Regulations for tangible product certification

This regulation includes the contractual requirements subscribed by the Organization and **ICONTEC**, and which govern Product Certification.

1. PURPOSE

This Regulation sets forth the conditions governing permanent Product Certification with marks of conformity granted by **ICONTEC** and is based on the requirements established in ISO/IEC 17065 "Conformity evaluation. Requirements for bodies certifying products, processes and services" and ISO/IEC 17067 "Conformity evaluation - Fundamentals of product certification and guidelines for product certification schemes".

2. SCOPE

2.1 This Regulation applies to Product Certifications issued by **ICONTEC** through Operating Agreements entered into with other Certification Bodies (see section 3.1).

2.2 Manufacturers, importers or marketers are the types of organizations that may apply for Product Certification.

2.3 When the Organization requesting Product Certification is other than the manufacturer and subcontracts the manufacture of the product to another Organization (Maquiladora), the evaluation process evaluations cover the Maquiladora and must ensure compliance with the applicable requirements of these Regulations.

2.4 Depending on the type of product to be certified, the Organization may apply for one or more of the following types of marks of conformity:

a.) Quality Seal (Type 4 or Type 5)

b.) Seal with Technical Regulation (Type 4 or Type 5)

Note 1. In the case of certification under Ecuadorian certification standards (INEN Technical Standards and Ecuadorian Technical Regulations), the seal will be called "Product Conformity Certificate".

Note 2. Annex 2 sets out the conformity evaluation activities that apply and will be evaluated for each seal according to the type of certification scheme.

3. DEFINITIONS

For the purposes of these Regulations the following designations shall be used:

3.1 **Operating Agreement.** Agreement made between **ICONTEC** and another certification body whereby each party performs conformity evaluation activities on behalf of the other party and such activities are recognized.

3.2 **Appeal.** Request by the client of the conformity evaluation service to **ICONTEC** to reconsider the decision it made in relation to its request for appeal for review, by an independent body (adapted from ISO 17000).

3.3 **Certificate cancellation**. Definitive loss of certification validity.

3.4 **Marketer.** Organization whose economic activity consists of the reception, storage and sale of products.

3.5 **Standard test.** Test performed in a laboratory to validate a product design. It must be performed each time a product characteristic (design, material, process, composition, among others) is modified.

3.6 **Evaluation Team.** Person or group of persons assigned to carry out an evaluation and which is constituted by a product leader evaluator, who may be accompanied by evaluator(s), technical expert inspector(s), evaluator(s) in training who may be external personnel hired by **ICONTEC**, evaluator(s) from accreditation bodies and other observers.

3.7 **Extraordinary evaluation.** Evaluation additional to follow-up evaluations aiming at verifying the manufacturing process effective operation and maintenance, as well as compliance with the requirements established for the product after changes implementation in the company that may affect the integrity of the conformity of the quality management system or production control system evaluated during the certification granting or renewal or by materials, parts or components replacement or by modification of the design presented in the previous granting or follow-up.

3.8 **Witnessed Assessment.** Part of an accreditation body's evaluation of a conformity evaluation body, which consists of observing and evaluating the audit team competence and

the application of the conformity evaluation body's procedures to meet the accreditation requirements.

3.9 **Manufacturer.** Organization manufacturing a finished product and is included in the scope of application of the reference.

3.10 **Product Family.** Identification established by the Organization to group product references with similar technical characteristics.

3.11 **Importer.** Organization whose economic activity consists of bringing products of foreign origin into the country.

3.12 **Maquiladora.** An organization manufacturing a product under contract for another organization that is or intends to be the certification holder. This product is understood as a finished product and is included in the scope of application of the reference.

3.13 **Conformity mark granted by ICONTEC.** Registered mark issued by **ICONTEC** indicating that a product is in conformity with the requirements specified in the reference under which the certification is issued. The mark of conformity includes Quality Seal and Seal with Technical Regulation.

3.14 **Non-conformity.** Non-compliance with a requirement, which can be classified as a:

a.) Critical non-conformity: Any non-compliance with a requirement established for the product in the reference used for certification.

b.) Major non-conformity: Absence or total failure of the quality management system or production control system to comply with an established requirement or that significantly reduces its ability to ensure controlled processes or products or, a failure to comply with a requirement set forth hereunder that demonstrates lack of certification management by the Organization. A number of minor nonconformities of a requirement may represent a total failure of the management system and thus be considered as a major nonconformity.

c.) Minor nonconformity: A failure to comply with the requirements of the quality management system or production control system that is not likely to result in the failure of the quality management system or production control system or in the reduction of its ability to ensure controlled processes or products. It may be a failure in some part of the documented management system, or a single error observed in the monitoring thereof.

3.15 **Observer.** Person who accompanies the evaluation team, but does not evaluate.

Note. An observer may be a competent person appointed to assess the evaluation team or an evaluator from the Accreditation Body, or any other person whose presence has been justified.

3.16 **Organization.** Company, corporation, firm, institution, sole proprietorship, association or a part of the above incorporated as a legal entity, requesting or holding permanent product certification with marks of conformity granted by **ICONTEC**.

3.17 **Certificate Reactivation.** It refers to the resumption of the certificate validity after a suspension. The Certification reactivation is given only once after the decision taken by **ICONTEC** as a result of the solution of the condition leading to suspension.

3.18 **Product reference.** Identification established by the Holder for each of the certified product models.

3.19 **Reference**. For certification purposes, Technical Standard, Resolution, Regulation or technical document establishing the requirements to be met by the certified product.

3.20 **Appeal for review.** Request from the client of the conformity evaluation service, before the same **ICONTEC** body, to consider the decision taken in relation to the evaluation performed.

3.21 **Certificate Renewal.** This is the approval of a new certification cycle, after a satisfactory evaluation has been carried out before the certificate expiration date and the renewal of the certificate has been approved.

3.22 **Certificate restoration.** This consists of restoring a certificate that failed to be renewed prior to its expiration date. Restoration is approved only in those cases in which all renewal activities have been completed within six (6) months of expiration.

3.23 **Certificate suspension.** Temporary loss of certificate validity up to a maximum of one hundred and fifty (150) calendar days.

4. DESCRIPTION / ACTIVITIES

4.1 Obligations of the organization

4.1.1 The Organization shall comply with the requirements of the product certification scheme, for which it applies for and/or holds the certification and all specific requirements related to that scheme and those established hereunder.

Note. In addition to the requirements of the certification reference, product certification scheme and those of these regulations, the Organization shall comply with the requirements laid down in the sectoral documents issued by **ICONTEC**, wherein provisions (sampling, type and routine tests, among others) particular to the sector and certification reference to be evaluated are set forth.

4.1.2 Own or have a contract for the use of the trademark(s) of the products for which certification is requested/obtained, have trademark registration with the competent authority for the products covered by the certification and be legally constituted as a manufacturer, importer or marketer of the product for which certification is requested. The Organization may be national or foreign.

4.1.3 Sign by an authorized legal representative, the contract as acceptance of the proposal and conditions of the certification set forth hereunder.

4.1.4 Provide the documentation required by the lead evaluator and/or the evaluation team, necessary for the evaluation preparation and the development of the evaluation plan with the required timeliness prior to each evaluation and submit valid evidence to demonstrate compliance with the requirements of the certification scheme. Test result reports supplied by the Organization must be submitted in English or Spanish and cover both the product being certified and the manufacturing plant.

Note. In no case and under no circumstances, **ICONTEC** is obliged to check or verify the authenticity of the documentation submitted by the Organization. In accordance with its corporate nature and by virtue of the principle of good faith, **ICONTEC** receives the documents from the Organization for the sole purpose of collating them with provisions set out in the reference on which the Certification is granted.

4.1.5 Ensure **ICONTEC**'s free access to all sites and documents corresponding to the activities for which it requests/obtains Certification for all verifications defined as necessary and designate a person responsible for the coordination of activities with **ICONTEC**. Therefore, all sites of product handling and storage, testing laboratories, manufacturing (in the case

of manufacture by third parties) and commercial representation in the country where the product is marketed are considered as an extension of the sites covered by the certification, being the Organization solely responsible for compliance with this Regulation..

For Organizations requesting the seal other than the one manufacturing the product, there must be a contract or contractual agreement between the Organization and the manufacturing companies that guarantees that **ICONTEC** can carry out evaluations in the manufacturing facilities. Those companies, as well as the Organization shall ensure compliance with the applicable requirements set forth hereof.

4.1.6 Allow the participation of teams of accreditation body evaluators in the evaluations that such bodies select as part of their accreditation activities, as members of the evaluation team, in accordance with the provisions of Paragraph 3.6 of this regulation. The Organization is not required to be informed in advance of the participation of accreditation body evaluators during the product evaluation.

Note. During the evaluation process, the members of the accreditation body's evaluation team do not perform activities such as: evaluation process-related interventions, non-conformities reporting, decision making related to the evaluation results and reporting evaluation results to the Organization.

4.1.7 To allow the participation in the evaluations of all the people making up the evaluation team and observers designated by **ICONTEC**, in accordance with the definitions established in section 3 of these regulations.

4.1.8 To pay fees and expenses established by **ICONTEC** for the activities of certificate management within set out terms, including fees for use of laboratories for tests performance. **ICONTEC** established the corresponding fees and communicates them every year within the Certificate term.

ICONTEC may refrain from delivering the certificate to the Organization, if the client has debts payable the Institute due to granting, maintenance, reactivation and renewal or any other concept..

4.1.9 ICONTEC may increase invoices values in the following instances:

a.) Changes in the agreements initially agreed upon in the certification contract;

b.) Detection of differences in information initially provided to **ICONTEC** to determine the contract values;

c.) Any part or all evaluation or activities repetitions due to recording procedures and rules that are not being followed;

d.) Development of additional activities due to Certificate suspension, cancellation and/or reactivation;

e.) Execution of extraordinary evaluations;

f.) Performance of activities arising from changes in the management system or products, processes or services affecting the certificate scope, which must necessarily be notified by the Organization.

ICONTEC reserves the right to increase the costs during the contractual term, taking into account that the value initially defined is based on the rate in force at the signing of the contract. Any increase in the value of the certification will be notified to the Organization.

4.1.10 Not to reproduce partially or totally the documents provided by **ICONTEC**, nor to allow access thereto by third parties other than the competent authorities.

4.1.11 The holding Organization shall inform **ICONTEC** within fifteen (15) working days of the change, about modifications that may affect the Management System, the product manufacture or both, the scope of the Certificate or any of the following instances:

a.) Changes in the name or corporate purpose;

b.) Changes in the contact address or permanent sites under the scope of the Certification;

c.) Changes in the contact information with **ICONTEC**: Representative, address, telephone numbers, among others;

d.) Changes in the Organization, size, organizational structure; in management personnel, in personnel making decisions on the certified product, in personnel assigned to activities requiring prior qualification of their competence that may alter the nature of the product; in the manufacturing processes, quality system or production control system;

e.) Adverse events occurring with the product or service that affect the integrity, safety, health or life of persons;

f.) Changes in the certified product or important changes in the quality management system or in the production control system;

g.) Merger, spin-off, liquidation, takeover, transfer of shares and in general any other operation entailing a change in the legal nature of the Organization or its ownership;

h.) Judicial or administrative intervention, initiation of investigations by competent authority or penalties imposed by competent authority;

i.) Changes in the design or materials of the products with conformity mark that may affect the conformity with the relevant reference. Failure of the Organization to notify **ICONTEC** shall be grounds for a penalty or declaration of major non-conformity.

j.) Temporary cessation of production for more than three (3) months;

k.) Voluntary or compulsory cessation of activities, or temporary or definitive closure decided by the Organization or ordered by the competent authority;

l.) Product recalls from the market. This notification must be made to **ICONTEC** within 72 hours from the recall beginning.

Note. Changes made by the Organization without consent or acceptance and which are of such a nature as to modify the conditions of the authorization to use the certificate, automatically result in the suspension of the certificate. All rights to use the certificate cease in case of merger, liquidation or takeover, purchase or sale, of the Organization.

In accordance with the above, **ICONTEC** reserves the right to carry out extraordinary evaluations to verify compliance with the certification requirements, which may result in the certificate modification, suspension or withdrawal. Suspension shall not result in the extension of the Certificate validity.

4.1.12 The Organization shall inform the lead evaluator about the risks to which he/she is exposed and the rules that the evaluation team must comply with in the facilities of the Organization, in order to prevent damage to the integrity of people, equipment, etc.

4.1.13 While the Certification is in force, maintain a controlled record of the following, as applicable to the type of certification scheme:

a.) Complaints or claims from applicable interested parties according to the requirements to be met by the product (such as customer, community, employees, etc.), as well as the treatment given to them, including corrections and corrective actions;

b.) Product recalls;

c.) Investigations and penalties imposed by the competent authority for non-compliance with legal or regulatory requirements applicable to the scope of product certification.

