PRODUCT CERTIFICATION REGULATION

RG-01i V19

Responsible	Version of the document	In force since
Certification Director	19	March 4 2019

Changes to the document	
Cause of change	Change made on V.13 (August 2016)
Recommendation and noncompliance of the internal audit	• The requirement of use of the registered trade mark is deleted according with the schemes 1a and 1b. • The footnote related with duration of the process is complemented and is reference in the section. • The section “right” and “obligations” of the client were corrected in order to improve the wording. • The note of the clause 5.5 has been deleted.
Cause of change	Change made on V.14 (June 2017)
Periodic Review of the documents of SGC	• Drafting improvements were introduced into the table number 1 clause 5.1. • The drafting of the document in general has improved. • The presentation of the evaluation execution process was changed (number 5.3.4), showing the 4 possible cases that can be presented for a scheme type 5. • The writing of literal A clause 5.3.4 was simplified. • The applicable numeral of ISO 9001: 2015 was included in paragraph E numeral 5.3.4. • The tests for certifications in voluntary field was specified in detail. • The complementary evaluation is included, as an activity to be carried out whenever there are nonconformities. • the drafting of literal B number 5.4. is improved. Besides, Provisions on the updating and repeal of voluntary standards are clarified. • The literal I number 5.4 was included. • Additional situations were included which requires withdrawal of certification. • Number 10 of the “register on SICERCO” is included. • Added the obligation of the client to inform QCERT when the certificates of conformity of products issued by other OEC and that are integral part of a product certified by QCERT, are modified. Number 5.8 • The logo and the footer of the document was modified.
Cause of change	Change made on V.15 (september 2017)
Coherence of document	• It is clarified that monitoring evaluations should be conducted before the completion of the annuity periods. • Footnote 3 is added, also what refers to randomized trials, in note 3 of clause 5.3.4.

Cause of change	• Change made on V.16 (april 2018)
Review viability process.	• In the number 5.3.1 was included the information that the review of test report in the viability process could have cost for the customer.
Cause of change	• Change made on V.17 (november 30 de 2018)
Internal Audit Recommendations Request of the certification director General review of the document	• Note 1 and section 5.5 are modified defining the use of mark as optional in accordance with the revision of RG-04 V10 . • In section 5.2 was included that QCERT may use different means to collect information that allows it to study the certification request, such as email or interview with the client. • In section 5.3.2 was cleared that modifications can be presented to initial request, which are clarified before sending a commercial proposal and once this is approved it becomes the final agreement with the client. • It is clarified in note 3 that it applies to follow-up or renewal. • In section 5.3.4 Stage I, it is clarified that the complementary assessment may have a cost depending of the number non-conformities or if additional tests or on-site evaluation are required. • In section 5.4, letter G was added reason for suspension by delay in the sending of samples or in the delivery of information required by evaluator. • In numeral 6.1.2, was added the obligation to deliver the samples before annuity due and 45 days after the evaluator is assigned and the obligation for certifications with regulatory field to be registered as manufacturer or importer in the Superintendence of Industry and Commerce – SIC.
Cause of change	• Change made on V.18 (March 4 2019)
ONAC request by new expression of Scope Recommendation Training Sampling	• In section 5.2 It is clarified that the client defines the version of the standard and QCERT informs him if there is a more updated version. • In section 5.3.4 Flow chart for scheme 1a is separated of flow chart for the scheme 1b by differences in sampling conditions.

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 has to 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:

Multilateral agreement: Agreement between two or more parties under which each party recognizes or accepts the results of conformity assessment of other parties.
Scope of the attestation: Extension or characteristics of conformity assessment objects covered by attestation.
Corrective actions: Actions which aims to eliminate the cause of a detected nonconformity and prevent recurrence.
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.
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. .
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.
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.
Conformity assessment schemes: On specific objects of conformity assessment, which the same specified requirements, rules and procedures apply.
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.
Regulatory bodies: The regulatory bodies for product certification services are the Accreditation of Colombia - ONAC and the Superintendency of Industry and Commerce -SIC.

