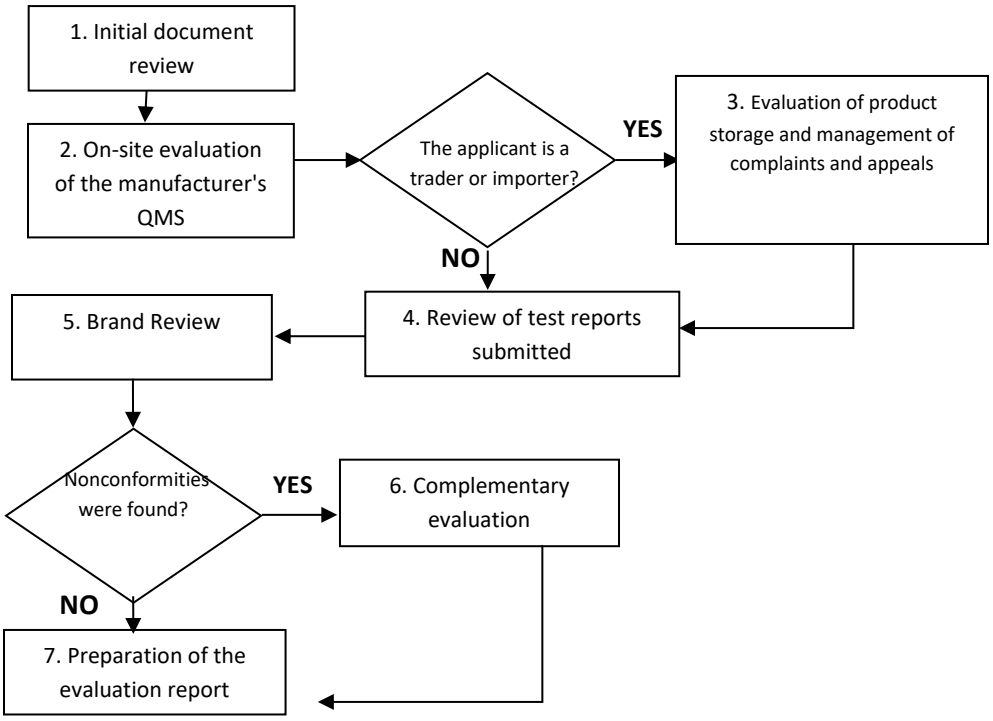
  - **Case 1**: Manufacturer without ISO 9001 certification and the applicant does not submit test reports



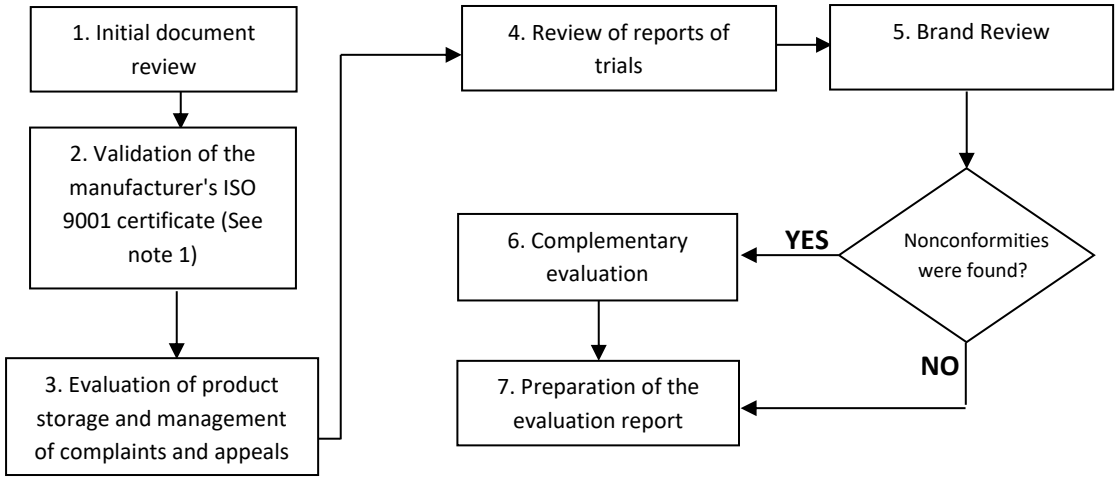
  - **Case 2**: Manufacturer with ISO 9001 certification and the applicant does not submit test reports



- **Case 3**: Manufacturer without ISO 9001 certification and the applicant submits test reports (see note 3)



- **Case 4**: Manufacturer with ISO 9001 certification and the applicant submits test reports (see note 3)



The following describes each stage of the process, which must be executed by the evaluator considering the information related in the document **RG-02 Evaluation Regulation**:

A. Initial document review: At this stage, the evaluator reviews the documents submitted by the applicant, in order to plan the audit.

