Regulation for the certification of products and services

07	01/05/2020	Update of paragraph 2 with introduction of Accredia Regulations and insertion of the energy product technical note	OPE	HEAD OF ISG	CEO
06	07/11/2019	Update on request of Accredia para. 1.0 (included: Regulation 2017/745)	OPE	HEAD OF ISG	CEO
05	09/09/2019	Update on request of Accredia on the directives. Para. 1.0, 2.0, 4.4.2,	OPE	ISG	CEO
04	28/05/2019	Update on request of ACCREDIA with regard to the definitions of Reviewers and site	OPE	ISG	CEO
03	21/08/2017	Update for Accredia requests and for compliance with rev 01 of the Quality Manual	OPE	ISG	CEO
02	22/01/2016	Updated: chap. 4.2 (Offer for the inclusion of USA insurance) and chap. 5.1 and 5.2 (Review/Certification - Clarification)	PR&EN	ISG	DIV-CEO
01	12/07/2015	Update due to passage to EN17065	PR&EN	ISG	DIV-CEO
00	31/03/2015	Voids and replaces the “Regulation for product certification ex 45R003” document in rev. 00 and the Regulation for certification in the field of energy business 0025CR in rev. 2. Voids and replaces the document “Regulation for product and service certification” in rev. 4	PR&EN	ISG	DIV-CEO
Rev.	***Date***	***Description***	***Drawn up***	***Verified***	***Approved***
IDENTIFICATION: 0003CR_07_EN					

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Share capital € 260,000.00 fully paid up and resolved - Tax Code and VAT number registration in the Business Register of Milan no. 12908230159 – EAI no. 1596292

SUMMARY

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1.0 PURPOSE AND SCOPE

This Regulation defines the methods and conditions that an Organisation must comply with to obtain and maintain Product Certification issued by ICIM and to be registered in the Registry of Businesses in possession of Certification (Registry).

The term Product Certification refers to the certification of products, services or processes.

The certifications proposed by ICIM are available for any Organisation applying therein, in observance of this Regulation.

Further details, for the various types of products, are contained in the Certification Schemes (SCPExxxx) relative to the individual types. The SCPExxxx refer to one or more specific regulatory documents. If the said documents are not part of a specific national, European or international reference standard or a specific technical specification governed by national laws, directives or European regulations, are developed by Work Groups. The Work Groups are composed of ICIM technicians, technicians listed in the ICIM List of Expert Technicians and/or external expert technicians, representing the stakeholders pertaining to Certification.

In some cases, connected to national laws, directives or European regulations, the SCPExxxx are replaced by specific verification and control documents.

In case of EU Regulations or European Directives that define, as the certification procedure for mandatory products, modules to which the corporate management systems apply (e.g. modules H, D, E, or for Regulation (EU) 2017/745 annexes IX and XI part A), this Regulation applies in combination with the Regulation for the Certification of management systems ICIM doc. 0002CR, each for the matters under its purview.

The Certification, issued by ICIM, grants the Organisation the right to apply the ICIM Conformity Mark, demonstrating product or service compliance with the reference standards (Also see the Manual for the Use of the ICIM SpA Certification Mark - 0260CR).

2.0 REFERENCES

2.1 Input documents

Standards and documents valid at the issue date of this document

UNI IEC EN ISO/IEC 17000	Assessment of conformity - Glossary and general principles
UNI EN ISO 9000	Quality Management Systems - Fundamentals and glossary
UNI IEC 70006	General rules for a standard product certification system by an independent body.
UNI IEC EN ISO/IEC 17021-1	Assessment of conformity. Requirements for bodies providing audit and certification of management systems
UNI IEC EN ISO/IEC 17025	General requirements for the competence of testing and calibration laboratories
UNI IEC EN ISO/IEC 17065	Assessment of conformity - Requirements for bodies that certify products, processes and services
UNI IEC EN ISO/IEC 17067	Assessment of conformity - Fundamentals of product certification and

	guidelines for product certification schemes
0001CR	ICIM General Regulation
0002CR	Regulations for the Certification of management systems
ACCREDIA RG-01	Accreditation regulation of Certification and Inspection Bodies - General Part
ACCREDIA RG-01-03	Accreditation regulation of Product Certification Bodies
ACCREDIA RG-09	Regulations for the use of the ACCREDIA mark
ACCREDIA RG-15	Regulation for the accreditation of Audit Bodies for greenhouse gas emissions
ACCREDIA DT-01-DC	ACCREDIA approach to accreditations for the purpose of notifications regarding the CE marking and consequent provisions for CABs requesting this type of accreditation
ACCREDIA DT-02-DC	Guidelines for the Accreditation of Bodies performing the Certification of Quality Management Systems in the Medical Device sector
ACCREDIA PG-13-01	Procedure for launching the Accreditation of new Conformity Assessment schemes
ACCREDIA TECHNICAL REGULATIONS RT-XX	Various TR related to the accredited certification schemes
ACCREDIA TECHNICAL CIRCULARS	Various technical Circulars related to the accredited certification schemes
Other applicable related documents	

3.0 DEFINITIONS

For the terminology regarding the certification of Products and Services, the definitions reported in standards UNI IEC EN ISO/IEC 17000, UNI EN ISO 9000 and in the ICIM General Regulation - 0001CR generally apply. Below are some definitions of terms used repeatedly herein (in alphabetical order).

- **Certification Schemes (SCPExxxx)**

  A document that specifies, for each product or homogeneous group of products or service, the conditions under which it is possible to obtain and maintain product or Service Certification for the applicable Certification Scheme.

- **Model**

  The representative configuration of the product that the Organisation is requesting ICIM Product Certification for.

- **Variant**

  A Product Configuration which, regardless of its discrepancies with the Model, still refers to it, as it complies with the provisions and requirements of the standard, draft standard or applicable regulatory document.