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.
Conformity Assessment: Demonstration that specified the achievement of the requirements relating to a product, process, system, person or body.
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 S.G.C.
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.
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.
Nonconformity: Failure of a requirement.
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.
Sampling: To obtain a representative sample of the object of conformity assessment, according to a procedure.
Body conformity assessment: Services organization that performs conformity assessment.
Accreditation body: Body with authority that performs accreditation.
Procedure: Specified way to carry out an activity or process.
Product: Result of a process.
Assessment Program: A set of one or more evaluations planned for a period of time determined and directed towards a specific purpose**.**
QCERT: Quality Certification. Conformity Assessment body, which resources come from private capital and the fulfilment and supply of product certification services.
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.
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.
SGC: Refers to a Quality Management System (QMS).
Quality Management System: Rules, procedures and management for carrying out conformity assessment.
Suspension: temporary invalidation of the declaration of conformity for all or part of the attestation specified range.
Requirement specified: Need or expectation established.
Remove: Action to annul the declaration of conformity.
Monitoring: A systematic repetition of conformity evaluation activities in order to keep the validity of the conformity declaration.

5. DESCRIPTION OF THE CERTIFICATION PROCESS

5.1 TYPES OF SCHEMES OF PRODUCT CERTIFICATION

The certification body QCERT responds to requests certification product 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 send back to QCERT by email along with the entire request 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 drawbacks of understanding of it occurring, QCERT communicates with the client, in order to clarify the respective questions. Additionally, QCERT notifies the client when evidence in the application for certification referred to an outdated standard.

On the other hand, if you do not have the competence or the scope, QCERT certification body declines of conducting specific certification; whatever the decision is informed to the customer and the record is left in each request. If the client appealed that decision, QCERT reviews the application again and informs the client the reasons why cannot develop the assessment; if such an appeal is in favor to the client, the body begins the process of certification sending the formal quote of quote to carry out conformity assessment product.

When QCERT certified any product from a particular manufacturer, they can skip activities already developed in advance; as long as it leaves record in the process of assessment of which certifications were issued before. 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 QUOTE

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 clarified application form in order to be accepted. The proposal is composed of:

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

The business proposal is accepted upon payment, via email or by the filling of Annex 1 **FRG-02-04**, and this becomes in the final agreement. Subsequently, it is made a service agreement, which is described in **FRG-02-05** (which can be accepted expressly or impliedly). Once the payment is received, QCERT proceed and program the evaluation.

5.3.3 THE ALLOCATION OF EVALUATION.

QCERT has a procedure which explains how the selection is done and how the evaluator's made the qualification for the different products identified within the scope of their accreditation.

It is reported in writing to the applicant and the evaluator about the schedule of evaluation activities. After the evaluator is assign, the applicant has the right to accept or reject the evaluator within five (5) working days. QCERT analyze the reasons stated by the customer and communicate its decision. The justification will be evaluated on the following criteria:

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

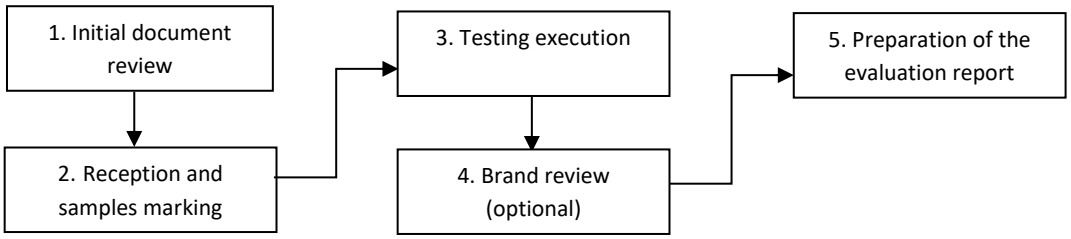
In case QCERT has not received any type of communication during the period of time establish before it means the allocation is considered approved. The evaluator will contact the applicant during a period of five (5) working days in order to set the evaluation date.

If by the contrary the evaluator had reasons that could compromise the independence or impartiality must withdraw the assessment and QCERT must assign other evaluator, as described in the **RG-06** Regulation of the interested parties committee.

