GENERAL REGULATION FOR ACCREDITATION  
DRC001 • 2022-10-06

Table of Contents

1 Objective and scope  2
2 Bibliographic references  2
3 Definitions  2
4 IPAC Presentation  2
5 National Accreditation System  3
  5.1 International Recognition  3
6 Accreditation Criteria  4
  6.1 Measurement Traceability Policy  4
7 Access to Accreditation  4
8 Accreditation Process  5
  8.1 Application  5
  8.2 Assessment  7
  8.3 Decision  12
  8.4 Accreditation maintenance  13
  8.5 Changes to the Accreditation Scope  13
  8.6 Transfer of accreditation  14
  8.7 Voluntary Suspension  15
  8.8 Voluntary Withdrawal  15
9 Sanctions  16
  9.1 Suspension  16
  9.2 Withdrawal  16
10 Complaints and Appeals  17
  10.1 Complaints  17
  10.2 Appeals  17
11 Obligations of the Parties  18
  11.1 Obligations of the Entity  18
  11.2 IPAC Obligations  19
12 ANNEX - Flowchart of the Accreditation Process  21

Total of Pages: 22

Modifications

This version incorporates some clarifications and updates, namely regarding remote assessments.

The changes have only been highlighted in the Portuguese original version, which always prevails.
1 Objective and scope

The current General Regulation for Accreditation contains the general rules applicable to all entities that are accredited or applying for accreditation to the Portuguese Accreditation Institute (IPAC).

This document is originally made available in Portuguese, but translated versions in other languages may exist, if justified. Nevertheless, the Portuguese version will always prevail for interpretation and all legal purposes.

2 Bibliographic references

The documentation issued by IPAC regarding the process for accreditation is made publicly available on IPAC website (www.ipac.pt) or upon requested to IPAC.

Regulation (EC) 765/2008 can be found in the EU website: http://eur-lex.europa.eu.

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

- European cooperation for Accreditation (EA): www.european-accreditation.org
- International Laboratory Accreditation Cooperation (ILAC): www.ilac.org
- International Accreditation Forum (IAF): www.iaf.nu

There are mandatory documents which must be applied by the accredited bodies issued by these international bodies that are subject to regular updating, therefore it is recommended to make regular visits to these websites in order to obtain updated information.

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

There may be other documents prepared by interested parties or other bodies that are relevant, and which are referred to in the remaining IPAC documentation.

3 Definitions

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

- ISO/IEC 17011 “Conformity assessment — General requirements for accreditation bodies accrediting conformity assessment bodies”
- ISO/IEC 17000 “Conformity assessment — Vocabulary and general principles”

4 IPAC Presentation

IPAC is the national accreditation body, under the Regulation (EC) 765/2008 as established by its Founding Act (Decree-Law Lei 81/2012 of 27th March) and the Decree-Law 23/2011 of 11th February.

IPAC’s mission is to provide accreditation services, recognizing the technical competence of conformity assessment bodies (CABs) acting in the market. As such, IPAC acts as technical regulator for the CABs’ market, namely inspection and certification bodies, as well as calibration, testing and medical laboratories and validation and verification bodies.

The methodology adopted by IPAC to manage the national accreditation system respects the Regulation (EC) 765/2008, the normative standard ISO/IEC 17011, as well as the relevant applicable documents.

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

IPAC recognizes the importance of ensuring an objective and impartial operation, managing the eventual conflicts of interest in an appropriate manner, as foreseen in the relevant provisions - thus, IPAC approved a Code of Ethics (DECO05) and a Plan for the Management of Risks of Corruption and Related Infractions (DE008), that are publicly available in its website. To ensure the impartiality of its operation, IPAC does not offer or provide conformity assessment activities, consultancy services or technical assistance on such said activities, nor does it have any financial or managerial interest in CABs. IPAC does not recommend or promote specific consultancy services to obtain and maintain accreditation, nor authorize any association of its name and symbols with such consultancy services.
To monitor its impartiality, obtain strategic advice and manage any appeals on its accreditation decisions, IPAC established an Advisory Board with representatives of interested parties (namely Government, regulators, clients, clients of clients, users, consumers and experts).

In order to obtain technical advice and support to its activities, as well as obtaining feedback from interested parties, IPAC uses Technical Commissions and/or Working Groups, involving technical experts and representatives from interested parties. IPAC makes available on its website information about the active Technical Commissions.

To perform assessments, IPAC selects, trains and qualifies a pool of assessors and experts, who are bound to confidentiality, impartiality and independence duties with IPAC.

5 National Accreditation System

The national accreditation system operated by IPAC consisting in a set of rules and procedures used for the recognition of the technical competence of entities to perform specific conformity assessment activities. This system covers the accreditation services set forth in Table 1 below.

<table>
<thead>
<tr>
<th>Type of CAB (Accreditation Domains)</th>
<th>Conformity assessment activity (Accreditation Schemes)</th>
<th>Complementary Accreditation Procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Laboratories</td>
<td>Calibration Testing Medical examinations</td>
<td>DRC005</td>
</tr>
<tr>
<td>Certification Bodies</td>
<td>Certification of Management Systems Certification of Products, Processes and Services Certification of Persons</td>
<td>DRC006</td>
</tr>
<tr>
<td>Inspection Bodies</td>
<td>Vehicles Inspection Sectoral Inspection</td>
<td>DRC007</td>
</tr>
<tr>
<td>Validation and Verification Bodies</td>
<td>Environmental Verifiers (EMAS) Validation &amp; Verification</td>
<td>DRC008 DRC009</td>
</tr>
</tbody>
</table>

The present General Regulation for Accreditation is thus applied in conjunction with a complementary Accreditation Procedure that specifies the provisions of the current document, and as such, prevails over it, both of which being available on the IPAC website. It may also be necessary or convenient for IPAC to amend or establish provisions expeditiously, using Circular Notices to do so.

Although accreditation is generally done on a voluntary basis, sectoral schemes might exist where accreditation is mandatory, and in these cases, it is considered a regulatory scheme. Other bodies external to CABs may also define additional criteria for accreditation and/or conformity assessment, considered then to be a proprietary scheme, which must comply with the applicable provisions, namely those established by EA, ILAC and IAF.

Considering that accreditation is the recognition of technical competence to perform specific conformity assessment activities, it is delimited to a given accreditation scope, defined upon rules established in the complementary Accreditation Procedures and made public by the Accreditation Certificate and corresponding Technical Annex(es).

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

5.1 International Recognition

Since the national accreditation system managed by IPAC is based on operational and accreditation standards adopted internationally, it is possible to participate in Multilateral Recognition Agreements (MLA or MRA) between accreditation bodies. For that purpose, IPAC is periodically peer-evaluated by EA and makes publicly available the corresponding outcome - the EA peer-evaluation also serves for ILAC and IAF purposes.

IPAC is currently a signatory to the following MLA/MRAs:
- EA MLA for testing, calibration and medical examinations, certification of management systems, certification of products, certification of persons, inspection and validation & verification;
• ILAC MRA for testing, calibration, medical examinations and inspections;
• IAF MLA for management systems certification, product certification, certification of persons and validation & verification.

The international recognition of accreditations shall be made pursuant to Regulation (EC) 765/2008 and the applicable provisions of EA, ILAC and IAF. Accreditations granted by IPAC are given mandatory recognition status by national authorities of the EU and EFTA Member-States.

