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Total of Pages: 18

Modifications

This document incorporates the changes related to the closing of NCs, the new terminology of assessor instead of auditor, editorial clarifications, and update of normative references.

1 Objective and scope

The present Regulation for Accreditation contains the general rules applicable to all entities that are accredited or applying for accreditation.

This document is made available in Portuguese, but translated versions in other languages might be made, if justified. Nevertheless, the Portuguese version will always prevail in case of interpretation doubts.

The present Regulation refers to other documents relevant to the accreditation process and its international recognition, namely from the European co-operation for Accreditation (EA), from the International Laboratory Accreditation Co-operation (ILAC) and from the International Accreditation Forum (IAF). These documents can be downloaded from the respective websites in Internet - see below.

2 Definitions

The general definitions applicable to the accreditation process are established in the following documents:

- NP EN ISO/IEC 17000
- NP EN ISO/IEC 17011

3 Bibliography

The documentation issued by IPAC on the accreditation process is made available on IPAC website (www.ipac.pt) or by direct request to the secretariat.

During the accreditation process, it might be necessary to consult or buy normative standards, and for such purpose the Portuguese Institute for Quality (IPQ) should be consulted (www.ipq.pt).

The documentation from the international entities that co-ordinate the accreditation activity can be consulted in the following websites:

- EA: www.european-accreditation.org
- ILAC: www.ilac.org
- IAF: www.iaf.nu

Such entities issue documents that are of mandatory application for accredited bodies, and are regularly updated, so it is recommended to periodically visit their websites, in order to get the latest information.

The below mentioned organizations are representative of interested parties on the accreditation process, and interesting advisory documentation can be obtained in their websites:

- Eurolab: www.eurolab.org
- Eurachem: www.eurachem.org
- Euromet: www.euromet.org

4 IPAC Presentation

IPAC, the Portuguese Accreditation Institute is the national accreditation body, as established by the Decree-Law Lei n° 125/2004 of 31st May, succeeding to IPQ, the Portuguese Quality Institute that since 1986 was responsible for such function.

IPAC has the mission to develop the accreditation activity recognizing the technical competence of conformity assessment bodies (CABs), in accordance to conformity assessment standards. IPAC acts as market regulator for the CABs, namely inspection and certification bodies and calibration and testing laboratories.

IPAC's methodology for accreditation is based on NP EN ISO/IEC 17011, as well as in relevant applicable guides.

IPAC is an EA member, organization that congregates the European accreditation bodies, and of ILAC and IAF, that congregate the accreditation bodies at international level.

To assure its impartiality, to get strategic advice, and manage the eventual appeals, IPAC has an Advisory Board, constituted by the interested parties.

In order to obtain technical advice to support its activities, IPAC establishes Technical Commissions and Working Groups, involving technical experts and representatives from interested parties. There is an available list of active Commissions at the IPAC website.

To perform the assessment tasks, IPAC selects, trains and qualifies a Pool of Assessors (lead and technical assessors, experts and witnesses), who are committed to confidentiality, impartiality and independence through a Collaboration Agreement signed with IPAC.

5 Accreditation System

IPAC operates on the accreditation domains listed below, according to the methodology described in this General Regulation for Accreditation together with the corresponding complementary Accreditation Procedure for each domain. Both documents should be consulted and complied with by applicants and accredited bodies.

Accreditation Domain	Schemes	Complementary Accreditation Procedure
Laboratories	Calibration Testing Medical examinations	DRC005
Certification Bodies	Products Certification Management Systems Certification Personnel Certification	DRC006
Inspection Bodies	Vehicles Inspection Sectorial Inspection	DRC007
	Environmental Verifiers	DRC008

Accreditation is generally done on a voluntary basis, but sectorial schemes might exist where the accreditation is mandatory, and/or the accreditation criteria are legally established, and in these cases, it is considered a mandatory scheme.

Considering that accreditation is the recognition of technical competence to the perform specific conformity assessment activities, it is limited to an accreditation scope, based on established rules in specific Accreditation Procedures and to become public on the Accreditation Certificate.

Each Entity shall define and propose to IPAC the accreditation scope that it applies for, according to the rules established in each accreditation domain. IPAC limits its requirements, assessments and decisions to the scope defined by the Entity.

5.1 International Recognition

Since the accreditation system managed by IPAC is based on operational and accreditation standards adopted internationally, it is possible to participate in Mutual Recognition Agreements between accreditation bodies. For that purpose IPAC is periodically peer-evaluated.

IPAC is currently a signatory to the following MLA/MRAs:

- EA MLA and ILAC MRA for testing, calibration and medical exams;
- EA MLA and IAF MRA for the QMS and EMS certification, and product certification;
- EA MLA for personnel certification and inspection - no IAF MRA or ILAC MRA exist for these areas.

To make it possible for IPAC to promote the acceptance of bodies accredited by it or by other signatories to the relevant MRAs, it is necessary that the documents containing the results of accredited activities (reports, certificates, etc.) bear correctly the Accreditation symbols.

6 Accreditation Criteria

The general policy of IPAC is to follow the accreditation criteria established on international standards, however it can be necessary to adopt other documents like application documents and interpretative guidelines. In these cases, preference is given to documents produced by EA, ILAC and IAF.

If these entities do not have such documents available, IPAC will promote their elaboration with the collaboration of all interested parties as justified.

If applicable, other documents such as legal regulations can be used additionally to the assessment standards and guidelines.

The accreditation criteria applicable are described in each Complementary Accreditation Procedure mentioned before.

The following IPAC documents are applicable to all accredited bodies or applicants, and are available in IPAC website:

- DRC001 - General Regulation for Accreditation
- DRC002 - Regulation for the use and reproduction of the accreditation symbols
- DRC003 - Regulation for Appeals
- DRC004 - Regulation for Accreditation Fees

6.1 Measurement Traceability Policy

IPAC has a policy to require the traceability of measurements whenever the measurements affect significantly the conformity assessment results or when traceability is a requirement of documents that describe the conformity assessment process. Such traceability to internationally recognized standards, such as the International System of units (SI), is required for accredited Laboratories, Inspection and Certification Bodies whenever applicable.

IPAC adopts the traceability recommendations defined by EA and ILAC/IAF that are described in IPAC interpretative Guide to Laboratories Accreditation (OGC001).

7 Access to Accreditation

IPAC makes available its accreditation to all Entities under an impartial and non-discriminatory policy.

IPAC's accreditation is available to all entities, regardless of its dimension, activity or possible association with other groups or institutions, private or public nature, with or without a profits aim, whenever they fulfil the correspondent accreditation criteria.

IPAC, as the National Accreditation Body of Portugal, performs its activity preferentially in the Portuguese territory. However, it can carry out accreditation of foreign entities, namely in countries where does not exist an Accreditation Body or when the Accreditation Body is not signatory of the Multilateral Agreements (MLA).