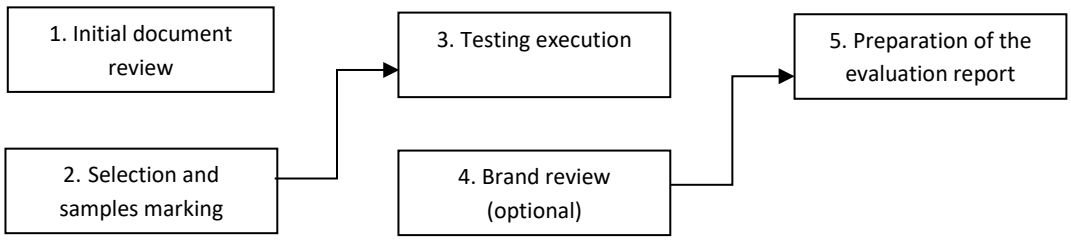
5.3.4 EXECUTION OF THE EVALUATION.

Following the evaluation stages are presented for the different schemes of accredited certification by QCERT. Evaluations of the quality management system can be made by document[2] or at the organization building and it will be defined by QCERT Certification Directorate and the applicant is automatically informed by the proposal **FRG – 02- 04**:

- **For schemes 1a**



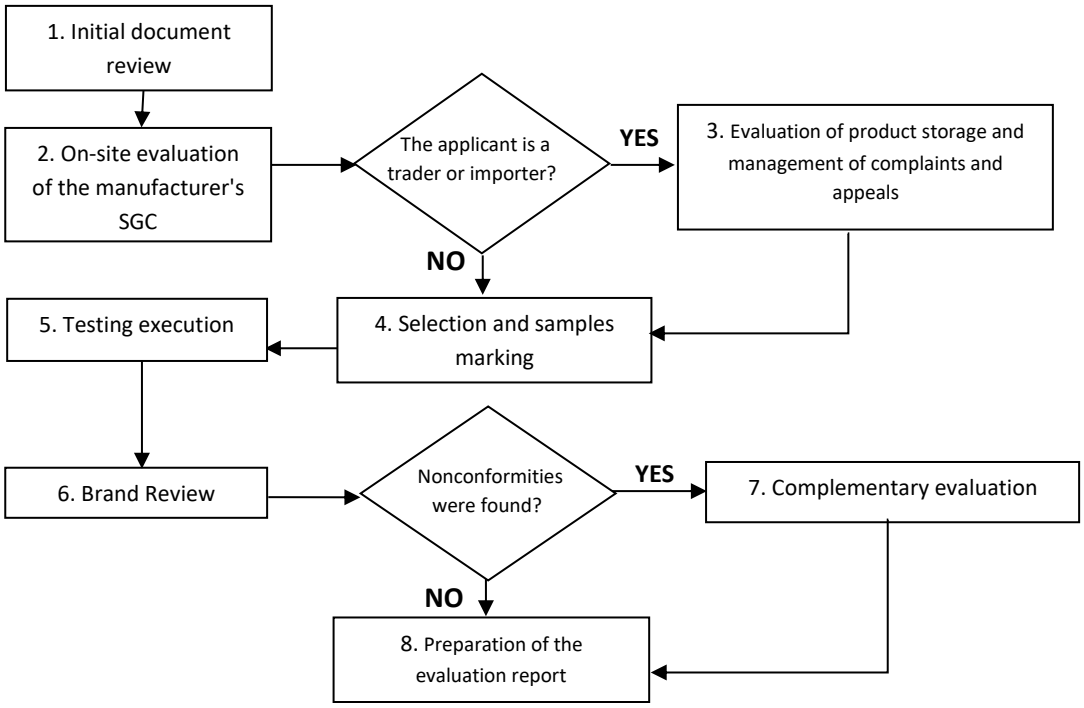
- **For schemes 1b**



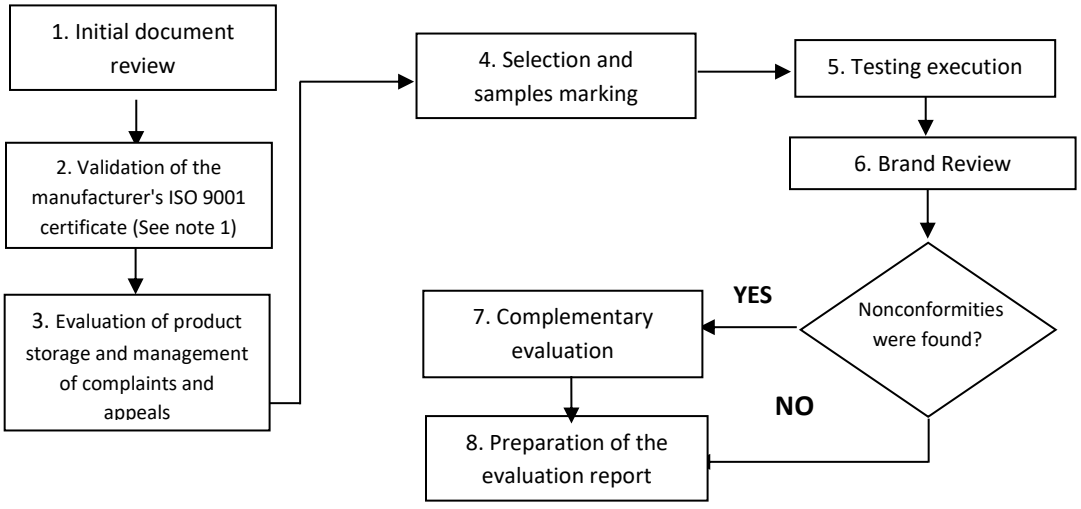
[2] Only applies for ISO 9001 certified manufacturers.

- **For scheme 5**

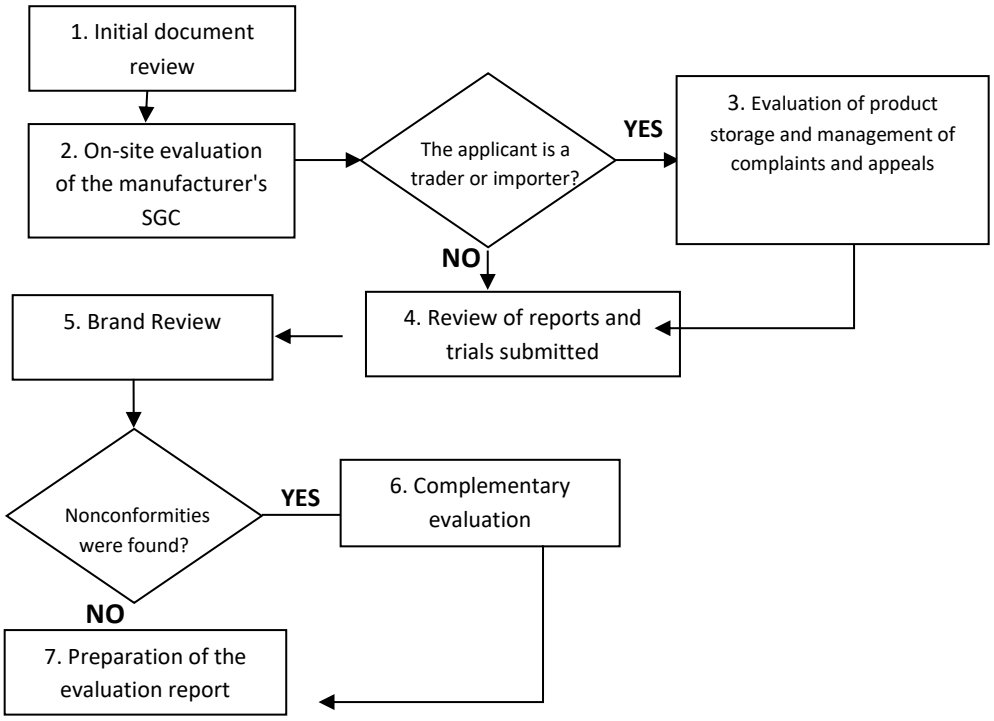
  - Case 1: Manufacturer without ISO 9001 certification and the applicant does not submit test reports