6 Accreditation Criteria

IPAC’s policy is to adopt as accreditation criteria those established in harmonized and / or international standards, using additionally and when necessary normative documents produced by the standardization activity or by EA, IAF or ILAC. If these entities do not have the documents with the information deemed necessary, IPAC may develop (or adopt) documents involving interested parties, including specific accreditation requirements (OECxxx) or examples of application or interpretation of accreditation criteria (OGCxxx).

Additionally, other documents can still be used, such as legal documents or documents relating to proprietary or regulatory schemes, understood as those containing additional or particular requirements for the accreditation process and/or for the CABS.

The accreditation criteria adopted for each accreditation domain or scheme are described in the corresponding complementary Accreditation Procedure mentioned in Table 1.

The following IPAC documents are always applicable to all accredited or applicant bodies, and are available in IPAC website for consultation:

- DRC001 - General Regulation for Accreditation
- DRC002 - Regulation on the Accreditation Symbols
- DRC003 - Regulation for Appeals
- DRC004 - Regulation for Accreditation Fees

In order to safeguard the principle of non-competition between IPAC and CABS, these cannot offer nor provide conformity assessment services against normative documents which IPAC uses to provide accreditation services.

6.1 Measurement Traceability Policy

IPAC has a policy to require the traceability of measurements performed by its accredited entities to internationally recognized measurement standards, integrated in the International System of units (SI), whenever applicable and when those measurements significantly affect the conformity assessment results or when traceability is a requirement contained in the documents that prescribe or describe the conformity assessment process.

IPAC adopts for all accreditation domains the traceability requirements given by EA, ILAC and IAF, that are described in IPAC Application Guide to Laboratory Accreditation (OGC001).

7 Access to Accreditation

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

The national accreditation system is available to all entities, regardless of its dimension, activity or possible association with other groups or institutions, of having a private or public nature, with or without a non-profit aim, as long as they fulfil the correspondent accreditation criteria.

However, the IPAC reserves the right to reject applications from any Entity whose owners or representatives have been known to previously have committed acts that harm the name and/or image of IPAC and/or the functioning and the credibility of the national accreditation system, namely through:

- abusive use of accreditation symbols, of reference to the Accredited Body Statute and/or to the IPAC logos;
- fraudulent actions or injurious or harmful statements.

This refusal will be effective for the period corresponding to one accreditation cycle per act. If IPAC decides to accept these applications, it may establish particular conditions, such as additional evaluation mechanisms or more frequent or unannounced assessments.
In the event of a past breach of financial obligations by an Entity, IPAC will refuse new applications from this Entity for as long as the period of unfulfillment continues, without prejudice to legal or judicial actions. This refusal shall cover new entities to which the missing commitments can be attributed, in particular in the case of request for transfer of accreditation or joint ownership with the Entity under unfulfillment.

IPAC will also refuse to provide accreditation services for compliance with legally applicable sanctions, as well as in cases involving travel to countries or territories for which there are travel restrictions issued by the competent authorities - if applicable and convenient, geographic restrictions may be established to the accreditation scope.

IPAC, as the national accreditation body of Portugal, performs its activity preferentially in the Portuguese territory. However, it can carry out accreditation of entities established in foreign countries, under the conditions set out in the Regulation (EC) 765/2008. For the cases where it is not legally prevented from acting, IPAC has a policy to not offer accreditation services in a competitive manner with the local accreditation body (if existing), articulating with him the best way to operate, taking into account the eventual provisions laid down by EA, ILAC and IAF.

IPAC’s policy is to only provide accreditation services to entities legally constituted, i.e., with juridical personality legally demonstrable.

In those cases where the accredited or applicant activity is performed only by an identified and delimited part (designated as a technical unit) of a larger legal body where it is inserted, it must be demonstrated to IPAC that this legal body fulfils the identity, impartiality, integrity and independence requirements as applicable to the corresponding accreditation scheme.

8 Accreditation Process

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

In general, the accreditation process comprises an application phase, followed by an evaluation phase and a decision phase. After the accreditation is granted, the process continues with the accreditation maintenance phase, which includes follow-up and renewal actions. The accreditation cycle is considered the period of time during which the whole accredited scope is sampled in a representative manner - thus, the initial assessment corresponds to its own and separate cycle, and the first accreditation cycle begins after the granting decision and ending with the renewal decision; the 2nd cycle begins after this renewal decision and ends with the next renewal decision; and so on.

Any Entity already holding a particular accreditation can request the amendment (e.g. extension, suspension or withdrawal) of its scope of accreditation.

It should be noted that the complimentary Accreditation Procedures mentioned in Table 1 contain particularizations and specializations in relation to the provisions of this document, the former prevailing.

Throughout the accreditation process, the Portuguese language is used and should be adopted in the documentation and as a language of communication, unless specifically agreed otherwise.

The accreditation process involves payment of the respective costs, which are described in document DRC004 - Price Regulation, available on the IPAC website.

In the description of the accreditation process made below, the Entity shall be designated either the technical unit applying for accreditation or the accredited technical unit, as applicable.

The deadlines expressed in days indicated in this document are counted in working days, unless otherwise stated or deriving from a legal provision. Deadlines expressed in weeks, months or years refer to days in the calendar, counted up to the corresponding day of the week / month / year concerned.

Communications with the Entity will be made by electronic means (electronic mail or intranet), unless the Entity objects with reason or there is a failure of the electronic means, without prejudice to the legal provisions. Unless otherwise stated by IPAC, electronic communications addressed to IPAC shall be addressed to the mailbox accredita@ipac.pt - electronic communications regarding financial and administrative matters should be addressed to geral@ipac.pt. Nevertheless, the management of the accreditation process (and its interactions and communications) can be done through a web portal designated by IPAC.

8.1 Application

IPAC will give all the necessary clarifications so that entities can properly present their application, although, IPAC shall not give any specific advice on how the accreditation criteria can be fulfilled, in order to not provide consultancy.

The application documents to be filled in and sent to IPAC to formally apply for accreditation are available on IPAC’s website and described in the complementary Accreditation Procedures.
The application documents shall be preferably sent by electronic means and be officially validated by a duly authorized representative of the Entity, with the authority to legally commit the entity into legal contractual relationships.

It is established that by sending an application for accreditation, the Entity accepts this Regulation, as well as the documents it refers and the eventual future changes that may be introduced and communicated.

8.1.1 Registration of the application

For an application to accreditation be registered as such, IPAC must properly receive the application forms, the demonstration of juridical personality, the documentation demonstrating the organization of the management system to comply with the accreditation criteria (for example, the Quality Manual) and the means of payment for the application fee (or an objective and documented evidence of payment). Any sending of documents requesting accreditation that does not include all the documentation referred to above will be considered as a mere expression of interest and will not lead to registration as an application or be given sequence by IPAC as an application.

Upon receipt of the documentation above stated, IPAC will make a review to verify whether the necessary and sufficient conditions are met for establishing a contractual relationship between IPAC and the applicant, including:

- If IPAC has the technical resources to assess the requested accreditation scope;
- If the requested accreditation scope is clearly described and corresponds to an activity that can be accredited.

If the application doesn’t fall into an accreditation scheme already made available, IPAC may need some time for its development, and the Entity will be informed about the expected steps and deadlines for the process, before IPAC registering the application. However, IPAC may decide not to proceed with the development of a new accreditation scheme, if that is advised by interested parties, if it doesn’t fit into its accreditation policy or if it contradicts the provisions of international Multilateral Recognition Agreements or applicable legislation.

The final step of the registration process of an application is the assignment of a registration code with the format ‘Xnnn’ (where ‘X’ is a code identifying the accreditation scheme and ‘nnn’ is a sequential number, as detailed in DRC002, table 1), referred to by IPAC as a ‘NIP’ (Process Identification Number in Portuguese) which should always be referenced in all communications made between the Entity and IPAC. In case of an application for extension of accreditation, the Entity is already accredited and already possesses its NIP, so it is not necessary to assign it.

