Regulations for certification of quality management systems

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1.0 SCOPE

These Regulations define the requirements which an Organization applying for certification of its Quality Management System (QMS) needs to comply with in order to obtain and maintain the certification issued by ICIM and to be recorded in the Register of certified Organizations.

“Special instructions” referring to specific certification schemes are defined in apposite Appendices which form an integral part of these Regulations and which the Organization needs to comply with.

ICIM services are available, without any discrimination, for any Organization which applies in compliance with these Regulations.

These Regulations do not include consulting activities related to arranging of QMS documentation or to designing or implementing of QMS.

The application of these Regulations is controlled by a Committee for Safeguarding Impartiality (CSI) where the parties interested in certification are represented.

ICIM certification is a document where ICIM states that the applying Organization works with a QMS compliant to the rules.

The Organization, not the Certification Body, has the responsibility for conformity with the certification requirements.

The Certification Body has the responsibility for the objective evaluation of the evidence which a certification decision is based on.

2.0 REFERENCES

The following normative references are applying for QMS certification. The latest edition of the referenced documents applies:

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<thead>
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<tr>
<td>UNI CEI EN ISO/IEC 17021:2006</td>
<td>“Conformity Assessment – Requirements for bodies providing audit and certification of management systems”</td>
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<td>UNI EN ISO 19011:2003</td>
<td>“Guidelines for Quality and/or Environmental Management Systems auditing”</td>
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3.0 DEFINITIONS

For the purposes of this document the definitions given in UNI CEI EN ISO/IEC 17000:2005 and UNI EN ISO 9000:2005 apply.
4.0 GENERAL CONDITIONS

4.1 The certification process can be started by ICIM if the applying Organization:
   ▪ has a QMS which conforms to the requirements of the applicable management system standard and to specific requirements set for type of process/product/services;
   ▪ accepts both the conditions stated in these Regulations and the contractual conditions for certification.

4.2 The contractual conditions for certification:
   ▪ define the applicable QMS model and the normative reference;
   ▪ identify the Organization and the Operative Unit where the activities related to QMS certification take place;
   ▪ define the process/products/services interested in QMS certification;
   ▪ define the steps of the certification process (initial audit and maintenance audit);
   ▪ define specific applications of these Regulations, where required.

4.3 To obtain a QMS certification, the Organization needs to have a QMS which is fully operative and in accordance with the requirements of UNI EN ISO 9001: 2000 and/or any other normative references which can be applicable by contract.
   QMS is intended to be fully operative when:
   ▪ it has been applied for at least 3 months;
   ▪ the internal audit system is fully operative and its effectiveness can be demonstrated;
   ▪ a management review of the QMS has been made and recorded;
   ▪ objectives necessary to obtain results in conformity with Client requirements and corporate policies have been defined;
   ▪ the process necessary to ensure that the Organization’s objectives are in conformity with Client’s requirements and legal applicable prescriptions, is defined, controlled and monitored;
   ▪ actions improving the process and the quality of products or services offered have been carried out.

4.4 The initial certification audit of the Organization QMS is composed of 2 stages:
   ▪ Stage 1 Audit adequacy of QMS documentation review;
   ▪ Stage 2 Audit evaluation of QMS implementation and effectiveness.

4.5 During initial or surveillance or recertification audit, the Organization which started the certification process with ICIM, needs to ensure that ICIM auditors have free access to operational areas, information and documentation necessary to follow the programme of the visit.
   The free entrance shall be extended, when required, to auditors accompanying ICIM, for the accreditation and/or for mutual recognition agreements, otherwise the certification is not issued or it can be suspended because the obligation has not been respected.
4.6 If during initial or surveillance or recertification audit, it is necessary to conduct an audit on processes performed at suppliers’ sites, the Organization needs to ensure that ICIM auditors and, when required, auditors accompanying ICIM (see par. 4.5) have free access to their suppliers’ operational facilities.

4.7 Issuance and maintenance of certification are subject to the payment of the respective fees.

5.0 PROCESS FOR CERTIFICATION OF QUALITY MANAGEMENT SYSTEM

5.1 Offer

An Organization, starting the QMS certification process, shall provide ICIM with all the necessary information to enable it to make a correct and complete economical offer. In particular, the following information shall be provided:

- Applicable normative reference;
- essential information regarding the Organization and its activities;
- any requirements of the standard considered for exclusion, specifying the reasons;
- identification of the Organization’s processes, both internal and outsourced processes that will affect the conformity to requirements;
- number of permanent and temporary sites interested in certification and relevant activities performed.