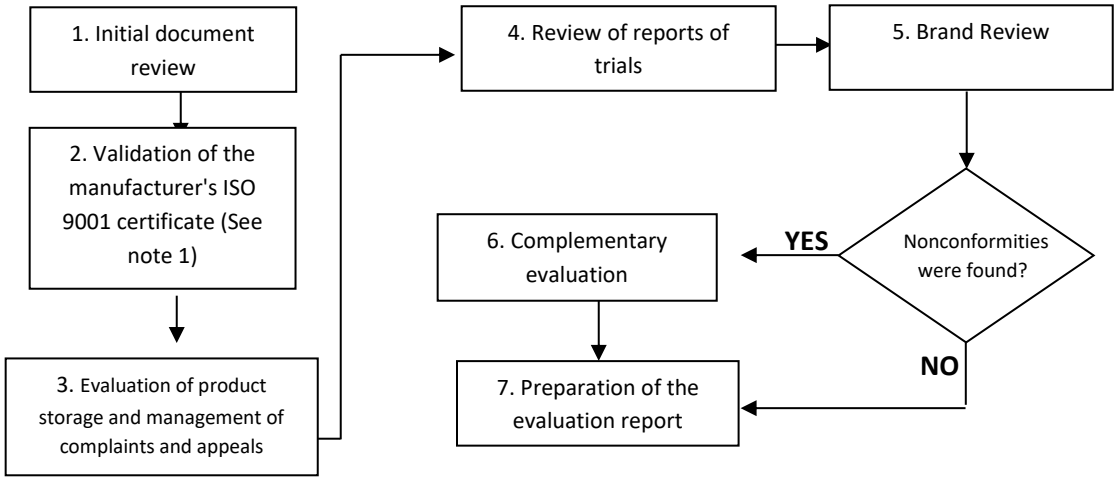
  - Case 2: Manufacturer with ISO 9001 certification and the applicant does not submit test reports



- Case 3: Manufacturer without ISO 9001 certification and the applicant does submit test report (see note 3)



- Case 4: Manufacturer with ISO 9001 certification and the applicant does submit test report (see note 3)



Notes:

1. In the granting and renewal of certification, domestic producers, national marketer-importer and international producers, which have certified quality management system, the quality system evaluation can be performed in a documentary way, thereby:

    - Request the certificate of quality management system 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 of Colombia ONAC.
    - The product to be certified must be covered within the scope of the certified quality management system.
    - The Certificate must be in force at the date of verification.
    - The address of the manufacturing plant from which the product to be certified must be included in the certificate of quality management system.

2. 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 know from the time the business proposal is submitted. When visit takes place during the opening meeting certification rules must be remembered, however, does not relieve the obligation by the customer to know the regulations on this document.

3. Laboratory tests may be omitted, when these cannot be developed in the country and the applicant meets the test reports[3] issued by an accredited laboratory by the ONAC under NTC-ISO / IEC 17025 or by accreditation bodies that is part of the multilateral recognition agreements signed by the ONAC. This also applies when there are special provisions in the applicable technical regulation (see note 1 “test implementation”) or when the applicant submits reports results issued by accredited laboratories in Colombia by the ONAC. In the latter case, QCERT may at its discretion request randomized tests that prove that the reports delivered correspond to the reality of the product, in such a way as to guarantee the responsibility that it has as a certification body.

The following describes each stage of the process, which must be executed by the evaluator taking into account the information related in the document **RG-02 Implementing Evaluation Regulat**ions:

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

[3] The test reports cannot be more than one-year old and must be different from those used in the immediately preceding process. This applies for maintenance and renewals.

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

C. Quality System Evaluation (if applicable): At this stage the operation of the quality system is observed, we look into inquiries about compliance of the evaluation requirements set out in the FRG-02-07 (available on the Web site QCERT) and the evidence supporting the conformity of the process are collected.

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

E. Storage Review (if applicable): the conditions of preservation of the product are evaluated according with the NTC-ISO 9001 requirements (clause 7.5.1 for ISO 9001:2008 or clause 8.5.4 for ISO 9001:2015) and the guidelines that the applicant (manufacturer / marketer) has for the management of complaints and claims related to the products subject to certification**.**

F. Performance of tests (if applicable): Laboratory tests required in compliance with technical regulations must be developed in accredited laboratories by the ONAC or by accreditation bodies that are part of the multilateral recognition agreements signed by the ONAC; 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 perform laboratory tests previously assessed under the NTC-ISO / IEC 17025, in accordance with the guidelines established in the RPF-09-05 Supplier Management**.**

QCERT can only use these laboratories until the first laboratory in Colombia is accredited or up to one year after certifying that the laboratory has been defined by the body.