4.1.14 To allow **ICONTEC** to make information on certifications granted, suspended or withdrawn available to the public or provide it upon request. If, for exceptional reasons, the Organization considers that access to such information should be limited, it must notify **ICONTEC** of such fact, indicating the corresponding justifications. These justifications must be validated by **ICONTEC**.

4.1.15 Deliver within the agreed deadline the pending test results, for which, without exception, the corresponding payments for the tests at the external laboratories must be made. Failure to deliver the test results by the due date shall prevent the certification process from continuing.

4.1.16 Submit appropriate corrections and corrective actions for approval by the **ICONTEC** lead evaluator, maximum seven (7) calendar days after completion of the field evaluation, when non-conformities occur during the evaluation. In cases where the evaluator requests adjustments to the action plans proposed by the Organization, such adjustment must be made within maximum five (5) working days. The final approval of the action plans for non-conformities shall be within maximum thirty (30) calendar days from the end of the field evaluation. Failure to comply with the aforementioned deadlines, **ICONTEC** proceeds to send the report with the opinion of the process that is being conducted indicating that it does not proceed. For follow-ups, the Certificate is suspended. For critical non-conformities, the process of presentation and approval of the action plans must be carried out within seven (7) calendar days and a complementary evaluation shall be carried out within sixty (60) calendar days after the field evaluation is completed.

4.1.17 Provide **ICONTEC**, within the established deadlines, with the information relevant to investigations initiated by the corresponding authority and allow the investigation of third-party complaints that users report to the Organization or to **ICONTEC**.

4.1.18 To provide the information requested by **ICONTEC** within the established deadlines. Failure to timely provide information to **ICONTEC** shall be grounds for penalty in accordance with the provisions of Section 4.7 hereof.

4.1.19 For Certificate renewal purposes, the Organization must update the information at least six (6) months prior to the expiration date, through the form provided by **ICONTEC** and related to: addresses of the permanent sites included in the Certification scope, company name, name of the legal representative, name of the management representative, e-mails, standard or regulation to be certified and references, among others. This activity is a necessary condition for **ICONTEC** to schedule the renewal evaluation. The Organization must formally request **ICONTEC** to schedule the renewal evaluation six (6) months prior to the Certificate expiration date.

For those cases in which tests may take longer than six (6) months, the application for renewal must be submitted before the six (6) months set forth herein, taking into account the tests duration.

For renewal request, the Organization must send the respective form to the account executive assigned by **ICONTEC** or to the following e-mail address **cliente@icontec.org.**

4.1.20 Renunciar a cualquier acción legal en contra de **ICONTEC** por la suspensión o cancelación del Certificado. Así mismo, la Organización no podrá seguir utilizando el Certificado ni la colocación del logo símbolo de la marca de conformidad para ningún fin a partir de la fecha en que le sea notificado por escrito o por cualquier otro medio la suspensión o cancelación del Certificado. En caso de que la Organización siga utilizando el Certificado o el logo símbolo, **ICONTEC** puede iniciar las acciones legales correspondientes y exigirle el pago de los derechos y compensaciones por uso indebido del Certificado o marca de conformidad

4.1.21 Waive any legal action against **ICONTEC** for the Certificate suspension or cancellation. The Organization may no longer use the Certificate or the logo symbol of the conformity mark for any purpose from the date on which written notification or any other means is served of the certificate suspension or cancellation. If the Organization continues to use the Certificate or the logo symbol, **ICONTEC** may initiate the corresponding legal actions and demand the payment of the rights and compensations for the improper use of the Certificate or conformity mark.

4.1.22 Use the Certificate and the conformity seal or mark in accordance with the provisions of Section 4.6 hereof.

4.1.23 Not to trade products covered by the certification and in the commercial mark authorized by **ICONTEC**, which do not comply with the requirements of the certification reference, even if those products are not labeled with the logo, seal symbol or **ICONTEC** conformity mark.

4.1.24 Not to use the **ICONTEC** seal or mark of conformity in a manner that may result in a bad reputation for **ICONTEC**. Not to place the logo symbol of the **ICONTEC** conformity mark on products of the same trademark, type, model and reference as those covered by the certification that are manufactured in not **ICONTEC** authorized sites. The right to use the Certificate is non-transferable, so in case the Organization plans to transfer totally or partially the manufacture and/or commercialization of the certified products, it must inform **ICONTEC** with due anticipation, in order to decide on the Certificate continuity.

4.1.25 Ensure that the product covered by the scope of certification and released to the market complies with the requirements of the corresponding reference.

In case of product non-compliance with the requirements of the corresponding reference the Organization shall:

a.) Treat, pursuant to law and prudent action, non-conforming units found in the market, whether or not they are in the possession of consumers or customers.

b.) Accept and carry out the collection, withdrawal and destruction of the product when the observed units present nonconformities that, due to their nature, pose dangers or

risks for the integrity, safety, health or life of people or other living beings. This provision may be applicable to the entire lot corresponding to the non-conforming product and to the products on the market. furthermore, according to the failure seriousness and its impact on the safety of consumers or users of the certified product, the Organization must publish a prevention notice in a mass circulation media.

c.) Remove from the product, packaging and/or packing any reference to product certification.

d.) Assume responsibility for the guarantees corresponding to the company in accordance with the law.

e.) Assume sole legal liability to third parties for any damages that may arise from the breach of the product or this document.

4.1.26 Provide information evidencing maintenance of the certification of the quality management system or of the producer's quality management system abroad upon **ICONTEC** request in the case of organizations with quality management system certification.

Note. In case of loss of validity of the quality management system certification, **ICONTEC** reserves the right to carry out an extraordinary evaluation in order to determine certification maintenance under the conditions granted.

4.1.27 Make the implementation required to demonstrate certified product, quality management system or production control system or laboratory competence conformity, when changes in the reference or certification requirements or both occur.

4.1.28 In the case of a product certification under a technical regulation supervised by the Superintendence of Industry and Commerce (SIC), the Organization must register as Manufacturer or Importer in the Certificate of Conformity Information System (SICERCO) as a previous step for **ICONTEC** to upload the granted product certificate to SICERCO. **ICONTEC** assumes no responsibility for the uploading of certificates in SICERCO if the company has not registered within three (3) working days after the date of granting the product certificate.

4.2 ICONTEC obligations

4.2.1 To treat as strictly confidential all information and documents obtained from the Organization in connection with the activities carried out for the management of the Certificate, and to use it only for the purposes related to the management thereof. If an administrative authority requires information related to the Organization, **ICONTEC** shall inform the Organization, so that it may grant the due authorization. The above notwithstanding the strict **ICONTEC** compliance with the Law and with orders coming from the judicial and administrative

authorities.Lo anterior sin perjuicio del estricto cumplimiento que el **ICONTEC** debe dar a la Ley y a las órdenes provenientes de las autoridades judiciales y administrativas.

4.2.2 Verify compliance of the quality management system, the production control system and the product with the requirements set forth in the reference under which certification is granted and hereunder. Certification does not exempt the Organization from its responsibility to comply with current legal legislation and to supply products meeting the applicable requirements. The authorization of the use of the mark of conformity granted by **ICONTEC** does not replace the obligations assigned to the control bodies, according to their competences.

4.2.3 Submit the reports of the evaluations carried out and the product certificate (in the case of grants, extensions and renewals) within the deadlines established in sections 4.3.2.4 and 4.3.3.2 of these Regulations.

4.2.4 Communicate to the Organization any decision taken in relation to the granting, monitoring, reactivation, renewal, suspension, cancellation and any other decision to the Certificate.

4.2.5 Develop actions aimed at maintaining and preserving the good name of **ICONTEC**'s product certification as well as of the organizations holding the certification.

4.3 Certificate management

Certificate Management comprises the activities necessary to decide on the certificate, for which **ICONTEC** retains autonomy, regarding the product certification granting, maintenance, renewal, extension, reduction, suspension, reactivation and cancellation thereof.

Once the certification contract is signed, **ICONTEC** establishes an evaluation program for each certificate cycle for certificate maintenance. This program is based on periodic evaluations of the quality management system and/or production control system, verification of product compliance through sampling in the factory, in the market or both, and evaluation of the technical competence of the laboratory where the tests are performed.

4.3.1 Request

4.3.1.1 Any Organization, without discrimination whatsoever, may apply for certification for the products it manufactures, imports or markets. In the event that the Organization's product certification has been cancelled due to ethical or technical non-compliance, **ICONTEC** may consider the facts leading to cancellation in order to define whether or not to initiate the process of the new application and within what period of time the application may be submitted again. The same procedure shall apply when the Organization has requested the cancellation of any of the **ICONTEC** seals or Marks of Conformity. Notwithstanding the foregoing, **ICONTEC** reserves the right to grant a certification if there are technical reasons

that may affect the integrity, safety, health or life of people or other living beings, the image or good name of **ICONTEC** or prevent the provision of the service.

4.3.1.2 The application for the use of a mark of conformity must be in writing through the applicable prior information form established by **ICONTEC** indicating, in addition to other information, the product to be certified and its references, the corresponding reference, the identification of the laboratories where the tests are carried out, the product manufacturing plants and the inspection plan established by the applicant to evaluate the product conformity with the reference under which the certification will be carried out. The Organization must attach all the documentation set out in the certification application form for the certification process commencement. In addition to the application form, **ICONTEC** will provide the organization with the necessary documents to make the application. If standard tests are indicated in the reference, the Organization is required to provide brochures or photographs of the product models to be certified, marking information, technical specification sheet of the product and diagrams of the different models (electrical, parts, functional, etc.).

4.3.1.3 **ICONTEC** shall review the documentation making up the application for certification and may require clarification or additional information if deemed necessary.

4.3.1.4 Once the application is accepted, **ICONTEC** shall proceed to make the proposal for the granting of certification. If the Organization approves the proposal, the certification process shall begin.

4.3.2 Granting of certification

The granting of certification comprises the following stages:

4.3.2.1 Programming of the initial or granting evaluation and assignment of the Evaluation Team. Once the certification contract has been signed, **ICONTEC** shall assign an Evaluation Team to carry out the evaluations for granting, follow-up, renewal, extension, reactivation and/or reduction of certification. In case the Organization objects the Evaluation Team, it must notify **ICONTEC** in writing the reasons within five (5) working days from the date the evaluation was notified. If upon said term elapsing the Organization does not present objection, **ICONTEC** will assume that the evaluation team has been accepted without restrictions on the scheduled date. **ICONTEC** will review the objections to a member of the Evaluation Team in cases where any of the members present a conflict of interest.

4.3.2.2 Initial review and evaluation planning. The assigned Evaluation Team shall review the documentation provided by the Organization and may request additional documents if deemed necessary. The initial review shall be carried out at the Organization's headquarters and shall include:

a.) The evaluation of the documentation submitted to evaluate whether the Organization has considered the conformity evaluation of all the requirements established in the corresponding reference for each of the product families to be covered in the certification. This information shall be submitted to the auditor before starting stage 2 of the evaluation. Moreover, the documentation related to the production control system or the quality system shall be evaluated;

b.) The definition and evaluation of the technical competence of the laboratories to be used in accordance with the provisions of Section 4.3.2.3.3.3 of these Regulations and the evaluation of the Organization's laboratories as applicable;

c.) The validation of the information submitted by the Organization related to product references, trademarks, manufacturing and storage sites, among others, as well as the availability of records evidencing the product conformity with the reference requirements;

d.) Allocation of resources for the evaluation (stage 2) and coordination with the Organization on the details for its implementation;

e.) The development of the evaluation plan.

If it is concluded that the Organization is not prepared for the on-site evaluation, the on-site evaluation may be suspended and rescheduled when the Organization remedies the identified deficiencies, not exceeding a maximum of one hundred and eighty (180) days after the initial review. If the Organization deems it appropriate, it may require a new initial review, prior to the on-site evaluation, which must be paid in accordance with the current rates.

The lead evaluator prepares a report and submits it at the end of this stage. This report includes findings, areas of concern or aspects that may constitute nonconformities in stage 2 and conclusions regarding the feasibility of conducting stage 2 of the evaluation.

4.3.2.3 Grant evaluation (Stage 2). The on-site evaluation shall be carried out within one hundred and eighty (180) calendar days after the initial review and includes the verification of compliance and application of the requirements set out in Annex 3 and Annex 4 hereof at the Manufacturer's or Marketer's facilities and the evaluation of the product to verify compliance with the reference requirements under which the certification is requested.

4.3.2.3.1 Product evaluation is performed by testing samples of the product references, in accordance with the respective technical certification standards and in evaluated and approved laboratories, as established in Section 4.3.2.3.3.3 of this Regulation. The company shall send the samples previously selected by **ICONTEC** to the accredited laboratories or selected third party laboratories within the deadlines established along with the evaluator

and report to the Evaluation Team the results of the tests performed in the company's laboratories, according to the deadlines defined with the Evaluation Team. Failure to send samples or to deliver the test results within the defined deadlines shall be grounds for non-granting, maintenance, renewal, reactivation and extension of the certificate. **ICONTEC** may accept certifications of components or materials from other certification bodies, to demonstrate product conformity, as long as the criteria established for the acceptance of certificates defined by **ICONTEC** are met.