The Organization, when requesting an offer, has to send the “Request for Services Offer (RdOS/MG12)” filled-in in all its parts, available on www.icim.it. On basis of the information provided in the “Request for services offer” and in conformity with the normative requirements and accreditation rules, ICIM elaborates and sends the offer to the Organization.

If accepting the economical offer, the Organization (Client) makes a formal request for certification by sending ICIM the application for QMS certification, which will be filled in, stamped and signed by the Client’s legal representative. The offer is an integral part of the application.

5.2 Application

A Client wanting to be certified, needs to send the QMS application to ICIM by using the relevant form and enclosing, or making available later, the following documentation:

- Quality Manual;
- Informative Questionnaire;
- List of the main rules and regulations applicable to the product/ service supplied;
- List of the operational sites and description of their activities;
- Planning of internal audits;
- Latest Management’s review
- Certificate issued by CCIAA;
- Declaration stating that the Client can fully exercise its rights, not being in liquidation, or insolvent or in arrangement with creditors;
- Document showing that the advance payment in order to open the certification file has been made.
5.3 Application review

When receiving the Application and the related documents, after their review in order to verify information completeness mainly regarding:

- Scope of certification;
- ICIM has the competence and abilities to perform the certification activity.

ICIM records the application in the informative system and informs the Client that its application has been accepted.

The Client’s application, where these Regulations are mentioned, and ICIM acceptance represent the contractual formalization of the relation between ICIM and the Client, and the applicability of these Regulations. The contractual agreement between ICIM and the Client includes:

- Initial certification audit divided in 2 stages;
- Surveillance and recertification audit.

ICIM informs the Client about the selected team in charge of conducting Stage 1 and Stage 2 audits; the Client has the right to ask for replacement of personnel selected by ICIM in case of clear conflicts of interest.

5.4 Stage 1 audit

The Stage 1 audit shall be performed to verify the adequacy of the management system documentation in relation to the certification scope. It also evaluate the Client readiness for Stage 2 audit. In particular, stage 1 audit shall be performed:

- to audit the Client’s management system documentation;
- to evaluate the client’s location and site-specific conditions and to undertake discussions with the Client’s personnel to determine the preparedness for the Stage 2 audit;
- to review the Client’s status and understanding regarding requirements of the standard, in particular with respect to the identification of key performance or significant aspects, processes, objectives and operation of the management system;
- to collect necessary information regarding the scope of the management system, processes and location(s) of the Client, and related statutory and regulatory aspects and compliance;
- to review the allocation of resources for Stage 2 audit and agree with the Client on the details of the Stage 2 audit;
- to provide a focus for planning the Stage 2 audit by gaining a sufficient understanding of the client’s management system and site operations in the context of possible significant aspects;
- to evaluate if the internal audits and management review are being planned and performed, and that the level of implementation of the management system substantiates that the Client is ready for Stage 2 audit.

The documentation which the Client shall make available to ICIM personnel in charge of performing Stage 1 audit is described in par. 5.2 of these Regulations.

Stage 1 audit is usually carried out at the Client’s premises in order to safeguard the confidentiality of the documents, to facilitate the collection and analysis of the information and to achieve the objectives above stated.

In case of small-sized organizations, with simple and/or traditional processes, QMS review of adequacy (Stage 1) can be done upon agreement on a documentary basis at ICIM’s premises.
Stage 1 audit findings shall be documented and communicated to the Client including any observation that could be classified as non-conformity during the Stage 2 audit.

A copy of the Stage 1 audit report shall be sent to the Client.

Any action performed by the Client in order to solve these observations, are verified during Stage 2 audit.

If there is any observation regarded as significant by Stage 1 audit team, its resolution can be requested before the stage 2 audit takes place.

5.5 Stage 2 audit

If the Stage 1 audit has given positive results, the Stage 2 audit can be performed. The Stage 2 audit shall take place at the Client’s site in order to evaluate the implementation of QMS in conformity with the requirements of the normative document.