- **Production Unit**

  The site where the Organisation produces the product that the Application for Certification refers to.

  The site may be:
  a) permanent, i.e. it continues to exist or be a site for a long period of time, without interruptions or changes;
  b) temporary, i.e. not stable or defined, but provisory (e.g. a worksite).

- **Conformity Certificate with Authorisation for Use of the ICIM Conformity Mark**

  This is the document whereby ICIM declares that, with reasonable reliability, a product is compliant with a specific standard or another regulatory document and is therefore authorised to bear the ICIM Marking according to the criteria defined in the ICIM Certification Mark User Manual.

- **Sales extension**

  A sales extension is defined as the possibility of an Organisation in possession of ICIM certification to extend the use of its certification to a partner/customer, in its name.

- **Certification extension**

  Certification extension is defined as the addition of one or more products (with identical characteristics to the model) to a series/family of certified products.

- **ICIM Conformity Mark**

  This is the graphic identification for certification issued by ICIM. It is under the exclusive ownership of ICIM and, as such, is covered by a collective mark with a patent that is filed and registered in Italy, Europe and around the world at the relative Offices.

  Use of the ICIM Conformity Mark is granted to the Organisation that has been issued with Product Certification, and is applied under its responsibility and in compliance with the requirements of the applicable Certification Scheme.

  The said marking, applied to the product, proves compliance with the specific standard referred to in the Certificate for Authorisation for Use of the ICIM Conformity Mark, and proves that production is under the surveillance of ICIM according to the single certification schemes.

- **Permanent (marking)**

  Permanent marking means that it has defined characteristics of:

  - resistance to the elements (UV rays, humidity, extreme temperatures);
  - resistance to corrosion;
  - resistance to acid attacks (only for particular cases).

- **Unremovable (marking)**

  An unremovable marking refers to a marking that can not be removed from the site of application without proven intention and the use of specific tools.

- **Minor non-conformity (NCm) or Observation (OSS)**

  Observation formulated by the Organisation, having the reference regulatory document and/or Certification Schemes as reference, in cases where some requirements are only partially fulfilled.

Also, the said requirements must not compromise the conformity of the products that the Certification refers to. The corrective measures, proposed by the Organisation, must be considered easily implementable according to the proposed methods and timescale. One or more NCm or OSS do not block the certification sequence and ICIM's verification of implementation of the corrective action by the Organisation is usually carried out during the next auditing visit.

- **Major Non-Conformity (NCM) or Non-Conformity (NC)**

  A non-conformity formulated by the Organisation, having the reference regulatory document and Certification Schemes as reference, in cases where some requirements of the Certification Scheme are not fulfilled. An NCM or NC blocks the certification sequence at the initial inspection visit stage or suspends the use of the Mark, under surveillance, until the non-conformity is duly resolved. ICIM's verification of implementation of the corrective action could require an additional auditing visit to the Organisation.

- **Recommendation (REC)**

  A guideline formulated by the Organisation, using the reference regulatory document or Certification Schemes as reference. One or more recommendations do not pose any variation to the final assessment expressed by the Inspection Group, nor the requirement of the Organisation to implement corrective action.

- **Initial Inspection Visit (VV)**

  An action used by ICIM to ascertain that the requesting Organisation fulfils the technical-organisational requirements set forth in the applicable Certification Scheme. This visit includes the Assessment of the Quality System of the Organisation's production unit.

- **Initial Tests (ITT)**

  A process used by ICIM, before granting or extending Certification, to determine product conformity with the requirements of the relative standards.

  Herein, the Initial Test is referred to as "Type Test".

- **Surveillance (VSV)**

  An activity conducted by ICIM to verify maintenance of conformity of the Organisation, product or service, with the requirements of the applicable Certification Scheme.

- **Surveillance Tests (ST)**

  A process conducted by ICIM to verify, with reasonable reliability, that the certified product maintains conformity of the tested product with the standard, draft standard or reference regulatory document. The cycle of surveillance tests is described in the specific rules.

- **Assessment**

  An activity conducted by ICIM to determine product conformity with the requirements in the reference regulatory documents referred to in the applicable Certification Scheme and applied by the Organisation. The Assessment includes the Examination of the Documentation, attached to the Application for Certification, the Inspection Visit and the Tests. For historical reasons, in order not to confuse operations related to UNI IEC EN ISO/IEC 17021-1 (Management System certification) with those related to UNI IEC EN ISO/IEC 17065 (Product Certification), ICIM defines the on-site assessment operations as "**inspections**" and the personnel who performs the assessment of documentation and on-site assessments as "**inspectors**". The aforementioned indications are therefore applied in this regulation and in all documents relating to Product Certification.

4.0 CERTIFICATION PROCESS

4.1 General conditions

The conditions set forth in the General Regulation ICIM 0001CR apply.

4.2 Offer

The Organisation that intends to start the certification process must provide ICIM with all the necessary data to prepare a correct and complete financial offer. Namely, the following need to be provided:

1. the applicable reference legislation;
2. the essential details of the Organisation and relative activities;
3. any exclusions of elements in the standard and the reasons;
4. elements suitable for identifying the type of product (model/variant), or service (type) that the application refers to;
5. identification of the Organisation's processes, internal and outsourced, which affect conformity with the applicable requirements;
6. the number of permanent and temporary sites affected by certification and the relative conducted activities (see also Appendix 1 on contractual agreements with external operational units and/or main suppliers);
7. the availability of any Quality System Certification, suitable for the Certification Scheme of the Product that the application refers to, issued by ICIM or another CB (Certification Body) that ICIM has mutual recognition agreements with.

The Organisation must submit a request for an estimate through the contacts on the website www.icim.it in the contacts area.