In the event that the evaluation requires to perform standard tests, such tests must be performed in their entirety in the granting evaluation, i.e., at least once during the certification term, provided that there are no changes in the product design, material, process or composition. When any change in the product is identified, all standard tests must be performed again to confirm that the changes do not affect the product conformity.

Note 1. For components or raw materials included in the reference, **ICONTEC** may take samples and test them to verify compliance with the corresponding requirements.

4.3.2.3.2 For the different schemes, samples to be tested shall be taken from production, from the company's warehouses or stores, or from the market.

4.3.2.3.3 Tests corresponding to the granting, maintenance, renewal, reactivation and extension of certification are performed at:

a.) Laboratories accredited by the national accreditation body. Accredited laboratories must be used to verify the product according to the requirements of the certification reference, as long as the scope of the laboratory accreditation includes the test method and its respective validity established in the certification reference and regardless of whether the company also has laboratories.

b.) Organization or third-party laboratories. These laboratories must be previously evaluated and approved by **ICONTEC** in accordance with the requirements established in the ISO/IEC 17025 standard. Furthermore, if third party laboratories are contracted by the Organization, the Organization must make them aware of the provisions established by **ICONTEC** for the contracting of external laboratories set forth in document I-PS-0063 PROVISIONS FOR CONTRACTING EXTERNAL LABORATORIES.

c.) Laboratories in other countries. Results of tests performed in laboratories of other countries may be accepted, if due to the nature of the requirement to be evaluated or the difficulty of performing a test in domestic laboratories, it is not possible to verify to satisfaction the fulfillment of such requirement. In such a case, the foreign laboratory must have a current accreditation with the requirements of the ISO/IEC 17025 standard issued by a body belonging to a recognized laboratory network such as ILAC or similar,

or have been evaluated and approved by **ICONTEC**. To validate the results of tests performed in laboratories in another country, these must correspond exactly with those established in the product certification reference or there must be equivalence between the test methods.

In all cases the Organization shall bear the costs incurred for the use, evaluation and approval of the laboratories, as well as the value of the product samples taken by **ICONTEC** for the purpose of verifying compliance with the reference requirements, sample transportation, storage and insurance required.

4.3.2.3.4 At the end of the evaluation, the evaluator shall inform the Organization of the findings and conclusions obtained. When only minor non-conformities are found, the Organization shall establish corrective actions and report them to the Evaluation Team who shall review them and, if they are adequate to the findings, prepare the respective report for submission to **ICONTEC**.

When critical or major nonconformities occur, a complementary evaluation must be performed on a date agreed upon with the Organization, within sixty (60) calendar days of the completion of the on-site evaluation for critical nonconformities or ninety (90) calendar days for major nonconformities, to verify that corrective actions have been effectively implemented for the aspects detected as nonconformities or to verify that the required conditions have been met. The Organization must submit to the Evaluation Team the corrective actions to solve the nonconformities (minor and major) within the deadlines established in section 4.1.16 of this Regulation. The complementary evaluation shall be paid by the applicant according to evaluation duration.

Note. If, due to the need to implement the corrective action, a time longer than the times defined in the previous sections is required, the Organization must request authorization in writing to **ICONTEC** with due justification. **ICONTEC** shall evaluate the situation and issue the corresponding report.

4.3.2.3.5 When the complementary evaluation shows that critical or major nonconformities and/or pending minor nonconformities have not been resolved, the procedure below shall be followed:

a.) For a granting evaluation, the Organization shall start the certification process again from Stage 1.

b.) For reactivation evaluation: The Certificate is cancelled.

c.) For follow-up evaluation: The Certificate is suspended.

d.) For renewal evaluation: The Certificate is not renewed.

e.) For extension evaluation: The certificate is not extended.

4.3.2.4 **Report.** Based on the results obtained from the evaluation, the lead evaluator presents a report, which includes the activities carried out, the results obtained, the conclusion and the recommendation on the feasibility of granting, maintaining, renewing, extending, reducing, suspending, canceling or reactivating the Certificate.

A copy of this report is sent to the Organization at the latest one (1) month after completion and approval of the evaluation process to satisfaction (decision of the reporting person, see 4.3.3.1). This includes, among other things, having the results of tests conforming to the reference requirements.

4.3.3 Review and decision on certification

4.3.3.1 The report submitted by the evaluator is reviewed by a certification reporting person, who reviews all information contained in the evaluation report, as well as the evaluation-related results. This review verifies, among other aspects, the adequacy and conformity with all applicable requirements, the evidence supporting compliance with requirements, or in the event of major or critical non-conformities, whether these have been solved and verified through complementary evaluation. As a result of the review, the certification reporting person confirms the recommendation presented by the evaluator or presents observations that the evaluator must address before approval. The certification reporting person has the authority to conduct the review and decide on the product certification.

4.3.3.2 Based on the approval by the certification reporting person, **ICONTEC** submits the Certificate to **ICONTEC**'s Legal Representative for ratification and proceed to issue the certificate. Additionally, certificates ratified by the Legal Representative are periodically disclosed to the Board of Directors. The authorization for the use of the Certificate covers those product references for which inclusion was agreed upon between both the Organization and **ICONTEC**. Moreover, the authorization applies only to the products of the commercial brand included in the granting. When in the opinion of the Legal Representative of **ICONTEC** or the Board of Directors and whenever warranted by the circumstances, the use of the Certificate can be authorized only for one or some of the references of the product manufactured, imported or commercialized by the company. **ICONTEC** may refrain from authorizing the granting, extension, maintenance, reduction, renewal or reactivation of the Certificate, if in the opinion of the Legal Representative or the Board of Directors, there are conditions of the Organization or the product, which may be against the image or credibility of the certification or **ICONTEC**. The product certificate is delivered to the Organization within five (5) working days after ratification by **ICONTEC**'s Legal Representative.

4.3.4 Certification period

The Quality Seal Certificate or Seal with Technical Regulations is granted for the periods established in Annex 1 of these regulations according to the type of certification scheme. The certification period starts from the date of certificate approval.

Note. The certification validity may be modified when granted under a Technical Regulation which establishes especial provisions regarding the certification validity. In such a case **ICONTEC** will inform in the commercial proposal the special conditions of the certification validity defined in the technical regulation.

If the Organization wishes to continue with the certification, a renewal evaluation must be carried out under the same conditions as the granting evaluation.

4.3.5 Maintenance of certification

4.3.5.1 Once certification has been granted, the Organization assumes full responsibility for compliance with the requirements established in the reference under which the certification was granted, performing the corresponding controls, including conformity evaluation of the certified product, using the laboratories as defined in Section 4.3.2.3.3.3 hereunder.

4.3.5.2 During the Certificate validity, **ICONTEC** confirms to the Organization at least fifteen (15) calendar days in advance, the date and the members of the Evaluation Team assigned for the execution of the follow-up and renewal evaluations. The Organization is obliged to accept and received these evaluations on the scheduled dates. Non-confirmation by **ICONTEC** of follow-up or renewal evaluations does not exempt the Organization from the obligation to request and receive the evaluation on the assigned date.

Failure to complete the follow-up evaluation shall result in the certificate suspension. This suspension does not result in the Certificate validity extension.

4.3.5.3 During follow-up evaluations or at any time **ICONTEC** may take samples of the certified product in the market or in storage warehouses or in the production plant. In case samples are taken from the market, the Organization shall provide the necessary logistics for such procedure. **ICONTEC** may also make unscheduled follow-up evaluations by taking samples in the market or visiting the Organization's facilities. The costs associated with the purchase of products, sampling and laboratory testing of samples taken by **ICONTEC** in the market shall be borne by the Organization.

4.3.5.4 If no references or product families covered by the certification have been manufactured or marketed during the certification validity, the evaluator shall proceed to remove such references or product families from the list of product certification references.

4.3.5.5 If during a follow-up evaluation the product cannot be evaluated due to non-existence in the manufacturing plant for reasons not related to the technical capacity to manufacture

the product according to the reference or in the market, the product shall be evaluated on record and the certification shall be kept active without suspension until the next evaluation. If at the next evaluation, the product cannot be evaluated again, the Certificate must be suspended.

Note. ICONTEC takes market samples at most once a year, unless there are substantiated investigations or complaints about possible non-compliance of the certified product, in which case market samples will be taken as required.

4.3.5.6 The number of follow-up evaluations to be carried out within the certification validity is established in Annex 2 hereof according to the type of certification scheme.

Note. The frequency of certification follow-up evaluations may be modified when the certification is granted under a technical regulation which establishes special provisions regarding certification follow-up. In such a case **ICONTEC** shall inform in the commercial proposal the special conditions of the certification validity defined in the technical regulation.

4.3.5.7 The request for postponement must be submitted by the legal representative of the Organization, stating the reasons why the evaluation cannot be carried out. Such communication must be sent to the Regional Coordinator who issued the original scheduling notice.

Postponements will only be accepted if requested at least fifteen (15) calendar days prior to the start of the service or due to force majeure. The reasons for force majeure are:

a.) Loss at the company's facilities;

b.) Temporary restrictions for contracting in public entities;

c.) Terrorist actions preventing the evaluation from being carried out;

d.) Death or serious accident of directors or the representative of the Organization's management..

4.3.5.8 If critical or major nonconformities are found in the follow-up evaluation, a complementary evaluation shall be carried out on a date agreed upon with the Organization, within sixty (60) calendar days of the end of the on-site evaluation for critical nonconformities or ninety (90) calendar days for major nonconformities, to demonstrate that corrective actions have been taken to remedy the detected nonconformities. The Organization shall submit to the Evaluation Team the corrective actions to solve the nonconformities within the deadlines established in Section 4.1.16 of this Regulation. When the complementary evaluation finds out that the nonconformities have not been corrected or new nonconformities have occurred, it shall be proceed as indicated in Section 4.3.2.3.5.

4.3.5.9 If nonconformities are of such a nature that safety or health of the product user are affected, certification shall be immediately suspended. In such cases, the evaluator shall analyze whether the products on the market are susceptible to nonconformities and if so, the Organization shall recall the product and treat it in accordance with Section 4.1.24 of this Regulation.

4.3.5.10 When minor nonconformities are found during a follow-up or renewal evaluation, the Organization shall submit an action plan to resolve the nonconformity. The Organization shall submit to the Evaluation team the corrective actions to resolve the nonconformities within the deadlines established in Section 4.1.16 of this Regulation. The evaluator shall review and approve the action plan and the effectiveness thereof shall be verified at the next follow-up evaluation. If the follow-up evaluation cannot evidence the implementation of corrective actions corresponding to minor nonconformities detected in previous evaluations, proceed as indicated in Section 4.3.2.3.3.5.

4.3.5.11 In addition to follow-up evaluations, **ICONTEC** may carry out the following surveillance activities to ensure maintenance of certification:

a.) Request for information from the Organization on matters relating to the certification at any time within the Certificate validity.

b.) Review any statement by the Organization or public information relating to its operations (e.g., promotional material, websites) that may affect the reputation of the certification granted.

c.) Request the Organization to provide documents and records.

d.) Treatment and actions taken by the Organization due to complaints, claims, investigations or penalties or any requirement imposed by a regulatory or control authority.

e.) Use of the certification mark in the scope granted for the product.

f.) Evaluation of product samples, taken by **ICONTEC** in the market.

As a result of these certification surveillance activities, information, correction or corrective actions on certification issues may be requested from the Organization at any time within the effective date of the certificate or the execution of an extraordinary audit.

4.3.5.12 For certification holders that have the **ICONTEC** seal with Technical Regulations, which are controlled in Colombia by the Superintendence of Industry and Commerce (SIC), it is necessary that the follow-up evaluations for schemes 4 (validity of 3 years) or 5 (validity of 6 years) start at least three (3) months before, i.e., in months 9, 21, 33, 45 and 57 as applicable, of the maximum time to perform the follow-up. The foregoing, so that the follow-up is closed

at a maximum of 12, 24, 36, 48 and 60 months respectively, according to the certification cycle.

4.3.6 Certificate renewal

4.3.6.1 **ICONTEC** confirms to the Organization the date and the members of the audit team assigned to carry out the renewal evaluation once the information necessary for the definition of the evaluation times and conditions have been received to satisfaction. The Organization shall submit such information to **ICONTEC** at least six (6) months prior to the certificate expiration date. Failure to provide such information to satisfaction and the application within the indicated term, the evaluation for renewal of the certificate shall not be scheduled.

