

# CERTIFICATION RULES FOR VOLUNTARY CERTIFICAZIONE OF PRODUCT/PROCES/SERVICE

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*This document, issued selectively, is a true copy of the original.*

*The original version, bearing the signatures of the authorized bodies, is deposited at the ICEA National Office in Bologna*

## 1. FOREWORD

**Istituto per la Certificazione Etica ed Ambientale**, hereinafter referred to as **ICEA**, is a nonprofit Consortium composed of associations and organizations operating in a field of activities oriented towards environment-friendly, fair and long-lasting development, pursuant to Art. 2612 and the relevant ones of the Civil Code.

The Consortium was founded by AIAB (Italian Association for Organic Farming), Banca Popolare Etica (Ethical Bank), Demeter (Association for the protection of biodynamic quality in Italy), ANAB (National Association for Bio-ecological Architecture) and ACU (Consumers' Association), with a view to offering a certification service based on the principles of independence, transparency, objectivity, impartiality and competence, capable of building up suppliers' and consumers' confidence in the certified product, process or service, through verification of the conformity of the product/process/service to voluntary or binding regulations.

ICEA obtains financial support from proceeds resulting from certification and training activities.

ICEA is entitled to open offices, branch offices and agencies in Italy and abroad.

ICEA authorizes all operators, who observe the certification scheme governed by this Regulation, to affix to products the conformity label and the certification mark provided by relevant regulations and/or standards.

- a) ICEA guarantees admission of Applicants to the certification schemes governed by this Regulation, without any discrimination whatsoever. In particular:
  - there are no undue economic or other conditions applied;
  - qualification for evaluation and certification is not conditioned by the size of the unit or the membership of particular associations or groups.
- b) ICEA undertakes to apply current procedures and expenditure accounts based on its own national List of Fees in force, guaranteeing uniformity of application.
- c) The request for inspection and certification does not entail any obligation for the concerned Organization to utilize other ICEA's services not contemplated in this Regulation.
- d) The request for inspection and certification does not entail any obligation for the concerned Organization to join the ICEA Consortium or any other related body.

## 2. DEFINITIONS

**Product:** the result of a process.

**Process:** the total correlated or interacting activities which transform inputs into outputs.

**Product Specification:** a document, which establishes the requisites of a product. (Hereafter it is called Standard).

**Regulatory Body:** a public or private body which draws up and publishes the regulations governing the standards of product/process/service.

**Organization:** a body, unit, organ, enterprise or parts thereof, with share capital or not, public or private, with its own functions and administration, which concurs in the formation, marketing and supply of the product/process/service.

**Applicant:** an organization requesting certification. In case the certification concerns a chain of products, the Applicant is also the coordinator of the chain.

**Licensed Operator:** an organization to which ICEA issued the conformity certification and which is, consequently, authorized to use the conformity label and certification mark.

### 3. REFERENCES

- UNI EN 45011/99 (ISO 65/EC)
- ICEA Operating Manual, Sect. 06

### 4. GENERAL CONDITIONS

**4.1** This Regulation describes the procedures followed by ICEA for the certification of products, processes and services.

**4.2** The Technical Reference Standard (DTR) is the document that contains the technical specifications of the product/process/service subject to certification. This document must be submitted in advance to ICEA for evaluation.

**4.3** The purpose of the certification of the products, processes and services of an Organization is to give, through initial assessment and subsequent surveillance, an independent, trustworthy assurance that such products, processes and services comply with rules and/or requirements specified and contained in a DTR.

**4.4** The certification system is based on auditing and approving the production process and control system set up by the Applicant operator, and also on the execution of type tests (where required by the DTR), followed by continuing surveillance through periodical verification of the conformity of processes and quality systems, and through the testing of samples taken both from the market and from production and/or processing sites.

In particular, the quality system established by the Organization shall take into consideration the management and application of the following requisites:

- traceability and possibility to recall the product in case of serious nonconformities;
- identification and separation of certified products from uncertified products;

- management of customers' complaints;
- management of quality records.

**4.5** Application for certification can be submitted by any Applicant Organization whose activity falls within the sectors covered by ICEA. If another sector is concerned, acceptance will depend on the evaluation and decision of the CSQA Management. At any rate, the certification will be granted to the Applicants responsible for the products/processes/services before the law.

**4.6** In order to obtain certification, the Applicant Organization shall demonstrate that it complies with the DTR and the legislation in force for the concerned type of products. ICEA conformity certification authorizes the Applicant Organization to display the indications referring to compliance with the DTR and the certification mark specified in this Regulation, in labels and/or any other promotional and information material about the product/process/service.

**4.7** If certification projects involve more than one Applicant under the responsibility of only one organization, the applications shall be directly submitted by this responsible organization.

In this case, the responsible Organization shall have legal status and shall

- a) have entered into precise agreements with the other organizations involved in the certification project for the implementation of the provisions laid down in the DTR and in this Regulation;
- b) have defined criteria for the involved Organizations' admission to, participation in and renunciation of the certification project;
- c) have defined penalties for the Organizations which do not comply with the provisions of the agreements entered into;
- d) have established procedures for informing each sub-licensee about reference standards, regulations, certification procedures and subsequent revisions, and also about the rights and duties connected with the organic production scheme;
- e) have formally assumed (through a statement) the responsibility for the conformity of all Organizations interested in the project, and allow the personnel of ICEA and the accreditation bodies, to access the Organizations' premises, production sites and all records, including fiscal ones concerning the certified product/process/service, at any stage of the production chain.

**4.8** ICEA undertakes to apply expenditure accounts based on current fees, guaranteeing fair and uniform application.

**4.9** ICEA does not supply Organizations with any sort of advisory service including ways to overcome obstacles to certification, or direct promotional and information activity aimed at marketing specific products of certified organizations.