Within 20 working days after sending the necessary information to register the application, IPAC will notify in writing the respective sequence, communicating the assigned NIP and the contact person (designated as File Manager) to manage the corresponding accreditation process, if the application has been accepted - in case of refusal of the application and / or the need to develop the accreditation scheme, IPAC will also notify in writing to the Entity within the said deadline.

Any registration made shall be valid up to 12 months to conduct the corresponding initial assessment (see section 8.2). If the validity of the registration ends, a new application must be submitted.

8.1.2 Preliminary Review

For an application to be considered complete and be given sequence, it is necessary that all the elements indicated on the IPAC application forms or that are requested by IPAC must be received. The preliminary analysis is intended to confirm that all the elements required in the application documentation have been received, as well as to identify any situations that require special attention or clarification during subsequent phases, as well as a preliminary risk analysis regarding the inappropriate provision of accreditation services by IPAC.

Thus, within 20 working days after registration, IPAC will request in writing any documentation or missing information, as well as any clarifications or reformulations that may be necessary to give sequence to the process; if the application is in conditions to proceed for the evaluation, the evaluation team will be appointed (see section 8.2.1).

If it is necessary to reformulate the application scope, this can be done once without incurring in additional costs of a new application whilst the application phase goes on (section 8.1). After the assessment team has been designated and accepted (section 8.2.1) and up to 7 working days before the start of the assessment, IPAC may accept a reformulation, subject to the variation in costs inherent to the corresponding adaptations of the planning and/or the assessment team, without prejudice to reimbursement and compensation for costs already incurred. Any eventual reformulation of the application with regard to changing the legal entity will be treated in the same way as a transfer (see section 8.6), where applicable.

If the application refers to an Entity whose headquarters or critical facilities (meaning those facilities under the Entity’s control, assignment or property where key activities are carried out or have a direct impact on the result of the conformity assessment activity) are located outside the Portuguese Republic, it is understood that the applicant authorizes IPAC to contact the accreditation body of that country or countries in order to
confirm the justifications presented for applying for accreditation by IPAC and to agree on appropriate forms of cooperation to proceed with the application. If there is no local accreditation body, IPAC will liaise with local authorities, where relevant. IPAC will inform of the results of the actions taken and confirm the possibility and eventual conditions to proceed with the application.

8.1.3 Application termination

IPAC may terminate or close an application upon written notice to the Entity if:

- past 12 months after the registration of the application, the Entity did not make itself available to be assessed or has not sent on time the required application documentation;
- the application does not fall within a scope that may or should be subject to accreditation by IPAC;
- the Entity doesn’t answer to IPAC’s requests within the periods defined in this document or in a related document, or for more than three months;
- the Entity evidences a fraudulent behaviour, or intentionally provides false information or conceals information from IPAC.

The application can also be closed upon request from the Entity.

8.2 Assessment

8.2.1 Assessment team nomination

The management of assessors and assessment programs by IPAC is based on the relevant international standards. Thus, the assessment team is generally constituted by a team leader and by one or more technical assessors and/or experts. The team leader or another assessor nominated by IPAC will ensure that the assessment is performed according to IPAC rules and procedures, as well as co-ordinate the contacts between the assessment team and the Entity.

Assessor’s selection by IPAC takes into account that each assessment team will have to possess the necessary technical competence for the assessment scope and its objectives, as well as ensuring its impartiality. IPAC promotes the periodical rotation of assessment teams, whenever possible, in order to refresh the assessment focus.

Assessment teams may also include observers without an active participation in the assessment, for example for IPAC’s assessor monitoring, or to demonstrate IPAC’s assessment methodologies to third parties. In regulatory accreditation schemes, representatives from the regulatory bodies can be included in the assessment teams, with observer status.

In exceptional cases, IPAC may subcontract a given assessment (or part of it) to another accreditation body(ies) that is(are) signatory(s) to the relevant mutual recognition agreements for the subcontracted scope, through the prior knowledge and consent of the Entity. IPAC assumes responsibility for the subcontracted assessment task and acts as an interlocutor whenever necessary.

For initial assessments (and extension, as applicable), when an application is accepted, IPAC informs in writing the Entity about the composition of the assessment team selected. For maintaining accreditation, such information is sent together with the regular assessment planning made by IPAC and confirmed before each assessment, together with the corresponding date(s).

The Entity can express its disagreement relatively to one (or more) persons appointed for the assessment team, detailing in writing to IPAC the corresponding conflict of interest within 5 working days after receiving the written notice about the assessment team. If no objections from the Entity are received during this period, IPAC assumes that the Entity has accepted the assessment team proposed and proceeds to the next step of the process, the documental review.

In case that the Entity’s objection is accepted, and no other national assessor/expert(s) is available to replace the objected assessor(s), IPAC may as a last resource include a foreign assessor/expert (s). If IPAC cannot find assessors who do not raise objections from the Entity, the corresponding application scope will have to be terminated, or the concerned accredited scope will have to be suspended or cancelled, as applicable.

8.2.2 Documental Review

After the assessment team is accepted, it shall perform a documental review of the documentation sent by the Entity, with the purpose to evaluate if the necessary conditions (from a documental point of view) exist to proceed to the following steps in the assessment. If an Entity does not accept to send relevant documents to IPAC, a preliminary visit will be made (for an applicant Entity) or the duration of the assessment will be extended (for accredited entities). Although it may vary depending on the complexity and quantity of documentation to be examined, the result of the documental review in the case of the granting and extension of accreditation is normally notified up to 20 working days after all required documents have been delivered.

In the granting and extension phase, the result of the preliminary analysis by IPAC or documental review by the assessment team may advise to make a preliminary visit in order to prepare and plan the corresponding on-site assessment, and/or to divide it into phases, which will be discussed and agreed with the Entity.
When the result of the documental review or preliminary visit concludes that the Entity does not significantly or seriously comply with the applicable accreditation criteria, the Entity will be informed of the corresponding findings in writing, having then to perform the necessary corrections and clarifications that IPAC deems necessary, before proceeding with the assessment process.

### 8.2.3 Assessment Programming

The program for the initial assessment (or extension) will aim to cover in a representative way the application scope and all the critical locations and key staff, balancing the risks to be considered and the objectives to achieve. In the case of accreditations outside the Portuguese territory, IPAC applies the cross-frontier dispositions from EA, IAF and ILAC that are applicable.

After a favourable documental review, IPAC establishes the assessment program, including the actions and period (month) planned to occur, and the assessment team should agree with the Entity the concrete assessment date(s), following IPAC’s instructions. IPAC will then confirm in writing to the Entity, the assessment programme.

Eventual requests for changing the date(s) scheduled for an assessment shall be duly justified and presented by the Entity to IPAC within at least one month before the start of the planned month for the beginning of the assessment. Whenever the change requests do not fulfil the anticipation period stated before, the costs related to the time spent on the assessment preparation or hotel or transports and stay reservations may be invoiced to the Entity.

In maintenance phase, the programme is communicated with the closing of the previous assessment and/or upon the periodical planning. Since accredited entities have to continuously and permanently be able to demonstrate the fulfilment of the accreditation criteria, IPAC considers that a request to change the assessment date should not exceed by more than one month the IPAC programme, unless it configures a suspension request.

If an Entity has or requests accreditation for schemes within the same accreditation domain (or referring to the same accreditation criteria), which are under the same management system of the Entity, and that allow a simultaneous and effective assessment, IPAC may conduct a combined assessment, with the agreement of the Entity.