Based on the data received and in conformity with the applicable provisions of the standard and accreditation rules and with reference to specific fees, ICIM prepares and sends the offer to the Organisation.

Before issuing the offer for certification of the products or services for an Organisation (or with a main or crucial supplier, or with a critical subcontractor, etc.) based in the USA (United States of America) and/or Canada, ICIM will have to assess the need for insurance coverage for these countries. ICIM will therefore have to supplement the current coverage with what is necessary for these countries, if it intends to proceed with the offer. If necessary, ICIM may reassess the offer made to the Organisation to partially cover the additional insurance costs.

4.3 Presentation of the application for certification

The Organisation that intends to request certification, must present the Application for Certification (hereinafter referred to as the "Application") to ICIM, using the designated form, wherever possible, and attaching, when required:

1. technical documentation, which provides details on the technical characteristics and specific requirements of the service/product that the certification refers to, according to the regulatory documents of the individual product/service scheme. The said documentation must be handed into ICIM preferably in electronic format and in Italian, it must have a table of contents and include information on the organisation and its management systems;
2. proof of payment of the amount required for examination of the Application (if applicable);
3. all other elements necessary to fulfil the requirements of the Certification Scheme.

The form must be filled out completely in order for the Application to be considered valid. The parts that do not apply must be crossed out.

The Organisation must inform ICIM of any later variations to the contents of the aforementioned documentation.

For certification requested by foreign Organisations, all the conditions that govern the concession of national Organisations apply, in observance of international agreements made with ICIM.

4.3.1 Technical documentation

The technical documentation provides details on the technical characteristics and the specific requirements of the service/product that the certification is for, according to the regulatory documents and the requirements set forth in the individual product/service scheme (see also Appendix 1); also, the said documentation must include information on the Organisation and its management systems. The technical documentation will be managed and filed by ICIM as per Energy Product Technical Note 0155BM.

4.4 Examination of the application

4.4.1 Review of the Application and Offer

Upon receipt of the Application and of the accepted Offer, ICIM acknowledges them and verifies them, in order to:

- assess whether the product, that the Application refers to, falls within the certification scheme relative to the reference regulatory document identified by the Organisation in the Application;
- assess whether the Organisation possesses the technical-organisational requirements required by the Certification Scheme (see also Appendix 1 referring to the agreement with outsourced operational units and/or main suppliers);
- ensure that the general information (e.g.: supplied products, headquarters, production units, number of employees, etc.) and the Technical Documentation for the product that the Application refers to is complete and suitable;
- ensure that the operation and maintenance manuals are correct and complete.

After reviewing the Application and the Offer, if there are no problems, ICIM proceeds with the certification process, opening the job order according to the SCPExxxx scheme. Otherwise, the Organisation must be informed of what has emerged and if necessary, re-issue a new Offer. *Any exceptions must be approved by the DIR OPE (if operational) or by the DIR MKV (if commercial) or by the DIR ISG (if technical).*

4.4.2 Technical examination of the Application and of the Technical File

On positive outcome of the review, the Application with the relative Technical File/Technical Documentation is subject to in-depth technical evaluation, conducted by ICIM, with the aim of preparing whatever is necessary for the Initial Inspection Visit and for the following Initial Tests. If the submitted documentation is incomplete and unsuitable, or if the product/service does not fall within the Certification Scheme for the standard identified in the Application, ICIM will inform the Organisation of the results of its assessments. The process will be suspended until the Applying Organisation officially fulfils ICIM's requests. Conversely, if the result of the Examination is positive, ICIM goes ahead with the certification procedure agreeing the deadlines with the Organisation.

If the documentation is incomplete, but sufficient to launch the certification procedure (e.g. presence of at least the certification Application, assembly drawings, basic product technical data, risk analysis (where required), Technical File/Technical Documentation (where required), etc. and any other

documents mentioned in the specific Certification File SCPExxxx), ICIM may complete the certification procedure by collecting the documentation until the approval.

Only in product certification may ICIM conduct a pre-inspection at the conditions described in the offer.

4.5 Choice of inspectors

When the Application passes the Examination, the members of the Inspection Group (IG) are chosen from the inspectors registered in the ICIM list of inspectors, as well as the Group Manager (IGM), and the roles are assigned. The IG may be composed of a single inspector, who, by default, is considered the IGM.

4.6 Preparation for the inspection visit

The IGM prepares the visit by studying the Technical documentation and the offer for the technical part, defining the programme for the visit (see also Appendix 1) and preparing the report documentation.

The other members of the IG have, at least, the technical documentation attached to the Application available to them.

Based on what is defined in this phase and by verifying the availability of the Organisation, ICIM notifies the Organisation of the purpose of the visit, the proposed date and the names of the IG.

ICIM sends the Organisation, at least 10 days prior to the agreed date, notice of the audit with the programme and names of the inspectors.

Within 5 working days of receipt of the notice and, nonetheless no more than 5 working days from the expected date of the visit, the Organisation can ask for, by highlighting the reasons:

- the recusal of one or more members of the visiting group;
- to change the date of the visit.

The Organisation has the option of informing ICIM of its disagreement with the choice of the members of the IG. In this case the notice is sent back with the new names of the IG and any change to the date of the visit.

4.7 Initial Inspection Visit (VV)

The VV has the following purpose:

- to assess the Organisation's means of production and testing or the equipment and the service procedures (Manufacturing and Control Plan or Service and Control Plan), suitable to guarantee attainment and maintenance of product/service conformity with the requirements of the applicable Certification Scheme (see also Appendix 1 concerning agreement with outsourced operational units and/or main suppliers);
- where applicable, to verify and possibly qualify the company laboratory, by filling out the relative form;
- to verify that the product/service are in accordance with the technical documents sent along with the application;
- to ensure that the general information provided by the Organisation is complete and adequate (headquarters, personnel, operational units, test laboratories, service equipment, etc.);
- wherever necessary, to take, identify and seal samples of the products that the Application refers to, in accordance with the Sample Taking Plan defined in the Specific Certification Scheme.