B. Opening Meeting: Between the client and the evaluator or evaluation team. The presentation of the staff involved in the evaluation is done, the evaluation plan is confirmed, the scope and the methodology to follow.

C. Quality Management System Evaluation (if applicable): This evaluation only applies to certifications with Scheme 5 and can be made by documental review or in site. This is informed to the client in the commercial proposal **FRG-02-04.**

- In Site: QCERT visits the manufacturer or distributor to observe the Quality Management System (QMS) and verifies the compliance of the requirements set out in the FRG-02-07 (available on QCERT website) and also the evidence supporting the conformity of the process.
- Documental Review: For manufacturer or distributor having a certified quality management system, the evaluation can be performed in a documentary way. The certificate must comply with the following requirements.

    - The certificate of quality management system must be in English or Spanish.
    - The certificate must have been issued by a certification body accredited by an accreditor belonging to the international forum and it must be signatory of the multilateral recognition agreements IAF or accredited by the National Accreditation Body of Colombia ONAC.
    - The product to be certified must be covered within the scope of the certified quality management system. That is, the "Manufacturing" activity must be included for manufacturers, and include the product to be certified.
    - The Certificate must have a minimum validity of 6 months from the date of verification and in case of expiration, the one defined in number 6.1.2 must be considered.
    - The address of the manufacturing plant of the product to be certified must be included in the certificate of quality management system.

When the Management System evaluation is documentary it is implicit that the client understands all the rules of the certification process described in these regulations, which must be known since the commercial proposal is submitted. When visit takes place, during the opening meeting all certification rules must be remembered, however, it does not reliefs the obligation of the customer to know the regulations on this document.

D. Inspection of general requirements and labeling: The general inspection and labeling requirements according to the scope of certification are reviewed.

E. Choice and labeling of samples (if applicable): Samples are selected from the point of production, market or warehouse manufacturer/distributor and subsequently labeled by the evaluator assigned to the process or alternatively by an international accredited body which is subcontracted by the certification entity.

F. Storage Review (if applicable): the conditions of preservation of the product are evaluated according to the ISO 9001 requirements (clause 8.5.4 for ISO 9001:2015) and the guidelines that the applicant (manufacturer/distributor) has for the management of complaints and claims related to the products subject to certification**.**

G. Performance of tests (if applicable): Laboratory tests required in compliance with technical regulations must be carried out in laboratories that are under the following conditions in order of priority

- Laboratories accredited by ONAC that include within their scope, the test standards applicable to the product to be evaluated.
- In absence of any accredited laboratory in Colombia for the performance of the tests required in compliance with the applicable technical regulations or if the ones accredited cannot supply the services in less than 30 days, QCERT can use clients or third part laboratories previously assessed under the NTC-ISO/IEC 17025, in accordance with the guidelines established in the FPR-09-09 Laboratory Evaluation And Witnessed Testing. The tests evaluated using the methodology described in FPR-09-09 will have a validity of one (1) year for an accredited laboratory that does not have the trial of interest in its scope; In the case of using non-accredited third-party laboratories or non-accredited client´s laboratories, test witnessing must always be done.
- Laboratories accredited by bodies that are part of the multilateral recognition agreements signed by ONAC, must prove they include within their scope all the required tests, under the test standards applicable to the product to be evaluated or international laboratories of recognized prestige.

The tests required for compliance with the product requirements in the voluntary field may be carried out in laboratories accredited by ONAC or by accreditation bodies that are part of the multilateral recognition agreements signed by ONAC or in laboratories evaluated by QCERT under the NTC-ISO / IEC 17025, in accordance with the internal guidelines of the Certification Body.

Note 1: If the technical regulation allows it, QCERT can accept the test reports performed out of Colombia, as long as they are developed by accredited laboratories recognized by ILAC or IAF or by any with a recognized prestige.

Note 2: In any case, to hire the laboratories services it is required to sign the contract to provide services (**FPR-09-03**) and the confidentiality and impartiality agreement (**FPR-03-12**), in order to preserve the principles of confidentiality and impartiality.

Note 3: QCERT is responsible for contracting and controlling the laboratories in accordance with the requirements of the certification scheme, ensuring impartiality and minimizing any conflict of interest that may affect the certification process. In the case that the client pays directly to the laboratory, QCERT in order to guarantee the conditions of security and confidentiality of the information, will select the samples and send them to the laboratory, manage the communications and reception of test results.

H. Test Reports: Laboratory tests may be omitted when they cannot be developed within the country and the applicant has test reports issued by an accredited laboratory by the ONAC under NTC-ISO / IEC 17025 or by accreditation bodies that are part of the multilateral recognition agreements signed by the ONAC. This also applies when there are special requirements in the applicable technical regulation (see note 1 "Performance of test") or when the applicant submits reports issued by accredited laboratories in Colombia by the ONAC. In the latter case, QCERT may request randomized tests at its discretion that prove that the reports correspond to the reality of the product, in such a way that they guarantee the responsibility that it has as a certification body.