Whenever it is an assessment that is to be made with prior notice to the Entity, the Entity will be informed of its assessment plan with a minimum of 5 working days in advance of its beginning, containing the subjects to be addressed, the responsible persons to contact, and if relevant the activities to be witnessed and the documents to be considered - if necessary due to the type of activity to be witnessed or for its preparation, the advance notice will be increased to at least 10 working days. The plan is a forecast of the activities to be carried on, and as such can be modified by the assessment team depending on the progress of the assessment. If the Entity knows of facts or information that may significantly alter the assessment plan communicated, it should alert IPAC and the assessment team as soon as possible.

It is described below the standard assessment process, although the complementary Accreditation Procedures need to be consulted for other types of assessment.

### 8.2.4 Assessment Methodology

The assessment consists in a systematic and detailed examination of the activities included in the accreditation scope and has the purpose to assess the fulfilment of the accreditation criteria.

As a principle, initial (granting) and maintenance assessments are carried out in person (face-to-face), although in specific circumstances they may be carried out remotely (in whole or in part), using information technologies (for example, via teleconference, access or remote viewing of equipment, files or electronic sharing), taking into account a risk analysis validated for the corresponding option, guaranteeing its effectiveness, efficiency, integrity, security and confidentiality, as well as a prior agreement with the Entity - it is not allowed the recording of remote assessments, unless upon prior written agreement. It is considered whenever it is necessary to witness the practical performance of conformity assessment activities, the use of a remote assessment hardly provides the same effectiveness and efficiency as a face-to-face assessment, so the latter is preferred and generally used to carry out these witnessing. It should also be noted that carrying out assessments remotely may be prohibited, conditioned or imposed by legal, regulatory or scheme owner provisions.

In each accreditation scheme, other assessment/evaluation actions can be performed, as described in the complementary Accreditation Procedures.

Under the accreditation process of an Entity whose head office or critical locations are situated outside the Portuguese Republic, IPAC may subcontract the assessment (in total or partially) to the local accreditation body (if it is a signatory to the relevant MLA), as well as to perform joint assessments, or have local observers. In the case of subcontracting the assessment, IPAC will inform the Entity on the sequence and procedures agreed for the assessment.
The content, scope, duration and terms of each assessment are established by IPAC following a risk analysis considering:

- The dimension, diversity and criticality of the scope of accreditation or application;
- The type, complexity, volume and experience of the Entity in carrying out the activities in question;
- The geographical dispersion of operations and activities, as well as the existence and distribution of them by several critical facilities of the Entity, if applicable;
- The type, complexity and volume of subcontracted activities by the Entity, if applicable, as well as the subcontracting methodology employed;
- The requirements from applicable regulatory or sectoral schemes;
- The result of previous assessments made by IPAC or another accreditation body, if applicable;
- The relevant information on the performance of the Entity, if applicable;
- The relevant changes to the key staff or procedures of the Entity, if applicable.

The performance of an assessment can be distributed over several phases and/or visits, if necessary or convenient.

Eventual requests for change of the assessment scope must be delivered to IPAC with at least one month before the planned assessment date, and its acceptance can originate the redesigning of the assessment team composition and/or the assessment duration.

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

- refuse it, if the preparation status, programming or qualification of the assessment team will be significantly affected;
- charge the costs resulting from the preparation, travels and stay already made by persons nominated for the assessment team that will not be used because of the requested changes.

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

During the assessment phase, situations may be identified that are not in compliance with the accreditation criteria, that thus considered as nonconformities (NCs), which IPAC classifies in two categories, as shown below in Table 2:

<table>
<thead>
<tr>
<th>Type of NC</th>
<th>Description</th>
<th>Closing</th>
<th>Concepts</th>
</tr>
</thead>
<tbody>
<tr>
<td>Major NC Identified by a capital letter 'M'</td>
<td>Absence or systematic failure of: - the implementation of accreditation requirement (s), with significant implications for the reliability of the results of the conformity assessment activity (incorrect practice), or - in the independence or impartiality applicable to their operation, or - compliance with obligations to IPAC, as expressed or referenced in this document.</td>
<td>It implies: - to carry out the cause analysis (1); - to evidence the correction (2) and / or the implementation of the corrective action (3).</td>
<td>(1) Cause analysis: Investigation of the underlying motives or causes of nonconformities and consequent determination of the extent of the failure. (2) Correction: Action to eliminate a detected nonconformity, and therefore implies to correct the fault, considering and covering the extent determined in the analysis of causes; in cases where correction is not possible, a corrective action should be taken. (3) Corrective action: Action to eliminate the cause of a detected nonconformity, in order to prevent the same nonconformity or the same cause from occurring again; it should consider and cover the extent determined in the cause analysis.</td>
</tr>
<tr>
<td>Minor NC Identified by a capital letter 'N'</td>
<td>Isolated failure of an accreditation requirement that does not significantly jeopardize the reliability of the results of the conformity assessment activity or the confidence in the independence or impartiality of its operation. It is usually a documentary failure (e.g., correct practice but not documented), or an isolated and non-serious procedural failure (incorrect practice but without significant implications)</td>
<td>It implies: - to carry out the cause analysis (1); - to evidence the correction (2) and / or, in case of recurrence of past or related situations, to evidence the implementation of corrective action (3).</td>
<td></td>
</tr>
</tbody>
</table>
Whenever a NC has serious and direct implications for the results of the conformity assessment, making them incorrect or unreliable, the Entity shall immediately refrain from issuing accredited results that are affected by that NC until it has implemented the respective correction and/or corrective action in order to ensure the reliability of the results to be issued.

When such NC is encountered and confirmed by IPAC in the validation of the corresponding assessment report, IPAC can immediately initiate a suspension process (see section 9.1) of the accreditation scope that is affected by the NC, if the Entity has not taken the initiative to request voluntary suspension (see section 8.7).

In order for IPAC to take a favourable decision on an accreditation process, the Entity must act on the NCs in order to satisfactorily close them within the deadlines indicated in Table 3, counted from the date of delivery of the corresponding (final) assessment report, even when the assessment involves separate visits in time, except if they are distinct phases (as laid down in a complementary Accreditation procedure), where a report is delivered at the end of each phase. The Entity must thus detail in a corrections and corrective actions plan (PAC) how it has acted or will act to close the NC.

<table>
<thead>
<tr>
<th>Phase</th>
<th>Type of NC/Action</th>
<th>Deadlines after the delivery of the assessment report</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial assessment or Extension</td>
<td>Sending of PAC</td>
<td>1 month for sending</td>
</tr>
<tr>
<td></td>
<td>Major NC (M)</td>
<td>6 months to close</td>
</tr>
<tr>
<td></td>
<td>Minor NC (N)</td>
<td></td>
</tr>
<tr>
<td>Surveillance, Reassessment</td>
<td>Sending of PAC</td>
<td>1 month for sending</td>
</tr>
<tr>
<td></td>
<td>Major NC (M)</td>
<td>1 month to demonstrate the correction and/or have been accepted the corrective action, as applicable</td>
</tr>
<tr>
<td></td>
<td>Minor NC (N)</td>
<td>3 months to close</td>
</tr>
</tbody>
</table>

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

Besides the non-compliance with the accreditation criteria, other findings can be registered, designated as opportunities for improvement (OM), with the following objectives:
- Call the attention to risky situations that in the future can evolve into NCs;
- Identify situations that may bring added value to the Entity by making more transparent and clear the fulfilment of the accreditation requirements.