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 allowed, QCERT can accept the testing reports made outside Colombia, as long as they are developing by accredited laboratories recognized by ILAC or IAF or by default 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.

G. Use of the label: In surveillance assessments is verified that the customer is using the QCERT brand, according to the regulations **RG-04.**

H. Nonconformities solution (if applicable): When nonconformities are detected in the assessment, the evaluator must inform the customer before the closing meeting and record them in the FRG-02-08 format. If the customer wants to continue the certification process, must send to 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 of the same. Received this information, the evaluator must consider whether the proposed actions are appropriate and subsequently notify the customer in writing the acceptance thereof.

If the evaluator considers the corrections and proposed actions insufficient, the time set for the delivery of adjustments by the customer and new reviews and approvals is fifteen (15) calendar days, time limit in which if continued disagreement between the parties regarding the adequacy of the action plan, the client may appeal in accordance with the procedure provided for in PR-04, available on the website of QCERT.

If the customer decides not to appeal through 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 corresponding records that support the closure of the nonconformities detected, 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 monitoring or renewal evaluations, when nonconformity affects product quality, the certificate of conformity of that product is automatically suspended. If the non-compliances are related to the quality management system, the certification director will determine whether or not to continue the certification issued. The deadlines for the lifting of 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 is detected, the evaluator will have the power to request additional evidence of the proposals made by the client in the closure plan (FRG-02-08). This, in order to prevent new defaults different from the initial ones which can affect the product quality.

I. 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 surveillance or renewal processes. In the case of evaluation of grant, the process will be considered abandoned; However, in this case, before the expiration of the term, the client may request the certification director an authorization for the extension of the term 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 made.

J. 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 products.

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 decrease)[4], maintain, renew, refuse, suspend or withdraw the certification, measure who 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 decided to grant, maintain, extend or renew the certification, only when it has sufficient evidence on compliance with certification requirements and nonconformity, if there were any, have been properly closed.

The following is a detailed explanation of each of the decisions:

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

b. Modify (expand or upgrade) the scope of certification (Applies only to Scheme 5) The client must request the extension of the certification scope by written, either through a 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.

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

- 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 upgrades 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 do 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 of 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 following surveillance 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.

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, also requires a complete evaluation, as described in clause 5.3 .4 of this Regulation.

c. Maintain 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:

- Verify that the client has met over the past with the criteria set out in the Contract provision of certification period **FRG-02-05.**
- Check if the products continue to meet regulatory requirements and / or regulations by routine testing, if the management system implemented meets the certification requirements in effect and if they are making proper use of the brand QCERT.

QCERT will inform the customer every year about the surveillance 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 the QCERT responsibility if the customer does not accept the assessment with a reasonable time and this generates delays in proceedings.

d. Recertification (Applies only to Scheme 5): An evaluation similar to the granting is made before three years from the initial certification in order to re-evaluate whether the products continue to meet

regulatory requirements and / or regulations, if the management system implemented meet certification requirements in effect and whether it is making proper use of the brand QCERT.

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

e. Modify (reduce) 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 does not meet the specified requirements and the customer does not provide an effective causal treatment that resulted in the breach.

f. Denying certification (Applies to all schemes): the body refrains from granting certification in the following cases:

- If during the assessment is detected that the products being evaluated are already certified by the Agency and has a current certification.
- If malicious use of the documentation is presented associated with the process.
- When obligations of contract accepted by the parties have not been canceled.
- When the report has non conformities open and there was validated by the certification committee.

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

- When it has evidence of breach of obligations as a user of the mark of conformity.
- When the economic obligations to which they are entitled in accordance with the provisions of the contract signed between the two sides are not canceled.
- When nonconformity is found and affects the quality of the product.
- When there is a complaint made 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 by the agency.
- Not allow the conduct of evaluations.
- Not deliver 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 an initiative of the customer.