In countries where the Accreditation Body is a signatory or candidate to an MLA, IPAC has a policy not to act, unless the Entity presents a valid justification. In this case, IPAC will contact the respective National Accreditation Body and agree on the best way to perform the accreditation process.

In those cases where the accredited or applicant activity is performed only by an identified and delimited part (designated as a technical unit) of the legal body where it is inserted, [the body is responsible to demonstrate that it fulfils the identity, impartiality, integrity and independence requirements applicable to the correspondent accreditation scheme.](#)

8 Accreditation Process

A simplified flowchart of the accreditation process is presented in Annex to this Regulation.

In general the accreditation process consists of a registration phase followed by a review and assessment phase and then the decision-making. After the granting, the process enters the maintenance phase, which includes surveillance and renewal activities. The accreditation cycle is considered the time period between the granting and the first renewal, or between successive renewals. Any accredited entity may present an application for an extension or ask for a reduction, suspension or withdrawal of the accreditation scope.

The accreditation process (including the documentation and spoken language) takes place in Portuguese, except when it is specifically agreed otherwise.

Fees for the accreditation process are defined in DRC004 - Accreditation Fees Regulation, available at IPAC website or by request.

In the accreditation process description hereafter, it will be designated by Entity either the accredited body or the applicant body, as applicable. In annex to this document the phases and sequence of the accreditation process are generically described as a flowchart.

[The time periods established in this document are counted including Saturdays, Sundays and holidays, except where otherwise stated.](#)

8.1 Application Presentation

IPAC will give all the necessary clarifications so that Entities can properly present their application, however, IPAC shall not give advice about the specific steps to be taken so that the accreditation criteria becomes fulfilled.

The documents for application are specified on IPAC's website and described in the Complementary Accreditation Procedures, and should be duly filled in and sent to IPAC.

The documents for application shall be sent by mail (electronic and/or postal) or delivered in person, and shall be officially validated by a duly authorized element of the Entity, with the authority to legally commit the Entity.

It is established that by sending the application, the Entity accepts this Regulation, [as well as the eventual future changes that may be introduced](#).

8.2 Application Management

In the first phase of the accreditation process, there's an administrative reception of the application and afterwards, a preliminary review.

8.2.1 Application Reception

At this stage, it is verified the reception of requested documentation for application and the initial payment.

8.2.2 Preliminary Review

Before the establishing a contractual arrangement between IPAC and the applicant there will be a preliminary review with the purpose to verify:

- If IPAC has the technical capability for the accreditation scope applied;
- If the accreditation scope applied is clearly defined in accordance with the instructions provided.

If the intended accreditation scope isn't under an accreditation scheme already available, IPAC can take some time for development, and the Entity will be informed about the expected steps and its deadlines. However, IPAC may decide not proceed with the development of a new scheme, if advised in that way, or if it isn't appropriate towards its Accreditation Policy or international Recognition Agreements.

During this preliminary review it may be necessary to reformulate the application. In this case, the Entity has six months to reformulate its application. Each Entity can reformulate once its application without any additional expenses.

If the application is accepted, IPAC will confirm to the applicant Entity the application reception, its acceptance and will inform the registration number and IPAC's element (File Manager) responsible to follow the accreditation process (file). If the application is incomplete or needing additional information, this shall be communicated, and asked to perform the necessary actions to complete. This communication by IPAC shall be made within 1 month after receiving the application.

Each application register shall be valid for 1 year to perform the initial assessment. If the validity expires, a new application shall be formulated.

[If the application refers to an Entity whose legal address or key locations \(i.e. those where key activities are performed, or that have a direct impact on the conformity assessment results\) are situated outside the territory of the Portuguese Republic, it is understood that the applicant authorizes IPAC to contact the corresponding accreditation body\(ies\), for the purpose of validating the justifications presented for IPAC cross-border request, and agree on the cooperation mechanisms appropriate to proceed with the application. IPAC will inform the applicant of the conclusions reached, and detail the terms of service necessary to continue with the application.](#)

8.2.3 File Closing

IPAC can close the process in the following situations:

- when the applicant Entity can't present an application according to the established rules or accreditation schemes;
- when the Entity doesn't answer to IPAC's requests in the defined periods or at least in a maximum period of three months.

The process can also be closed by request of the applicant Entity.

8.3 Assessment phase

8.3.1 Assessment Methods

During the assessment phase of the accreditation process the following methods are basically used:

- Document Review: It includes the review the documentation supplied with the application, such as the Quality Manual, procedures and records, in order to evaluate its system, as documented, for conformity with the applicable accreditation criteria.
- Preliminary Visit: The preliminary visit is an activity, independent of the assessment that has the purpose to clarify some aspects resulting from the documental review, and/or to have a perception of the Entity to assess in order to allow an adequate planning of the on-site assessment.
- Assessment: Consists in a detailed verification undertaken on the locations/sites where the applicant Entity develops the activities and has the main purpose to assess the competence and conformity towards the accreditation criteria.
- Complementary Evaluations: In each accreditation domain, other evaluation actions can be performed, as described in the Complementary Accreditation Procedures.

The assessment methodology applied to each accreditation domain is described in the corresponding Complementary Accreditation Procedure.

Under the accreditation process of an Entity whose main office or critical location are situated outside the Portuguese territory, IPAC may subcontract the local accreditation body (if it is a signatory to the relevant MLA) the assessment (in total or partially), as well as perform joint assessments, or have observers. In the case of subcontracting the assessment, IPAC will inform on the sequence and procedures agreed for the assessment.

8.3.2 Nonconformities

During the assessment phase there can be identified situations that are not in compliance with the accreditation criteria, and are thus considered nonconformities (NCs).

IPAC distinguish two categories of nonconformities:

Major Nonconformity, [signalled by a capital letter 'N' and sequentially numbered](#), defined as:

- Absence or systematic failure in the implementation of an accreditation requirement, with implications in the results of the conformity assessment developed (incorrect practice), in its management system or in the obligations to IPAC.

Minor Nonconformity, [signalled by a capital letter 'M' and sequentially numbered](#), defined as:

- Isolated failure of an accreditation requirement that does not compromise, in a significant way, the quality of the results of the conformity assessment developed or the functionality of the management system. Generally is a documental failure (for example: correct practice but not documented) or isolated failure without seriousness (incorrect practical without significant implications).

If nonconformities (NC) arise, IPAC asks the Entity to resolve them, namely implementing the following actions:

- Correction: action to eliminate the identified NC, therefore it's a failure correction; [it may imply the need to review previous non-conforming work, if the criticality and consequences justify](#);
- Corrective Action: action to eliminate the cause of identified NC . With this action it's expected to avoid the occurrence of the same or similar NC.