**4.10** On the Italian territory, ICEA carries out its activity with Italian staff and documents in the Italian language.

For inspection and certification activities abroad, ICEA undertakes to use when necessary, the English language or the language used by the local populations, reserving the possibility to utilize translators and interpreters appreciated for their ability and accepted also by the operators under the inspection scheme.

The same principle is adopted when drawing up and distributing documents which are necessary for requesting, obtaining and maintaining the certification (e.g. standards, regulations, registration forms, etc.)

Certification documents are generally issued in Italian and English. When the product/process/service is intended for countries where the English language is not widely known, ICEA undertakes to use the local language or another language known by the population.

**4.11** In order to facilitate access to information for all persons interested in this certification scheme, ICEA undertakes to make all unclassified documents and materials available, either on request or on the web site, [www.icea.info](http://www.icea.info). Moreover, in order to make the system more transparent, ICEA undertakes to make public, through the internet or other media, any unclassified information relating to its own activity, and in particular the list of licensed operators, penalties imposed and results of type tests.

**4.12** The correct application of the inspection and certification system is constantly monitored by the National Certification Commission (CNC), which is an organ that guarantees impartial and correct execution of certification activities and ensures fair representation of all parties involved in certification.

The involved parties belong to the following areas:

- a) Producers;
- b) Technical/scientific area;
- c) Consumers.

The CNC may set up and delegate an appropriate Certification Commission (CoCer), for the purpose of surveillance and correct execution of all assessments required by this certification scheme, and verification of the performance of the Voluntary Certification Manager (RCV), in particular as concerns the implementation of a correct Inspection Plan and the decisions about the issuance of certificates and penalties.

**4.13** At a preliminary stage, the CNC evaluates whether the DTR submitted by the Applicant Organization is correct, clear and value-adding.

CNC's approval of the DTR is a key prerequisite for ICEA to start the certification process.

## **5. CONDITIONS FOR OBTAINING AND MAINTAINING THE CERTIFICATION**

**5.1** In order to obtain and maintain the certification, the Applicant Organization shall observe the provisions of this Regulation and do the following:

- a) implement and maintain a documented management system demonstrating compliance with product/process/service requirements laid down in the DTR;

- b) identify and monitor the specified requirements, including the ones legally binding and regulated;
- c) complete the document assessment stage and any necessary type tests with satisfactory results;
- d) take all measures which may be needed for correct assessment, as required by this Regulation;
- e) allow staff appointed by ICEA or by accreditation bodies, to access documentation, records, areas and personnel involved in certification;
- f) maintain, throughout certification validity, the conditions that permitted such certification to be granted;
- g) downgrade product/process/service or recall the product from the market as needed, as soon as it learns of any irregularities which invalidate the conformity of product/process/service, and promptly inform ICEA accordingly;
- h) promptly inform ICEA of any change in the Organization;
- i) in case ICEA ascertains any Nonconformities (NCs), propose Corrective Actions (ACs) by accomplishing and signing the appropriate forms, one copy of which shall be sent via fax to ICEA within 10 calendar days from the date of notification;
- j) satisfy all ICEA's requests for ACs within the agreed deadline;
- k) pay to ICEA the fees due for inspection and certification activity, no matter what the outcome is;  
*Any inspection visits not included in the surveillance plan, which should be necessary as a consequence of NCs found, will be charged to the Applicant Organization as per List of Fees in force at the moment such visits are carried out.*
- l) pay the annual flat rate for maintaining the certification also in case of suspension.
- m) retain, throughout certification validity, a record of all complaints received and the documents pertaining to the relevant ACs implemented;  
*The Applicant Organization is required to also take into consideration any complaints received by other subjects involved in the certification project, for which the Organization assumes responsibility as far as product/process/service conformity is concerned.*
- n) inform ICEA of the Organization's involvement in cases of judicial proceedings for infringement of laws on product/process/service responsibility or related to the certification obtained.

**5.2** Certified Organizations shall keep the records related to product/process/service, which shall be made available to ICEA's personnel.

**5.3** The above mentioned records shall be updated daily. They may be in electronic format, subject to ICEA's approval.

When records are in electronic format, it is necessary to keep on file a hard copy (or back-up disk) of the monthly summary.

ICEA reserves the possibility to ask for one copy of such records (also in electronic format).



The records concerning productions subject to conformity certification, shall be clearly distinguishable from those concerning products which are not subject to certification.

**5.4** ICEA's Control Technicians shall also be allowed to access all the accounting, fiscal and financial documentation which may be needed in order to cross-check mandatory records with a view to verifying correct and systematic filing of records.

**5.5** If the abovementioned conditions are not fulfilled, ICEA will take the necessary measures proportionate to the frequency and severity of infringements, to the extent of certification suspension and withdrawal.

## **6. APPLICATION FOR CERTIFICATION**

**6.1** To start the certification process, the Applicant Organization shall forward to ICEA the duly accomplished APPLICATION FOR VOLUNTARY CERTIFICATION OF PRODUCT/PROCESS/SERVICE (Form M.RCVOL 01).

The application shall contain in particular, the following information:

- Applicant Organization's business name and registered address;
- Request for Pre-Certification Inspection Visit (if needed).

**6.2** By signing the APPLICATION FOR VOLUNTARY CERTIFICATION OF PRODUCT/PROCESS/SERVICE (M.RCVOL 01), the Applicant Organization fully accepts this Regulation and the REGULATION FOR PUBLICITY AND USE OF THE ICEA LOGO.