The VV must also be extended to the operational units and, depending on the contents of the certification schemes, to the main suppliers (see also Appendix 1).

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The availability of Quality System certification, certified by ICIM or other accredited/notified CB, does not exempt ICIM from assessing all aspects of the Organisation's Quality System that have an impact on the product/service both in the case of voluntary and mandatory certification.

At the beginning of the visit, the IG holds an opening meeting with the Organisation to present the members of the IG and to organise the visit. When necessary, during the visit, the IG proceeds with sampling for the Initial Tests.

At the end of the verification, the IGM re-examines the findings of the inspection to ascertain that all the elements and the affected areas have been assessed, and prepares the visit reports.

At the following closing meeting with the Organisation, the IG presents the results of the assessment, specifying any discrepancies with the requirements of the Certification Scheme (defined as REC, NCm/OBS, NCM/NC), providing the Organisation with the opportunity of clarifying its position on these results and proposing possible corrective actions.

The report, prepared by the IG, which reports the results of the VV must be signed by the Organisation and by the IGM for acceptance, delivering a copy to the Organisation.

The Organisation agrees to inform ICIM, in writing and in accordance with the proposed deadline for implementation of the established corrective actions, providing documented evidence.

The Organisation has the option of clarifying its position based on these results and of proposing any corrective actions.

In the case of non acceptance of the descriptions contained in the reports, within 15 days of conducting the visit, ICIM must inform the Organisation of any changes to them. The Organisation must then inform ICIM, within the deadline established at the closing meeting, to have completed the established corrective actions, providing documented proof.

4.8 Initial tests (ITT)

4.8.1 Sampling

The choice (type and quantity) of samples required for testing and samples to be kept in stock, where applicable, for any re-testing is defined in the standards, draft standards, regulatory documents and/or SCPExxxx and is established based on the type of product and type of test.

Sample taking is conducted either by the IG during the visit or by the individual designated by ICIM.

Sampling will be carried out at the warehouse containing finished products of the Organisation applying for certification or from the market, any exceptions will be assessed on a case by case basis.

The cost of the samples taken from the market will be charged to the Organisation.

Transportation and preservation of the sample must be carried out to prevent damage and alterations to the characteristics relevant to testing.

Samples and relative technical documentation are held strictly confidential, and access to the ICIM files and Test Laboratory are restricted exclusively to personnel authorised by ICIM.

4.8.2 Use of company laboratories

ICIM can use the laboratory of the Organisation applying for certification, under the condition that the laboratory is accredited according to UNI EN ISO 17025 or that the following conditions subsist:

- the Organisation's laboratory has been preemptively qualified by ICIM through the relative procedure;

- the tests, carried out by expert personnel at the Organisation with a Manager assigned with coordination duties for executing and issuing the relative report, are carried out under the supervision of an ICIM inspector;
- for duration tests occupying the laboratory for more than one day, the ICIM inspector will seal the test sample and the cycle meter. ICIM also reserves the right to run unannounced controls to ensure there has been no tampering.

ICIM participates, in part or in whole, in the preparation and execution of the tests.

4.8.3 Use of external laboratories

ICIM will use external laboratories under the condition that they are accredited according to UNI EN ISO 17025 or qualified by ICIM for the specific certification tests according to the relative procedures. The tests are carried out by expert personnel at the testing Laboratory with a Manager who coordinates the execution and issue of the relative report.

If it has not been identified in the offer, ICIM provides the Organisation, applying for certification, with the name of the laboratory it will be using for testing, before and no later than 15 days prior to the date that tests are due to start. The Organisation has the right to recuse, wherever possible, the external laboratories if there are motivated conflicts of interest.

ICIM reserves the right to participate in the preparation and execution of testing, through agreements with the testing Laboratory.

The Organisation applying for certification is in charge of sending, picking up and disposing of the tested samples, unless specified otherwise.

4.8.4 Performing initial testing

The test samples must be completely compliant with the model subject to certification.

When the models require the samples to be duly arranged by ICIM, they must be comprised of the assembly of parts provided by the Organisation, by following the installation instructions established by the Organisation itself. The Organisation has the option of assembling the models that will be subject to testing first hand.

The samples must be prepared by an individual designated by the Organisation, who will issue the relative conformity report for the completed assembly, signed by both parties.

Before proceeding with testing, ICIM or the laboratory designated by ICIM, checks that the test samples have identification applied to them, that they are not damaged and that any accessories identified in the technical documentation have been assembled.

Testing must be interrupted if a non conformity, in terms of sample requirements, is discovered during ITT, or if the test objective can not be achieved.

If the results of ITT do not comply with the requirements of the SCPExxxx (results that are negative and/or determine a lower class than the one stated in the Technical Documentation for the product seeking Certification), ICIM will inform the Organisation of the non conforming points, specifying the discrepancies. In this case the Organisation can:

- ask for re-testing, even without completing the testing cycle.
- accept the product downgrade, upon completion of the required testing cycle,
- withdraw the product from the certification sequence, even without completing the testing cycle.

In the third scenario, the modified product can be represented as a "Modified model", using a short certification sequence (the preliminary stage is reduced to checking only the variations of the Technical Documentation, Inspection Visit at the sole discretion of ICIM, Complete Initial tests).

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Re-testing is also carried out if there is a negative result in the following tests carried out under Surveillance. At its discretion, ICIM can repeat the tests on partial or total product sampling.

ICIM charges the sampling costs for these tests to the Organisation, in full.