The Entity has the right to contest the identification of a NC, presenting a written argumentation. However, the decision to maintain or not the NC identified and ask for its resolution is made by IPAC.

In order for IPAC take a favourable decision on the Accreditation process, the Entity shall resolve the NC in the following periods:

Phase	Type of NC	Deadline to resolve
Initial assessment or Extension	Major NC	6 months
	Minor NC	6 months
Surveillance, Reassessment	Major NC	1 month
	Minor NC	3 months

If the deadlines are not respected, IPAC can start a suspension process for accredited entities or a closing process for the applicant entities.

8.3.3 Improvement Opportunities

Besides the non-compliance of the accreditation criteria, it can be registered other findings, designated as improvement opportunities (OM), with the following objectives:

- Call the attention to situations that in the future can origin or develop into non-conformities;

- Identify situations that will bring added value to the assessed entities.

It is up to each Entity to react or not to OMs, since it is not mandatory to reply to them except when justifiably asked by IPAC.

8.3.4 Assessment team nomination

After the preliminary analysis conclusion, previously described, IPAC proceeds, through a written contact with the applicant Entity, to inform on the appointed assessment team constitution and on the global assessment program.

IPAC assessor's management and assessment programs are based on international relevant standards. The assessment team is generally constituted by a team leader and by one or more technical assessors/experts. It's the team leader responsibility to assure the assessment realization according to IPAC rules and procedures, as well to co-ordinate contacts between the team and the Entity.

Assessor's selection takes into account that each assessment team will have the necessary technical competence for the aims of the assessment. IPAC promotes the periodically change of the assessment teams, when possible, in order to refresh the evaluations incidence.

Assessment teams can include observers with no active participation in the assessment, namely for IPAC assessor's qualification process, or to demonstrate to third parties IPAC assessment methodology. In the mandatory schemes of accreditation, representative elements from the regulatory Entity can be included in the assessment teams, as observers.

IPAC can also nominate elements to follow assessment teams' performance, for monitoring the assessors, or for MLA purposes.

The Entity can express its disagreement relatively to one or more of the appointed assessment team elements - the disagreement should be explained in writing in the maximum period of five working days after the reception of the appointment, clearly indicating its reasoning.

If the Entity disagreement is accepted, and no other national assessor/expert is available, it is possible that:

- An assessor/expert from a foreign country will be added, with **additional** expenses paid by the Entity;
- Or that a part of the scope cannot be assessed, and thus accredited.

8.3.5 Documental Review

After the appointed team is confirmed, they shall execute a documental analysis of the documents sent by the Entity, with the purpose to evaluate if the necessary conditions (from the documental point of view) exist to proceed with the following phases of the assessment. If an Entity does not wish to send relevant documents, the evaluation of these documents shall take place in the Entity's office and the duration of the assessment will be extended (or made a preliminary visit).

When the result of the document review demonstrates that the Entity does not significantly or seriously comply with the applicable accreditation criteria, the Entity will be informed of this by letter, having then to proceed to the necessary corrections and clarifications in order to proceed with the assessment process. **If the Entity is accredited, IPAC may start the suspension process and/or change the assessment program.**

8.3.6 Assessment Programming

After a favourable documental analysis, IPAC establishes the assessment program, including the month in which it shall occur, and the assessment team shall agree the date with the Entity. IPAC will then confirm to the Entity, by letter, the assessment programme.

Eventual requests for changing the assessment date(s), shall be justified and delivered to IPAC within 30 days before the assessment programmed month. Whenever the change request communication does not fulfil the stated period, the additional costs related to the time spent on the assessment preparation or hotel or transports reservation may be invoiced to the Entity.

In initial, it is considered that the applicant Entity should make itself available to be assessed within the six months after the application date. The same principle is applied to the extension request, unless the Entity prefers to combine the extension with surveillance or renewal assessments. **The program for the initial and extension assessment will aim to cover in a representative and relevant way the applied scope and all the critical locations.**

In maintenance phase, accredited Entities shall continuously and permanently demonstrate the fulfilment of the accreditation criteria - therefore it is considered that a request to change the assessment date might configure an accreditation suspension, if it exceeds by more than one month the IPAC programming.

The assessment team shall send to the Entity the assessment plan within 5 days anticipation to the assessment date. The assessment plan shall describe the activities to be witnessed, the persons to be contacted, and the subjects and documents to be discussed. The assessment plan is a forecast of activities and the assessment team can change it during the assessment.

It is described below the preliminary visit and assessment mechanisms, but nevertheless the Complementary Accreditation Procedures should be consulted for other types of evaluations.

8.3.7 Preliminary Visit

Preliminary Visits can occur by agreement with or by the applicant Entity request, and has the purpose to clarify and define the accreditation scope, rules and applicable criteria related to the accreditation process and allow a proper assessment preparation, enhancing the success chances of the following stages.

IPAC can suggest a Preliminary Visit **namely** if:

- The **applied** scope involves areas under development by IPAC;
- It is a multidisciplinary Entity, with large dimension and/or high complexity;
- It is a Entity with several key locations.

The Preliminary Visit duration is previously agreed with the Entity considering its objectives.

As a result from the preliminary visit, a report is elaborated by the assessment team, which is presented to the Entity. If serious situations are detected during the visit, IPAC will ask for its correction. IPAC makes only one preliminary assessment per application.

8.3.8 Assessment

The assessment duration is established by IPAC, and is based on the scope of accreditation (namely its size and complexity of the technical areas), and the sites where key activities are developed (activities covered by accreditation criteria - e.g. contract review, planning of conformity assessment, approval and decisions on the results of conformity assessments, etc.) and in the results of the preliminary visit, if occurred. The duration of the initial assessment is usual more or equal to one day.

The assessment can be distributed over several phases and/or displacements, if necessary or convenient.

Eventual requests for change of the scope must be delivered to IPAC with an anticipation of, at least, 45 days, relatively to the assessment month, and its acceptance can originate the need for reformulating the composition of the assessment team and/or the assessment duration.

When a change in scope is requested with an anticipation inferior to the stipulated above:

- IPAC can refuse it if the state of preparation, programming or qualification of the assessment team will be significantly affected;
- IPAC can also charge the costs resulting from the preparation and travels already made by the appointed assessment team elements that will not used because of the requested alterations.

Any request for reduction of the scope by the Entity in an initial application or extension will result in its exclusion of the application scope. In the surveillance phase, any request for reduction of the scope of the assessment corresponds to a request of suspension or reduction of the corresponding part.

The assessment starts with an opening meeting with the presence of the assessment team and the representatives of the Entity, during which will be made the presentations, and described the objectives, methods and criteria of the assessment, and confirmed or adjusted the assessment plan. IPAC does not accepted requests of alteration of the scope made in the beginning or during the assessments.