The application for certification shall be accompanied by the following documents:

1. Applicant Organization's Chamber of Commerce Registration Certificate.
2. Copy of VAT Number Certificate.
3. Description of product/process/service (Description of production process and flow chart, audit trail, composition of product, list of suppliers, etc.).
4. CERTIFICATION CONTRACT (M.RCVOL 02a) showing the cost of the service, signed for acceptance. The cost of the service is determined on the basis of the ICEA LIST OF FEES FOR VOLUNTARY INSPECTION AND CERTIFICATION OF PRODUCT/PROCESS/SERVICE (M.RCVOL 02).
5. (if accepted) Declaration authorizing the use of personal data.
6. Form for acceptance of the conditions laid down in this Certification Regulation, duly signed and stamped by the Legal Representative.
7. List of all products/processes/services for which certification is requested.
8. Facsimile of label on the package and/or of the promotional or information material concerning the process/service.

*ICEA will evaluate the abovementioned material for what concerns the application of the DTR and the correct use of relevant conformity indications and the LOGO.*

9. Number, full address and details of the Operating Units (or other concerned organizations) involved in the production subject to certification. In the case of agricultural farms, it is necessary to indicate also the Land Register data of land, animal housings and other facilities involved.

10. Copy of administrative and health authorizations required by current legislation, including plan of facilities and intended use of premises.
11. Organization Chart and declaration signed by the Production Manager stating that the facilities and staff dedicated to the production subject to inspection, fully comply with general requirements.
12. Quality Plan of products to be certified, indicating measures implemented for monitoring and governing critical points.
13. Broad Annual Production Plan, indicating quality and quantity of products.
14. (In case of third-party processing) Copy of the contract signed with the Processor, whereby the Processor:
  - a) *undertakes to perform contract operations in compliance with relevant rules and/or the DTR and this Regulation.*
  - b) *undertakes to give advance notice of date and time when processing begins.*
  - c) *undertakes to allow ICEA appointed staff free access to relevant processing units and documentation.*
  - d) *indicates his broad qualitative/quantitative Annual Production Plan.*

## 7. PRE-CERTIFICATION INSPECTION VISIT

7.1 If the Applicant Organization considers it advisable, it may ask ICEA to carry out a pre-certification inspection visit.

The request shall be made when accomplishing the Application for Certification, or by sending ICEA a written request.

The purpose of the pre-certification inspection visit is to:

- determine the Applicant Organization's size, structure and activity;
- determine to what extent the Applicant Organization is prepared to face the certification process and guarantee compliance with the DTR and this Regulation.

7.2 The pre-certification visit is optional and can be requested only once. The relevant time and costs will be established on the basis of the Applicant Organization's type and size.

The date and schedule for the pre-certification visit will be jointly fixed by ICEA and the Applicant Organization.

## 8. ASSESSMENT

Assessment is performed by ICEA with the purpose of verifying the conformity of Applicant Organization's product/process/service to the requirements laid down in the DTR. It includes:

1. evaluation of documents;
2. inspection visit to the structure of the Applicant Organization (and of any other Organizations involved in certification);
3. type tests (when required by the DTR).



The assessment phase starts only after the Applicant Organization has submitted the documents mentioned in Chapter 6.

ICEA classifies the situations as NCs, where product requirements laid down in relevant Standards are not met.

NCs are subdivided into Major (G) and Minor (M).

Major NCs are the ones which do not guarantee the product requisites laid down in the DTR. Such NCs require immediate downgrading of the product and the arrangement of ACs accepted by ICEA.

ICEA classifies some remarks denoted as “(O)” as recommendations to be carefully taken into consideration by the Applicant Organization in order to obtain improvements.

When the Applicant Organization’s documentation is complete, ICEA will make arrangements with the Organization regarding the verifications to be carried out for the purpose of certification.

## **8.1 Evaluation of documents**

**8.1.1** Documents are evaluated by qualified staff appointed by the RCV, by accomplishing the form DOCUMENT EVALUATION CHECK-LIST (M.RC VOL 04) within 30 working days from receipt of document.

The appointed technician will evaluate all the documents submitted by the Applicant Organization with a view to verifying their compliance with the DTR and this Regulation. ICEA reserves the possibility to ask for further information which may be useful for the purpose of evaluation. In this case, as in any other case where documents are incomplete, the 30-day term for the completion of verification starts again from the date of receipt of the new documents.

**8.1.2** When the assessment of Applicant Organization’s documentation has been completed, a judgement will be issued, as follows:

- a) **Approved:** if no NCs have been found;
- b) **Approved on condition:** where ICEA’s overall evaluation of detected NCs does not prejudice the subsequent evaluation phases (elimination of NCs can be directly demonstrated on the first inspection visit);
- c) **Not Approved:** where ICEA’s overall evaluation of detected NCs prejudices the subsequent evaluation phases. In this case, the evaluation process is suspended until NCs are eliminated.

**8.1.3** If the operator does not eliminate the NCs detected and does not update the documentation within three months, the application will become null and void. A new application may be presented against a new payment of the fees due to ICEA.

**8.1.4** In the cases a) and b), a qualified Control Technician will be entrusted with the execution of the first inspection visit.

## **8.2 First Inspection Visits**

**8.2.1** The purpose of first inspection visits is to verify the conformity of the Applicant Organization, and of any other subject participating in the project, to the requirements laid down in the DTR.

In case the Organization has several production units, the number of sites subject to inspection will be determined on the basis of a significant Sampling Plan equivalent, at least, to the square root of the concerned production units.

**8.2.2** The first inspection, which shall be carried out within 30 working days from the positive conclusion of document evaluation, includes:

- an initial meeting with the Applicant Organization's Managers (or a Representative appointed by the Managers) and with other concerned persons included in the Organization Chart. The purpose of the initial meeting is to introduce the ICEA Evaluator or Evaluating Team, illustrate the inspection schedule and confirm that all ICEA evaluators are bound by a confidentiality agreement.
- accurate verification of compliance of all products to be certified with the provisions of the DTR and verification of correctness and reliability of statements written on the label and in the presentation of the product;
- audit of production process management, analysis and control of points which are critical as concerns product conformity and application of Applicant Organization's control plan;
- verification of Quality Plan implementation and effectiveness; verification of relevant records;
- a final meeting where the Applicant Organization's Managers will be informed of the result of the inspection visit.