4.3.6.2 Once the application has been received and before the certificate expiration date, an evaluation is carried out to determine the renewal of the Certificate. In cases where critical or major non-conformities are identified in this evaluation, deadlines for the implementation of corrections and corrective actions shall not exceed the certificate expiration date, otherwise the Certificate became void. Moreover, if the review and decision on the certification renewal is not conducted before the Certificate expiration or an appeal for review process is not carried out, the evaluation must be processed as an expiry grant. Therefore, this evaluation is recommended to be carried out three (3) months prior to the expiration date of the certificate, to ensure that the Organization has sufficient time for the implementation of corrections and corresponding corrective actions and the certification review and decision processes.

4.3.6.3 This evaluation is informed to the Organization upon certification granting or before certification renewal, so that the renewal decision is made before the certificate expiration date. These evaluations durations may vary according to changes in the characteristics of the Organization and in the Certificate scope.

4.3.6.4 When the complementary evaluation detects nonconformities not corrected, proceed as indicated in Section 4.3.2.3.5.

4.3.6.5 Certificate Restoration. After the certification expiration, at the request of the Organization, **ICONTEC** may restore the certification within six (6) months after the expiration date, provided that the pending certification renewal activities have been completed within that term. Restoration is applicable only for product certificates issued under voluntary technical standards.

In this case, the Certificate effective date should be the date of the Certificate approval decision and the expiration date should be based on the previous certification cycle. Otherwise, commencing a granting process shall be necessary without completion of Stage 1.

Between the date of expiration of the Certificate and the date of restoration, the Organization must make all necessary arrangements to ensure that the Certificate and the **ICONTEC** seals or marks of conformity are not used. Failure to comply with this provision is grounds for Certificate cancellation in accordance with the provisions of Section 4.7 of these Regulations.

ICONTEC may make visits to manufacturing plants and other locations of the Organization to verify compliance with the above provision.

4.3.6.6 If there is a need for standard testing in the evaluation, the tests shall be repeated in their entirety at the renewal evaluation, i.e., at least once during the certification period, provided that there are no changes in the design, material, process or product composition. When any change in the product is identified, all standard tests must be performed again to confirm that the changes do not affect the product conformity.

4.3.7 Extraordinary evaluations

4.3.7.1 **ICONTEC** may perform extraordinary evaluations in one or more of the following instances:

a.) One or more of the events set forth in Section 4.1.11, after evaluation of the need for such evaluation;

b.) Changes in legal or regulatory requirements that could affect the Organization's compliance status;

c.) Changes in organizational structure, procedures, operations, activities or manufacturing sites, which may, in **ICONTEC** opinion lead to a temporary Certificate suspension;

d.) Agreements entered into by **ICONTEC** with other certification bodies; e.) Company change or transfer to other owners;

e.) By request of the product certification reporting person;

f.) Change in product design;

g.) Change in the corresponding reference;

h.) For results of appeals for reviews or appeals;

i.) Complaints or claims from the Organization's clients or other interested parties that affect the scope of the certification and that, according to their magnitude and impact, warrants it.

The Organization shall pay the corresponding value of these evaluations and any expenses incurred according to their duration.

4.4 Certificate extension and reduction

4.4.1 The Organization may request an extension of certification in the following instances:

a.) New products different from the authorized ones, but covered by the corresponding reference and manufactured in the same line, authorized plant. Extension evaluation is carried out under the same conditions set out in Chapter 4.4 of this Regulation.

b.) New products manufactured in other plants that are not authorized. Extension evaluation is carried out under the same conditions set out in Chapter 4.4 hereof. If there are common elements with the plant that has already been authorized, the extension evaluation will be carried out with a shorter duration.

c.) Products holding the certification, but need to be labeled with other trademarks different from those that are certified. **ICONTEC** reserves the right to carry out an on-site or documentary evaluation to verify the requirements established for the certification extension.

d.) Products holding certification, for which a modification was made and such modification affects their technical characteristics, such as design or formulation. Extension evaluation is carried out under the same conditions set out in Chapter 4.4 of this Regulation.

e.) Products holding certification, for which a modification was made, but this modification does NOT affect their technical characteristics, such as design or formulation, **ICONTEC** reserves the right to perform an on-site or documentary evaluation to verify whether the products meet the requirements established for the certification extension.

4.4.2 In all cases, the Organization must make the extension request in writing, using the form implemented by **ICONTEC** and attaching the documentation requested in the form. Extensions are authorized based on the results of the activities carried out by **ICONTEC** and are ratified by the Legal Representative.

Note. For products covered by a different reference than the one already authorized, the Organization shall submit a new application for certification. The granting process is carried out in accordance with provisions set forth hereunder.

4.4.3 Reduction to the scope of the Certificate is made by written request from the Organization or may be identified and reported by **ICONTEC** in follow-up or renewal evaluations. Extraordinary evaluations may be carried out to verify the application of the requirements laid down for certification, if there is a risk of the reduction affecting the remaining scope.

4.5 Changes to certification references

When the reference (Technical Standard or Technical Regulation) used for product certification is updated or cancelled, **ICONTEC** establishes a maximum transition period of one (1) year for the certification holder to implement the changes and perform the evaluation of updating or granting the new reference. **ICONTEC** shall notify the certification holder about the change of the reference and the corresponding transition period. **ICONTEC** performs product certifications with the current versions of the technical standards.

4.6 Conditions of certificate use

4.6.1 The Organization that has obtained authorization to use **ICONTEC** certificates shall use the corresponding seal or mark of conformity to demonstrate that its product complies with the requirements set out in the certification reference, with the exception of those products that due to their presentation, size or finish it is not possible to do so; in which case **ICONTEC** shall be informed as soon as they are identified. The Organization may not make any publicity about the certificate or future granting until after certification approval. Failure to comply with this provision may result in certificate denial or postponement.

4.6.2 The Organization may not transfer the rights of Certificate use. If the Organization plans to transfer all or part of the activities covered by the scope of the Certificate, it shall inform **ICONTEC** with due notice, in order to define the Certificate continuity, reduction in scope or cancellation.

4.6.3 The Organization may use the seal or mark of conformity following the provisions below

4.6.3.1 In Organization advertising

a.) With the company name of the Organization;

b.) With the reference number, version or date;

c.) With the scope of the certified product;

d.) With the authorized trademark;

e.) For the product references covered by the certification and for the authorized manufacturing plants;

f.) Within the certificate validity period;

g.) When reproduced, the Certificate and logo symbol shall comply with the provisions of specification E-GM-0002 USE OF **ICONTEC** CERTIFICATION MARKS OF CONFORMITY FOR INSPECTION, PRODUCT, PROCESSES AND SERVICES.

h.) With the specified colors, enlargements or reductions are allowed while preserving the original proportions and provided they are legible and in accordance with the provisions

of the specification E-GM-0002 USE OF **ICONTEC** CERTIFICATION CONFORMITY MARKS FOR INSPECTION, PRODUCT, PROCESSES AND SERVICES.

i.) In documents, notices and other advertising media with a clear description of the scope of the Certification;

j.) The reference to the **ICONTEC** accreditation body, in accordance with the provisions established in the specification E-GM-0002 USE OF **ICONTEC** CERTIFICATION CONFORMITY MARKS FOR INSPECTION, PRODUCT, PROCESSES AND SERVICES. The certified Organization may not use the ONAC Accreditation Body mark.

In case of doubts about the authorized content of the advertisement, the Organization may consult **ICONTEC** beforehand about the advertisement content.

4.6.3.2 On the product

a.) On the primary packaging with the number, version or date of the reference and the product name of the authorized trademark;

b.) When due to space reasons it is not possible to place the above information, at least on the primary packaging shall have the reference number and the product name of the authorized trademark;

c.) When the Organization has been awarded the **ICONTEC** Quality Seal with Technical Standard and Seal with Technical Regulation, and the regulation requirements are covered by the technical standard, the Organization may label the product using only the **ICONTEC** Quality Seal as long as it mentions the two references, according to the provisions of specification E-GM-0002 USE OF **ICONTEC** CERTIFICATION MARKS OF CONFORMITY FOR INSPECTION, PRODUCT, PROCESSES AND SERVICES.

d.) The mark of conformity shall comply with the provisions of specification E-GM- 002 USE OF **ICONTEC** CERTIFICATION MARKS OF CONFORMITY FOR INSPECTION, PRODUCTS, PROCESSES AND SERVICES.

Note. In the case of seals issued to traders, imported products must be individually labeled with the trader's name, with the reference number and the product name of the authorized trademark, at least, and with the manufacturing lot or equivalent..

4.6.4 Certification may also be used for commercial purposes in which it is necessary to demonstrate product compliance with the requirements set forth in the corresponding reference and in documents referring to authorized products. This should be done in a non-misleading manner, clearly specifying the product(s) bearing it.

4.6.5 The Organization assumes full responsibility for the affixing of the **ICONTEC** mark of conformity on the units of sale of the certified product for which it has verified that they meet the requirements established in the reference under which the certification was granted.

4.6.6 If only a component, part or element of a product has been authorized to bear the certification, the certification may be used on the product, provided that it is made clear that the seal covers only that component, part or element instead of the product as a whole.

4.6.7 The use of the certification does not exclude the use of another seal or mark of conformity with a similar purpose, as long as these are not detrimental thereto.

4.6.8 The Organization may only advertise the Certificate after approval. Once the suspension or cancellation of the Certificate has been ordered, the Organization may not use the **ICONTEC** seals or marks of conformity.

4.7 Product certification penalties, suspensions and cancellations

4.7.1 **Penalties.** The penalties to be applied, jointly or separately, and depending on the seriousness of the violations of the conditions set forth herein, may be as follows:

a.) Written warning requiring to cease violations within a specified term;

b.) Written warning accompanied by an extraordinary evaluation;

c.) Economic penalty of 15% of the value corresponding to the notified and scheduled evaluation, if not receiving it or rescheduling is required, with less than fifteen (15) days prior to the service rendering. Exceptions to this penalty are requests for rescheduling due to force majeure;

d.) Certificate Suspension, which shall be decided by **ICONTEC** and may not exceed one hundred and fifty (150) calendar days, to remedy the situation leading to penalty, otherwise the Certificate shall be withdrawn. **ICONTEC** may demand as a condition to lift the suspension, the proven compensation of damages suffered by third parties or by **ICONTEC**;

e.) Decision not to grant the Certificate or cancellation thereof.

4.7.2 **Suspensions**. 1.1.1 The suspension of the Certificate is requested by the Organization supporting the reasons motivating the request or decided by **ICONTEC** in case of non-compliance of requirements and conditions set forth hereunder and those related to the results obtained in the evaluations carried out in the Organization. The Certificate may be suspended for one of the following causes:

a.) By written request of the Organization;

b.) When there is a temporary cessation of activities or relocation of facilities or there is no production or provision of services or performance of the scope activities for two consecutive follow-ups;

c.) For arrears of more than sixty (60) days in the payment of the evaluation services established contractually or failure to comply with payment agreements;

d.) For engaging in activities harming the **ICONTEC** image or the certification activities;

e.) Breaching conditions set forth hereunder;

f.) Permanence of a non-conformity or non-compliance with the established deadline for a modified requirement or for failure to establish and communicate the corrections, causes and corrective actions adequate to solve the non-conformities within the deadlines set forth herein;

g.) Failure to send the test results within the agreed deadlines;

h.) Delay in the submission of corrective actions for nonconformities solution, in reporting of test results or any information requested by **ICONTEC** during the evaluation process;

i.) Failure to resolve critical, major or minor nonconformities pending from previous evaluations in a complementary verification;

j.) Failure to receive follow-up and renewal evaluations on the scheduled dates;

k.) If the Organization is involved in any type of public scandal in press, radio, television, social networks or Internet, or in judicial or administrative investigations for engaging in illicit or illegal activities or for the unjustified infringement of third-party rights. These criteria, together with those of the foregoing paragraph, shall be validated according to the parameters and committees designated within **ICONTEC**;

l.) If the Organization or any person related thereto is judicially condemned for any of the facts described in the foregoing paragraph. This criterion shall be validated by **ICONTEC**'s Chief Legal Officer;

m.) Failure to meet the **ICONTEC** requirements within the established deadlines;

n.) The non-acceptance of the realization of an extraordinary evaluation or when critical and/or major non-conformities are detected in this audit.

ICONTEC is entitled to suspend the certificate(s) issued as a result of investigations and penalties imposed by the competent authority for non-compliance with legal or regulatory requirements applicable to the scope of product certification. This criterion shall be validated according to the parameters and committees designated within **ICONTEC**.

In case of occurrence of grounds set forth in Section 4.7.2 (k) and (l) of this Regulation, **ICONTEC** reserves the right to file the corresponding legal actions against the Organization, claiming the payment of damages and indemnities, not limited to the amount set out in the first paragraph of Section 4.7.1 (c), Section 4.7.1 (c). This, without prejudice to file the relevant legal actions for any other type of aggression, injury or fault against **ICONTEC**, its intellectual capital, rights and team of collaborators.