During the assessment, the assessors will assess the technical competence of the Entity to the applicable accreditation criteria, based on a representative and significant sampling of all the activities to accredit. In the initial assessment, all the **critical** locations are assessed, all the key-responsible for the activities will be interviewed, and it should be evidenced the functioning of the management system through the performance of at least one complete internal audit cycle and one management review. It is up to the Entity to demonstrate to the assessment team its competence and show experience for the performance of the activities under the scope of the assessment.

If the Entity asks for, external persons (namely consultants) can be present during the assessment, but they must always keep a passive attitude, without intervening, answering or influencing the performance of the Entity. In case that does not happen, IPAC can interrupt the assessment and request the external elements to leave before restarting the assessment. In case that the Entity does not create conditions to restart the assessment, IPAC can charge its partial accomplishment **and apply sanctions in the case of accredited Entities**.

The assessment finishes with the closing meeting, in which the Entity's top management should be present, and the assessment team will announce the results and conclusions of the assessment done. In this meeting the Entity representatives should completely clarify eventual doubts on the conclusions presented by the assessment team, namely eventual nonconformities reported.

If NCs with direct consequences to the results of conformity assessment arise, the Entity must refrain from issuing results (affected by the NC) under the accreditation, until the correction has been implemented.

The assessment team will write an assessment report, detailing aspects of competence and conformity, and listing eventual nonconformities to be resolved. One copy of the report is delivered to the Entity at the end of the assessment, and the assessment team sends the original report to IPAC.

8.3.9 Assessment Sequence

Upon knowing the existence of nonconformities the Entity must immediately initiate its analysis and implementation of the adequate corrections and corrective actions to resolved them. For this, the Entity must define an action plan indicating which corrections and corrective actions are going to be taken, and the corresponding deadline. The corrective action's plan (PAC) must be sent to IPAC until one month after the delivery of the report.

The Entity must also send to IPAC the evidence of effective implementation of the corrective action's plan within the prescribed periods for each category of nonconformity. The required evidences to confirm the resolution of nonconformities found in assessments may be documental or practical, depending on the nonconformity nature. *After the first accreditation cycle, IPAC in agreement with the assessment team, may decide not to ask the evidence of resolution of (all or some) minor nonconformities, depending on the nature of those, and the Entity history in the proper and timely resolution of findings - in this case the evidences can be analysed in the next assessment.*

In case that the evidences are insufficient or incomplete, or are of practical nature, a follow-up assessment may be carried out by IPAC (after an initial assessment or extension) or an extraordinary assessment (in the remaining cases) to confirm the resolution of the corresponding nonconformities. *To limit the impartiality risks for IPAC and its assessors, only one follow-up assessment can be performed for each application - if after this follow-up a positive decision is not possible, the Entity must reformulate and present a new application.*

IPAC can request the opinion of other assessors or experts in case of disagreement between the assessment team and the assessed Entity relating to the content and resolution of nonconformities.

Any significant reduction of the assessed scope, requested by the applicant Entity after the assessment, will be evaluated by IPAC to confirm if the dimension of the requested reduction is correct, and if the sampling made in the assessment continues to be representative - if such doesn't happen, it might be necessary to carry out an additional evaluation.

If regulatory accreditations are involved, IPAC requests to the regulatory body(ies) a non-binding opinion that will be considered in the decision-making process of initial accreditation.

8.4 Decision Phase

8.4.1 Decision-making

The decision-making by IPAC is lead by people independent of the evaluation, and is based namely, in the study of the reports and other evaluation information, in the assessment team recommendation (and regulatory body, if applicable), and in the corrective actions plan (PAC) and its resolution.

In principle, the decisions are taken covering all the evaluated scope. However, upon justified request by the Entity, and if it is possible to restrict the conclusions of the evaluation/assessment to a part of the scope, and therefore no generic failures exist, IPAC can anticipate a decision on a part of the scope.

The accreditation decision is valid while the Entity fulfils the accreditations criteria and obligations.

IPAC decisions are always transmitted by letter to the Entity. When applicable, with the communication of the decision IPAC will inform the Entity of the programming for the next evaluation cycle.

In case of an initial assessment or extension, if the decision is negative, IPAC will justify its decision and will consider a new evaluation (follow-up assessment), to carry out in the maximum period of one year after the previous assessment. If it is not carried out during this period, IPAC may close the process or to request a new evaluation of all the scope.

IPAC decisions are taken in the maximum period of 30 days after the gathering of the necessary information.

8.4.2 Accreditation Certificate and symbols

If the accreditation decision is favourable, IPAC will issue a Certificate of Accreditation and its Technical Annex(es), *that remain valid as long as the Entity demonstrate to fulfil this Regulation and the requirements referred by it.*

The Accreditation Certificate describes the denomination of the accredited Entity, the date on which the accreditation was granted, the accreditation standard(s) according to which the assessment took place, and the respective period of validity. In case that the accredited activity is carried out only by a part of the legal entity (technical unit), this will also be identified in the Accreditation Certificate. The Technical

Annex describes the scope of accreditation in accordance with the complementary Accreditation Procedure. Each Certificate of Accreditation and Technical Annex is identified by a unique registry code.

In case the Certificate of Accreditation and Technical Annex are issued in foreign language, the Portuguese version prevails, except if specifically agreed otherwise.

A Certificate of Accreditation is issued in the initial granting for each accreditation scheme and whenever part of the information contained is modified. A Technical Annex is issued in the initial granting for each accreditation scheme, and for each [critical location](#). A new edition of the Annex will be issued when the accredited scope or information contained is modified.

When the accreditation is granted, the Entity is authorized to use the applicable Symbol of "Accreditation" and to advertise its Accredited Statute in accordance with the applicable Regulation (DRC002). IPAC makes available the symbols in the appropriate formats, [and no others can be used, unless explicitly authorized by IPAC](#).

8.5 Accreditation maintenance

8.5.1 Accreditation Surveillance and Reassessment

After granting accreditation, IPAC will program the realization of periodic assessments to the accredited Entity, so that maintenance of accreditation criteria can be confirmed.

IPAC programs annual evaluations, trying to keep 12 months interval between [regular assessments \(initial, surveillance and renewal\)](#), and a reassessment every 3 years. [If the Entity has accreditations in distinct accreditation schemes that allow for a annual combined assessment, IPAC may propose this procedure.](#)

Before finishing each accreditation cycle and with the proper anticipation, IPAC will program the reassessment of the accreditation, which involves an evaluation similar to the initial assessment.

During an accreditation cycle all the accredited scope and sites should be evaluated, so the surveillance and renewal assessments are programmed in accordance.

The Entity must send to IPAC all the requested documentation for preparation of the assessment, including the described in the complementary Accreditation Procedures, in order to reach IPAC at least [30 days](#) before the assessment month.