The results of ITT must be documented, by the laboratory with a Test report, in accordance with the SCPExxxx.

The test report will be filed by ICIM and if the Organisation makes an express request, it will receive a compliant copy.

At ICIM's discretion, the presentation of the Laboratory Test Reports recognised by ICIM can exempt, in full or in part, the Organisation from performing ITT.

4.8.5 Sample preservation

The samples representing certified models, with the residues of laboratory testing, sealed and handed over to the Organisation, must be kept by the Organisation for the entire duration of certification and for 10 years thereafter with samples representing models, 2 years for laboratory test residues.

If the above cannot be applied, due to issues of storage space or maintaining the state of preservation or economic value of the samples, the technical documentation and the registers of the test results, along with any re-testing, will be, to all effects, considered as a replacement of the samples mentioned above, through prior agreement between ICIM and the Organisation.

This documentation must be kept for no less than the amount of time specified for the samples.

5.0 ISSUING THE CERTIFICATION

5.1 Final review

The documentation for product certification is delivered by ICIM to the Approval Committee for the issue of the certification, only if it has been previously verified with a final review by the ICIM representative for the certification and if the following conditions are met:

- positive results of the analysis of the technical documentation presented by the Organisation;
- positive or conditional positive results (in case of NCm.OBS) of the audit at the Organisation's facility, the external operational units, the main suppliers (as per the specific procedure);
- positive results of initial testing.

The final review is carried out directly and at the same time by the Approval Committee if the relevant ICIM representative for the certification has taken part directly in the certification process (e.g. present in the audit team IG), unless indicated otherwise in the SCSxxxx certification schemes (e.g. Medical Device Directive).

In the event of a failed final review, ICIM will ask for clarifications or for the documentation necessary to the IG or the laboratory to complete the review successfully.

5.2 Certification

The documentation for product certification is sent to be checked by ICIM's Approval Committee, in accordance with the specific procedure, only if the final examination is successful.

ICIM prepares the documents required for the Deliberation Committee, namely:

- sales documentation (offer and order with all the Organisation's details);
- application for certification (signed by the Organisation and counter-signed by ICIM);

- technical documentation required by the certification scheme, which defines the certified products/services, the applied standards, any applied certification system (e.g. ISCC);
- report from the examination of the documents;
- report from the initial auditing visit;
- initial test report;
- Certification programme;
- facsimile of certificate.

If the Deliberation Committee does not grant certification, the reasons for this decision are provided (in writing, to the Organisation), specifying the discrepancies in relation to the requirements of the applicable certification scheme. The Organisation must undertake to make the corrections within the deadline set by ICIM, which will not exceed 6 (six) months. When this term expires, if the Organisation has not provided the required elements, the Application lapses and the Organisation will be required to start the certification process anew. The costs sustained by ICIM in this phase are charged to the Organisation.

An Organisation that does not accept the decision made by ICIM can request an additional investigation, presenting its reasons for non-agreement, according to the process set forth herein and in the ICIM General Regulation.

When certification is granted, on the other hand, ICIM issues a certificate defining:

- the product/service that certification is issued for, identifying the production unit/headquarters, or in full, or with a code;
- the reference regulatory document and any applied Certification system (e.g. ISCC, Keymark);
- the certification date and the duration of the validity of certification.

In the event that the certification is granted with reservations (e.g. partial existence of NCm/OBS), the Approval Committee can request surveillance audits or testing, anticipated or unscheduled, which are notified in writing to the Organisation.

When certification has been issued, ICIM enters the Organisation in the register of businesses in possession of ICIM product certification, with at least the following details:

- Name
- Address
- Certificate number
- Certified product/service
- Applied certification scheme (SCPExxxx)

and sends this information to the Bodies (national and international) that ICIM has agreements of mutual recognition with and/or who are required to receive this information by standard or law. This register is updated at least annually and is available to anyone requesting to consult it.

When Product certification has been issued, the series/family of products/services contained in the ICIM certificate must be marked, in accordance with the applicable scheme. The mark must be applied to the product, on the packaging and on the accompanying documents, unless stated otherwise in the SCPExxxx.

The ICIM Mark must be used according to the Manual for the Use of the ICIM Certification Mark – 0260CR. It must be legible, permanent, non-removable and must be placed in a clearly visible position,

possibly after installation, on the outer surface of the product, by and at the discretion of the Organisation, and nonetheless accepted by ICIM.

The manner and method of applying the ICIM Conformity Mark and standard references on the product must nevertheless be preemptively approved by ICIM.

The product ICIM Conformity Mark must not be placed on any other product than the one the Certificate refers to or, in any case, used in such a way that could generate confusion between certified and non certified products. In this case, the Organisation is also required to monitor and block, wherever possible, unauthorised use of the ICIM Conformity Mark, which includes use by dealers of the Organisation's certified product; otherwise ICIM will hold the Organisation liable for these violations.

The costs for the use of the Mark shall be charged to the certified Organisation.

Marks intended for application on products that are used indoors (homes, offices, etc.) must be permanent (in outdoor use conditions) for at least 5 years.

Marks intended for application on products that are used outdoors or in particularly aggressive environments (such as swimming pools) must be permanent (in outdoor use conditions) for at least 10 years.

6.0 SURVEILLANCE PROCEDURE

ICIM monitors the facility, operational units and/or main suppliers of Organisations in possession of certification for the purpose of ensuring that the conditions that enabled certification subsist.

The verifications performed in VI are carried out during Surveillance visits, though less extensively, as well as checks on:

- the suitability of the manufacturing/service means and procedures;
- the manufacturing plan and service and control check/plan;
- ensuring that production is relative to the certified products/services;
- the use of the Mark or markings.

The IG must have complete access to the technical documentation of the product that certification refers to.

Failure to produce one of the aforementioned documents can lead to the suspension of the certification process.