During the final meeting, the ICEA Evaluator responsible shall:

- a) illustrate the remarks written down in NONCONFORMITY REPORT forms (M.RCVOL 03a), and ask the Applicant Organization to sign these forms for acceptance;
- b) illustrate the contents of the INSPECTION REPORT (M.RCVOL 03), write down any remarks made by the Applicant Organization and ask the Applicant Organization to countersign the report for acceptance. One copy of the report is given to the Applicant Organization.

**8.2.3** One copy of the INSPECTION REPORT written by the technician is given to the Organization only on request.

One copy of the NONCONFORMITY REPORT is given to the Organization that will have to return it (also via fax) to ICEA within 10 calendar days from the date of the visit, complete with ACs and/or Nonconformity Treatments (TNCs), implementation periods and names of the persons responsible for implementation.

The RCV or his delegate verifies the TNCs and the ACs proposed by the operator. If no communication to the contrary is given within 5 calendar days from receipt, they are deemed approved.

In case such TNCs and ACs are not considered sufficient or valid, the RCV or his delegate will inform the operator in writing, giving reasons.

**8.2.4** In case of major NCs, ICEA may arrange special inspection visits with a view to evaluating the effective implementation of approved treatments and/or preventive actions.

If irregularities concern documentation, it will be sufficient to complete such documentation and send it to ICEA within the deadline.

**8.2.5** The visits will be carried out by qualified staff appointed by ICEA on the basis of the following documentation:

- DTR and/or rule
- Organization's standard or procedures
- ICEA Evaluation Check-list

### **8.3 Type Tests**

**8.3.1** In the course of evaluation, ICEA reserves the possibility to subject the products to type tests (analyses). For this purpose, ICEA will take a sufficient number of samples and will subject them to any tests and analyses needed to verify their conformity to the specifications contained in the DTR.

**8.3.2** The tests shall be carried out by test laboratories accredited within the European certification system, in accordance with European rules governing test laboratory accreditation. The costs incurred shall be borne by the Applicant Organization.

In case it is difficult to find accredited laboratories for the execution of certain tests, such tests will be carried out by other laboratories, Applicant Organization's laboratory included, subject to ICEA's approval.

**8.3.3** In case the tests show that the product does not conform to the DTR and the indications shown on the label and in product presentation, the assessment will be suspended until the Applicant Organization, within the agreed deadline which may not exceed six months, restores the conformity of the product and asks ICEA to subject the product to new type tests.

The samples for type tests may be taken on the First Inspection Visit.

## **9. DELIBERATION**

**9.1** The certification file will be submitted to the RCV for evaluation only when the Applicant Organization has eliminated any existing NCs and/or has clearly and credibly committed itself to reaching full conformity within a deadline established and considered acceptable by the CNC.

ICEA undertakes to submit the certification file to the RCV for evaluation, within 30 working days from the date of elimination of the NCs found during the previous evaluation phases (documents, first inspection visit and type tests).

On completion of the evaluation, the RCV will decide whether to grant or deny the Conformity Certificate.

**9.2** In case a negative judgement is issued and the certificate is not granted, the Applicant Organization will be informed in writing of the decision and reasons for the decision.

**9.3** If within 90 calendar days, the Applicant Organization does not implement the necessary ACs, the application for certification will officially become null and void. A new application may be presented against a new payment of the fees due to ICEA.

**9.4** In his judgement, the RCV will take into account any previous derogations and decisions. For this purpose, ICEA undertakes to keep and update a Register of Derogations and Decisions, which shall always be available to CNC members. The same register, without any references to the organizations concerned, will be made public by ICEA.

**9.4.** RCV's decisions will be communicated to the Control Technician who carried out the inspection visit.

## **10. ISSUANCE OF CONFORMITY CERTIFICATE**

Following RCV's positive evaluation and decision to grant certification, ICEA (within 15 working days) will issue the CONFORMITY CERTIFICATE (M.RCVOL 05) showing the following details:

- Certificate registration number;
- Name and/or business name of the Organization holding the certification;
- Number of registration in the Register of Licensed Operators;
- Date of issue (beginning of validity period);
- Validity end date;
- Name and class of product, process or service judged conforming and certified;
- Revision status of document (revisions are needed in case new products are certified);
- DTR to which conformity was granted, and revision status.

The ICEA President or his delegate will sign the Conformity Certificate. The list of delegates is available as a public document at ICEA's office or at the web site, [www.icea.info](http://www.icea.info).

At the Organization's specific request, ICEA may issue certification documents attesting to the conformity of specific production lots or batches, reserving the possibility to request additional checks or analyses. All costs incurred, including secretarial fees, will be borne by the Organization.

In any case, such documents will be issued only after the Organization has obtained the Conformity Certificate.

### **10.1 Use, validity and renewal of Conformity Certificate**

- a) The validity of the Conformity Certificate is subject to the observance of the DTR and this Regulation for Certification.
- b) During the validity period, surveillance visits will be carried out in order to verify continuing compliance with requirements.
- c) The term of the Unit Conformity Certificate is three years. On its expiry, the CNC will reassess the Applicant Organization in its entirety and decide whether to renew the Certification. The new assessment will be based on all the information gathered in the course of inspections during the preceding two years.

Once the Applicant Organization has received the certificate, it is entitled to:

- publicize the certification obtained;
- make the Conformity Certificate public;
- affix the conformity label and Logo specified in this Regulation to the label of certified products;
- utilize the conformity label and Logo specified in this Regulation, in technical specifications and promotional material explicitly referring to certified products.

The operator may renounce inspection and certification by communicating his withdrawal by registered letter. In any case, the operator will be obliged to pay the fees due for ICEA's activity in the course of the year.