The certification suspension implies the waiver by the Organization to any legal action against **ICONTEC**. Moreover, the Organization shall not be able to continue using the Certificate for any purpose from the date on which it is notified in writing of the suspension thereof.

If the Organization continues to use the Certificate, **ICONTEC** may initiate the corresponding legal actions and require the Organization to pay the fees and compensations for improper Certificate use. **ICONTEC** may request the dissemination and publicity it deems appropriate about the suspension.

The suspension status shall not exceed one hundred and fifty (150) days from its beginning; if this period is exceeded, the certification shall be cancelled. If the term defined for the suspension exceeds the effective date of the certificate, the latter shall prevail.

All suspensions are lifted after verifying that the causes leading to suspension have been remedied; a reactivation evaluation is required in all cases except in the conditions indicated in Items c and d of this section. The reactivation decision must be made before the maximum suspension term. The reactivation evaluations shall have a duration equivalent to the renewal evaluation and the Organization shall bear its cost.

Note. In case the Organization does not accept the evaluation to be conducted after the second rescheduling, the Certificate shall automatically be suspended.

4.7.3 **Cancellation.** The cancellation of the Certificate may be requested by the Organization or decided by **ICONTEC** in case of non-compliance with the requirements and conditions set forth hereunder and those related to the results obtained in the evaluations carried out in the Organization. The Certificate may be cancelled for one of the following causes:

a.) At the written request of the Organization;

b.) Failure to remedy within the established deadlines the causes leading to certification suspension;

c.) Failure to reactivate within the suspension period;

d.) By merger, spin-off, liquidation, takeover, transfer of shares and in general any other operation that implies a change in the legal nature or ownership of the Organization,

which has not been notified to **ICONTEC** and that does not ensure the continuity of compliance of the product in relation to the reference.;

e.) For recidivism in a penalty of suspension of the Certificate;

f.) For more than ninety (90) days in arrears in the payment of the evaluation services established contractually or failure to comply with the payment agreements;

g.) For engaging in activities harming the **ICONTEC** image or certification activities;

h.) Violation of the conditions set forth hereunder;

i.) Failure to receive follow-up and renewal evaluations on scheduled dates;

j.) Alter or change the content of the scope of the Certificate or validity thereof;

k.) Submitting false documentation to obtain or maintain certification;

l.) Misuse of Certificate or for unlawful acts;

m.) Failure to carry out the follow-up or renewal evaluations within the deadlines set forth herein;

n.) non-acceptance of an extraordinary evaluation carrying out or critical or major non-conformities are detected in this audit.;

o.) **ICONTEC** is entitled to cancel the certificate(s) issued as a result of investigations and penalties imposed by the competent authority for non-compliance with legal or regulatory requirements applicable to the scope of product certification. This criterion shall be validated according to the parameters and committees designated within **ICONTEC**.

En caso de presentarse las causales contempladas en los Literales j, k, l del Numeral 4.7.3 In the event of any of the causes set out in paragraphs j, k, l of Section 4.7.3 of these Regulations, **ICONTEC** reserves the right to file the corresponding legal actions against the Organization, claiming the payment of damages and indemnities, not limited to the amount set forth in the first paragraph of letter c of Section 4.7.1, without prejudice to file the relevant legal actions for any other type of aggression, injury or fault against **ICONTEC**, its intellectual capital, rights and team of collaborators.

The Certificate cancellation shall be communicated in writing to the Organization. Once the above has occurred, all the rights of use cease pursuant to law, being the Organization obliged to suspend all publicity thereof and to recall the products authorized with the Certificate, unless **ICONTEC** for justified reasons exempts the organization from such obligation. Failure to comply with this provision shall be penalized with a fine in an amount equivalent to

twenty (20) legal monthly minimum wages in force. Moreover, the Organization undertakes to provide in writing an evaluation of the stock of the product that held the certification and an estimate of the time needed for such product is exhausted in the market.

Based on this information, **ICONTEC** will make the respective liquidation of the rights of use of the Certificate and will define the date from which it will be definitively cancelled.

The cancellation of the certification implies the waiver by the Organization to any legal action against **ICONTEC**. In case Certificate withdrawal, all rights of use thereof cease immediately, being obliged the Organization to suspend all publicity related thereto from the date on which it is notified in writing of the cancellation of the Certificate. The cancellation includes the return of the Certificate to **ICONTEC**.

In case the Organization continues to use the Certificate, **ICONTEC** may file the corresponding legal actions and require the Organization to pay the fees and compensations for improper use of the Certificate. **ICONTEC** may request the Certificate cancellation be disseminated and publicized as it deems appropriate.

4.8 Processing of appeals and appeal for review

The decisions taken by **ICONTEC** regarding certification are subject to the process of appeal for review, which must be submitted by the Organization to **ICONTEC**, and whose process is carried out in accordance with the procedure established by **ICONTEC**. This appeal for review must be presented by the Organization with the supporting evidence, within five (5) working days following the receipt of the notification of the decision taken. If after such period the Organization does not submit the appeal for review in writing, it shall be understood that it accepts such decisions without any further judicial or extrajudicial claims. **ICONTEC** shall respond to the dispute within a maximum of thirty (30) calendar days after receiving the communication of the appeal for review.

The decisions taken by **ICONTEC** regarding certification in the appeal for review process are subject to appeal before the Appeals Committee, whose process shall be carried out in accordance with the procedure established by **ICONTEC**. This appeal shall be presented by the Organization, with the supporting evidence, within five (5) working days following the receipt of the notification of the deed resolving the appeal for review. If after this term the Organization does not file an appeal, it is understood that it accepts such decisions without any further judicial or extrajudicial claims. **ICONTEC** shall answer the appeal within a maximum of thirty (30) calendar days after receiving the communication of the appeal.

4.9 Complaints or claims about ICONTEC's certification services

If, in the opinion of the Organization's representatives, there are some dissatisfactions with the product certification services provided by **ICONTEC**, the Organization may submit a complaint

or claim with the evidence that in their opinion supports the dissatisfaction at the e-mail address cliente@icontec.org.

ICONTEC investigates the complaint or claim in accordance with the procedures established for this purpose and formally responds to the Organization. If the investigation of the complaint or claim implies non-compliance with the requirements established by **ICONTEC** in its procedures, the pertinent corrections and corrective actions are implemented..

4.10 Complaints or claims for ICONTEC certified products presented by third parties

If in the opinion of a person or organization there are some dissatisfactions with a product certified by **ICONTEC**, such person or organization may file the corresponding complaint or claim attaching the evidence that in their opinion supports the non-compliance of the product, including test results reports, information from the laboratories where such tests were performed, photographs and information of the samples tested, among other aspects. **ICONTEC** may request the performance of tests under supervision to confirm the non-compliance of the product with the requirements of the certification reference. The information should be sent to the e-mail address cliente@icontec.org.

ICONTEC investigates the complaint or claim in accordance with the procedures established for this purpose and formally responds to the person or organization. If the investigation of the complaint or claim shows non-compliance with the **ICONTEC** procedures requirements, the relevant corrections and corrective actions are established with the holder of the certification.

4.11 Manifestation of willingness

The Organization freely, voluntarily and spontaneously accepts that it has contracted **ICONTEC**'s services without any kind of pressure, constraint, conditioning or impact to its will, and that it has not received any promise of remuneration, benefit, compensation, prize or preference treatment with respect to the services it has contracted from **ICONTEC**, and therefore unconditionally and irrevocably waives the right to claim from **ICONTEC** the recognition of rights or any other consideration outside the provisions of the contracted service, either judicially or extra-judicially. Therefore, any provision contrary to what is described herein, even in internal documents of the Organization, are not opposable or enforceable to **ICONTEC**, except with its prior, express and written authorization.

The Organization will use the information provided by **ICONTEC**, including the evaluation report, in accordance with the policies on industrial and intellectual property established by **ICONTEC**, including the form and procedure with which evaluations are carried out, arguments are presented and relevant information is submitted, in which sense, from now on it is prohibited and the Organization accepts that it will not record or reproduce by any audiovisual or photographic means nor the evaluations, conferences or documents property of **ICONTEC**, being clear that

any violation of this provision generates in favor of **ICONTEC** and against the Organization the legal actions and compensation for damages established by law.

4.12. Anti-money laundering and anti-terrorist financing parameters

With the acceptance and contracting of the services offered by **ICONTEC**, governed by these regulations, you will be subject to these provisions that seek to benefit the country by attacking the financing of terrorism and money laundering. By contracting the services offered by **ICONTEC** makes the contracting party an immediate acceptor of these regulations, so that it will not be able to allege ignorance or different reasons to abstain from complying with them.

By virtue of the foregoing, **ICONTEC** is entitled to suspend or cancel at any time the certificate(s) it has issued, when it becomes aware that the Client has been involved or is being under investigations for these facts before the competent judicial or administrative authorities.

Provisions:

a.) The Organization expressly and clearly declares that its funds and resources are of legal and legitimate origin, the result of operations carried out in compliance with its corporate purpose, within the legal and regulatory framework of the industrial and commercial activities it performs. It further declares that it has verified the delivery and unencumbered property certificate of the goods it owns, verifying that said properties have not belonged to persons engaged in crimes related to money laundering and financing of terrorism.

b.) The Organization expressly declares that it is not being investigated by any private or government entity for facts in any way related to money laundering or terrorist financing, or that, if it has been the subject of such investigation, it has already been completed with satisfactory results and no criminal offenses. In case of ongoing investigation, it shall inform **ICONTEC** expressly and in advance to the provision of the contracted service, submitting all relevant documentation and information, to be evaluated by **ICONTEC**, who, at its discretion and sole will, may decide whether or not to execute the contract and provide the service to the Organization.

c.) In the event that it conducts business operations directly or indirectly in countries qualified as tax havens, the Organization undertakes to inform **ICONTEC** expressly and in a timely manner, clarifying what those operations consist of. In this case, **ICONTEC** at its discretion and sole will may decide to execute or not the contract and provide the service to the Organization.

d.) The Organization expressly authorizes **ICONTEC** to inform private and government entities in charge of investigating and attacking money laundering and financing of terrorism, those facts or circumstances suspected of being related to money laundering

or financing of terrorism, without this violating the duty of confidentiality of information or causing compensation or payment of damages in favor of the Client.

e.) The Organization accepts that all commercial operations it enters into with **ICONTEC** will be carried out using the mechanisms of the financial system, and documenting each operation with contracts and invoices.

f.) The Organization's failure to comply with any of the provisions contained in this chapter shall imply, and it is hereby accepted, the non-contracting of the services offered by **ICONTEC**.

g.) The Organization declares that it has verified the judicial background of all its employees, and therefore certifies that it has not hired persons who have been or are under administrative or judicial investigations for acts related to money laundering and financing of terrorism.

h.) The Organization declares awareness about the identity of its clients, and that, in case it becomes aware of any suspicious operation by any of its clients, it will report it to the private and government entities responsible for investigating and attacking money laundering and terrorist financing and to **ICONTEC**, immediately. Moreover, the Client declares that it will keep a record of the operations it enters into with its clients.

i.) The Organization declares that it has trained or will train its employees in operations suspected of being linked to money laundering and financing of terrorism. The Organization further declares that it will prohibit its employees from informing clients of the report made of suspicious operations to the competent authorities.

j.) The Organization declares, accepts and acknowledges that it will hold **ICONTEC** harmless from any investigation and connection with operations related to money laundering and financing of terrorism, so that in the event that **ICONTEC** is linked to one or more of these investigations for facts originating or in which the Client is a party, it will assume the costs and expenses of legal, judicial and technical defense in which **ICONTEC** has to incur to protect its interests. In the event that **ICONTEC** directly assumes its defense, it will be able to repeat for the corresponding values against the Organization.

5. REFERENCED DOCUMENTS

- I-PS-0063 PROVISIONS RELATED TO THE CONTRACTING OF EXTERNAL LABORATORIES
- E-GM-0002 USE OF **ICONTEC** CERTIFICATION CONFORMITY MARKS
- FOR PRODUCT, PROCESS AND SERVICE INSPECTION
- R-PS-0019 REGULATIONS FOR THE CERTIFICATION OF TANGIBLE PRODUCTS

6. REFERENCED POSITIONS

- Account Executive
- Chief Legal Officer
- Regional Coordinator

ANNEX 1

DESCRIPCIÓN DE LOS ESQUEMAS DE CERTIFICACIÓN TIPO 4 Y TIPO 5

1. TYPE 4 SEAL (QUALITY SEAL OR ICONTEC SEAL WITH TECHNICAL REGULATION)

Permanent certification scheme, which includes verification of the product according to the requirements of the reference on samples taken in the market and/or at the point of manufacture and verification of the production control system.

Option 1:

Application for certification. The application must include a detailed list of the product references to be certified, classified by family and for each of the plants to be covered by the certification. The applicant must indicate the criteria applied for the grouping of the references in families. **ICONTEC** will review these criteria and may adjust the classification of references by families.