6.1 Scheduled Surveillance (VSV)

The frequency of surveillance (auditing visits and/or product testing) carried out at the Organisation’s facility, production units and/or main suppliers is defined by the frequency and method set forth in the SCPExxxx.

The Organisation is informed of surveillance at least 15 working days ahead of time, through notice of the programme and the names of the inspectors chosen by ICIM and the members of the inspection group. Within 5 working days of the date on which the notice was received and, nonetheless no more than 5 working days from the expected date of the visit, the Organisation can ask for, by highlighting the reasons:

- the recusal of one or more members of the visiting group;
- to change the date of the visit.

ICIM assesses the Organisation's request and provides an official reply regarding acceptance, or not, of the proposed actions.

Certain Scheduled Surveillance Visits for SCPExxxx certification scheme obligations (e.g. Directive on Medical Devices or Vigilance Institutes) are performed by ICIM through surprise unannounced surveillance visits to the Organisation.

6.2 Unscheduled surveillance

Unscheduled surveillance visits (inspections and/or testing of products) may be performed if ICIM becomes aware of shortcomings in the conditions that made it possible to grant the certification, unless otherwise indicated in the SCPExxxx certification schemes (e.g. in certain EU Regulations and Directives where this intervention is mandatory).

Surveillance visits are normally scheduled with prior notice of at least 15 working days, nonetheless, for particularly serious cases or if indicated otherwise in the SCPExxxx certification schemes, ICIM reserves the right to make surprise unannounced visits.

The costs of this surveillance are charged to ICIM if the results are positive, unless specified otherwise in the offer.

6.3 Surveillance Tests (ST)

Surveillance tests have the purpose of verifying that certain “critical” requirements are maintained over time.

The type of surveillance tests and the number of samples are specified in the certification schemes of the various products.

If it is necessary to take into account the critical configuration of the certified series/family and the production statistics of the certified models, ICIM and the Organisation define a surveillance test plan whereby the models or configurations that will be monitored during the period of validity of the certification are planned. The plan is arranged based on the period of duration of the certification, and is re-examined annually.

For sampling methods, please refer to point 4.8.1 of this document.

The surveillance tests will be carried out at laboratories identified by ICIM (see point 4.8.3) or at the Organisation’s laboratories under the condition that point 4.8.2 herein is fulfilled.

During the term of validity of the certificate, at least one test will be carried out on the specimen identified as "more critical" referred to in the certificate, the said assessment will be highlighted in the surveillance test plan. If the technical data sheets of the applicable schemes specify a different frequency, the above is annulled.

Any requests for exceptions by the certified Organisations must be duly documented and will be carefully assessed by ICIM.

When testing is finished, a test report will be drawn up.

6.4 Results

General

If major non conformities are discovered during surveillance, whether scheduled or unscheduled (negative result), ICIM will suspend certification and adopt the provisions required by the ICIM General Regulation, charging all sustained costs to the Organisation.

If Surveillance (scheduled and not) leads to the discovery of discrepancies from the set requirements, ICIM will inform the Organisation in writing, inviting it to eliminate any discovered shortcomings.

In the case of serious shortcomings or the persistence of discrepancies after the agreed term for their elimination, ICIM can, at its sole discretion, revoke certification.

If the Organisation wishes to re-present the modified product for certification, it will be necessary to follow the certification process described in the ICIM General Regulation.

Tests

If surveillance tests conclude with negative results or downgrade the product to a lower class than certification (product downgrade), ICIM will need to repeat the tests on spare samples and, at the same time, the causes that generated the negative results of the test will be analysed.

If negative results (or downgrading) recur on the spare samples, ICIM will be required to implement the suspension procedure on certification, subsequently temporarily interrupting the possibility of applying the ICIM Conformity Mark on the series/family represented by the tested model, and asking the Organisation to immediately set up a technical investigation to ascertain the reasons that led to negative results of the test.

If the technical investigation finds a shortcoming in design or production, and any additional re-testing on specimens sampled at a later time provide negative results and/or downgrade the product to a class below certification, ICIM will withdraw the certificate.

If suspension cannot be annulled within 6 months, the certificate will be revoked.

ICIM will also reserve the right to ask the Organisation to implement a recall for the products with negative results.

7.0 CERTIFICATION VALIDITY

7.1 Duration of Certification

The Certificate is valid for 3 (three) years from the date of issue, unless stated otherwise in the certification scheme. The certificate can be renewed as indicated in chap. 8, unless indicated otherwise in the SCPExxxx.

7.2 Conditions of certificate validity.

The Organisation agrees to maintain the conditions that allowed the certificate to be issued unaltered:

- the certification applies exclusively to the products/services identified in the ICIM certificate and provided in compliance with the requirements set by this regulation, by the certification scheme and by the standards, draft standards and/or applicable regulatory documents. The products must refer to the model subject to the Initial tests:
- any variants in construction/modifications to the certified products/services must be preemptively approved by ICIM;
- ICIM must be promptly informed of any variations to the company conditions that allowed certification to be granted;
- product certification is not transferable to production units or main suppliers other than those identified, verified and accepted by ICIM.

Any exceptions will be examined individually by ICIM.

Regarding single certified products, the certificate itself lapses as soon as any modifications (made by the Organisation or user) or damage are discovered, or if it is exposed to property-altering events.

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8.0 RENEWAL PROCEDURE

8.1 Renewal visit (VRV)

Prior to the expiration of the certificate, ICIM makes a renewal visit (VRV) which is arranged by ICIM at least 60 (sixty) working days prior to the expiration date of the first certificate to be issued for each certification scheme in force in the certified Organisation.

The topics verified in the VRV concern the organisational situation, production statistics, the findings of the last surveillance, the complaints, the Manufacturing and Control or Service Plan, marking and Use of the Mark.