Withdrawal from inspection and certification has no influence on the other services offered by ICEA.

### **10.2 Register of Licensed Operators**

All the Organizations, which are granted the Conformity Certification, are entered in the REGISTER OF LICENSED OPERATORS (M.RCVOL 06) with the following data:

- Date of issue and validity of certification
- Registration number of certificate/license

- Name and/or business name of the Organization holding the certification, address of the registered office and of the production plants, phone/fax number, e-mail address and web site (if any);
- DTR to which conformity was granted, and revision status;
- Name and class of product/process/service subject to certification;
- Indications as to certification status (operating, suspended on ..., withdrawn on...).

The Register of Licensed Operators is a public document updated at least monthly, and is available at ICEA's office.

ICEA may send it (also in electronic format) to any person submitting a written application, and also publish it in its own publications, promotional material and/or web site, [www.icea.info](http://www.icea.info).

## **11. CONFORMITY LABEL AND LOGO**

The Organizations which obtained Conformity Certificates from ICEA thanks to observance of the DTR and this Regulation, may use the conformity label and/or Logo specified in the DTR in accordance with the Regulation for Publicity and Use of the ICEA Logo.

### **11.1 Support for protection initiatives**

In addition to the ordinary surveillance activity, ICEA will check, at least once a year, whether the certification mark and conformity label are correctly used. ICEA personnel will also check these marks and labels in shops, supermarkets and other points of sale, trade fairs, web sites etc., also as a follow-up to substantial evidence supplied by third parties.

In case of irregular use, ICEA will:

- Require ACs and apply sanctions to the organizations subject to the control system;
- send warning letters, and where necessary, claim compensation for damages through legal action and request the recall of the product from the market.

The person responsible for all the above-mentioned activities is the RCV of ICEA, who may avail of the support and collaboration of all ICEA staff.

## **12. MODIFICATION OF CERTIFICATION CONDITIONS**

### **12.1 Modification of Regulations and/or Technical Standard**



All certified Organizations will be informed about changes (e.g. a new revision) and will also be given a deadline for meeting the new requirements. On the expiry of this deadline, the Applicant Organization has the right to renounce certification. If the Organization decides to maintain certification, ICEA will check conformity to new requirements through verification of documents or, where needed, inspection visits and/or type tests. Any costs incurred for inspections shall be borne by the Applicant Organization.

### **12.2 Modification of Regulation for Certification**

If the provisions laid down in this Regulation are amended, the revised Regulation will be sent to the Applicant Organization, which shall return the Acceptance Form, duly signed, dated and stamped, to ICEA. In the event of nonacceptance, the Organization shall send ICEA its renunciation of certification within 30 calendar days from receipt of communication.

### **12.3 Modification of List of Fees**

If the economic terms specified in the List of Fees are changed, the revised List of Fees will be sent to the Applicant Organization, which shall return it to ICEA duly signed for acceptance. In the event of nonacceptance, the Organization shall send ICEA its renunciation of certification within 30 calendar days from receipt of communication.

In all the above mentioned cases of renunciation, the operator will anyway be obliged to pay the fees due to ICEA for the activity carried out in the course of the year.

## **13. SURVEILLANCE ACTIVITY**

**13.1** During the period of validity of certification, ICEA will perform surveillance activity with its own qualified personnel, through inspection visits and type tests within a specific inspection and sampling plan approved by CNC.

The purpose of surveillance activities is to verify continuing compliance with all requirements laid down in the DTR and in this Regulation.

**13.2** ICEA will carry out product tests on samples taken either from the production line or storage premises, or from distribution points and points of sale, in accordance with the Sampling Plan (and whenever the Control Technician, during inspection, gathers evidence of irregularity).

Such tests will be carried out in accordance with the same criteria as established for type tests and aim at supporting and validating the tests directly carried out by the Applicant Organization in the context of its internal Quality Plan.

**13.3** Surveillance visits may either be announced or unannounced.

For announced visits, ICEA's inspectors will communicate the date of the visit directly to the Applicant Organization.

The announced visits are scheduled at least one per year, in compliance with the surveillance plan approved by CNC.

For announced visits, the operator has the right to ask for a change of the date proposed by ICEA, giving reasons. ICEA reserves the right to accept the change only if it is not prejudicial to the significance of the inspection.

The surveillance visit schedule always includes:

- evaluation of changes in the Applicant Organization's production processes (if any);
- verification of remedial action for NCs detected during previous inspections and satisfaction of conditions;
- verification of continuing conformity to the requirements of the DTR and its modifications, if any;
- observance of CNC's specific requirements and correct implementation (also within the deadlines of any derogations granted);
- examination of customers' complaints;
- verification of requirements laid down in this Regulation;
- verification of substantial changes in the production plan.

**13.4** The procedures for accomplishing and managing the Nonconformity Reports are the same as the ones described in paragraph 8.2.

**13.5** Unannounced visits are scheduled within the surveillance plan, to cover a sample of units determined on the basis of statistical criteria approved by CNC. They may also be decided, at ICEA's discretion, with a view to verifying continuing conformity, as a follow-up to complaints, reports from the market, product test results and surveillance activity in other organizations.

During inspections, the operator shall offer maximum collaboration to the staff appointed by ICEA. If the operator fails to communicate his absence on the occasions of announced inspections, he shall bear the cost of the visit.

**13.6** If the annual surveillance activity has given positive results, the RCV or his delegate will send the concerned Organization a letter confirming the validity of the certificates issued and of the products under certification. If the types of products under certification have changed, a revised Conformity Certificate will be issued.

## **14. MODIFICATION AND EXTENSION OF CERTIFICATION SCOPE**

**14.1** The certified Organization is entitled to request changes in the scope of certification.

These changes may be:

- change of business name and/or modifications in the Organization;
- modification or extension of production units;
- modification or extension of products and/or processes subject to certification.