Once the decision of suspension is in firm, the customer must immediately suspend the use of QCERT mark and the certificate of conformity. QCERT Certification Directorate shall inform the customer the reasons for the suspension by a formal letter which has to describe the necessary actions to be made in order to end the suspension and restore the product certification. The suspended has 120 calendar days from the notification to resolve or address the causes that led to the suspension[5]. QCERT can perform further assessments if they are necessary to verify the nonconformities are being closed efficiently, following the steps described 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 has not been remedied, the certification committee will decide on the withdrawal of certification.

h. To withdraw the certification (Applies to all schemes): The withdrawal of certification can occur as a result of:

- Expiration or termination of the contract between the applicant and QCERT certification authority.
- If the causes that led to a suspension are not remedied in the time limits.
- When the certification holder requests in writing the withdrawal of the certification granted.
- When a breach of obligations as a user of the mark of conformity is repeated.
- 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 wishes to modify the scope of certification and requests that the evaluation be carried out before the date of follow-up.
- QCERT's 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] When the suspension is for non-conformities during the evaluation process, the 120 days are applied in accordance with clause 5.3.4 literal H.

5.5 USE OF QCERT MARK

For all certification scheme type 5 and in accordance with the provisions of the contract, the certification holder may use the QCERT brand in its advertising associated with the product, such as website, catalogs, documents referring to the product, among others following the provisions of 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 the brand QCERT.

5.6 CERTIFICATE

After a positive decision of the certification committee and once the customer has signed the contract and paid the costs, QCERT will issue a certificate of conformity product[6], which expresses at least:

- Certification type, in accordance with the provisions establish on the NTC-ISO / IEC 17065 (Scheme 1a, 1b and 5).
- Certificate number.
- Scope of certification. Product, references, normative references.[7]
- Certification holder and address.
- Name and address of the certification body.
- Date when the certification is granted.
- Due date.
- Renewal date.
- Date "Nro." of the 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 body itself.

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

[6] The estimate time from the beginning of the process and the certificate issuance is two (2) months, as long as the following requirements are met: provide the complete documentation, If nonconformity has not been submitted or if the process follows the normal development without any setback and it have had few satisfactory results of the evaluations.

[7] 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, this will be valid for three years within which monitoring should be done on an annual basis. The certification is conditioned on the results of the evaluation thereof. If the holder of the certification does not want to continue he must report the fact to the certification body and justified 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.

Before a notification change, QCERT proceeds to review and establish evaluation activities which have to 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

- Request modification of the tentative dates set for the assessment visit, on justification and mutual agreement.
- If the process is terminated before starting the evaluation, for justified reasons and unconnected to the certification body, the applicant is entitled to a refund of 80% of the amount paid to the certification body.
- To use the product certification for commercial purposes according to the extent specified in the certificate of conformity.

- To present claims and complaints related with the service provided that he considers justified to QCERT certification body, following the procedure established.
- 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.

6.1.2 OBLIGATIONS

- Comply with the provisions established by the QCERT product certification body established in this document and the commitments acquired in the evaluation contract.
- 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.
- 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).
- Pay within the prescribed time limits, fees and expenses related to the certification process, including monitoring assessments.
- In the case of certification of scheme 1a or 1b the units must be marked in order to allow fully identification.
- 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:

    - For certification scheme 1b, the certificate is only valid for the sample evaluated, cannot be extended to any other unit.
    - In the case of certification 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.

- Ensure that no certificate or its annexes is used deceptively or make partial reproductions thereof.
- 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.
- Do not use the certificate in cases where the product no longer meets the conditions under which certification was granted.
- Provide to QCERT the information regarding complaints and claims made by their clients regarding the conformity of the product and the actions taken with respect to claims or any deficiencies detected in the product.
- Be registered as manufacturer or importer in the Superintendence of Industry and Commerce - SIC for certifications with regulatory field.

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.

6.2 QCERT

6.2.1 RIGHTS

- 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.
- 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

- 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.
- 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.
- 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.
- 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.
- To give the applicant once the certification process is finished the product conformity certificate or notification of results.
- Address complaints and appeals of any applicant.
- To keep updated the record of all certified products and the name of the holder of the certificate.
- 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 agency certification 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.

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 Procedure for handling complaints, appeals and risks of impartiality, available on the agency's website. The notice must be in writing using the FPR-04-01 format, also available on the website.

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.