ICIM will verify the Client’s availability for the audit and communicate the programme of the audit.

At the beginning of the audit, the team will have an opening meeting with the Client in order to:

- clarify how the audit will be performed;
- establish an official channel for the communications between the team and the Client;
- determine any other point relevant for the audit.

At the end of the audit, during the closing meeting and in the presence of the Management of the Organization, the team shall report its conclusions regarding the conformity of the Organization’s QMS with the reference standard, pointing out the noticed deviations, if any.

During the meeting the Client Organization has the opportunity to question the team and to clarify its own position on the assessment results and to propose the eventual corrective actions.

The result of the audit is recorded in a confidential report pointing out the deviations form the requirements of the standard, if any, and the opportunities for improvement.

This report shall be officially handed over to the Client by the Audit Team Leader during the closing meeting.

ICIM will receive the report from the Audit Team leader and if ICIM needs to make any changes, it has to inform the Client in writing.

As for the corrective actions decided, the Client shall inform ICIM in writing, within the agreed time, and give documented evidence of the corrective actions implementation.

ICIM shall evaluate the corrective actions proposed by the Client; if ICIM does not accept the proposed actions concerning time and modalities for solving the non-conformities found, ICIM shall inform the Client in writing.

In case of major non-conformities, the certification process will be temporarily suspended.

A major non conformity is either a failure to fulfil one or more requirements of the management system standard; a situation that raises significant doubts about the ability of the Client’s management system to provide product that meets customer and regulatory requirements.

In this case, the non-conformity handling and the relevant corrective actions shall be implemented within 90 days from the last day of the Stage 2 audit. ICIM can perform a supplementary audit to verify the correct implementation of corrective actions.

In case the 90 days time limit cannot be respected, the Client’s QMS shall be subject to a full audit which will be performed within 6 months from Stage 2 audit.
Under special conditions, these terms can be modified by ICIM upon justified request from the Client.

ICIM shall make the certificate decision on the basis of the evaluation of the audit findings and conclusions.

5.6 Issue of Certification

5.6.1 When certification is granted, ICIM will issue a certificate which defines:

- the reference standard;
- the scope of QMS certification with respect to product/process as applicable at each site;
- date of granting, extending or renewing;
- the expiring date.

5.6.2 The certification is not granted in cases of:

- Major non-conformities;
- Product/service non-conformities related to legal requirements.

5.6.3 In case the certification is not granted, the reasons for this decision will be communicated to the Client in writing. The Client shall correct any non-conformities to QMS certification requirements within the time limit proposed by the Client and accepted by ICIM.

In this case, on the due date, ICIM shall decide if another audit is needed or if it can accept a declaration written by the Client, with adequate evidence, stating that the corrective actions have been implemented.

This implementation shall be verified during the first surveillance audit.

5.6.4 If the Client does not accept ICIM decision, the Client can ask ICIM for more verifications and the Client’s reasons of disagreement shall be presented as per modalities indicated in par.14.

Following the certification issuance, ICIM will register the Client in the Register of Organizations holding ICIM certificate and will give this information to National and International Bodies having mutual recognition agreements with ICIM. The Register contains the name and location of the Client, QMS normative reference, the scope and the certificate validity period. The Register is updated every 3 months and it is available to anybody upon request.

Upon written request, ICIM shall supply any evidence confirming the validity of the certification.

5.6.6 Following ICIM’s agreements with National and International Bodies, ICIM can issue further certification.

6.0 MAINTENANCE AND RENEWAL OF CERTIFICATION

6.1 Validity period

The certification will be valid for a period of 3 years from the date of issuance.

6.2 Maintenance of certification

ICIM will conduct Surveillance audit at the Client’s site to confirm that the Client’s QMS continues to conform to the requirements of the standard to which it is certified.

Surveillance audits will be conducted at least once in a year. The first Surveillance audit shall take place within 12 months from the last day of the Stage 2 audit.
During the certification validity period of 3 years, 2 Surveillance audits shall be conducted. Every Surveillance audit shall evaluate the effectiveness of some QMS processes so that all the processes will be reviewed every 3 years.