**14.2** The procedure for requesting such modifications is the same as the one indicated for submission of application for certification. Of course, the request shall exclusively refer to the processes and/or products modified or extended.

The assessment may just be limited to a verification of documents, an inspection and a type test, only where such modifications have no significant influence on the Organization's activity and production process management, but are just to introduce new products into the same category.

**14.3** The issuance and/or revision of the Conformity Certificate, taking into account the modification and/or extension of the scope of certification, depends on the observance of the provisions laid down in Art. 8 of this Regulation.

## **15. CONFIDENTIALITY**

**15.1** ICEA undertakes to treat as strictly confidential (except in cases of particular legislative or judicial provisions) all the data and information gathered in the course of the relationship with the Applicant Organization.

ICEA's personnel involved in inspection and certification activities also undertake to treat the data acquired as strictly confidential, in particular as regards product process and formula.

**15.2** The documentation acquired will be filed only at ICEA's offices and access to files will only be allowed for authorized personnel who signed the appropriate Confidentiality Agreement.

**15.3** ICEA will not divulge the Organization's data and information (other than the ones contained in the Register of Licensed Operators) to third parties, without the Organization's written consent.

If the Judicial Authority requests data and information, ICEA will supply the information requested and will inform the Organization accordingly.

**15.4** The data which may be considered public and can be disseminated without any written consent, are the ones contained in the Register of Licensed Operators and the significant information regarding test results and penalties (if any) imposed on the Organization (date, type, concerned products). Notice of such penalties may also be displayed on the ICEA website, [www.icea.info](http://www.icea.info).

## **16. VALIDITY OF CERTIFICATION CONTRACT**

**16.1** By signing this Regulation, a contractual relationship between ICEA and the Applicant Organization is constituted.

**16.2** The contract will be valid for three (3) years starting from the date of its stipulation and has the tacit approval of its renewal upon expiry, unless either party gives notice of termination at least three months before expiry.

In any case, the renewal of the contract entails a new overall assessment of the Organization and the renewal of the Conformity Certificate (see point 10.1).

**16.3** In particular, the validity of the contract is bound to the fulfilment of the following obligations:

- a) Observing the provisions of national and Community regulations concerning the products subject to certification;
- b) Supplying the documentation required by the application of the inspection system;
- c) Accomplishing and constantly updating the forms envisaged by the application of the inspection system;
- d) Allowing inspection personnel access to locations and documentation, as required by such inspection personnel;
- e) Making available to inspection personnel all the products and raw materials (including therefore, water, additives, etc.) for analysis as may be required for the purpose of inspection and certification;
- f) Fulfilling the requirements of the inspection system and paying any fees due to ICEA within the deadlines prescribed by ICEA;
- g) Issuing a notification of any substantial change in the operator's situation or in any activity connected with the inspection system and product conformity, within the prescribed deadlines. In case the variations which occur require a specific evaluation by the inspection and certification body, the operator shall wait for ICEA's conformity judgement before affixing the conformity label and logo to the concerned products.
- h) Observing the provisions of the regulations concerning product labelling and promptly report to ICEA any misuse, even by other operators;
- i) Making comments about the certification only when referring to the purposes for which the certification was issued;
- j) Not using the certification in such a way as to discredit the Certification Body and not making comments about product certification which may be considered not correct or not authorized by the Certification Body;
- k) in case of suspension or withdrawal of the conformity certification, stop using all documents bearing indications referring to the certification and/or stop using,

in case of withdrawal of the certification, advertising material containing such indications; returning any certification document at the Certification Body's request;

- l) Using the certification only to indicate that the products have been certified in compliance with relevant regulations;
- m) Behaving as prescribed by the Certification Body when dealing with media regarding product certification (i.e. documents, brochures or advertising).
- n) Accepting, without prejudice to the possibility of filing an appeal, the penalties applied in accordance with the provisions laid down in this Regulation;
- o) Keeping records of all complaints received regarding the products subject to inspection and certification;
- p) Managing in a controlled way the distribution of ICEA's Conformity Certificates to customers, recording for each distributed copy, the registration number of the copy (to be indicated also in the document), date of delivery, and name of recipient;
- q) Communicating any withdrawal or suspension of the Conformity Certificate to all persons to whom such certificate had been distributed.

## **17. RENUNCIATION OF CERTIFICATION**

The Applicant Organization may renounce certification in case it decides not to accept the modifications to certification conditions introduced by ICEA (see point 12) and in any other case, by sending ICEA a written notice within the time limits.

## **18. PENALTIES**

### **18.1 Precautionary suspension of the use of Product Certificate and Labels**

**18.1.1** The precautionary suspension of the use of Conformity Certificate and, consequently, of the license to use the mark and the conformity indications, is applied:

- whenever the operator does not allow access for the execution of surveillance visits at the stages of the production cycle which are critical or most significant for regular and effective control;
- whenever infringements or serious irregularities have been found in the course of surveillance visits and product inspections, or when analysis results are such as to cast doubts on product compliance with the DTR and the provisions laid down in this Regulation.

**18.1.2** The measure is communicated to the operator by registered letter (sent in advance via fax) signed by the ICEA President or his delegate, pending the necessary

evaluation by CoCer. The measure may be applied to specific production lots and batches, types of products/production lines or to the entire production of the enterprise, depending on the infringements detected.

The evaluation by CoCer will take place, in any case, within 30 days from the date of application of the measure. The RCV or his delegate will inform the operator about test results and any other reason which determined the measure, and about the deadlines for submission of any remarks, comments, documents and/or counter-analysis reports.

## **18.2 Suspension of certification validity**

**18.2.1** The suspension of certification validity for a limited period of time is decided after ascertaining substantial infringements of the certification rules laid down in this Regulation.