8.2 Renewal tests (RT)

Renewal tests have the purpose of ensuring that “critical” requirements are maintained over time.

The type of RT is specified in the specific sheets for the various types of product.

For sampling methods, please refer to point 4.8.1 of this document.

The RT will be carried out at laboratories identified by ICIM (see point 4.8.3) or at the company's laboratories under the condition that point 4.8.2 herein is fulfilled.

Within 60 working days prior to the expiration of the certificate, at least one renewal test will be carried out on the specimen identified as "more critical" referred to in the certificate, the said assessment will be highlighted in the test plan.

When testing is finished, a test report will be drawn up.

8.3 Negative renewal results

Visit

If major NCM/NC are discovered during the renewal visit (negative result), ICIM will suspend certification and adopt the provisions required by the ICIM General Regulation, charging all sustained costs to the Organisation. In this case, the procedure described in chapter 6.4 of this Regulation will be followed, unless otherwise indicated by the SCPExxxx certification schemes.

Tests

With negative results (or product downgrade) for the renewal tests, ICIM will be required to repeat the tests on spare samples. Wherever necessary or required by the Certification scheme, the causes that generated the negative results of the test may be analysed.

If negative results (or product downgrade) recur with the spare samples, ICIM will be required to suspend product certification and apply the procedure defined in chapter 6.4 of this Regulation, unless otherwise indicated in the SCPExxxx certification schemes.

8.4 Positive results and re-issuing the certificate

The positive results of the visit and renewal tests are binding in order to proceed with issuing a new certificate with 3-year validity, unless stated otherwise in the certification scheme, and which will be identified by the same alphanumerical code as the previous one, except for the revision index.

Organisations that do not intend to renew the Certificate must give official notice.

Organisations can withdraw from the Contract/Certificate based on the conditions set forth in chapter 9 of this Regulation and the ICIM General Regulation.

9.0 CHANGES TO CERTIFICATION CONDITIONS

9.1 Extension of the certification to new models/services

The extension of the certification applies when:

- the product/service has the same characteristics as the certified model/type;
- the product/service is developed at the Production Units/facilities already verified by ICIM.

The Organisation must present ICIM with

- an extension request (Application);
- Technical documentation for the product as required by the certification scheme;
- declaration relative to the production operational unit/headquarters of the service.

ICIM examines the received documentation and decides whether:

- the new product/service is consistent with the model/type and can be incorporated in the issued certificate;
- any supplementation of the received documentation is required;
- a test cycle is required (partial or complete);
- an additional audit is required.

Following the technical assessments described above, ICIM issues its economic offer to the Organisation.

When acceptance of the economic offer is received and the activity is carried out successfully, the file is submitted to the Approval Committee.

The certificate can only be issued in the case of positive results of the deliberation by the Approval Committee (see point 5.2).

If the Approval Committee does not grant certification, the reasons for this decision are provided (in writing, to the Organisation), specifying the discrepancies in relation to the requirements of the applicable certification scheme. The Organisation must undertake to make the corrections within the deadline set by ICIM, which will not exceed 6 (six) months. When this term expires, if the Organisation has not provided the required elements, the Application for extension lapses and the Organisation will be required to start the certification process anew. The costs sustained by ICIM in this phase are charged to the Organisation.

An Organisation that does not accept the decision made by ICIM can request an additional investigation, presenting its reasons for non-agreement, according to the process set forth herein and in the ICIM General Regulation.

9.2 Change to a certified product/service or process or a change/addition of an operational unit

If the Organisation decides to make changes of any type:

- to the certified product (changes to products, range extensions, etc.);
- to the certified service;
- to the production process;
- to the production and testing means;
- to the operational facilities, operational units and/or main suppliers;

- to the Quality System;

it must immediately notify ICIM in advance; if these changes are deemed able to affect product conformity under the applicable Certification Scheme, ICIM will request proof of design and assess their impact on the certification.

The Organisation must provide ICIM with:

- a request for modification;
- Technical documentation of the product/service, with proof of the implemented modifications.

ICIM examines the received documentation and decides whether:

- any integration to the received documentation is required;
- to assess whether the modifications have an impact on the requirements defined in the certification scheme;
- a test cycle is required (partial or complete);
- an additional audit is required.

Within 30 (thirty) days from receipt of the request from the Organisation, ICIM will notify any need for repetition of the assessments, complete or partial, or non acceptance of the said modifications. During this period, and until any certification is issued, the Organisation agrees not to use the ICIM Conformity Mark for products manufactured according to these modified conditions, until ICIM has made a decision relative to the need to issue new certification or extend the existing one, and until this has been granted.

Following the technical assessments described above, ICIM issues its economic offer to the Organisation.

When acceptance of the economic offer is received and the activity is carried out successfully, the file is submitted to the Approval Committee.

The certificate can only be re-issued, with the same code and with a change in revision, following a positive deliberation by the Deliberation Committee

If the Organisation does not accept ICIM's decisions, it must waive certification of the modification, giving notice, according to the procedure described herein (see point 5.2).

The expenses for the new assessments are charged to the Organisation.

9.3 Certification with a different standard of another product manufactured in the same Production Unit

On the other hand, the Organisation that wishes to ask for new certification for other products/services with the same Production Unit/headquarters, but referring to a different standard than the one that ICIM previously granted certification for, must repeat the entire procedure set forth in chapter 4 herein.

When this procedure is completed, ICIM issues a new certificate.

9.4 Other changes

Other changes are described in chap. 8 of the ICIM General Regulation.

10.0 COMMERCIAL CERTIFICATION EXTENSIONS (FOR PRODUCTS ONLY)

Wherever it is accepted by the implemented Certification Scheme and in accordance with the forms and methods defined in the Scheme, the organisations with product ICIM certificates may ask for a commercial extension of their certification to another Organisation.