The routine test reports presented to follow-ups or renewals cannot be more than one-year old and must be different from those used in the immediately preceding process. In all cases, the reports must be limited to the requested test, in case it is necessary to review the test reports on several times this may imply the non-acceptance of the same or generation of additional charges due to the need for additional time to review them.

I. Use of the label: In follow-up assessments it is verified that the customer is using the QCERT brand, according to the regulation **RG-04.**

J. Nonconformities solution (if applicable): When nonconformities are detected in the assessment, the evaluator must inform the customer before the closing meeting and write them in the FRG-02-08 format. If the customer wants to continue the certification process, he must send the evaluator the action plan for the closure of non-conformities, in a time span of no more than 15 calendar days from the notification. Once this information is received, the evaluator must consider whether the proposed actions are appropriate and subsequently notify the customer by a written acceptance.

If the evaluator considers the corrections and proposed actions are insufficient, the time set for the delivery of adjustments by the customer, new reviews and approvals is fifteen (15) calendar days. In case the disagreement continues between the parties regarding the adequacy of the action plan, the client may appeal in accordance to the procedure **PR-12 Appeals**, available on the website of QCERT.

If the customer decides not to appeal by written communication, the evaluator will proceed to finalize the evaluation report and justifications supported therein and shall make the recommendation to the committee regarding the certification process.

Once the corrections, causes and corrective actions have been approved, the client must send the evidence that supports the closure of the nonconformities within a period of no more than 90 calendar days from the date of acceptance of the plan by the evaluator. If the client presents the evidence of nonconformity closing on a date before the deadline, it will be understood that he waives the remaining time and therefore, the documents presented shall be considered as the definitive ones.

Note 1: In follow-up or renewal evaluations, when nonconformity affects product quality, the certificate of conformity of that product will be automatically suspended. If the non-compliances are related to the quality management system, the certification coordinator will determine whether to continue with the certification. The deadlines to dismiss the suspension are defined in the section "Suspending the certification" of clause 5.3.5 of this regulation.

Note 2: When non-conformities related to the product are detected, the evaluator will have the power to request additional evidence over the ones in the closure plan (FRG-02-08). This, in order to prevent new avoidances different from the initial ones which can affect the product quality.

K. Further evaluation (if applicable): It is performed to verify the sufficiency of the evidence presented by the applicant, for the closure of the detected nonconformities. For this purpose, QCERT may schedule complementary documentation or on-site evaluation, which must be carried out within the same 90-calendar-day period as from the date of acceptance of the plan by the evaluator. Once this deadline has expired without the specific evidence being obtained or the on-site evaluation carried out, certification will be automatically suspended, in the case of follow-up or renewal processes. In the case of grant evaluation, the process will be considered abandoned; However, in this case, before the expiration of the terms, the client may request the certification coordinator an authorization for an extension up to 30 calendar days.

Once the additional assessment is made, the report is submitted for review by the certification committee.

An additional assessment could generate additional charges, according to the number of non-conformities or if laboratory tests or evaluation in situ had to be performed.

L. Evaluation report: The evaluator prepares a report **(FRG-02-09)** with the results and information gathered during the stages of the evaluation, which is sent to the certification body for review and subsequent submission to the certification committee of product.

5.4 REVIEW AND CERTIFICATION DECISION

For its decision, the certification committee of products reviews the information generated during the evaluation process and based on this, it takes one of the following decisions: To grant, modify (expand, update

or reduce)[2], maintain, renew, deny, suspend or withdraw the certification. This is communicated to QCERT in written form, following the guidelines established in the **RG-03**. At the same time, the certification body informs the client the decision about the certification by written communication, as described in **RG-03.**

The certification committee decides to grant, maintain, extend or renew the certification, only when it has sufficient evidence on compliance of certification requirements and when nonconformities, if there were any, have been properly closed.

The following is a detailed explanation of each decision:

A. Granting certification, issuing the certificate (Applies to all schemes).

B. Modifying (expand or upgrade) the scope of certification (Applies only to Scheme 5) The client must request the extension of the certification scope, either through a written communication or using the application form. In some cases, QCERT may exclude any of the stages of the certification process (mentioned in 5.3.2, 5.3.3, 5.3.4 y 5.4), provided that such exceptions are justified.

When updates are required by new versions of regulation, the certification body will consider the following guidelines:

- Apply what is defines for the regulator entity.
- If the regulator is not pronounced, it shall apply what the supervisory authority indicates.
- If there is no statement from the authorities, QCERT notifies the customer of the novelty and verifies that the new version has been implemented and is being applied in the next evaluation.