IPAC can agree with the Entity to perform non-announced assessments or with short-term warning, and in this case the documentation and assessment scope shall be sent and defined in the beginning of the year, or as otherwise agreed.

The evaluation process and decision-making is equivalent to the described for the initial assessment (where applicable).

The Accredited Entity statute implies that the Entity must be able at all times to demonstrate the adequate fulfilment of the applicable accreditation criteria. Therefore, IPAC can at any moment request the Entity to supply information, documents, records and evidence that the accredited activities are being correctly and competently performed.

8.5.2 Extraordinary assessments

Extraordinary assessments can be carried out in the following cases:

- If significant changes have occurred in the organization and its management system, namely at level of key-staff, conformity assessment procedures, equipment or facilities;
- If an assessment is necessary to confirm that withdrawal of a suspension or closing of nonconformities can be done;
- If IPAC receives credible information, claims or complaints about transgressions of accreditation criteria and obligations.

In the last case the extraordinary assessment can be made without prior notice to the Entity or with a very short time.

The costs for extraordinary assessments will be charged to the Entity, unless its execution resulted from an unjustified claim, complaint or information.

8.6 Changes to the Accreditation Scope

The scope of accreditation can be subject to extensions, including changes related to review or substitution of normative or legal documents, and also to changes of sites where key activities are performed.

The Entity must require by written the change of the accreditation scope, which may lead to the issuing of a new Technical Annex or Certificate of Accreditation.

8.6.1 Extension of accreditation

The request for an extension of scope must be made using the forms applicable to each accreditation domain.

IPAC considers an extension of scope an enlargement within the same accreditation scheme.

Depending on the dimension and nature of the extension request, IPAC will determine the type of evaluations actions to carry out and will inform in written the Entity.

The extension assessment can be carried out together with the regular surveillance / reassessment or through an independent assessment, as agreed with the Entity.

To combine the extension assessment with the regular assessment, IPAC recommends that the application for extension arrive to IPAC with a minimum anticipation of 3 months, relatively to the programmed month for the regular assessment. The minimum anticipation required to deliver the documentation is 30 days before the month of the regular assessment.

To join the extension with the regular assessment, IPAC will evaluate the need to modify the appointed assessment team and the duration of programmed assessment, taking into consideration the dimension and specificity of the technical areas of the extension.

8.6.2 Other changes

Other changes to the accreditation scope can occur as described in the Complimentary Accreditation Procedures.

8.7 Transfer of accreditation

The transfer of accreditation consists in the passing of the Accredited Statute from a legal Entity to another, for example, after merging with or acquisition by another Entity, or splitting of Entity. For the transfer to occur there must be continuity in the competence and operation - if this does not happen, a temporary suspension should be requested, or simply cancel the accreditation and initiate a new process later on, when ready.

The transfer can be total or partial for new owner.

The new Entity must request the transference in written, justifying the reasons and sending to IPAC the necessary documents showing that the above conditions are met, the documentation that legalizes the transfer, and the application documentation to the accreditation domain clearly describing the accredited scope to transfer.

If the involved Entities foresee a period where the accreditation obligations will not be fulfilled, they must ask for voluntary suspension of the accreditation. If the transfer changes the assessments programmed, IPAC will reprogram and eventually include a full evaluation.

To accept a transfer, the following continuity conditions should be met (at least):

- The quality policy and the management system must remain unchanged;
- The technical management and technical staff must remain unchanged;
- The structure of the CAB should remain the same;
- The conformity assessment methods must remain the same;
- When applicable, the new Entity must demonstrate that impartiality requirements are met;
- When relevant, equipment and other resources (for example facilities) must remain the same.

If it isn't possible to check by documental analysis the continuity conditions described before, IPAC will program the evaluation actions deemed necessary.

The costs of the transfer shall be charged to the Entity to which the accreditation is transferred.

IPAC will determine the dates where the old accreditation finishes and the new accreditation starts, upon proposal of the Entities that request the transfer.

The new Entity will retain the accreditation number and receive the Certificate of Accreditation.

When two accredited entities request a merging of its accredited scopes, a similar procedure to the transfer of accreditation between two entities will be applied, however in this case the oldest accreditation number will be retained.

8.8 Voluntary Suspension

An accredited Entity can request the voluntary suspension of its accreditation, in total or partially, if considers (or foresees) that it won't be able, temporarily, to fulfil with the established accreditation

criteria. The request should be sent in writing, indicating the scope, reasons for suspending, and the suspension period, with a minimum anticipation of 15 days.

The period of voluntary suspension cannot exceed 6 months, extendable for more 6 months, if justified. During the suspension period, the Entity loses the right to use the accreditation Symbols or to refer to the Accredited Statute for the suspended scope.

IPAC can decide to carry out an extraordinary assessment aiming to evaluate if the Entity was fulfilling with the established accreditation criteria during the period between the last assessment and the programmed suspension start date.

To terminate a voluntary suspension it can be necessary to carry out an evaluation, if judged relevant to confirm in situ that the causes for suspension are resolved.

When the suspension period overlaps with the period programmed for a regular assessment [or other evaluation](#), this will have to be carried out when terminating the voluntary suspension period.

8.9 Voluntary Reduction and Withdrawal

The accredited Entity can request by writing the voluntary withdrawal of the accreditation, which can relate only to a part of the scope (reduction) or to the whole accredited scope (withdrawal).

The request for reduction or withdrawal should be made with a minimum anticipation of 30 days to its foreseen start.

If the Entity requests a reduction of the accredited scope, IPAC can ask for additional information or clarifications on the reasons for the request, to determine if the extension of the reduction is adequate.

The validity of the Accreditation Certificates end on the date that the reduction or withdrawal start, and the Entity is not allowed to use the accreditation Symbols or refer to the Accredited Statute for the corresponding scope.

IPAC will confirm in writing to the Entity the [acceptance](#) of the voluntary reduction or withdrawal, indicating the [starting date and the](#) eventual obligations to fulfil.

The voluntary reduction or withdrawal does not excuse the Entity to fulfil with the eventual missing obligations, namely financial, relative to acts occurred before the starting date.

8.10 Warning

The warning is a written notification by IPAC to alert the Entity to take measures to comply and fulfil the present Regulation, or to respond to previous requests made by IPAC.

If the Entity does not correspond to the requests within the deadlines, IPAC will initiate the closing (in the initial and extension) or suspension (in the remaining [maintenance](#) cases) of the process.