It is up to each Entity to react or not to OM, since it is not mandatory to include them in the reply to assessment reports, except when specifically asked and justified by IPAC.

### 8.2.5 Performing the assessment

The assessment starts with an opening meeting between the assessment team and representatives of the Entity, to introduce the participants, and describe the objectives, assessment methods and criteria, and confirm or adjust the planning of the work (Assessment Plan). IPAC does not accepted requests for changing the assessment scope presented at the beginning or during the assessment.

During the assessment performance, the assessment team members will assess the technical competence of the Entity against the applicable accreditation criteria, based on a representative and significant sampling of all the activities under the scope of the assessment.

In the initial assessment, all the critical locations are assessed, and interviewed all the key staff involved in the activities to be accredited and it must be demonstrated that the management system is implemented through an internal audit covering all the applicable requirements and a management review.

It is up to the Entity to demonstrate to the assessment team its competence and experience for the performance of the activities included in the assessment scope. IPAC considers as included in the assessment scope all the activities that are part of the accredited or applicant scope, except where otherwise indicated by IPAC.

Upon request from the Entity, external persons (namely consultants) can be present during the assessment, as long as they keep a passive attitude, without intervening, answering or influencing the Entity’s performance. If that doesn’t happen, IPAC can interrupt the assessment and request the external persons to leave before restarting the assessment. In case the Entity does not create conditions or provides the necessary cooperation to restart the assessment, it will be ended or cancelled, giving IPAC the possibility to charge its
partial accomplishment and apply sanctions in the case of accredited entities or terminate an application for applicant entities.

The assessment finishes with a closing meeting where the Entity’s top management should be represented and during which the assessment team will communicate the results and conclusions of the assessment performed. In this meeting the Entity’s representatives should clarify eventual doubts about the conclusions presented by the assessment team, namely eventual nonconformities - takin into account the deadlines for the closure of the major NCs (see table above), it is advisable to clarify their content so that the Entity can prepare a PAC that can be accepted and allow closing of the major NCs within the deadlines.

The assessment team will write an assessment report, detailing aspects of competence and compliance, as well as listing eventual nonconformities, and present it to the Entity at the end of the assessment, and afterwards will send the report to IPAC at once.

This report contains information whose validity for the purposes of decision-making is considered to be 12 months, after which the information may need to be updated and revalidated. The report will be subject to validation by IPAC and will usually be notified of any change to it within 5 working days after its delivery to the Entity.

IPAC acknowledges the right of the Entity to argue against the existence of nonconformities contained in the assessment report, and to justify its opinion on the alleged facts that support each nonconformity, and to communicate it in writing to IPAC at within 3 working days after delivery of the corresponding evaluation report. It is the responsibility of IPAC to maintain or change the existence of nonconformities and require its closure.

8.2.6 Assessment Sequence

After being informed of the existence of nonconformities, the Entity must immediately start its analysis and implement corrections and corrective actions appropriate to close them. In sequence, the Entity must prepare a corrective action plan and corrective actions (PAC) describing how it proposes to proceed to close each and the nonconformities, with their deadlines for implementation (see Tables 2 and 3). The PAC must be sent by the Entity to IPAC within a maximum of 1 month from the date of delivery of the corresponding assessment report. Although it may be adjusted for the quantity and complexity of nonconformities to be closed, IPAC estimates a period of 1 month after receiving the PAC to notify if it has been accepted or needs corrections and / or clarification, as well as to identify minor NCs whose evidence must be sent to IPAC for closure - in the case of major NCs, it is always mandatory to send this evidence within the timeframes set forth in Table 3. If no non-conformities have resulted from the assessment, it is not necessary to send the PAC, unless otherwise required by IPAC.

The Entity must send to IPAC the evidences of effective implementation of the PAC within the deadlines prescribed for each category of nonconformity (see Table 3). The required evidences to confirm the resolution of nonconformities may be documental or practical, depending upon the nature of the nonconformities under appreciation. After the first accreditation cycle, IPAC may decide not to ask for evidence of resolution of minor NCs (all or some), depending on the nature of those and the Entity history in the proper and timely resolution of nonconformities - in this case, the evidence not sent will be reviewed in the next assessment.

If there are doubts regarding the actions proposed in the PAC or the evidence of implementation of corrective actions, the Entity may be requested to hold a remote session or clarification meeting by IPAC (with the assessment team or some of its elements, if necessary) to make faster and more efficient the closing of the evaluation.

In case that the evidence is insufficient or incomplete, or need an on-site checking, a follow-up assessment will 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, it is established that only one follow-up assessment can be performed for each application (initial or extension) - if after this follow-up a positive decision is not possible, the application will be closed and the Entity must reformulate and present a new application for granting or extension, as applicable. The follow-up assessment must be done within 12 months after the initial assessment or the corresponding extension assessment.

If the PAC or the evidence sent are not appropriate, IPAC will ask for a reformulation, without which a negative decision will be taken.

IPAC can request the opinion of other assessors or experts in case of disagreement between the assessment team and the assessed Entity in relation to the content and resolution of nonconformities, as well as of regulatory bodies or proprietary scheme owners.

If the Entity requests a significant reduction of the assessed scope after the assessment has concluded, IPAC will evaluate it to confirm if the dimension of the requested reduction is correct, and if the sampling made in the assessment still continues to be representative - if that doesn’t happen, it might be necessary to carry out an additional assessment.
The PAC must be implemented as it has been accepted by IPAC, the Entity being able to increase or expand its extension, adding new actions to the PAC agreed with IPAC, but without reducing it, without which it is considered that there has been a breach of trust, resulting in the application of a sanction. Nevertheless, after the first accreditation cycle and in the case of minor NCs, the Entity may very exceptionally change the accepted PAC to improve or expand it at its own risk and responsibility, provided that it can afterwards demonstrate that to IPAC - if this is not demonstrated to IPAC, this option of introducing changes to the accepted PAC will be forbidden for the period corresponding to an accreditation cycle, as well as it will be required the implementation of corrective actions. In justified cases, in particular upon misleading, deceptive or abusive behaviour, IPAC may initiate a sanction as provided for in section 9. Whenever the Entity chooses this option to improve the accepted PAC, it must send to IPAC the reformulated PAC as part of the documentation for the preparation of the next assessment and IPAC may increase its duration, if necessary.

8.3 Decision

8.3.1 Decision-making

After the assessment, IPAC proceeds to the decision-making, performed by persons independent from the assessment, and is based, namely, in the study of the assessment reports and other relevant information, the assessment team recommendation and the corrective action’s plan and corresponding evidences, as applicable.

Decisions are taken by IPAC within a period of 1 month after gathering the necessary information, always being substantiated and transmitted in writing to the Entity. Whenever applicable, with communication of the decision, IPAC will inform the Entity of the planned schedule for the next stage of the assessment cycle.

In principle, the decisions are taken covering all the assessed scope. However, upon justified request by the Entity, namely because of an extension application, and if it is possible to restrict the conclusions of the assessment to a part of the scope, and therefore no generic failures are to be solved, IPAC can anticipate a decision on a part of the scope, once by assessment (and by technical unit in case of combined assessments). On reverse, IPAC may decide on closing the maintenance assessment as soon as possible and defer the decision on an extension or transition to a later time, without prejudice to the period of validity of the information contained in the report (according to section 8.2.5).

The accreditation decision is valid while the Entity demonstrates to fulfil the accreditations criteria and obligations.

For an initial assessment or extension, a negative decision in a follow-up assessment will lead to the closing of the corresponding application, and the Entity may appeal, as described in section 10.2. In any case of an unfavourable decision, the Entity has 10 working days to present allegations, acts or evidence with the intention to revert the decision.