When updates are for new versions of technical standards (voluntary field), the client must define if they want to update their certification scope, for which QCERT will verify that the new version has been implemented and is being applied in the following evaluation. Anyway, QCERT will guarantee availability of resources to develop the certification process with a new standard version or with an older one.

When the technical standards in the voluntary field have been repealed, the client must define if he wants to modify his certification with a new technical standard or if, on the contrary, he gives up on the certification. If the client decides to continue with the certification, the scope of the certification will be modified with the new normative reference in the next follow-up evaluation.

In all cases, if the client wishes, it may request that an extraordinary evaluation be carried out to update the version of the regulation or technical standard.

[2] In **RG-03** specials disposals related with decisions about modifying to certification scope are established.

QCERT may consider the equivalences between the two versions and determine whether to update the version of the regulation or standard, a documentary verification is enough, or if on the contrary, it also requires a complete evaluation, as described in clause 5.3.4 of this Regulation.

C. Maintaining the certification (Applies only to Scheme 5) an assessment of annual monitoring is made, counting from the date of issuance or renewal, with the purpose of:

- Verifying that the client has met over the past with the criteria set out in the certification regulations.
- Check if the products continue to meet regulatory requirements and/or regulations by routine testing, if the quality management system implemented meets the certification requirements in effect and if they are making proper use of the QCERT brand.

QCERT will inform the customer every year about the follow-up evaluation scheduling no later than two months before the completion of the annuity. These evaluations must be carried out before the expiration of the annual periods counted from the date of grant or reevaluation. It is not QCERT's responsibility if the customer does not accept the assessment with a reasonable time and this generates delays in the process.

D. Renewing certification (Applies only to Scheme 5): An evaluation similar to the granting is made after three years from the initial certification in order to re-evaluate whether the products continue to meet regulatory requirements and/or regulations, if the quality management system implemented meet certification requirements and whether it is making proper use of the QCERT brand.

QCERT will report about the evaluation of renewal on the same terms established in the previous item.

E. Modifying (reducing) the scope of certification (Applies only to Scheme 5): The decision may be given in the following cases:

- When the client requests.
- When a product or products within the scope of certification do not meet the specified requirements and the customer does not provide an effective causal treatment.
- Changes in regulatory references where the product is no longer subject to certification or the regulatory reference no longer applies to the product.

F. Denying certification (Applies to all schemes): the certification body denies to grant the certification in the following cases:

- If during the evaluation it is detected that the products object of the evaluation do not have authorization to use the brand, in case they are not the owner of the brand.

- If documentation associated with the process is presented with malicious use.
- When obligations of contract accepted by the parties have not been canceled.
- When the report has nonconformities opened and they are validated by the certification committee.

G. Suspending certification (Applies only to Scheme 5): the suspension is decided for the following reasons:

- When there is evidence of breaking obligations as a user of the mark of conformity.
- When the economic obligations agreed, in the commercial proposal, between the two sides are not canceled.
- When nonconformities are found and affect the quality of the product.
- When there is a complaint by a user of the certified product or supervisory body, supported in evidence. Case in which the suspension will continue until the end of the process of investigation.
- Not allowing the conduct of evaluations or not delivering on time the necessary information for the normal progress of the follow-up evaluation, this parameter will be measured in two ways:
    i. Once the annuity has expired and the samples have not been sent to the laboratory.
    ii. Two months after the expiration of the annuity and the client has not delivered all the required information to the evaluator.
- Request by initiative of the customer.

Once the decision of suspension is in firm, the customer must immediately suspend the use of QCERT brand and the certificate of conformity. QCERT Certification coordinator shall inform the customer the reasons for the suspension by a formal letter describing actions to be made in order to end the suspension and restore the product certification. The suspended customer has 120 calendar days from the notification to resolve the causes that led to the suspension[3]. QCERT can perform further assessments if they are necessary to verify that the nonconformities are being closed efficiently, following the steps described in 5.3.4, 5.4 and 5.6 of this regulation.

Once the above periods are over, if the causes that led to the suspension have not been remedied, the certification committee will decide on the withdrawal of certification.

H. Withdrawing the certification (Applies to all schemes): The withdrawal of certification can occur as a result of:

[3] When the suspension is for nonconformities during the evaluation process, 120 days are applied in accordance with clause 5.3.4 literal H.

- Expiration or termination of the certification between the applicant and QCERT certification authority.
- If the causes that led to a suspension are not remedied during the time limits.
- When the certification holder requests a written withdrawal of the granted certification.
- When there is a repeated break of obligations as a user of the mark of conformity.
- In case of dissolution of the company holding the certification.
- When the nonconformities detected during the evaluation are not remedied within the established time.