9 Sanctions

9.1 Suspension

The suspension consists in a temporary interruption of the Accredited Statute, applicable when an Accredited Entity is found no longer complying with the accreditation criteria or the present Regulation. [The suspension can also be applied due to acts or oblivions prejudicial to IPAC image and the Accredited Statute.](#)

[For each act, oblivion or unfulfillment mentioned before, a suspension penalty of 3 months, to which in case of re-incidence are added equal suspension periods.](#)

The suspension of accreditation can be total or partial relating to the accredited scope, depending on the seriousness and dimension of its causes.

The suspension of accreditation can be applied for a maximum period of 12 months.

IPAC will communicate by writing to the Entity the intention of suspending, and the Entity has then a period of 10 [working](#) days to present allegations, acts or evidence to interrupt or stop the process. [After this period, the suspension becomes effective, except if the Entity presents data or allegations and ask for a review of the decision.](#) In that case, IPAC will analyze the presented matter and decide if it [keeps](#), changes or cancels the [decision](#), communicating the decision to the Entity in writing.

During the suspension period and for the suspended scope, the Entity is forbidden to use the accreditation Symbols, and to advertise or issue any document with reference to the Accredited Statute. [IPAC may also](#)

forbid the participation of the Entity in meetings committees and/or other activities of IPAC which involve the presence or hearing of Accredited Bodies.

The Entity must notify this situation by letter to the customers that are concerned by the suspension.

The suspension of accreditation can only be lifted when the Entity demonstrates that no longer remain the reasons that motivated the suspension, and in the meanwhile significant changes have not occurred that affect fulfilment of the accreditation criteria and obligations - if the maximum period of suspension finishes and it is not possible to lift the suspension, IPAC will initiate the process of cancelling the accreditation.

In order to lift **one** suspension, it may be necessary to perform an extraordinary assessment, depending if it is necessary to prove in situ the resolution of the problems. The process of evaluation (if exists) and decision is similar to the previously describe, and the conclusion is transmitted in writing to the Entity.

9.2 Withdrawal

The withdrawal consists of the end of the contractual relation between IPAC and the accredited Entity, and consequently it loses the Accredited Statute and the right to use the accreditation Symbols. IPAC can withdraw the accreditation in case of continued or prolonged impossibility of fulfilment of the accreditation criteria or obligations. Accreditation can also be withdrawn in case that the Entity declares bankruptcy or insolvency, or be condemned judicially by acts that affect its reputation and competence. **The withdrawal may also occur in the sequence of acts or oblivions prejudicial to IPAC image and the Accredited Statute.**

The withdrawal can refer only to a part of the scope (reduction of the scope) or to the whole accredited scope.

IPAC will communicate in writing to the Entity the intention of withdrawing the accreditation, and the Entity has then a period of 10 **working** days to present allegations, acts or evidence to interrupt or stop the process. **After this period, the withdrawal becomes effective, except if the Entity presents data or allegations and ask for a review of the decision. In this case,** IPAC will analyze the available elements and decide if it **keeps**, modifies or changes the **decision**, communicating in writing to the Entity.

From the moment when the accreditation is withdrawn, the Entity is forbidden to use the accreditation Symbols or to make any reference or mention to the Accredited Statute. In case that doesn't happen, IPAC may initiate a legal action against the Entity.

The effects of the withdrawal can be reported to the date of the act, oblivion or unfulfillment that caused it, establishing that from that date on the consequent invalidity of all documents issued in the scope of accreditation.

Depending on the reasons of a withdrawn, IPAC can establish minimum conditions or a maximum probation period of one year to accept a new application.

10 Complaints and Appeals

10.1 Complaints

A complaint is any expression of dissatisfaction towards the **activities of IPAC** or **accredited bodies**. In any case, complaints should be submitted **in writing** to IPAC.

If the claims concern accredited entities, they are first directed to the Entity, and IPAC asks to be informed in case of unsatisfactory handling.

IPAC does not handle complaints on certified entities, since it is the respective certification body that is responsible for this - in case that the certification body does not give a satisfactory treatment, and IPAC is informed of this, IPAC will act as if handling a complaint about the certification body.

IPAC will give a reply to the entity presenting the complaint within a period of 30 days, after reception.

10.2 Appeals

An appeal is any allegation or plea presented by an Entity to **an adverse** decision taken by IPAC **concerning the Accredited Statute**.

The methodology for handling appeals is described in the Regulation for Appeals (DRC003), available in the IPAC website.

11 Obligations of the Parties

11.1 Obligations of the Entity

11.1.1 Continuity duty

The accredited Entity or applicant has the duty to fulfil and continuously demonstrate to fulfil the applicable criteria and obligations of accreditation. An Entity with suspended accreditation has still to fulfil its accreditation obligations.

11.1.2 Limitation duty

The accreditation granted by IPAC does not imply, in any case, the acceptance or validation by IPAC of specific results or products of the accredited activity, nor exempts the accredited Entity of its contractual responsibilities before customers and third parties.

Equally, the accreditation granted by IPAC should not be understood as recognition of isolated items of the accredited Entity, such as its equipment, staff or procedures, when considered outside of the context of its accreditation.

11.1.3 Co-operation duty

The Entity must cooperate with the accreditation process, providing the necessary conditions to perform an efficient, impartial and safe evaluation. The Entity must collaborate in order that:

- It shall be possible to check the compliance of the Entity's operation with the accreditation criteria;
- It is possible to assess the implementation of the management system;
- **It is possible to evaluate the impartiality, independence and integrity, when applicable;**
- It is possible to access all relevant locations, records and documents;
- It is possible to witness the Entity's activities under the accreditation / application scope, **and to evaluate all the key personnel;**
- The assessment team is provided with the necessary safety instructions and equipment;
- The assessors and IPAC staff shall not be put in a position where their independence and objectivity could be compromised;
- It answers to IPAC requests within the deadlines established in this Regulation, or if omitted, established by IPAC;
- The corrective actions agreed with IPAC are implemented in the established periods;
- Does not act or make public statements that are considered harmful or prejudicial for the accreditation system or IPAC.

In case of breach of any of the above situations, IPAC can initiate the application of sanctions foreseen in this Regulation, or close an application (as applicable), or initiate a legal action.

11.1.4 Reporting changes duty

The accredited entities have the duty to inform IPAC of all and any changes that can, directly or indirectly, significantly influence the performance of accredited activities, or compromise the fulfilment of the accreditation criteria.

Such changes include the following:

- Changes in the legal identity, ownership or denomination;
- Changes in the organizational structure and hierarchy;
- Changes in the key-staff (namely responsible for the technical validation of accredited results, or for the implementation of the management system);
- Changes in the activities developed (by itself or by related bodies) that originate or may origin conflict of interests with the accredited activities;
- Significant changes in facilities, equipment and other goods;
- Significant changes in conformity assessment procedures or methods (calibration, testing, analysis, certification or inspection).

The maximum period for notifying unexpected changes to IPAC is 15 days after occurrence or knowledge. In case that the changes are expected or planned by the Entity, then they should be notified immediately.