8.3.2 Accreditation Symbols and Certificate

If the accreditation decision is favourable, IPAC will issue an Accreditation Certificate and the corresponding Technical Annex(es), within 10 working days, that remain valid as long as the Entity demonstrates to fulfil this Regulation and the dispositions referred to in it - the validity can be verified at any time in the Directory of Accredited Bodies, in the IPAC website.

The Accreditation Certificate identifies the name of the legal entity, the date of granting the accreditation, the accreditation standard(s), and the provisions regarding its validity. If the accredited activity is carried out only by a part (technical unit - see section 7) of the legal entity, this part will also be identified in the Accreditation Certificate and Technical Annex. The Technical Annex contains a description of the accreditation scope in accordance with the provisions of the corresponding complementary Accreditation procedure, as well as the listing of all critical facilities from which the accredited Entity may perform or offer accredited activities. If the scope of accreditation includes a regulatory or proprietary conformity assessment scheme with additional criteria and/or accreditation requirements, IPAC will identify the corresponding legal document or normative document in the Technical Annex, unless otherwise provided by law, contractual or legal provisions. Each Accreditation Certificate and Technical Annex are identified by their respective NIP (see section 8.1.1), that is unequivocal and correspond to a given technical unit.

The Accreditation Certificate(s) and/or Technical Annex(es) can be issued in foreign languages, although the Portuguese version will prevail, except if specifically contracted otherwise.

An Accreditation Certificate and/or a Technical Annex will be issued whenever some of the information it contains is modified, and the corresponding costs are indicated in the Price Regulation (DRC004). The accreditation granted is valid only for the legal entity and technical unit mentioned in the Accreditation Certificate and Technical Annex, and the accredited Entity cannot transmit, delegate or otherwise pass or extend it to other bodies or include under its accreditation other units or legal entities.

The documents quoted above are issued in digital format and validated by affixing a qualified electronic signature, having probative legal value, pursuant to Decree-Law nr. 12/2021 of February 9th.
Likewise, when the accreditation decision is favourable, the Entity becomes authorized to use the applicable Accreditation Symbols and to advertise its Accredited Body Statute in accordance with the respective Regulation (DRC002), from that date on. IPAC makes available the corresponding graphical media, which are the only ones that can be used, unless explicitly authorized by IPAC.

8.4 Accreditation maintenance

8.4.1 Surveillance and Reassessment

After granting accreditation, IPAC will program the realization of periodic assessments to the Entity, to confirm the continuing fulfilment of accreditation criteria. The description of the regular surveillance and reassessment methodology, as well as accreditation cycles is specified in the complementary Accreditation Procedures.

The interval between the initial assessment and the first surveillance is 12 months and can be enlarged until 18 months if a follow-up assessment has been performed.

All the accredited scope and critical sites covered under accreditation have to be assessed during each accreditation cycle, so IPAC programs the surveillance and reassessment in accordance, taking into account the risk involved.

The Entity must send to IPAC all the requested documentation for preparing the assessments, namely the described in the complementary Accreditation Procedures, in order to be received by IPAC at least 1 month before the planned month for the assessment.

As agreed with the Entity, or foreseen in a sectoral accreditation scheme, IPAC can perform assessments without previous announcement or with short-term notice, 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 assessment and decision-making processes are equivalent to those described for the initial assessment (as applicable).

The Accredited Body Statute implies that the Entity must always be able to demonstrate the fulfilment of the applicable accreditation criteria. Therefore, IPAC can at any moment request the Entity to supply information, documents, records or evidence to show that the accredited activities are being correctly and competently performed, or the fulfilment of requirements, as well as information on the changes deemed to be relevant.

8.4.2 Extraordinary assessments and visits

Extraordinary assessments can be carried out namely in the following cases:
- If it is necessary to confirm that conditions are met for lifting a suspension or closing of nonconformities after an assessment to an accredited entity or for the acceptance of a transfer of accreditation;
- If IPAC receives credible information, claims or complaints about transgressions of accreditation criteria and obligations. In this case, the extraordinary assessment can be made without prior notice to the Entity or with a very short notice.

The costs arising from carrying out extraordinary assessments will be charged to the Entity, unless its performance was originated by an information, claim or complaint found to be unjustified.

Visits may also be carried out, to assess specific and focused changes in the Entity, namely in its structure, key personnel, conformity assessment procedures, equipment and/or installations, which do not result from the implementation of corrective actions of IPAC assessments, and which may significantly affect compliance with the accreditation criteria. The costs of visits are borne by the Entity.

8.5 Changes to the Accreditation Scope

8.5.1 Extension

The Entity may require changes to the accreditation scope, namely by presenting applications for extension (see below) and withdrawals (see sections 8.8).

IPAC considers as an extension of scope the enlargement or change of the accredited scope within the same accreditation scheme, as detailed in the complimentary Accreditation Procedures.

The request for extension of the accreditation scope must be made using the application forms applicable to each accreditation domain that are available in IPAC website and be accompanied by the corresponding evidence of payment of the applicable fees. Depending on the dimension and nature of the extension application, IPAC will determine the type of evaluations actions needed to be performed and will inform in written the Entity.
The methodology for processing an extension will normally be similar to the processing of an initial application (see section 8.1 and following), without prejudice to the dispositions in the complimentary Accreditation Procedures.

The assessment for the extension of the accreditation scope can be carried out together with the regular assessment for surveillance/renewal or through a separate assessment specific for the scope extension, as agreed with the Entity.

For an application for scope extension to be assessed simultaneously with the regular surveillance or renewal assessment, IPAC recommends that the application for scope extension arrives to IPAC with an anticipation of 3 months relatively to the month programmed for performing the regular surveillance/renewal assessment. However, if all the documentation is not received with an anticipation of at least one month before the starting date of the regular assessment, IPAC may decide not to do a combined assessment.

To combine an assessment for extension of the scope of accreditation with the regular assessment, IPAC will evaluate the need to modify the appointed assessment team and the nature or duration of the planned assessment, taking into account the dimension and specificity of the technical areas under extension.

8.5.2 Other changes

Other changes may occur, namely the legal name of the Entity, or its juridical form or its critical locations, and the Entity must timely inform IPAC (see section 11.1.4) so that it can confirm the need to update the Accreditation Certificate and/or the Technical Annex, as well as to perform other actions that may be deemed to be necessary.

8.6 Transfer of accreditation

The transfer of accreditation consists in passing the Accredited Body Statute from one accredited entity to another entity, namely after merging with or acquisition by another entity, or following splitting of an entity, assuming that it exists continuity in the operation and competence - accordingly, it is kept the current accreditation cycle and issued a new Accreditation Certificate and Technical Annex for the new Entity and simultaneously withdrawn those from the previous Entity. If continuity cannot be demonstrated, a temporary suspension may be needed until fulfilment of the accreditation requirements and criteria, or simply cancel the accreditation and present a new application later on.

There may be a total or partial transfer of the accreditation scope for the new Entity.

The new Entity receiving the partial or total transfer of the accreditation must request the transfer in writing, justifying the reasons for it and sending to IPAC the justification for the transfer request, the application documentation corresponding to the accreditation scheme concerned, containing a clear indication of the scope of accreditation to be transferred, in addition to all documents demonstrating compliance with the continuity conditions set out below. The Entity transferring the accreditation must accept the request for transfer and the corresponding withdrawal of the scope to be transferred.

The transfer of rights also implies transfers of obligations, in particular financial obligations, which are transferred to the receiving entity, unless otherwise explicitly agreed with IPAC.