Stage 1 evaluation. The Organization shall provide evidence of compliance with all applicable requirements of the certification standard for 100% of the families covered by the certification and defined in the service request. Failure to complied with this provision, tests must be carried out on the families for which results reports are not available for all the requirements of the certification standard.

Stage 2 evaluation (on site). In the granting evaluation, the requirements established for the production process control system of Annex 4 of the Regulation shall be verified at the production plant.

In the granting evaluation, the tests must be performed on 25% of the families in an accredited laboratory or in the organization's laboratory (laboratories of the organizations can only be used if there are no accredited laboratories, or such laboratories specify in a communication they unavailability to meet the request for testing in a maximum of thirty (30) days) and the product samples are taken in the market or in the manufacturing plant, or both.

Validity of the certification. The Certificate is valid for three (3) years with an annual follow-up.

Follow-up evaluation. At each follow-up, the requirements of the production process control system are rechecked and the product requirements are verified for 20% of the certified families (15% by means of tests performed on physical product samples and 5% verified by means of manufacturer's test records).

Option 2:

Application for certification. The application must include a detailed list of the product references to be certified, classified by family and for each of the plants to be covered by the

certification. The applicant must indicate the criteria applied for the grouping of the references in families. **ICONTEC** will review these criteria and may adjust the classification of references by families.

Stage 1 evaluation. The Organization shall provide evidence of compliance with all applicable requirements of the certification standard for 100% of the families covered by the certification and defined in the service request. If this provision is not complied with, tests must be carried out on the families for which results reports are not available for all the requirements of the certification standard.

Stage 2 evaluation (on site). As an alternative for clients whose production is located outside Colombia where **ICONTEC** does not operate, an on-site evaluation report of the production process control system requirements may be accepted from a product certification body accredited to ISO/IEC 17065 or a management system certification body accredited to ISO/IEC 17021-1 and whose accredited scope covers the IAF/NACE sector in which the product is manufactured. In both cases, the accreditation body of the certification bodies must be a signatory of the IAF mutual recognition agreement.

In this case, testing for granting the Seal must be performed on 45% of the families in an accredited laboratory and product samples are taken in the market.

Certification Validity. The certificate is valid for three (3) years with an annual follow-up.

Follow-up evaluation. At each follow-up, the requirements of the production process control system are re-verified through the on-site evaluation report of the Accredited Product Certification Body and verification of the product requirements is performed on 25% of the families at each follow-up (20% through tests performed on physical samples of the product in an accredited laboratory and 5% verified through the manufacturer's test records).

NOTES:

a.) In option 2, the Certification Body's report related to the requirements of the production process control system must be submitted based on the template provided by **ICONTEC**.

b.) For the use of laboratories, the particular requirements defined in Decree 1595/2015 of the Ministry of Commerce, Industry and Tourism, or in Technical Regulations, for example, Technical Regulation of Electrical Installations RETIE, among others, must be taken into account.

c.) The period of validity and follow-up of the certification can be modified when granted under a Technical Regulation which establishes special provisions regarding the validity of the certification. In this case **ICONTEC** shall inform in the commercial proposal the special conditions of the certification validity defined in the technical regulation.

2. TYPE 5 SEAL (QUALITY SEAL OR ICONTEC SEAL WITH TECHNICAL REGULATIONS)

Permanent certification scheme, which includes verification of the product according to the reference requirements on samples taken in the market and/or at the manufacture site and verification of the production control system and quality management system

Option 1:

Application for certification The application shall include a detailed list of the product references to be certified, classified by family and for each of the plants to be covered by the certification. The applicant must indicate the criteria applied for the grouping of the references in families. **ICONTEC** will review these criteria and may adjust the classification of references by families.

Stage 1 evaluation. The Organization must provide evidence of compliance with all applicable requirements of the certification reference for 100% of the families covered by the certification and defined in the service request. If this provision is not complied with, tests must be carried out on the families for which results reports are not available for all the requirements of the certification reference

Stage 2 evaluation (on site). In the granting evaluation, the requirements established by the service regulation R-PS-0019 REGULATIONS FOR THE CERTIFICATION OF TANGIBLE PRODUCTS for the quality management system and production control system will be verified at the production plant.

In the granting evaluation, the tests must be performed on 20% of the families in an accredited laboratory or in one of the Organization's laboratories (company laboratories can only be used if there are no accredited laboratories, or if these laboratories specify in a communication their unavailability to meet the request for tests within a maximum of thirty (30) days) and the product samples are taken in the market and in the manufacturing plant.

Validity of the certification. The certificate is valid for six (6) with an annual follow-up.

Follow-up evaluation. At each follow-up, the requirements of the quality management system and of the production process control are rechecked and verification of the product requirements is performed on 15% of the certified families (10% through tests performed on physical samples of the product and 5% verified through manufacturer's test records).

Option 2

Application for certification. The application shall include a detailed list of the product references to be certified, classified by family and for each of the plants to be covered by the certification. The applicant must indicate the criteria applied for the grouping of the references in families. **ICONTEC** will review these criteria and may adjust the classification of references by families.

Stage 1 evaluation. The Organization shall provide evidence of compliance with all applicable requirements of the certification standard for 100% of the families covered by the certification and defined in the service request. If this provision is not complied with, tests must be carried out on the families for which results reports are not available for all the requirements of the certification reference.

Stage 2 evaluation (on site). As an alternative for customers whose production is located in plants outside Colombia where **ICONTEC** does not operate, management system certifications under ISO 9001 (or IATF 16949 or ISO 13485) issued by a Certification Body accredited to ISO/IEC 17021-1, whose accreditation body is a signatory of the IAF mutual recognition agreement and whose accredited scope covers the IAF/NACE sector in which the product is manufactured, may be accepted.

In this case, the execution of tests for the granting of the seal must be carried out on 40% of the families in an accredited laboratory and the product samples are taken in the market.

Certification Validity. The certificate is valid for six (6) years with an annual follow-up

Follow-up evaluation. At each follow-up, the validity of the ISO 9001 (or IATF 16949 or ISO 13485) management system certificate is verified and verification of the product requirements is performed at 25% of the families in an accredited laboratory at each follow-up. Additionally, at **ICONTEC**'s discretion, a visit may be conducted to the manufacturing plant where product design activities are performed, or other critical sites related to product manufacturing and covered by the certification during certificate validity.

NOTES:

a.) For the use of laboratories, the requirements set forth in Decree 1595/2015 of the Ministry of Commerce, Industry and Tourism, or in Technical Regulations, for example, Technical Regulation of Electrical Installations RETIE, among others, must be taken into account.

b.) The period of validity and follow-up of the certification can be modified when it is granted under a Technical Regulation which establishes particular provisions regarding the certification validity. In this case **ICONTEC** shall inform in the commercial proposal the special conditions of the certification validity set forth in the technical regulation.

ANNEX 2

CONFORMITY ASSESSMENT ACTIVITIES EVALUATED FOR EACH SEAL ACCORDING TO THE TYPE OF CERTIFICATION SCHEME

Type of Evaluation	Granting/Renewal				Follow-up						
Type of certification scheme	Product testing at the plant and/or market or both.	Verification of quality management system at the marketer (Note 1)	In-plant quality management system verification	Verification of plant production control	Product testing in the market	In-plant product testing	Verification of quality management system at the marketer (Note 1)	Verification of quality management system	Verification of plant production control	**FFrequency of follow-up (per year) Note 2**	**Certificate Term (years) Note 2**
TYPE 4	X	X		X	X	X	X		X	1	3
TYPE 5	X	X	X	X	X	X	X	X	X	1	6

Notes:

1. This provision is applicable when the certification holder is the marketer of the product (see Section 1 of Annex 3 or Section 1 of Annex 4 according to the type of certification scheme). **ICONTEC** has the power to verify the requirements of the management system in the Colombian representation for Manufacturers Abroad.
2. The period of validity and follow-up of the certification can be modified when it is granted under a Technical Regulation, which establishes special provisions regarding the certification validity. In this case **ICONTEC** shall inform in the commercial proposal the special conditions of the certification validity set forth in the technical regulation.
3. For the purposes of this regulation, whenever the certification of the quality management system is mentioned, it should be understood that the certification reference is ISO 9001 (or IATF 16949 or ISO 13485) in its current version and that the

scope of the certification includes the manufacture of the products for which the certification is requested.

4. Annexes 3 and 4 establish the requirements of the quality management or production control system, respectively, according to the type of product certification scheme. Additionally, the requirements of the quality management or production control system are established for organizations that manufacture the product through a tolling agreement.

ANNEX 3

QUALITY MANAGEMENT SYSTEM REQUIREMENTS FOR ICONTEC GRANTED SEALS

1. SCOPE

This annex establishes the requirements to be met by the quality management system of the Organization requesting or having authorization for product certification for the **ICONTEC** Quality Seal and **ICONTEC** seal with technical regulation (Type 5 certification scheme).

In the event that product certification is desired for a marketer, in addition to the requirements established in the manufacturing plant, the requirements established in the following paragraphs must be evaluated at the point of commercialization:

Annex 3 Section	Requirement applicable to marketer (Schedule 5)
5.6	Documented information
6.3.2	Identification and traceability
6.3.3	Preservation
6.5	Control of non-conforming outputs
9.2	Non-conformity and corrective action
10	Complaint handling
11	Compliance with legal requirements

If the marketer is certified under ISO 9001 (or IATF 16949 or ISO 13485) and the scope of the certification covers the product subject to certification, no requirement mentioned above is evaluated

2. DEFINITIONS

For the purposes of this annex, the following apply in addition to the definitions set out in ISO 9000:2015 "Quality Management Systems. Fundamentals and Vocabulary":

2.1 **Product inspection and testing plan.** Document that indicates as a minimum: the product characteristics that guarantee compliance with all the requirements set forth in the reference, including labeling, frequency, acceptance criteria, test methods, equipment used and those responsible for verification at all stages of the process considered relevant by the Organization.

2.2 **Verification.** Confirmation by providing objective evidence that the specified requirements have been met.

2.3 **Traceability.** Ability to follow the history, application or location of the product after delivery. When considering a product, traceability may relate to: the origin of materials and parts, the processing history, and the distribution and location of the product after delivery.

3. LEADERSHIP AND COMMITMENT

Top management must demonstrate leadership and commitment to the quality management system:

a.) Ensuring availability of the necessary resources for the quality management system;

b.) Communicating the importance of effective quality management in accordance with the requirements of the quality management system;

c.) Ensuring that the quality management system achieves the intended results;

d.) Engaging, leading and supporting people, to contribute to the effectiveness of the quality management system;

e.) Promoting improvement;

f.) Supporting other relevant management roles to demonstrate leadership as it applies to their areas of responsibility.

4. ROLES, RESPONSIBILITIES AND AUTHORITIES IN THE ORGANIZATION

Top management shall ensure that responsibilities and authorities for relevant roles are assigned, communicated and understood throughout the organization. Top management should assign responsibility and authority for:

a.) Ensure that the quality management system conforms to the requirements of this annex;

b.) Report, in particular, to top management on the performance of the quality management system and on opportunities for improvement (see Section 9);

c.) Ensure that customer focus is promoted throughout the Organization;

d.) Ensure maintenance of the quality management system integrity when changes to the quality management system are planned and implemented.

5. RESOURCES

5.1 General

The Organization shall determine and provide the necessary resources for the establishment, implementation, maintenance and continual improvement of the quality management system. The Organization shall consider:

a.) The capabilities and limitations of existing internal resources;

b.) What needs to be obtained from external suppliers.

5.2 Persons

The Organization shall determine and provide the people necessary for the effective implementation of its quality management system.

5.3 Infrastructure

The Organization shall determine, provide and maintain the necessary infrastructure for its processes operation and achieve product conformity.

Note. Infrastructure may include:

a.) Buildings and associated services;

b.) Equipment, including hardware and software;

c.) Transportation resources;

d.) Information and communication technologies.

5.4 Monitoring and measurement resources

5.4.1 General

The Organization shall identify and provide the necessary resources to ensure results validity and reliability when monitoring or measuring to verify products requirement conformity.

The Organization shall ensure that the resources provided:

a.) Are appropriate for the specific type of monitoring and measurement activities performed;

b.) Are maintained to ensure continued adequacy for their intended purpose.

The organization shall retain appropriate documented information as evidence that the monitoring and measurement resources are adequate for their intended purpose.

5.4.2 Measurement traceability

To provide confidence in the validity of the measurement results, the measurement equipment shall be:

a.) Calibrated or verified, or both, at specified frequency, or prior to use, against measurement standards traceable to international or national measurement standards; where such standards do not exist, the basis used for calibration or verification should be retained as documented information;

b.) Identified to determine the status;

c.) Protected against adjustments, damage or deterioration that could invalidate the calibration status and subsequent measurement results.