The Surveillance audit programme shall include, at least:

- internal audits and management review;
- a review of actions taken on non-conformities identified during the previous audit;
- treatment of complaints;
- effectiveness of the management system with regard to achieving the certified client’s objectives;
- progress of planned activities aimed at continual improvement;
- continuing operational control;
- review of any changes.

During the Surveillance audit, ICIM will review the Client’s usage of ICIM certification. The Surveillance audits shall be notified to the Client at least 2 weeks prior to the visit.

If any non-conformity to the requirements is observed during the Surveillance audits, ICIM shall inform the Client in writing. The Client will be invited to resolve the issues found.

In addition to the surveillance audits as provided in the programme, ICIM shall conduct Surveillance audits at the Client’s site without notice:

- in case ICIM receives significant complaints and warnings that the Client does not satisfy the requirements of the QMS standard or these Regulations;
- in case of changes regarding the Client’s organization;
- in case the Client’s QMS certification is temporarily suspended.

Any expenses regarding Surveillance audits without notice will be paid by the certified Client if any non-conformity to the requirements is observed.

6.3 Recertification

ICIM will conduct recertification audit at client’s site every 3 years; the same procedure of Stage 2 audit will be followed.

The recertification audit shall consider:

- the effectiveness of the management system in its entirety in the light of internal and external changes and its continued relevance and applicability to the scope of certification;
- demonstrated commitment to maintain the effectiveness and improvement of the management system in order to enhance overall performance;
- whether the operation of the certified management system contributes to the achievement of the organization’s policy and objectives.

When, during a recertification audit, instances of non-conformity are identified, ICIM shall define time limits for correction and corrective actions to be implemented prior to the expiration of certification.

The recertification audit shall have a positive result in the due time so to allow ICIM to approve the request for recertification and to reissue the certificate.

ICIM shall plan the recertification audit 6 months prior to the certificate expiry date and shall conduct the audit at least 30 days prior to the expiration of certification.
When the Client does not respect this schedule and does not obtain the recertification within the certificate expiry date, the certificate shall be considered as expired from the day after the expiry date stated in the certificate.

At the end of the 3-year validity period, ICIM will send a quotation for recertification.

The recertification is subject to the satisfaction of what it is indicated in par.11 of these Regulations.

7.0 RIGHTS AND DUTIES OF ORGANIZATIONS HOLDING CERTIFICATION

7.1 An Organization having a QMS certificate shall make efforts in order to:

- maintain its QMS conform to the requirements of the standard to which it is certified;
- keep a record of all the complaints with the relevant corrective actions implemented;
- accept to pay the Surveillance audits for maintaining the certification during its validity period;
- accept to pay the Surveillance audits necessary to maintain the certification following relevant organizational changes happened after the date of certification issuance or after the latest Surveillance audit performed by ICIM.

7.2 The Client is committed to being in conformity with the legally binding requirements applicable to its products, services and personnel. The certification only refers to QMS conformity to the normative reference document. The Client is the only responsible for the legislative conformity; ICIM has no responsibility or obligation bonds.

7.3 The certification is reserved for the Organization and for the operational units quoted in the certificate. The certification is not transferable.

Organizational changes, variations in the staff or transfers of the Organization property allow the maintenance of the certification provided that:

- the Client shall inform ICIM in writing without delay;
- ICIM has verified that the changes are in conformity with the certified QMS.

The verification following these changes shall involve a revision of the fee: an extra fee can be charged.

7.4 If a Client wants to change and/or extend the QMS model or the certification scope, change and/or extend the products/processes/services involved in QMS certification, the Client shall inform ICIM in writing.

In response to this application, ICIM will review this application in order to make a decision.

7.5 An Organization holding a certification is committed in ensuring access to its site to ICIM auditors, to the Accreditation Body’s inspectors accompanying ICIM or to ICIM authorized representatives; in assisting them during Surveillance audits and in implementing any QMS corrective actions in relation to any non-conformity found. ICIM auditors are committed to limiting their interference with the operational activities.
7.6 The Client can advertise the possession of ICIM certification for its QMS provided that a correct reference is made to the scope and limits of the certification.

The Organization can use ICIM mark of conformity and any other mark of conformity whose usage is clearly authorized. ICIM requirements for the use of ICIM mark can be found in ICIM 0008CR document.

ICIM mark shall not be used on a product as this could be interpreted as denoting product conformity.