I. Extraordinary Evaluations: Are performed by:

- Client request: when the client needs to modify the scope of certification and requests that the evaluation be carried out before the follow-up date.
- QCERT decision: when complaints are filed against the client or requirements of the competent authority related to the certified product. In these cases, extraordinary evaluations may be carried out with or without prior notice, ensuring that during the initial meeting the client is informed of the purpose of the evaluation.

5.5 USE OF QCERT BRAND

QCERT is the brand's unique rightful owner. The use of QCERT brand will be authorized, once the "mark-of-conformity" certification has been granted, in its advertising associated with the product, such as website, catalogs, documents referring to the product, among others, following the rules in use of QCERT brand, RG-04. During the execution of the grant assessment, the evaluator must inform the customer that in case the certification is granted he may use of QCERT brand.

This authorization does not imply any cession or transmission to the client and with this is obligated to:

A. Using the brand in accordance to the conditions outlined in the RG-04 QCERT brand use Regulation, which is given along with the product certificate in magnetic format and / or can be consulted in the website http://www.qcert.com.co/biblioteca/.

B. To cease its use when certification has been suspended or withdrawn. The customer may not make any claim to the ownership of the brand logo, neither in Colombia nor abroad, for any of the different types of services and goods, even when the modification does not alter its distinctive character, and is required to pay compensation to QCERT as a consequence of any improper use of the QCERT brand in which it has incurred.

C. Use the symbol as it is indicated in the Regulation of the use of the QCERT mark, RG-04, without making any modification to it, even if said modification does not alter its distinctive character and indemnify QCERT as a result of the misuse it makes of the QCERT brand.

D. Not to make fraudulent publicity or that does not correspond to reality, as well as that which may lead to error; If so, QCERT will apply the sanctions established in the Product Certification Regulation

E. Immediately cease the use of the brand, as well as the advertising that contains it, in case of suspension or withdrawal of the certification. In this case, the client undertakes to destroy for all its labels, documents and other materials that they hold, as well as the Certificates and collect the Products that they have marketed in breach of the technical rules and / or regulations.
During the execution of the award evaluation, the evaluator will inform that in case of obtaining the certificate, he may use the QCERT brand.

5.6 CERTIFICATE

After a positive decision of the certification committee and once the customer has paid the associated cost to the commercial proposal, QCERT will issue a certificate of product[4] conformity, which expresses at least:

- Certification type, in accordance with the issues established on the NTC-ISO / IEC 17065 (Scheme 1a, 1b and 5).
- Certificate number.
- Scope of certification, product, references, normative references.[5]
- Certification holder and address.
- Name and address of the certification body.
- Date when the certification is granted.
- Due date.
- Renewal date.
- Current update (if applicable).
- Accrediting Agency Symbol with the resolution number of the accreditation granted to QCERT.
- Manager signature.

The product certificate is owned by QCERT and is under its control. Therefore, it cannot be modified, except by the certification body itself.

The certification status (suspended or withdrawn) will be published on QCERT website www.qcert.com.co. whenever there are changes (termination / removal, reduction, suspension, extension) the certification status for any of the above, QCERT will perform the appropriate updates in formal documents and public available information.

[4] The estimated time from the beginning of the process to the certificate issuance is two (2) months, as long as the following requirements are met: providing the complete documentation, If nonconformities have not been submitted or if the process follows the normal development without any setback and it have had satisfactory results of the evaluation.

[5] It refers to those related to technical regulations, technical standards in voluntary field and when applicable, normative references of tests.

5.7 DURATION OF THE CERTIFICATION

If the certification is scheme 5, it will be valid for three years and monitoring should be done on an annual basis. The certification is conditioned on the results of the evaluation. If the holder of the certification do not want to continue he must report the fact to the certification body and justify his decision by written communication.

5.8 NOTIFICATION OF CHANGES

In cases where significant changes occur in the certification process, QCERT sends a communication, providing information related to the modification. QCERT verify the implementation of the changes by its clients in the following evaluation.

The certification holder must inform QCERT about the changes he intends to do in relation to:

- Legal status.
- Changes to facilities, manufacturer or product characteristics.
- Changes in regulatory documents specified in the scope of certification.
- Changes in situation of the conformity certifies of products, that make integral part of a product certified by QCERT and that they had been issued by other certification body of product.
- Any other fundamental change that occurs in the initial conditions under which the certification is granted.

In the event that the applicable technical norms and/or regulations be modified, it is understood that the client, will inform QCERT of these changes and agrees that QCERT shall reserve the right to undertake additional sampling and testing in order to determine the continuity of the validity of the issued Certification. The client shall pay to QCERT the fees established in the commercial proposal as if it were an auditing process with the intent to Certify a new or different Product.