**18.2.2** ICEA will send written notification of the measure and of its own decisions to the Applicant Organization, stating the deadline for completing the ACs that are needed to eliminate the NCs, and the deadline for filing any appeal against the decisions.

The suspension will be revoked only when the Applicant Organization has given substantial evidence (within the prescribed time limits) that the ACs have been successfully completed.

The suspension will last a maximum of 60 calendar days. On expiry of that period, if the suspended Organization has not implemented the ACs required, ICEA will proceed with a notification of the Certification Withdrawal.

Where the detected NCs prejudice the conformity of specific products, the measure will be applied to these products only. Consequently, the Conformity Certificate will be revised by updating the list of certified products and/or activities.

The Organization is required to return to ICEA the outdated version of the Conformity Certificate.

**18.2.3** The Organization itself may ask ICEA to suspend the certification for a limited period of time (also for specific types of products), giving reasons, and ICEA will accept such request.

## **18.3 Withdrawal of certification**

**18.3.1** The withdrawal of certification is decided in the following cases:

- inadequate or insufficient ACs implemented by the Organization after certification suspension;
- substantial NCs detected during surveillance visits, and violation of obligations laid down in the regulations in force;
- serious or repeated infringements of obligation to properly use the certificate and conformity label;
- cessation of the Organization's production activity;



- bankruptcy of the Organization;
- Organization's formal request not to renew the certification on expiry, or formal request to renounce certification in the course of validity;
- non-payment, before the deadlines, of fees due for inspection and certification activities and of any fees due for the use of the mark.

**18.3.2** ICEA will send written notification of the measure and of its own decisions to the Applicant Organization, stating the deadlines for the implementation of ACs aimed at the elimination of NCs, and for filing any appeals against the decisions.

#### **18.4 Notification of sanctions**

**18.4.1** The sanctions will be decided by ICEA, following the resolution of CNC (or delegated committee).

In any case, the Applicant Organization will be notified of the sanctions by registered letter (sent in advance via fax) signed by the ICEA President.

**18.4.2** The Applicant Organization may file a written appeal against these sanctions stating detailed reasons, within 30 calendar days from the date of receipt of notification.

CNC (or the delegated committee) will supervise ICEA's activity, verifying files and technical documents (and also administrative documents regarding payment requests and reminders for defaulting Organizations), in order to guarantee that these measures are taken, fully observing the principles of independence and impartiality of the Inspection System.

### **19. CONSEQUENCES OF RENUNCIATION, NON-RENEWAL, SUSPENSION AND WITHDRAWAL OF CERTIFICATION**

**19.1** In case of renunciation, non-renewal, suspension and withdrawal of the certification, the Organization is obliged to:

- immediately stop using the Conformity Certificates and, in case of withdrawal, renunciation or non-renewal, immediately return them to ICEA;
- immediately stop using all documents/publications and letterheads bearing indications referring to certification;
- immediately stop using the conformity label and the certification mark provided;
- on ICEA's request, inform all the customers who had been advised of the certification.

**19.2** In case the Applicant Organization uses the certification infringing the abovementioned obligations, ICEA reserves the right to publicize, as it considers most convenient and without prejudice to any further action, that the Organization is no longer entitled to use the certification. The costs incurred for publication will be borne

by the defaulting operator, without prejudice to ICEA's possibility to claim compensation for any further damage.

## **20. INSPECTION AND TESTING ACTIVITY**

**20.1** For the purposes of inspection and testing, ICEA may avail itself of the services of contracted and/or qualified external structures, for whose professional competence it can vouch, fully complying with the Standards UNI CEI EN 45011 (March 1999), paragraph 4.4 concerning Subcontracts, without prejudice to the same activity being carried out by its own national structures.

In any case, ICEA is the only one entitled to and legally responsible for the issue, maintenance, extension, suspension or withdrawal of certification.

**20.2** The Organization may, in advance, express grounded objections to any particular Control Technician, inspection body or test laboratory which ICEA decides to utilize. For this purpose, ICEA undertakes to communicate in advance the names of the appointed professionals or bodies to the Organization.

The Organization shall communicate such objections and reasons in writing to the RCV. As concerns analyses, the Organization may write down its request in the Sampling Report.

The RCV shall evaluate whether to accept the request or not. The request may be accepted in those cases where there is formal evidence of conflicts/disputes/controversies/disagreements, either under way or past, between the operator and the professional or body appointed by ICEA.

The operator's request and RCV's consequent decision shall be communicated to CNC (or delegated committee) for information.

## **21. COMPLAINTS**

If the Applicant Organization deems that the quality of service supplied does not correspond to what is stated in this Regulation, it may file a complaint with ICEA.

Complaints may be forwarded by post, fax, e-mail or telephone to the attention of the ICEA Quality Assurance Manager (RAQ) who will evaluate whether the complaint is justified and will give a reply within 30 calendar days.

## **22. APPEALS**

**22.1** If the Applicant Organization deems that ICEA's decisions are unjustified and/or discriminating, it may file an appeal with the ICEA President.

**22.2** The appeal shall be filed in writing, stating reasons, within 30 calendar days from the date of notification of ICEA's decision.

Within 30 calendar days, ICEA will convene the CNC, which will examine the appeal within 60 calendar days from date of filing.

On such meeting, the Applicant Organization's representatives may request a hearing.

**22.3** The decision made at this point will be final and binding on the parties.

**22.4** All expenses incurred for the appeal will be charged to the losing party.

If the Operator's appeal is to include analysis results, these must be by Laboratories accredited within the European certification system, in accordance with European regulations concerning laboratory accreditation.