Upon reviewing the reported changes, IPAC can decide to carry out an extraordinary assessment or evaluation or procedure.

Whenever the changes compromise the fulfilment of the accreditation criteria or this Regulation, then the Entity should request a voluntary suspension, reduction or withdrawal of accreditation.

11.1.5 Financial Obligations

Any accredited Entity or applicant has the obligation to pay all the costs of the accreditation process before the final payment date specified on the invoice.

Any Entity has the obligation to support all the costs of the accreditation process, within the deadlines. If before payment the Entity needs to issue an internal document or provisional funds reserve, this should be done when the documentation for the evaluation is sent.

If an Entity does not pay on time, IPAC sends a reminder. Then if payment still does not occur, IPAC can launch a suspension or closing process (as applicable).

The eventual closing, reduction or withdrawal of accreditation does not exempt the Entity to fulfil the financial obligations applicable until the starting date - IPAC can take the judicial or legal steps necessary to reach this aim.

IPAC shall claim all payments concerning acts that occurred before the date of closing, reduction or withdrawal of accreditation.

11.1.6 Juridical Obligations

The Entity shall accept that IPAC and its collaborators can never be claimed responsible by eventual loss of profit, business, or others, if the accreditation services are provided in accordance with this Regulation.

The Entity shall accept to interpret the present Regulation in accordance with the Portuguese law, and under the jurisdiction of the Portuguese Republic.

In case of judicial or legal dispute, the Entity shall accept to submit to the judicial forum designated by IPAC in Portuguese territory, with IPAC being able to appoint legal representatives to represent it, when such representation is not a result of a legal imperative.

11.1.7 Advertising duty

The accredited Entity has the duty to use the applicable accreditation symbols and to refer itself with the Accredited Statute, in accordance with the Regulation for the Accreditation Symbols (DRC002), available in IPAC website. In case that the Entity is authorized to use or to make available to its customers other symbols licensed or authorized through IPAC, it will have to fulfil the corresponding rules of use, as established or communicated by IPAC.

If the accreditation is withdrawn, the Entity is immediately obliged to cease all use and to collect all the advertising material with reference to the accreditation. The Accreditation Certificates are property of IPAC, and IPAC can request to receive them back in case of total withdrawal.

11.2 IPAC Obligations

11.2.1 Service Performance duty

IPAC commits itself to provide an accreditation service in accordance to this General Regulation, to the documents here referred, and the applicable legislation.

11.2.2 Cooperation Duty

IPAC has the duty to dialogue and to cooperate with its customers and remaining interested parties, in order to know its expectations and continuously improve the accreditation service.

However, IPAC cooperation cannot go beyond the limits of hearing interested parties and customers, or to provide information and clarifications, abstaining from any consultancy activity.

11.2.3 Impartiality and Independence duty

IPAC guarantees an equal and non-discriminatory treatment to all Entities, using impartial staff and procedures, in accordance with the international standards. It is up to the Advisory Commission to oversee IPAC impartiality.

11.2.4 Confidentiality duty

IPAC protects the data and information obtained via the accreditation process, including from the evaluations, through confidentiality clauses in agreements with IPAC external staff and collaborators (e.g. assessors, experts, members of commissions, regulatory agencies), and controlling the access to the confidential information.

IPAC can give information on its customers to third parties with their previous knowledge and acceptance. If IPAC is legally obliged to supply information on its customers, IPAC will then notify the concerned customers, if allowed by law.

11.2.5 Advertising duty

IPAC promotes and publishes all granted accreditations, namely through its website, using Directories of Accredited Bodies. IPAC can also use other means and formats for advertising purposes, campaigns or events. The advertising will be made in an equal and non-discriminatory terms for all the Accredited Bodies.

IPAC also publishes all sanctions using the means judged adequate, taking into consideration the proportionality of the implications and response of the Entity, and communicating to the entities considered relevant, [namely regulatory authorities](#).

IPAC makes available Symbols to identify and differentiate the accredited entities and activities to third parties, as established in the corresponding Regulation (DRC002). The misuse or abusive use of the Accreditation Symbols and the Accredited Statute can lead to the suspension or withdrawal of accreditation, and IPAC can take the legal measures to terminate the use and be compensated.

11.2.6 Duty of Information and Communication of changes

IPAC commits itself to make public all the Regulations, Procedures and applicable accreditation criteria, as well as the corresponding fees, and the necessary documentation the present an application - [the publication is made through its website or upon request](#).

IPAC commits itself to inform the Entity of the staff member who will follow its accreditation process, and to give to clarifications and general information.

Eventual changes introduced by IPAC to the Regulations, Procedures and accreditation criteria, or application documents and guides, will always be previously communicated to the representatives of Accredited Bodies and other interested parties, and their opinion considered regarding its implementation.