In transfer processes where a period is expected to occur during which the accreditation obligations are not met, the Entities concerned shall agree to request a voluntary suspension of accreditation. If there is a change in the assessment actions previously scheduled, it may be necessary to reprogram it and possibly carry out a new assessment.

To accept a transfer, at least the following continuity conditions must be met as a minimum, by the new Entity receiving the transferred accreditation scope:

- The management system must remain significantly unchanged;
- The relevant technical management and staff must remain unchanged;
- The structure and internal organization of the technical unit performing the accredited activities must remain untouched;
- The conformity assessment methods used in the accredited activities must remain the same;
- Whenever applicable, it must be demonstrated that the impartiality and independence requirements are met;
- Whenever relevant, the equipment and other resources (for example facilities) must remain intact or demonstrated as appropriate.

If it isn't possible to check by documental analysis that the continuity conditions described above are met, IPAC will program the evaluation activities deemed as necessary.

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

IPAC will determine the dates when the old accreditation finishes and the new accreditation starts, upon proposal of the entities that request the transfer. In order that no periods of discontinuity happen, the transfer request and relevant technical documentation must be timely submitted.
The Entity receiving the transferred accreditation will be given the corresponding accreditation documents. When two or more accredited Entities request a merging of their accredited scopes, a similar procedure to the total transfer of accreditation between two entities will be applied.

8.7 Voluntary Suspension

An accredited Entity may request the voluntary suspension of its accreditation, which may cover the whole (total suspension) or only a part of the scope (partial suspension) if it considers (or foresees to be) temporarily inapt to comply with the established accreditation criteria. The request must be made in writing, stating the scope, reason(s), and the period foreseen to be in force, at least 1 working day before the intended start date for suspension. IPAC will confirm in writing to the Entity, within 10 working days after gathering all the necessary information, the acceptance of the voluntary suspension of the accreditation, indicating the effective date and the actions necessary to lift the suspension (when applicable).

The period for voluntary suspension should not exceed 12 months from the effective date of start. During the period of suspension, and for the scope of accreditation covered by it, the Entity is prohibited from using the Accreditation Symbols, to carry out publicity actions and/or issue any document with reference to the Accredited Body Statute or to make available the respective Technical Annex without a warning or a disclaimer as to the scope suspended.

The Entity must notify without delay in writing the clients affected by the suspension and with whom it has previously contracted accredited activities, as well as (if applicable) the entities that, because of the accreditation, have licensed or authorized the exercise of activities corresponding to the suspended scope.

To terminate a suspension, it may be necessary to conduct preliminary activities (for example, documental evidence, extraordinary assessment or actions), wherever applicable. If the suspension precludes the performance of the regular assessment for the maintenance of accreditation, this will be done upon the lifting of the suspension.

The suspension of accreditation will be lifted when it is demonstrated that the reasons that led to the suspension no longer exist and in the meanwhile no changes that affect the fulfilment of the accreditation obligations and criteria have occurred.

The successful lifting of the suspension will be notified in writing to the Entity.

IPAC will initiate the process of withdrawal of the accreditation if, following the actions taken, it is not possible to terminate the suspension before the maximum suspension period, or if it was not possible to perform the necessary actions to lift the suspension, for reasons attributable to the Entity.

8.8 Voluntary Withdrawal

The accredited Entity may request in writing to IPAC the voluntary cancellation or withdrawal of its accreditation, which may involve only a part of the scope (designated by partial withdrawal) or the whole accredited scope (designated by total withdrawal).

The request for voluntary withdrawal must be made in writing, identifying the scope to be withdrawn in the case of being partial, at least 1 working day in advance of its expected date of effectiveness. IPAC will confirm in writing to the Entity, within 10 working days after gathering all the necessary information, the acceptance of the voluntary withdrawal of the accreditation and indicate the effective date of withdrawal and eventual obligations to be complied with.

IPAC may ask additional information and clarifications on the reasons that motivate the request, to determine whether the extent and timing of the withdrawal is appropriate. In justified cases, IPAC can request to perform an extraordinary assessment before the withdrawal, to ascertain whether the accreditation criteria and obligations have been met, as well as require the implementation of corrections to reports and certificates issued.

The validity of the Accreditation Certificate issued and the corresponding Technical Annex(es) shall expire on the date of the total voluntary withdrawal, and the Entity is prohibited from that date on to use or make them available, as well as using the Accreditation Symbols and making any references or associations to the Accredited Body Statute. On the effective date of the partial voluntary withdrawal, the respective Technical Annex(es) will be amended accordingly, being prohibited the exhibition of previous version(s).

The Entity must notify without delay in writing the clients affected by the withdrawal and with whom it has previously contracted accredited activities, as well as (if applicable) those entities that, because of the accreditation, have licensed or authorized the exercise of activities that respect the withdrawn scope.

The withdrawal effects can be reported by IPAC to the date of any acts, omissions or failures that justify the withdrawal, establishing from that date on the subsequent invalidity of all documents issued under accreditation.
9 Sanctions

9.1 Suspension

The suspension consists of a temporary interruption of the Accredited Body Statute, applicable when an accredited Entity no longer complies with the accreditation criteria or the present Regulation and the dispositions herein referred to. The suspension can also be applied due to acts or omissions prejudicial to IPAC’s image and the Accredited Body Statute. For each prejudicial act or omission mentioned before, a suspension penalty of 3 months will be applied to which equal suspension periods will be added in case of re-incidence. Suspension may also be applied to comply with legally applicable sanctions, as well as in cases involving travel to countries or territories for which there are travel restrictions issued by the competent authorities and IPAC cannot resort to remote assessments - if applicable, it may be established geographical restrictions to the accreditation scope.

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

The suspension of accreditation can be applied for a maximum period of 12 months from the date of effective implementation.

Without prejudice to the legal provisions that may be applicable, IPAC will communicate in writing to the Entity the intention of suspending, and the Entity has a period of 10 working days to present allegations, acts or evidence to interrupt or stop the suspension process. After these 10 days period, the suspension becomes effective, except if the Entity presented information or allegations and asked for a review of the decision. In that case, IPAC will analyze the information and evidences submitted and decide if it enforces, changes or cancels the suspension, communicating the decision to the Entity in writing.

During the suspension period and for the suspended scope that it relates, the Entity is forbidden to use the Accreditation Symbols, to advertise or market suspended activities and/or to issue any certificate, report or any other document with reference to the Accredited Body Statute. IPAC may also forbid the participation of the Entity in meetings, committees and/or other IPAC work that involves the presence or consultation to accredited entities.

The Entity must notify without delay in writing the clients affected by the suspension and with whom it has previously contracted accredited activities, as well as (if applicable) entities that, because of the accreditation, have licensed or authorized the exercise of activities falling under the suspended scope.

The suspension of accreditation will be lifted when it is demonstrated that the reasons that led to the suspension no longer exist, and meanwhile there have been no changes that affect the fulfilment of the accreditation obligations and criteria.

To terminate a suspension, it may be necessary to conduct preliminary activities (for example, documental evidence, extraordinary assessment or actions), wherever applicable. If the suspension precludes the performance of the regular assessment for the maintenance of accreditation, this will be done upon the lifting of the suspension.

The successful lifting of the suspension will be notified in writing to the Entity.

If, following the preliminary activities taken, it is not possible to lift the suspension, IPAC will initiate the process for withdrawal of the accreditation, which may also occur if the maximum suspension period is exceeded and it has not been possible to carry out the necessary actions for the lifting, for reasons attributable to the Entity.