## **23. ARBITRAL AWARD**

**23.1** All disputes arising from the application of the ICEA Certification System, which were not possible to settle at the level of the appeals management, shall be submitted to an Arbitration Team composed of three experts in judicial and technical matters, chosen from the list of the Council of Arbitration of the territorially competent Chamber of Commerce. Two arbitrators shall be appointed by the two parties and the third one shall be jointly appointed by the two arbitrators chosen, or by the President of the territorially competent Court, who shall also appoint the arbitrator of the party that, though invited, has failed to appoint its own arbitrator within the required time limit.

**23.2** The arbitrators shall examine the case with equity, proceed with no formality except for the obligation to keep written records of the measures, and communicate their final award to the parties stating the reasons, within 90 days from the date of acceptance of the third arbitrator. For what is not foreseen, the arbitration shall comply with the rules of the territorially competent Chamber of Arbitration, which the parties declare that they know and accept.

## **24. INTERNAL AUDITS AND PERIODICAL REVIEWS**

In order to verify and monitor the correct application, compliance and effectiveness of this inspection and certification scheme, ICEA, under the responsibility of the Quality Assurance Manager, will carry out periodical internal audits (VII) at the national office and at regional offices.

The results of the audits will be reviewed by the Directors in accordance with the procedures applied for all the other certification schemes.

**25. INSPECTION SYSTEM CHART**

**Organization**

**RCV or his delegate**

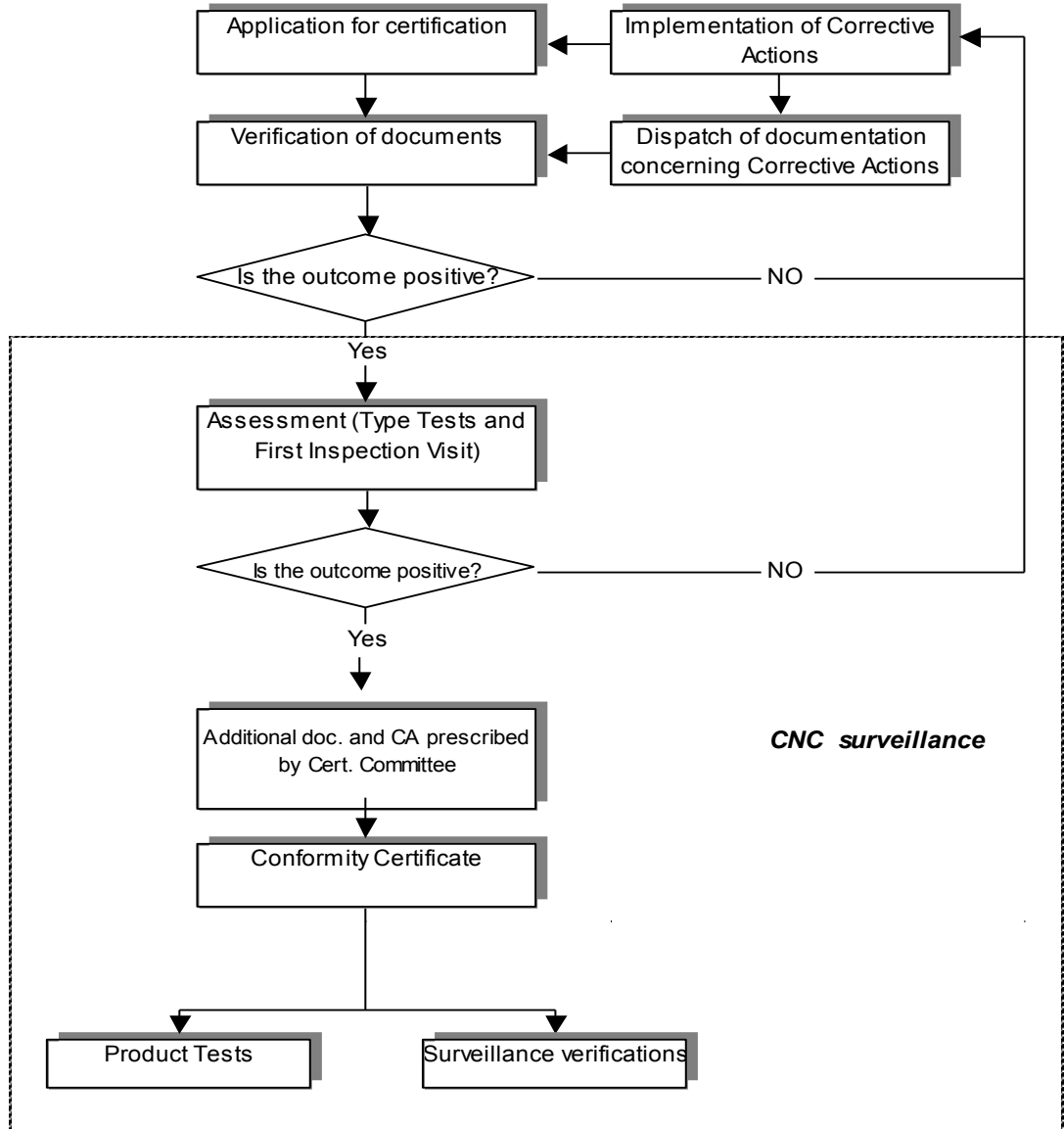
**RCV or his delegate**

**RCV or his delegate**

**RCV or his delegate**

**ICEA President or his delegate**

**RCV or his delegate and qualified TCs**



## 26. ACCEPTANCE OF PRESCRIPTIONS CONTAINED IN THIS REGULATION

*(This page, signed by the Applicant Organization's legal representative, must be sent to ICEA.)*

The Applicant Organization .....in the person of the Legal Representative ..... declares that all the provisions laid down in this Certification Regulation have been carefully read and accepted.

Date:

Stamp and signature

In accordance with the provisions of Art. 1341 and 1342 of the Civil Code, the Applicant Organization expressly approves the Art. 12, 14, 16, 17, 18, 19, 20, 21, 22, 23.

Date:

Stamp and signature