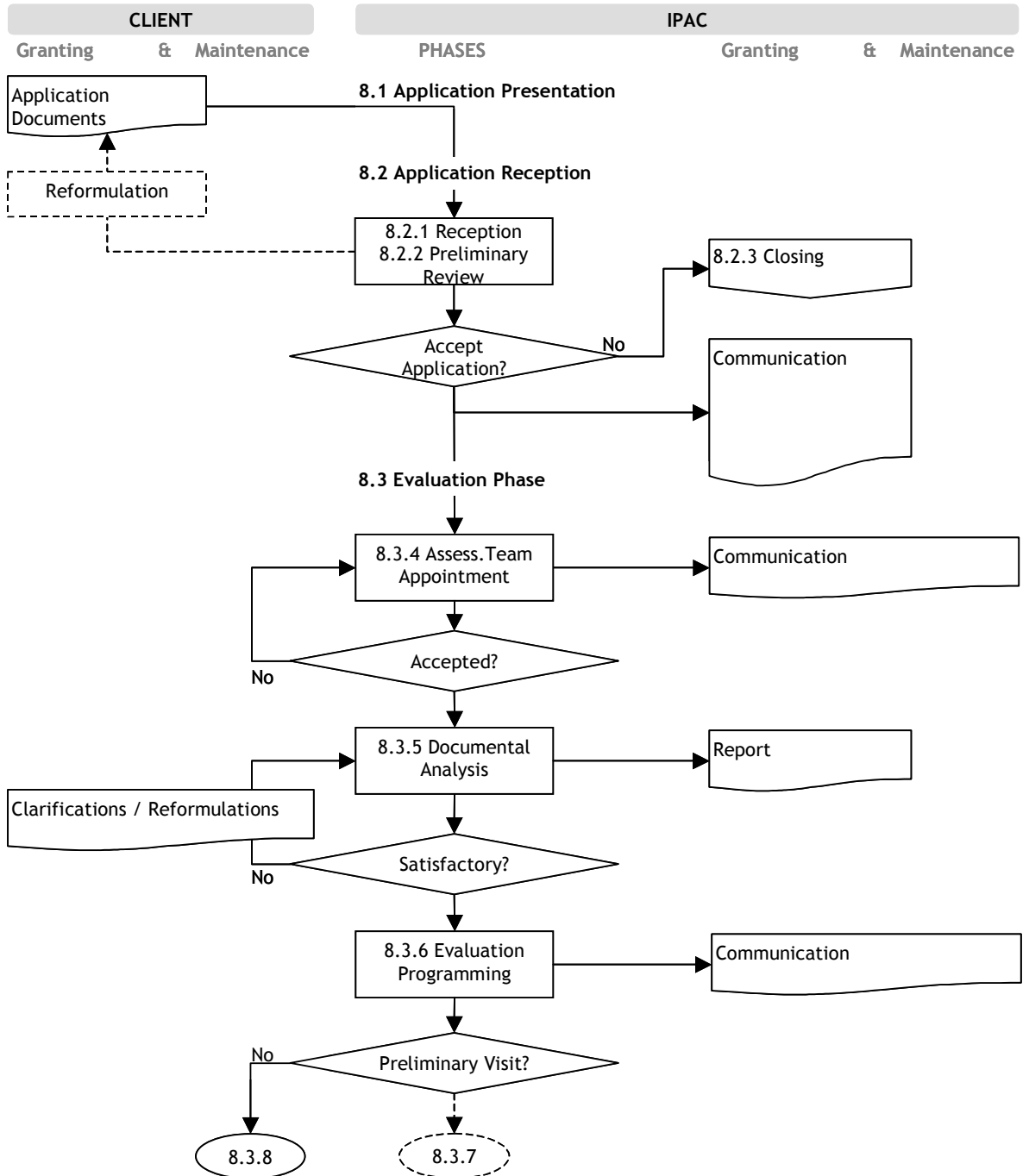
Whenever the accreditation standards are subjected to revision, IPAC will adopt the new versions of these documents, agreeing with the accredited bodies a [plan and a transition period](#). This transition period will respect the eventual international orientations made. If after the agreed transition period, an accredited Entity does not show to have made the changes planned by the transition, IPAC will consider that the accreditation of the Entity is to be withdrawn (in whole or part, as applicable).

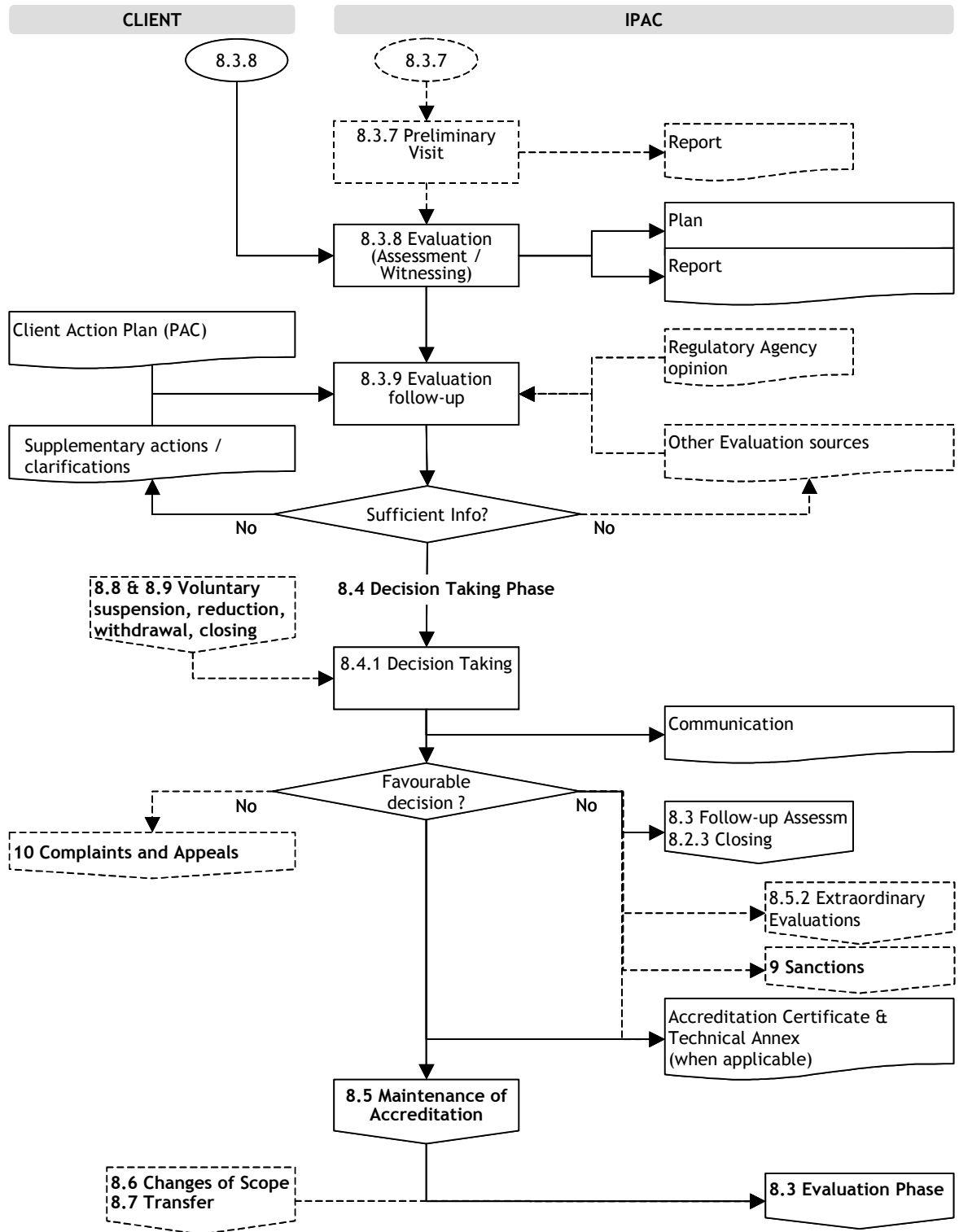
11.2.7 Representation duty

IPAC represents and defends the interests of its accredited bodies, at the national and international level, namely in the European and international arena. IPAC will communicate the results of its intervention in these federative accreditation organizations to its customers through its website or at meetings or news.

12 ANNEX - Simplified flowchart of the Accreditation Process

The flowchart below represents the generic case and the general procedure by IPAC; it can be modified and adapted for specific cases, respecting always the principles of impartiality, competence and confidentiality and ISO/IEC 17011.





It is recommended to periodically consult IPAC webpage to confirm the validity of this document - Saved on 2008-01-17, Printed on 2008-02-01.