The Organization shall determine whether the validity of previous measurement results has been adversely affected when the measurement equipment is found to be unfit for its intended purpose, and shall take appropriate action where necessary.

5.5 Competence

The Organization shall:

a.) Determine the necessary competence of persons performing, under its control, work affecting the performance and effectiveness of the quality management system;

b.) Ensure that these persons are competent, based on appropriate education, training or experience;

c.) Where applicable, take action to gain the necessary competence and evaluate the actions taken effectiveness;

d.) Retain appropriate documented information as evidence of competence.

Note. Applicable actions may include, for example, training, mentoring or reassignment of currently employed persons; or the hiring or subcontracting of competent persons.

5.6 Documented information

5.6.1 General

The Organization's quality management system shall include:

a.) The documented information required herein;

b.) Documented information that the Organization determines to be necessary for the quality management system effectiveness.

5.6.2 Creation and updating

When creating and updating documented information, the organization shall ensure appropriateness of the following:

a.) Identification and description (e.g., title, date, author or reference number);

b.) Format (e.g., language, software version, graphics) and media (e.g., paper, electronic);

c.) The review and approval with respect to suitability and adequacy.

5.6.3 Control of documented information

5.6.3.1 The documented information required by the quality management system and this annex shall be controlled to ensure the following:

a.) Is available and suitable for use where and when needed;

b.) Adequately protected (e.g., against loss of confidentiality, misuse or loss of integrity).

5.6.3.2 For the control of documented information, the Organization shall address the following activities, as appropriate:

a.) Distribution, access, retrieval and use;

b.) Storage and preservation, including preservation of readability;

c.) Change control (e.g., version control);

d.) Retention and disposition.

External origin documented information, which the Organization determines as necessary for the planning and operation of the quality management system, shall be identified and, as appropriate, controlled.

Documented information retained as evidence of conformity shall be protected against unintentional modification.

6. OPERATION

6.1 Operational planning and control

The Organization shall plan, implement and control the processes necessary to meet the requirements for the provision of products by:

a.) Determining product requirements;

b.) Establishing criteria for:
- Processes;
- Product acceptance;

c.) Determining resources necessary to achieve conformity with product requirements;

d.) Implementing process control in accordance with the criteria;

e.) Determining, maintaining and preserving documented information to the extent necessary to:
1. Gain confidence that the processes have been carried out as planned;
2. Demonstrate products conformity with their requirements.

This planning output must be appropriate for the organization's operations

The organization shall monitor planned changes and review the consequences of unplanned changes, taking action to mitigate any adverse effects as necessary.

6.2 Control of outsourced processes, products and services

6.2.1 General

The organization shall ensure that outsourced processes, products and services conform to requirements.

The organization shall determine the controls to be applied to outsourced processes, products and services when:

a.) Outsourced products and services are intended to be incorporated into the Organization's own products;

b.) Products and services are provided directly to customers by external suppliers on behalf of the Organization;

c.) A process, or a part of a process, is provided by an external supplier as a result of a decision of the Organization.

The Organization shall determine and apply criteria for the evaluation, selection, performance monitoring and re-evaluation of external suppliers based on their ability to provide processes or products and services in accordance with requirements. The organization shall maintain documented information on these activities and any necessary actions arising from the evaluations.

6.2.2 Type and scope of control

The Organization shall ensure that outsourced processes, products and services do not adversely affect the Organization's ability to consistently deliver conforming products to its customers.

The Organization shall:

a.) Ensure that outsourced processes remain within the control of the Organization quality management system;

b.) Define the controls it intends to apply to an external supplier and those it intends to apply to the resulting outputs;

c.) Take into consideration:
- The potential impact of outsourced processes, products and services on the Organization's ability to regularly meet product and applicable legal and regulatory requirements;
- The effectiveness of the controls implemented by the external supplier;

d.) Determine the verification, or other activities necessary to ensure that the outsourced processes, products and services meet requirements.

6.2.3 Information for external suppliers

The Organization shall ensure the adequacy of the requirements before communicating them to the external supplier.

The Organization shall communicate to external suppliers its requirements for:

a.) Processes, products and services to be provided;

b.) Approval of:
1. Products and services;
2. Methods, processes and equipment;
3. Release of products and services;

c.) Competence, including any qualifications required of individuals;

d.) The external supplier's interactions with the Organization;

e.) The control and monitoring of the external supplier performance to be implemented by the Organization;

f.) The verification or validation activities that the Organization intends to carry out at the external supplier's facilities.

6.3 Production

6.3.1 Production control

The organization must implement production under controlled conditions.

Controlled conditions should include, where applicable:

a.) The availability of documented information defining:
- Characteristics of the products to be produced, or the activities to be performed;
- Results to be achieved;

b.) The availability and use of appropriate monitoring and measurement resources;

c.) The implementation of monitoring and measurement activities at appropriate stages to verify compliance with the criteria for the control of processes or their outputs, and the acceptance criteria for products.

d.) The use of the appropriate infrastructure and environment for the process's operation;

e.) The designation of competent persons, including any required qualifications;

f.) The implementation of actions to prevent human error;

g.) The implementation of release, handover and post-handover activities.

6.3.2 Identification and traceability

The Organization shall use appropriate means to identify outputs, where necessary, to ensure product conformity.

The Organization shall identify the status of outputs with respect to monitoring and measurement requirements through production.

The Organization shall control the unique identification of outputs where traceability is a requirement, and shall maintain the documented information necessary to enable traceability.

6.3.3 Preservation

The organization must preserve the outputs during production, to the extent necessary to ensure conformity with the requirements.

Note. Preservation may include identification, handling, contamination control, packaging, storage, transmission of information or transport, and protection.

6.3.4 Post-delivery activities

The Organization must comply with the requirements for post-delivery activities associated with the products.

In determining the scope of post-delivery activities required, the Organization should consider:

a.) Legal and regulatory requirements;

b.) Products associated potential unintended consequences;

c.) The nature, use and expected service life of products;

Note. Post-delivery activities may include actions covered by warranty conditions, contractual obligations such as maintenance services, and supplemental services such as recycling or disposal.

6.3.5 Control of changes

The organization shall review and control changes for production to the extent necessary to ensure continued requirements conformity.

The organization shall maintain documented information describing the results of the review of changes, the persons authorizing the change and any necessary action arising from the review.

6.4 Product release

The Organization shall implement the planned arrangements, at appropriate stages, to verify product requirements compliance.

Product shall not be released until the planned arrangements have been satisfactorily completed.

The organization shall maintain documented information on product release. Documented information should include the following:

a.) Evidence of compliance with the acceptance criteria;

b.) Traceability to persons authorizing release.

6.5 Control of non-conforming outputs

6.5.1 The Organization shall ensure identification and control of outputs not conforming to its requirements to prevent unintended use or delivery thereof.

The organization shall take appropriate action based on the nature of the nonconformity and its effect on product conformity. This should also apply to nonconforming products detected after products delivery.

The organization shall deal with nonconforming outputs in one or more of the following ways:

a.) Correction;

b.) Separation, containment, return or suspension of product supply;

Conformity with requirements must be verified when correcting non-conforming outputs.

6.5.2 The Organization shall maintain documented information that:

a.) Describe the nonconformity;

b.) Describe the actions taken;

c.) Identify the authority that decides the action regarding nonconformities.

7. INTERNAL AUDIT.

7.1 The Organization shall carry out internal audits at planned frequency to provide information about whether the quality management system:

a.) It is in accordance with:
- The Organization's own requirements for its quality management system;
- The requirements of this annex;

b.) Effectively implemented and maintained.

7.2 The Organization shall:

a.) Plan, establish, implement and maintain an audit program(s) including frequency, methods, responsibilities, planning and reporting requirements, which should take into consideration the importance of the processes involved, changes affecting the organization and the results of previous audits;

b.) Define the audit criteria and each audit scope;

c.) Selecting auditors and conducting audits to ensure objectivity and impartiality of the audit process;

d.) Ensure audits results reporting to the relevant management;

e.) Make corrections and take appropriate corrective actions without undue delay;

f.) Retain documented information as evidence of the implementation of the audit program and the results of audits.

Note. See ISO 19011 for guidance.

8. REVIEW BY MANAGEMENT.

8.1 General

Top management should review the Organization's quality management system at planned intervals to ensure the system suitability, adequacy, effectiveness, efficiency and effectiveness.

8.2 Review by Management Inputs.

The review by management shall be planned and carried out including considerations on:

a.) Status of actions from previous reviews by management;

b.) Changes in external and internal issues that are relevant to the quality management system;

c.) Information on the performance and effectiveness of the quality management system, including trends relating to:
   1. Customer satisfaction and feedback from relevant stakeholders;
   2. Process performance and conformity of products and services;
   3. Non-conformities and corrective actions;
   4. Monitoring and measurement results;
   5. Audit results;
   6. Performance of external suppliers

d.) Resources adequacy;

e.) Opportunities for improvement.

8.3 Review by Management Outputs.

Review by Management outputs shall include the decisions and actions related to:

a.) Opportunities for improvement;

b.) Any need for change in the quality management system;

c.) Resource requirements.

The organization shall maintain documented information as evidence of the results of management reviews.

9. IMPROVEMENT

9.1 General

The organization shall identify and select opportunities for improvement and implement any actions necessary to meet customer requirements and increase customer satisfaction.

These should include:

a.) Improving products to meet requirements, as well as considering future needs and expectations;

b.) Correcting, preventing or reducing undesirable effects;

c.) Improving performance and effectiveness of the quality management system.

Note. Improvement may include correction, corrective action, continuous improvement, abrupt change, innovation and reorganization.

9.2 Non-conformity and corrective action.

9.2.1 When a nonconformity occurs, including any nonconformity arising from complaints, the Organization shall:

a.) React to the nonconformity and, where applicable:
   1. Take actions to control and correct it;
   2. Addressing the consequences;

b.) Evaluate the need for actions to eliminate the nonconformity causes, so that it does not recur or occur elsewhere, through:
   1. Nonconformity review and analysis;
   2. Determination of the nonconformity causes;
   3. Determination of whether there are similar nonconformities, or potentially occurring nonconformities;

c.) Implement any necessary actions;

d.) Review effectiveness of any corrective action taken;

e.) If necessary, update the risks and opportunities identified during planning; and

f.) If necessary, make changes to the quality management system.

Corrective actions should be appropriate to the effects of the nonconformities found.

9.2.2 The Organization shall maintain documented information as evidence of:

a.) The non-conformities nature and any subsequent actions taken;

b.) The results of any corrective action.

10. TREATMENT OF CLAIMS

The organization shall apply and maintain up-to-date documented procedures for the reception and treatment of customer complaints about products for which the **ICONTEC** mark of conformity is granted. There shall be evidence regarding the treatment of the complaint, and whenever possible, the satisfaction of the client or final consumer (for mass consumption products). A consecutively numbered record must be kept of customer claims and complaints, as well as the treatment given to them

Note. Numbering can be re-started at will. For marketers or importers, the numbering must be re-initialized each time the certification is renewed.n.

11. COMPLIANCE WITH LEGAL REQUIREMENTS.

Organizations manufacturing food products and medical equipment must demonstrate compliance with the requirements of Good Manufacturing Practices established by the competent authority, through the respective permit or certification issued or endorsed by the corresponding authority.

The Organization shall comply with applicable legal requirements and demonstrate evidence of compliance, upon **ICONTEC** request.

Quality management system evaluation requirements for Organizations with product manufacturing and through a tolling contract.

Section	Quality management system requirement	Organization		Maquiladora	
		No SG certification	With SG certification	No SG certification	With SG certification
3	Leadership and commitment	X			
4	Roles, responsibilities and authorities in the organization	X			
5.1	General	X			
5.2	Persons	X		X	
5.3	Infrastructure	X		X	
5.4	Monitoring and measurement resources	X	X	X	X
5.5	Competence	X		X	
5.6	Documented information	X			
6.1	Planning and operational control	X		X	
6.2	Control of outsourced processes, products and services	X		X	
6.3	Release of products	X		X	
6.4	Control of non-conforming outputs	X	X	X	X
6.5	Internal audit	X	X	X	X
7	Review by Management	X			
8	Improvement	X			
9	General	X			
9.1	Generalidades	X			
9.2	Nonconformity and corrective action	X	X		
10	Complaint handling	X	X		
11	Compliance with legal requirements	X	X		

ANNEX 4

REQUIREMENTS FOR PRODUCTION CONTROL SYSTEM FOR ICONTECT GRANTED SEALS

1. SCOPE

This annex sets forth the requirements to be met by the production control system of the Organization requesting or having authorization for product certification for the **ICONTEC** Quality Seal and **ICONTEC** Seal with technical regulation (Type 4 certification scheme).