Before a notification change, QCERT proceeds to review and establish evaluation activities which must be done (assessment, reviewing, decision and emission/publication of the certificate)

6. RIGHTS AND OBLIGATIONS

6.1 APPLICANT OR HOLDER OF CERTIFICATION

6.1.1 RIGHTS

A. Request modification of the tentative dates set for the assessment visit, on justification and mutual agreement.

B. If the process is terminated before starting the evaluation, for justified reasons and unconnected to the certification body, the applicant is entitled to refund up to 60% of the value of the activities not performed for evaluation or laboratory tests and the process will be completed with just cause.

C. To use the product certification for commercial purposes according to the extent specified in the certificate of conformity.

D. To present claims and complaints related to the service if he considers justified to QCERT certification body, following the established procedure.

E. If the client does not agree with a decision made by the QCERT certification body, can start the procedure for complaints, claims and appeals, according to the guidelines set forth in that document.

F. Give the certificate to whom it is considered, for which QCERT must be notified in writing. The assignment of the contract does not include modifications to the certificate, for modifications please review Section 5.4 literal B.

6.1.2 OBLIGATIONS

A. Comply with the requirements established by the QCERT product certification body in this document and the commitments acquired to accept the commercial proposal.

B. Permit QCERT's evaluator and other officials' access to its administrative and technical installations whenever necessary to observe manufacturing processes and product testing. To scheme 5, allow a minimum of one follow-up evaluation per year (be it scheduled or random), or any extraordinary evaluation in order to guarantee its capability to comply with the corresponding technical norms and/or regulations. In the various procedures, samples of the products which are to be certified by QCERT can be requested, which will be freely available to and at the full disposal of QCERT.

C. Adopt the necessary measures in order to guarantee that extern viewers and/or personal in training authorized, can observe evaluation activities undertaken by QCERT. The non-acceptance by an OEC client of this condition will imply the impossibility of issuing certificates / reports with ONAC.

D. To provide QCERT evaluators and other officials easy access to the documents, registries, test reports, manufacturing and assembly methods, in order to determine compliance with the products' evaluated requirements, once they have been requested. The validity of this information will be evaluated at any time by QCERT. The client guarantees that the documents delivered, especially the test reports provided, are a reflection of the products to be certified and that, at all times, the principles of independence, impartiality and security in the selection, transportation and handling of Samples chosen to carry out the tests provided are preserved. If for any reason QCERT proves that the above principles are violated in some way, it may not know the validity of the documents delivered. Under any circumstances QCERT, is required to verify or verify the authenticity of the documentation submitted by the organization. According to its corporate nature and by virtue of the principle of good faith, QCERT receives the documents from the organization with the only purpose of confronting them against what is established in the referential on the basis of which the certification is granted.

E. Provide QCERT's evaluator and officials the possibility to undertake any and all reasonable verification, in order to confirm client's competence, in case the Products might be violating the corresponding technical norms and/or regulations.

F. Use the certificate in an appropriate manner, preventing its deterioration, its fraudulent use, or any other use than its purpose: to certify the product's compliance to norms.

G. Establish its production, inspection and testing program so that it is assured that its products always comply with the corresponding technical norms and/or regulations .

H. Notify QCERT in writing, within 20 calendar days, any change related to:

- Its legal, commercial or organizational representation, as well as its address information.
- Policies or technical procedures, where applicable.
- Personnel, equipment, installations or other resources, when they be significant and can affect the initial conditions under which a product's certification process has been undertaken.
- Any other aspect which could affect client's capacity or competence, the certified products' reach, their compliance with requirements and other aspects, detailed in the RG-01 product certification Regulation.
- Any change in the Quality Management system which may affect the production methodology, the manufacture procedure, the raw materials used in the final products, as well as anything else associated with the RG-01 product certification.

I. In the event that QCERT carries out client's product sampling anywhere other than the company's factory, plant or warehouse, The client must guarantee that QCERT will be able to proceed in accordance with its functions, providing the necessary amount of Products required for the evaluation process.

J. Not to assign the certificate, without QCERT's previous written consent.

K. To initiate the evaluation process within at most 2 months following acceptance of the commercial proposal.

L. If during the certification evaluation process, nonconformities are detected, the company commits to begin a complementary evaluation process within, at most, ninety (90) calendar days after acceptation date of the action plan by evaluator in the FRG-02-08

M. Provide QCERT with information regarding customer claims and complaints related to a product's conformity to the requirements of the pertinent norm.

N. If the client provides copies of the certification documents to a third party, these documents must be reproduced in their entirety, including the certificate, as well as annexed specifications.

O. The client will retain a registry of all known complaints related to its compliance with the certification requirements and must place this documentation at the disposal of the certification body whenever it is requested by QCERT. Likewise, it must take the adequate actions with respect to these complaints and deficiencies found in the products which affect conformity with certification requirements, while documenting the undertaken actions.