The certification cannot be used for QMS models or activities outside the scope of certification; it cannot be used in a misleading manner.

ICIM certification for QMS does not release the Client from its liability for the products or services offered and from its liability towards its clients.

7.7 The Client shall ensure that the certification will not be used upon withdrawal or expiry.

8.0 TRANSFER OF ACCREDITED CERTIFICATE

If an Organization having a valid certificate issued by another certification body which has been accredited in this field by an Accreditation Body which adheres to the agreement of mutual recognition EA/IAF, applies for certification transfer, ICIM shall make a verification which includes:

- review of the application for certification (par 5.3 of these Regulations);
- review of the reports for the audit performed by the accredited body which issued the certification;
- non-conformities and corrective actions status;
- any on-site audit, whose extension depends on the conformity and validity of the certification previously issued.

The Client shall communicate to ICIM:

- the reasons for applying for certification transfer;
- any observation or recommendation received by national or local authorities in charge;
- any complaint received and relevant actions implemented.

The contractual agreement between ICIM and the Client has the same modalities stated in par.5.3 regarding the extension of audit activity.

If the above mentioned activity is completed with positive results, ICIM issues the QMS certification which maintains the expiry date stated in the previous certificate.

As for the Surveillance and Recertification QMS audits, the schedule decided by the Body which previously issued the certificate shall be maintained.

9.0 SUSPENSION, WITHDRAWAL OR RENONUCEMENT TO CERTIFICATION

9.1 Suspension

ICIM can suspend QMS certification in cases wherein:

- major QMS non-conformities and other non-conformities have not been solved in the time agreed with ICIM;
- the certified Client does not allow Surveillance audits to be conducted at the required frequency;
- major changes have been made to the Client’s management system or to its site without informing ICIM;
- relevant changes to the certified QMS have not been accepted by ICIM;
- the certified Client does not allow the Accreditation Body’s staff or its representatives accompanying ICIM to participate to the audit;
- QMS does not ensure the compliance to the laws and regulations applicable to the activity and/or site interested in certification;
- major and justified complaints are sent to ICIM.

The certified Client can voluntarily request a suspension, provided that reasons are given. The suspension would not exceed 6 months and the certificate expiry date.

ICIM communicates the official suspension to the Client by sending a registered letter where the condition for withdrawing the suspension are also stated.

In case of suspension, the client refrains from:

- further promotion of its certification;
- using any copy of the certification or ICIM mark.

ICIM shall make the suspended status of the certification publicly accessible and shall take any other measure it deems appropriate.

The suspension can be withdrawn in cases wherein, following ICIM audit, it is observed that the QMS compliance to the certified requirements is restored.

Failure to resolve the issues that have resulted in the suspension within 6 months, shall result in withdrawal of the certification.

Any expenses regarding the supplementary audit resulting from the suspension will be paid by the certified Client.

9.2 Renouncement

The Client can renounce to its QMS certificate by giving formal communication to ICIM within 6 months prior to the schedule of the audit.

The Client shall renounce to certification in case of:

- change of the normative reference as stated in par. 12 of these Regulations;
- non-acceptance of any revision of these Regulations;
- non-acceptance of changes in the economical contractual conditions;

The Client shall send communication to ICIM within 1 month from the date of notification of ICIM changes.

In case of renouncement, the Client shall:

- return ICIM original certificate;
- not use any eventual copy of the certificate and reproduction thereof;
- remove all reference or symbols to/of ICIM certification from its letterhead paper, technical or advertising documentation.
In case of renouncement, ICIM shall proceed with:

- the cancellation of the Client from the register of certified clients (par. 5.5.4).

The Client can apply for certification 1 year after resolution of the contract, unless exceptions which will be evaluated by the Committee for Impartiality.

9.3 Withdrawal

ICIM shall withdraw the certificate under the following circumstances:

- failure of the Client to observe the requirements deriving from the application of par. 6, 7, and 13 of these Regulations;
- failure of the Client to resolve the issues of suspension within 6 months as stated in par. 9.1;
- failure to resolve the issues regarding non-conformity with the QMS requirements;
- arrearrange for more than a month since receipt of warning given by ICIM by registered letter;
- cessation of activities for which the Client has obtained QMS certified;
- bankruptcy or liquidation.