The application for a commercial extension can be requested by the ICIM-certified Organisation (the certificate-holding organisation) or by the Organisation requesting the extension of certification (the applying Organisation), who will submit the following information to ICIM:

- the name of the applying Organisation and the certificate-holding Organisation;
- description of the models/products for which the extension is being requested (with reference to the ICIM certificates).

ICIM will examine the request and send an economic offer.

The following documentation is required to start the commercial extension of certification:

a. *Information on the applying Organisation*
   - registered offices;
   - any operational units;
   - name of the designated contact person for ICIM;
   - information on the products that the commercial extension(s) refer to;
   - reference certificates;
   - comparative table of product codes (comparison between the code on the ICIM certificate issued by the certificate-holding organisation and the new code requested by the applying Organisation);
   - facsimile of the mark on the products (applied by the applying Organisation on the product);
   - duplicate of the applying-Organisation's trademark;
   - definition of any variants of the certified products, i.e. the elements that characterise the possible variants of the certified product must be defined (e.g. dimensions, level of finish, material, etc.);
   - definition of the accessories connected to the product;
   - copy of the instructions for installation, operation and maintenance (issued by the applying organisation);
   - illustrative documentation for the product (photos, brochures, etc.);

b. *General*
   - letter of trade agreement between the holding Organisation and the applying Organisation, containing at least:
     a. a declaration of authorisation by the holding Organisation granting use of the certificate to the applying Organisation;
     b. a declaration from the applying Organisation committing to the correct management of non conformities and/or complaints/feedback from the market concerning certified products. The said information must also be duly submitted to the holding Organisation;
     c. a declaration from the applying Organisation committing to not modify, for any reason whatsoever, the certified product and/or technical documentation furnished with it and sent to ICIM;

d. a declaration from the applying Organisation committing to the correct use of the ICIM Conformity Mark, according to the rules.

Following acceptance of the economic offer, ICIM sends the Application, which must be filled out in the required sections and returned for acceptance, complete with attachments.

ICIM ensures that the received documents are complete and informs the applying Organisation of any missing elements.

If the examination of the documents provides a positive outcome, ICIM will call a meeting of the Approval Committee and, following the Committee's deliberation, will issue the certificate to the applying Organisation.

During the certificate's validity period, ICIM performs at least one audit at the applicant Organisation, unless otherwise indicated in the applicable Certification Scheme, to check the status of the certified products (placement on the market), the correct storage and the correct warehousing of the certified products, the management of non-conformities and/or of complaints/reports from the market, and the correct use of the ICIM Conformity Mark.

The product mark placed on the market by the applying Organisation must always be compliant with the requirements specified in the standards, draft standards and/or regulatory documents and reference SCPExxxx, and must be preemptively approved by ICIM.

The product placed on the market by the applying Organisation is not required to exhibit references to the ICIM certificate-holding Organisation mark unless agreed otherwise in trade agreements or required by law, and in observance of the principle of transparency of certificate ownership and product responsibility.

10.1 Lapsing/suspension of commercial extensions

In addition to the cases defined by ICIM's General Regulation, commercial extensions lapse or can be suspended in the following cases:

- cancellation of product certification contract with ICIM, by the certificate-holding Organisation;
- suspension of the product certification of the certificate-holding Organisation;
- withdrawal of the product certification of the certificate-holding Organisation;
- negative outcome of the surveillance visit at the applicant Organisation;
- failure of the applicant Organisation to fulfil the contractual commitments towards ICIM and the certificate-holding Organisation.

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APPENDIX 1.0 - MINIMUM REQUIREMENTS FOR CONTRACTUAL AGREEMENTS WITH EXTERNAL OPERATIONAL UNITS AND/OR MAIN SUPPLIERS

This paragraph applies to Organisations applying for product certification or which already have certified products that intend to make use of either external operational units that are not directly connected to them or of main suppliers, and defines the minimum requirements for the definition of a contractual agreement with the suppliers and/or external operational units that are not directly connected to the Organisation applying for certification and/or already with certified products.

With this situation in force, the contractual agreement is the basic requisite for obtaining product certification.

The contractual agreement must have the following specific references to:

- regulatory documents: It must be clearly reported in the contractual agreement that the production and/or assembly of the product at the main suppliers/external operational units must be carried out in compliance with the standards, draft standards, regulatory documents and reference SCPExxxx;
- Manufacturing and Control Plan: It must be clearly reported in the contractual agreement that the main supplier/external operational unit is required to produce a Manufacturing and Control Plan, defined and approved by the applying Organisation. The supplier is also required to:
  - perform and record product controls in documents, as preemptively agreed and defined with the applying Organisation;
  - perform and record non conformity on products;
  - notify the applying Organisation of any corrective actions adopted on the products (for example, what to do in the case of a non conformity);
  - preemptively notify the applying Organisation of any modifications that they intend to apply to the product, to the manufacturing and control plan and/or production means.

All the documentation listed above must be made available to the applying Organisation by the main supplier/external operational unit.

These documents are generally managed as attachments to the contractual agreement and must be promptly sent to the applying Organisation.

The agreement must state that the applying Organisation has the right (with due warning) to perform audits on the products and/or production (second party auditing).

The said audits (with due warning) can also be conducted by ICIM (third-party auditing).

If the mark is applied on the product directly by the main supplier/external operational unit, it must be clearly stated in the agreement that the ICIM Conformity Mark must be used exclusively for products that have received approval from ICIM.

The main supplier/operational unit will be informed by the applying Organisation of the possibility of applying the ICIM Conformity Mark on a given product.

The applying Organisation is nevertheless always responsible for the application and correct use of the ICIM Conformity Mark.

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