P. If the certification is applied to the current production, the certificated product shall continue to comply with the product requirements.

Q. Have a sufficient number of units of the product, within a period no longer than 45 days after the evaluator has been assigned, and before the annuity due in order to make all the tests requested by technical standards or by the regulation that applies to the product to be certified.

R. Ensure QCERT free access to all sites and documents related with the activities for which the certification is requested, like; product storage, testing laboratories and manufacturing (if applicable).

S. Pay within the prescribed time limits, fees and expenses related to the certification process, including monitoring assessments.

T. Notify QCERT of any investigation or sanction against it advanced by the competent authority.

U. In the case of certification of scheme 1a or 1b the units must be marked in order to allow fully identification. For Scheme 1a, the certification is valid for the batch evaluated, cannot be extended to any other consignment which did not intervene in the sampling process

V. Use properly of the certification obtained in such way the certification body does not been look discredit and only for products identified within the scope of the certificate granted, taking into account the following criteria:

a) For certification scheme 1b, the certificate is only valid for the sample evaluated, cannot be extended to any other unit.

W. When the applicant refers to its certification in communication media such as; documents, brochures or advertising he should make it completely and comply with the obligations mentioned above.

X. Do not use the certificate in cases where the product no longer meets the conditions under which certification was granted.

Y. Be registered as manufacturer or importer in the Superintendence of Industry and Commerce - SIC for certifications with regulatory field.

Z. In case of default of the product with the requirements of the benchmark that applies, the holder of the certificate must:

- Give treatment as established by law and prudent act to the non-conforming units that are on the market.
- Accept and carry out the collection, removal and destruction of the product when the units observed present nonconformity, which by their nature involve danger or risk to life or property of individuals.
- Remove from the product or packaging any reference to certification.
- Take responsibility for product warranties that by law corresponds to the company.
- Assume the exclusive legal liability to third parties for any damages that might result from the failure of the product or this regulation.
- Give treatment to the Nonconformity detected within the established deadlines. In case of not answer the NO Conformity, QCERT prior notification of the evaluator will terminate the certification process

AA. For certificates issued under scheme 5, the certificate holder must send QCERT, within a maximum period of two (2) months after its expiration, an updated copy of the manufacturer's ISO 9001 certificate. (Applies in case the applicant has presented said certificate and the quality system of the productive process has not been evaluated). If the certification has not been renewed, it will be necessary to carry out an evaluation of the manufacturer's quality system. If not done, QCERT may suspend product certification.

BB. Replace the products that QCERT can take from the market to carry out audits of Granting, Renewal and / or Monitoring or assume the costs associated with the purchase of the samples in the market.

CC. Attach the declaration issued by the manufacturer of the products on the changes made to the certification, in each surveillance audit.

6.2 QCERT

6.2.1 RIGHTS

A. To receive the payment, make by the applicant which is indicated in the commercial proposal during the periods and under the conditions set out in the proposal.

B. Take the necessary actions, including legal, civil or criminal relevant to any serious misconduct by the applicant, that violates consumer protection rules or harm the certification body as set forth in these regulations.

6.2.2 OBLIGATIONS

A. It is the responsibility of the Certification Body that each member of the Committee of Stakeholders and impartiality is active and has been previously informed when modifications are made to the certification requirements.

B. Execute in an impartial manner the certification activities free of any financial or economic pressure that compromises their independence.

C. Provide information about the certification process to any applicant, without discrimination of any kind including the scope of the service and the respective commercial proposal.

D. Treat as confidential all information and documents obtained by the applicant or holder in relation to the activities for managing the certification and use it only for purposes related to the process. In the event that an administrative or control authority requires information related to the applicant, QCERT will inform that fact to the applicant.

E. Verify that the quality system and the product meet the requirements specified in the benchmark in which certification is granted. The Authorization granted for the use of brand QCERT does not replace the obligations assigned to the control bodies, according to their skills.

F. To give the applicant once the certification process is finished the product conformity certificate or notification of results.

G. Address complaints and appeals of any applicant.

H. To keep updated the record of all certified products and the name of the holder of the certificate.

I. The certification body is obliged to make available to the public the following information from the applicant certification:

- Certificate number
- Certificate Status
- Name of certification holder
- Certified products
- Regulation or standard by which is certified.

7. PENALTIES

If the certification holder incurs in a fault related to the duties set forth in the preceding paragraph or misuses of certification, the QCERT certification body may proceed with the respective sanction which is related to the suspension and / or removal of the certification. The novelty of the sanction shall be notified in writing to the holder of the certificate and published on the website of QCERT. If the certificate is removed, it will terminate the contractual relationship for products related in the fault.

The breach may be total or partial, relative to one or more products, therefore, the sanctioning and restrictive advertising provisions will apply, with the necessary adjustments, to or to the Products related to the breach or non-compliance in question.