ICIM shall communicate the decision for QMS certification withdrawal to the Client by sending a registered letter.

Upon withdrawal, the Client shall:

- return the original ICIM certificate;
- not use of any eventual copy of the certificate and reproduction thereof;
- remove all reference or symbols to/of ICIM certification from its letterhead paper, technical or advertising documentation.

In case of certification withdrawal ICIM shall:

- Cancel the Client from the Register of certified Clients (par. 5.4.4) and make the Client certification publicly accessible and take any other measure it deems appropriate;
- Accept the Client’s application only 1 year after withdrawal and only if the Client can demonstrate that actions have been taken in order not to incur in the issues which brought to the withdrawal.

9.4 ICIM actions

If the Client which renounces to the certification or whose certification has been withdrawn by ICIM, will not respect the obligations described in par. 9.2 and 9.3, ICIM will take legal and advertising measures it deems appropriate.

10.0 CONFIDENTIALITY

All documents (technical documentations, letters, communications) and information regarding QMS certification activity, starting from the application, are confidential. The access to the Client’s confidential information is regulated by a special procedure. ICIM personnel, or co-operators acting on the certification body’s behalf, shall keep confidential all information obtained or created during the performance of their activities.

Where ICIM is required by law to release confidential information to a third party or authorities, the client shall be notified in advance of the information provided.
11.0 ECONOMICAL CONDITIONS

The sum due to ICIM for certification activities is stated in the offer and it shall be paid according to the modalities indicated in the offer.

The cancellation or the postponement of already scheduled visits gives the right to debit 50% of the sum due for the scheduled activity as compensation, unless the cancellation or postponement request is sent to ICIM in writing at least 10 working days prior to the visit date.

Moreover, in case of default or delay in payments during the present contractual agreement, ICIM is authorized to issue invoices with direct remittance payment, before performing any Surveillance audit indicated in the contract. The invoices shall be entirely paid before any Surveillance activity starts.

Any withdrawal or renouncements to ICIM certification for any reasons stated in the Regulations, shall involve the full payment of the sum due for a new application and its evaluation in case the Client applies for it.

In default of payment, ICIM will send the Client a warning letter and the notice of withdrawal of certification.

The Client will be charged for any cost related to any recovery of the credit and for any legal expenses.

12.0 CHANGE IN THE CERTIFICATION REQUIREMENTS

In case of changes to the requirements for certification including:

- the normative reference for the model of QMS certified;
- the Regulations.

ICIM shall inform the Clients without delay, using any means it deems appropriate.

In case the changes are accepted, the Client has to conform to them within the term communicated by ICIM when sending the change information.

In case the changes are not accepted, the Clients can renounce to the certification provided that they inform ICIM as per modalities stated in par. 9.2 of these Regulations.

ICIM has the right to evaluate the Client’s QMS conformity to the new requirements.

The Client will be charged for any expense for any Surveillance audit.

13.0 IMPROPER USE OF CERTIFICATION

The use of certification is considered as improper if it can mislead the addressees of technical, commercial and advertising information and, in particular when:

- the certification has not been granted yet;
- the certification is used or advertised outside its scope;
- the Client makes some changes to its QMS which are not accepted by ICIM;
- the Client does not consider the changes to the system requirements made by ICIM;
- there are circumstances which can have a bad impact on the Client QMS;
- the certification has been withdrawn or suspended;
- the Client renounces to the certification.
After verification of the Improper use of certification, ICIM will take any measure in order to stop it and safeguard its own interests.

**14.0 APPEALS AND COMPLAINTS**

The Organization applying for or already possessing the certification shall appeal against ICIM decisions, by stating the reasons for its disagreement within 30 days from communication of the decision.

ICIM shall review the appeal and provide the Client with the outcome within 90 days from receipt.

Complaints can be presented to ICIM by ICIM certified clients, or by the clients of the Organization holding ICIM certificate, or by Accreditation Bodies and/or by any of the parties interested in certification.

In case of written complaints, ICIM shall acknowledge their receipt within 15 days from receipt and shall provide a rapid outcome.

**15.0 DISPUTES**

Every and any dispute which arises between the parties in the execution, application or interpretation of the terms of these Regulations, which cannot be solved between the parties, shall be transferred to Foro of Milan.