In the event that product certification is desired for a marketer, in addition to the requirements established at the manufacturing plant, the requirements set forth in the following items of Annex 3 at the marketing point shall be evaluated:

Section Annex 4	Requirement applicable to the marketer (Scheme 4)
3.6	Documented information
4.3.2	Identification and traceability
4.3.3	Preservation
4.5	Control of non-conforming outputs
6	Claims managing
7	Compliance with legal requirements

If the marketer is certified under ISO 9001 (or IATF 16949 or ISO 13485) and the scope of the certification covers the product that is the subject of the certification, no requirement mentioned above is evaluated.

2. DEFINITIONS

For the purposes of this annex, the following definitions apply in addition to those given in ISO 9000:2015 "Quality Management Systems. Fundamentals and Vocabulary:

2.1 Product inspection and test plan. Document that indicates as a minimum: the product characteristics that ensure compliance with all the requirements set out in the reference, including labeling, frequency, acceptance criteria, test methods, equipment used and those responsible for verification at all stages of the process considered relevant by the Organization.

2.2 **Verification.** Confirmation by providing objective evidence that the specified requirements have been met.

2.3 **Traceability.** Ability to track the history, application or location of the product after delivery.

When considering a product, traceability may relate to: the origin of materials and parts, the processing history, and the distribution and location of the product after delivery.

3. RESOURCES

3.1 Generalities

The Organization shall determine and provide the necessary resources for the establishment, implementation, maintenance and continuous improvement of the production control system.

The Organization must consider:

a.) the capabilities and limitations of existing internal resources;

b.) what needs to be obtained from external suppliers.

3.2 Persons

The Organization must determine and provide the people necessary for the effective implementation of its production control system..

3.3 Infrastructure

The Organization shall determine, provide and maintain the infrastructure necessary for its processes operation and to achieve product conformity.

Note. Infrastructure may include:

a.) Buildings and associated services;

b.) Equipment, including hardware and software;

c.) Transportation resources;

d.) Information and communication technologies;

3.4 Monitoring and measurement resources.

3.4.1 General

The Organization shall identify and provide the necessary resources to ensure the validity and reliability of the results when monitoring or measuring to verify products compliance with requirements.

The Organization shall ensure that the resources provided:

a.) Are appropriate for the specific type of monitoring and measurement activities performed;

b.) Are maintained to ensure continued adequacy for the intended purpose;

The organization shall retain appropriate documented information as evidence that the monitoring and measurement resources are adequate for the intended purpose.

3.4.2 Traceability of measurements.

To provide confidence in the validity of the measurement results, the measurement equipment shall be:

a.) Calibrated or verified, or both, at specified frequencies, or prior to use, against measurement standards traceable to international or national measurement standards; where such standards do not exist, the basis used for calibration or verification should be retained as documented information.;

b.) Identified to determine the status;

c.) Protected against adjustments, damage or deterioration that could invalidate the calibration status and subsequent measurement results.

The Organization shall determine whether the validity of previous measurement results has been adversely affected when the measurement equipment is found to be unfit for its intended purpose, and should take appropriate action where necessary.

3.5 Competence

The Organization shall:

a.) Determine the necessary competence of persons performing work under their control that affects the production control system performance and effectiveness;

b.) Ensure that these persons are competent, based on appropriate education, training or experience;

c.) Where applicable, take actions to gain the necessary competence and evaluate the actions taken effectiveness;

d.) Retain appropriate documented information as evidence of competence.

Note. Applicable actions may include, for example, training, mentoring, or reassignment of currently employed persons; or hiring or subcontracting competent persons.

3.6 Documented information.

3.6.1 General

The Organization must have at least the following:

a.) The documented information required herein;

b.) Documented information that the Organization determines as necessary for the production control system effectiveness.

3.6.2 Creation and updating.

When creating and updating documented information, the organization shall ensure appropriateness of the following:

a.) Identification and description (e.g., title, date, author or reference number);

b.) The format (e.g., language, software version, graphics) and media (e.g., paper, electronic);

c.) The review and approval with respect to suitability and adequacy.

3.6.3 Control of documented information.

3.6.3.1 Documented information required by the production control system and by this annex shall be monitored to ensure that:

a.) Is available and suitable for use where and when needed;

b.) Is adequately protected (e.g., against loss of confidentiality, misuse, or loss of integrity);

3.6.3.2 For controlling documented information, the Organization shall address the following activities, as applicable:

a.) Distribution, access, retrieval and use;

b.) Storage and preservation, including preservation of readability;

c.) Change control (e.g., version control);

d.) Preservation and disposal.

External origin documented information, which the Organization determines to be necessary for the planning and operation of the production control system, shall be identified, as appropriate, and controlled.

Documented information retained as evidence of conformity shall be protected against unintentional modification.

4 OPERATION

4.1 Operational planning and control

The Organization must plan, implement and control the processes necessary to meet the requirements for the provision of products through:

a.) Determining product requirements;

b.) Establishing criteria for:
- Processes;
- Product acceptance;

c.) Determining the resources needed to achieve product requirements compliance;

d.) Implementing process control in accordance with the criteria;

e.) Determining, maintaining and retaining documented information to the extent necessary to:
- Have confidence that processes have been carried out as planned;
- Demonstrate products compliance with requirements;

This planning output should be appropriate for the organization's operations.

The organization shall monitor planned changes and review the consequences of unplanned changes, taking action to mitigate any adverse effects as necessary.

4.2 Control of outsourced processes, products and services.

4.2.1 General

The Organization shall ensure compliance of outsourced processes, products and services with the requirements.

The Organization shall determine the controls to be applied to outsourced processes, products and services when:

a.) Outsourced products and services are intended to be incorporated into the Organization's own products;

b.) Products and services are provided directly to customers by external suppliers on behalf of the Organization;

c.) A process, or a part of a process, is provided by an external supplier as a result of a decision taken by the Organization;

The Organization shall determine and apply criteria for the evaluation, selection, performance monitoring and re-evaluation of external suppliers based on their ability to provide processes or products and services in accordance with requirements. The organization shall maintain documented information on these activities and any necessary actions arising from the evaluations.

4.2.2 Type and scope of control.

The Organization shall ensure that outsourced processes, products and services do not adversely affect the Organization's ability to consistently deliver compliant products to its customers.

The Organization shall:

a.) Ensure that outsourced processes remain within the production control system;

b.) Define the controls intended to be applied to an external supplier and those intended to be applied to the resulting outputs;

c.) Take into consideration the following:
- The potential impact of outsourced processes, products and services on the Organization's ability to regularly meet product and applicable legal and regulatory requirements;
- The effectiveness of the controls implemented by the external supplier;

d.) Define the verification, or other activities necessary to ensure outsourced processes, products and services compliance with requirements.

4.2.3 Information for external suppliers.

The organization shall ensure requirements adequacy before communicating them to the external supplier.

The Organization must communicate to external suppliers its requirements for:

a.) Processes, products and services to be provided;

b.) Approval of:
- Products and services;

- Methods, processes and equipment;
- Release of products and services;

c.) The competence, including any required qualifications of individuals;

d.) The external supplier's interactions with the Organization;

e.) The control and monitoring of the external supplier's performance to be applied by the Organization;

f.) The verification or validation activities that the Organization intends to carry out at the external supplier's premises;

4.3 Production

4.3.1 Production control.

The organization shall implement production under controlled conditions.

Controlled conditions shall include, where applicable:

a.) The availability of documented information defining:
- The characteristics of the products to be produced, or the activities to be performed;
- The results to be achieved;

b.) The availability and use of appropriate monitoring and measurement resources;

c.) The implementation of monitoring and measurement activities at appropriate stages to verify compliance with the criteria for the control of processes or their outputs, as well as products acceptance criteria;

d.) The use of the appropriate infrastructure and environment for the operation of processes;

e.) The designation of competent persons, including any required qualifications

f.) Implementation of actions to prevent human error;

g.) Implementation of release, handover and post-delivery activities.

4.3.2 Identification and traceability.

The Organization shall use appropriate means to identify outputs, where necessary, to ensure product conformity.

The organization shall identify the status of outputs with respect to monitoring and measurement requirements throughout production.

The Organization shall control the unique identification of outputs where traceability is a requirement, and shall maintain the documented information necessary to enable traceability.

4.3.3 Preservation

The organization shall preserve outputs during production to the extent necessary to ensure compliance with requirements

Note. Preservation may include identification, handling, contamination control, packaging, storage, information transmission or transport, and protection.

4.3.4 Post-delivery activities.

The organization shall meet the requirements for product-associated post-delivery activities.

In determining the scope of the required post-delivery activities, the organization shall consider:

a.) Legal and regulatory requirements;

b.) Potential unintended consequences associated with its products;

c.) Nature, use and intended useful life of its products;

Note. Post-delivery activities may include actions covered by warranty conditions, contractual obligations such as maintenance services, and supplementary services such as recycling or final disposal.

4.3.5 Control of changes.

The organization shall review and control changes to production to the extent necessary to ensure continued conformity to requirements.

The Organization shall maintain documented information describing the results of the changes review, the persons authorizing the change and any necessary action arising from the review.

4.4 Product release.

The Organization shall implement the planned arrangements, at appropriate stages, to verify that product requirements compliance.

Product shall not be released until the planned arrangements have been satisfactorily completed.

The organization shall maintain documented information on product release. Documented information shall include:

a.) Evidence of compliance with the acceptance criteria;

b.) Traceability to persons authorizing the release.

4.5 Control of non-conforming output

4.5.1 The Organization shall ensure that outputs not conforming to requirements are identified and controlled to prevent their unintended use or delivery.

The organization shall take appropriate action based on the nature of the nonconformity and its effect on product conformity. This should also apply to nonconforming outputs detected after products delivery.

The organization shall deal with nonconforming outputs in one or more of the following ways:

a.) Correction;

b.) Separation, containment, return or suspension of product supply;

Conformance to requirements should be verified when correcting non-conforming outputs.

4.5.2 The Organization shall maintain documented information that

a.) Describes nonconformity;

b.) Describes the actions taken;

c.) Identifies the authority deciding the action taken with respect to the nonconformity.

5. IMPROVEMENT

5.1 General

The organization should identify and select opportunities for improvement and implement any actions necessary to meet customer requirements and increase customer satisfaction

These should include:

a.) Improving products to meet requirements, as well as considering future needs and expectations;

b.) Correcting, preventing or reducing undesirable effects;

Note. Improvement may include correction, corrective action, continuous improvement, abrupt change, innovation and reorganization.

5.2 Nonconformity and corrective action.

5.2.1 When a nonconformity occurs, including any arising from complaints, the organization shall:

a.) React to the nonconformity and, where applicable:
- Take action to control and correct it;
- Deal with the consequences;

b.) Evaluate the need for actions to eliminate the nonconformity causes, so that it does not recur or occur elsewhere, by:
1. Reviewing and analyzing the nonconformity;
2. Determining the nonconformity causes;
3. Determining whether there are similar nonconformities, or potentially occurring nonconformities;

d.) Implement any necessary actions;

e.) Review the effectiveness of any corrective action taken;

f.) If necessary, update the risks and opportunities determined during planning; and

g.) If necessary, make changes to the production control system;

Corrective actions should be appropriate to the effects of the nonconformities found.

5.2.2 The Organization shall maintain documented information as evidence of:

a.) The nature of the nonconformities and any subsequent actions taken;

b.) The results of any corrective actions;

6. CLAIMS HANDLING

The organization shall apply and maintain up-to-date documented procedures for the reception and treatment of customer complaints about products for which the **ICONTEC** mark of conformity is granted. There shall be evidence regarding the handling of the complaint, and whenever possible, the satisfaction of the client or final consumer (for mass consumption products). A consecutively numbered record must be kept of customer claims and complaints, as well as the handling thereto.

Note. Numbering can be re-started at will. For marketers or importers, the numbering must be re-started each time the certification is renewed

7. COMPLIANCE WITH LEGAL REQUIREMENTS.

Organizations that manufacture food products and medical equipment must demonstrate compliance with the requirements of Good Manufacturing Practices established by the competent authority, through the respective permit or certification issued or endorsed by the corresponding authority.

The Organization must comply with applicable legal requirements and demonstrate evidence of compliance, when requested by **ICONTEC**.

Evaluation requirements of the production control system for Organizations with product manufacturing and through a tolling agreement.

Section	Production control system evaluation requirements	Organization with own plant	Maquiladora – third-party
3	Resources	X	X
3.1	General	X	X
3.2	Persons	X	X
3.3	Infrastructure	X	X
3.4	Monitoring and measurement resources	X	X
3.5	Competence	X	X
3.6	Documented information	X	
4	Operation	X	X
4.1	Operational planning and control	X	X
4.2	Control of outsourced processes, products and services	X	X
4.3	Production	X	X
4.4	Release of products	X	X
4.5	Control of non-conforming outputs	X	X
5	Improvement	X	
5.1	General	X	
5.2	Non-conformity and corrective action	X	
6	Complaint handling	X	
7	Compliance with legal requirements	X	

Approved by the Board of Directors on April 21, 2021.