8. COMPLAINTS AND APPEALS

The customer has the right to lodge any complaint and / or appeal against QCERT decisions about the certification or the service, in accordance with the rules and terms indicated in document PR-04 *Treatment of complaints, Suggestions, Congratulations and Complaints of Impartiality* or in the PR-12 *Appeals* , available on the Qcert's website. Appeals must be filed within five (5) business days of notification of the decision.

9. SECURITY OF THE INFORMATION

All documentation generated during the certification process that required be transporting, transmitting or transferring will be handled through commercially reasonable procedures, so that the preservation of confidentiality of information is ensured.

Additionally, QCERT has a MANUAL POLICY TREATMENT OF PERSONAL DATA, available on the website, in order to meet the legal requirements and indicate the treatments given to them, so that achieves to secure and protect the fundamental right to Habeas Data.

10. REGISTRATION IN SICERCO

In order to comply with resolution 41713 of July 1/ 2014 and other regulations that modify it, it is necessary that all customers are registered in the Information System of Certificates of Conformity (SICERCO).

It should be taken into account that not registering in SICERCO, implies that the certificate of conformity of product granted will not be available for consultation by Inspection Agencies or Authorities and control bodies.

11. RATES

All of the agency's resources come from the provision of the certification service. Certification fees are presented in the commercial proposal considering factors such as the scope of certification, type and number of products to be certified, if evaluation of the Quality Management system is required, place of service provision, costs of laboratory tests among others. In no case the commercial conditions are subject to the results of the certification process.

The corresponding fees for surveillance are communicated annually in the commercial proposal. Any additional activity not included in the commercial proposal as complementary audits (if applicable), extraordinary audits, change in the agreements initially defined in the certification contract, repetitions of any part of the evaluation, laboratory tests or additional evaluation time, will generate additional charges which will be communicated in a timely manner by QCERT.

12. CONFIDENTIAL INFORMATION

Both, Qcert and the client, hereinafter the parties, commit to not reveal, publish or divulge to a third party any Confidential Information to which it has access by virtue of certification process, will not be considered Confidential information: (i) that which has been made public by the owner of said information; (ii) that which can be found in public records and/or documents; (iii) that which has been communicated to third parties by the owner of said information and is made public; (iv) that which is willingly made available by the parties without requiring that it be kept secret, or (v) that which must be divulged by virtue of the Law, a judicial order, or a competent administrative order. In any case, the party which releases information which has been deemed “confidential” must communicate the other party of the information’s provision.

QCERT will have free access to Confidential information related to or as a result of the services described in this Contract, for the express purpose of complying with said objectives, and thus commits to treat this information as confidential. QCERT commits to informing its client of any information which it provides to the public in advance, RG-01.

Furthermore, the Parties commit not to divulge Confidential Information without client’s explicit written consent, and to protect this information in order to prevent other parties’ access to this information, including the Client’s records, even if the “Confidential Information” is evident to a technician in the field. This

information shall be protected by an adequate level of care, in order to keep it from reaching the hands of a third party. However, this does not apply to information whose use is exclusively statistical or analytical, which QCERT may provide to a third party or to the appropriate authorities. QCERT commits to informing the client in advance regarding the information available to the public, RG-01.

Both QCERT and the client, hereinafter the parties, agree not to disclose, publicize or disclose to third parties the Confidential Information of the other Party to which they have access by virtue of the certification process. Confidential Information shall not be considered information that: (i) has been or is made public by the owner of said information; (ii) is contained in public records and / or documents; (iii) has been or is communicated to third parties by the owner of said information, and they make it public; (iv) is available or made available to the parties without the requirement that they be kept secret, or (v) must be disclosed by law or by order of a competent judicial or administrative authority. In any case, the party that must grant information that has been classified as “confidential” will notify the other party that has provided it. The information related to the client obtained from sources other than the client, and that has the qualification of confidential information will be treated as such.

QCERT will have access to the Confidential Information in relation to or as a result of the certification services and for the sole purpose of complying with its objectives, and therefore undertakes to give the confidentiality treatment to said information. QCERT undertakes to inform the customer in advance about the information it makes available to the public.

Likewise, the Parties undertake that, despite the fact that the 'Confidential Information' may be evident to a technician in the matter, not to disclose it without the express authorization of the client and to keep it at all times under proper care in order to avoid that comes to the knowledge of outsiders, including the files of the Clients. The foregoing shall not apply to information that is solely and exclusively for statistical or analysis purposes, in general QCERT, or that requested by the competent authorities.

The parties acknowledge and express that the files of the Clients are considered confidential information, therefore, they are subject to the protection granted in these regulations; likewise, the information obtained from sources other than the client that is relative to this.