9.2 Withdrawal

The withdrawal consists of the termination of contractual relations with the accredited Entity and consequent withdrawal of the Accredited Body Statute and the right to use the Accreditation Symbols.

IPAC may withdraw the accreditation in case of:

- continued or prolonged failure to comply with accreditation criteria and obligations;
- bankruptcy or insolvency of the Entity;
- judicial conviction for acts that affect the reliability and competence for being accredited;
- acts or omissions prejudicial to the image of IPAC and the Accredited Body Statute
- evidence of fraudulent behaviour or intentionally providing false information or concealing relevant information.
The withdrawal may refer only to the part of the scope (partial withdrawal) or encompass the entire accredited scope (total withdrawal).

IPAC will notify the Entity in writing of the intention to withdraw the accreditation, and the Entity has a period of 10 working days from the date of notification to submit allegations, acts or evidence to interrupt or cancel the process. At the end of this period, the withdrawal becomes effective, except if the Entity submits matter or allegations and request the reappraisal of the decision. In this case, IPAC will analyze the matter presented and decide whether or not the withdrawal and the respective terms will be effective, communicating the decision to the Entity in writing.

The validity of the Certificate of Accreditation issued and the corresponding Technical Annex(es) shall expire on the effective date of the total withdrawal, and the Entity is prohibited from that date on to use or make them available, as well as using the Accreditation Symbols and making any references or associations to the Accredited Body Statute. On the effective date of the partial withdrawal, the respective Technical Annex(es) will be amended accordingly, being prohibited the exhibition of previous version(s).

The Entity must notify without delay in writing the clients affected by the withdrawal and with whom it has previously contracted accredited activities, as well as (if applicable) entities that, because of the accreditation, have licensed or authorized the exercise of activities falling under the withdrawn scope.

The effects of the withdrawal can be reported by IPAC at the date of the acts, omissions or defaults that justify the withdrawal, determining from that date the consequent invalidity of all documents issued under the scope of the accreditation.

The withdrawal does not exempt the Entity from complying with possible defaulting obligations, in particular financial ones, related to acts passed until the effective date.

Taking into account the nature of the motivations for a withdrawal, IPAC may establish conditions and/or a minimum interregnum to accept a new application (see section 7).

10 Complaints and Appeals

10.1 Complaints

IPAC considers a complaint as any expression of dissatisfaction towards the activities of IPAC or accredited bodies, with an expectation of reply. Therefore, complaints must identify the complainant and the manner how it can be contacted, and be sent in writing to IPAC, either by postal mail, or by electronic mail. It is recommended the use of the QI031 template available on the IPAC website, which details the complaint handling process. Expressions of dissatisfaction that do not identify the issuer are considered as delations or denunciations, which will only be dealt upon weighing of the credibility of the proof and evidence provided, as well as the risk involved and perceived impacts.

If a complaint concerns an accredited Entity, it must first be directed to the Entity, and only if it is unsatisfactory handled by the Entity, this handling should be communicated to IPAC.

IPAC considers complaints as opportunities for improvement and therefore it will not act in a discriminatory manner against any complainer.

IPAC does not directly handle complaints on certified companies, or on certified products, processes or services, as well as on certified persons, since they all fall under the responsibility of the corresponding certification body, and to whom the complaints must be sent in the first place - only if the certification body does not provide a satisfactory treatment, then the complainant should inform IPAC thereof, enabling it to act as if handling a complaint about that certification body.

10.2 Appeals

IPAC considers as an appeal any request, contrary allegation or plea that it receives from an Entity concerning an adverse accreditation decision taken by IPAC regarding the corresponding Accredited Body Statute, following the methodology described in the Regulation for Appeals (DRC003), available in the IPAC website.

IPAC ensures that it will not act in a discriminatory manner against any Entity that presents an appeal, independently of its outcome.
11 Obligations of the Parties

11.1 Obligations of the Entity

11.1.1 Continuity duty

Every Entity has the duty to fulfil and continuously demonstrate to fulfil the applicable criteria and obligations of accreditation, including the eventual modifications that may be introduced. An Entity with its accreditation suspended still has to fulfil the obligations contained in this Regulation and in the regulations and procedures referenced in it.

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 with clients, customers and third parties.

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

11.1.3 Co-operation duty

The Entity must cooperate for the accreditation process, providing the necessary conditions for performing an assessment in an efficient, impartial and safe manner. The Entity must collaborate in order that:

- It is possible to assess the Entity’s operation against the accreditation criteria;
- It is possible to access all the relevant locations, equipment, information, records and documents;
- It is possible to observe/see/witness all the Entity’s activities under the accreditation or application scope, and to interview all the staff;
- It contracts with its clients the possibility for IPAC assessment teams to observe/see/witness all the Entity’s activities under the accreditation or application scope that are performed on the facilities or sites of the clients;
- The necessary safety instructions and equipment are made available to IPAC’s assessment teams;
- The assessors and IPAC staff shall not be put in a position where their independence and objectivity could be compromised, nor subject to undue pressures;
- It answers to IPAC requests (namely for assessment replies and evidences requests) within the deadlines established in this Regulation, or if omitted, established by IPAC;
- the actions agreed with IPAC for the resolution of non-conformities are implemented in the established or agreed terms and periods;
- IPAC can investigate the grounds for any complaints or denunciations and make possible that they can be resolved;
- It does not act or make public statements that are considered harmful or prejudicial for the national accreditation system or IPAC.

In case of unfulfillment of any of the above situations, IPAC may initiate the application of the sanctions foreseen in this Regulation, or close an application (as applicable), without prejudice to start a legal proceeding.

11.1.4 Reporting changes duty

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

Such changes may include the following:

- Changes in the legal or juridical personality, ownership or designation;
- Changes in the persons or structures performing relevant technical functions (namely responsible for the decision-making or approval of results from accredited activities), except if the substituting persons have already been assessed by IPAC for the performance of those functions;
- Changes in the organizational structure or activities developed by the Entity or by related bodies (whenever applicable by the accreditation criteria) that originate or may originate conflict of interests with the accredited activities;
- Significant changes in critical facilities;
- Significant changes in conformity assessment procedures or methods.

The maximum period for the Entity to notify unexpected changes to IPAC is 10 working days after its occurrence or knowledge. In case the changes are expected or planned by the Entity, then it must notify IPAC as soon as the intention to change is established.
If because of a change it is necessary to perform an extraordinary evaluation or other action, IPAC will notify the Entity within 10 working days of receipt of the corresponding change notification (or of any additional information requested by IPAC).

Whenever the changes that have occurred or will occur compromise the fulfilment of the accreditation criteria or this Regulation, then the Entity should take the initiative to request a voluntary suspension or withdrawal of accreditation.

11.1.5 Financial Obligations

Any Entity is obliged to pay all the costs inherent to the accreditation process provided for in the Price Regulation (DRC004), at the date specified for that purpose. If in order to make the payment it is necessary for the Entity to issue an internal document of reserve, commitment or capitulation of funds (e.g. requisition) prior to the realization of the assessment, it shall do so at the moment in which it sends the documentation for the assessment or when it is confirmed.

In the event that the Entity does not process and pay the amounts due on the invoice due dates, IPAC will initiate the process for suspension of accreditation, or the termination of the application or extension process, as applicable. The principle of payment of debt by order of seniority is assumed, so that the amounts delivered to IPAC will be used for the discharge of debts by that order (unless otherwise agreed by writing with IPAC), thus rendering it impossible to carry on with any request to change the accreditation scope before the discharge of the oldest debt, since the amounts foreseen for the instruction of the request in question must be used in the settlement of the debt.

The eventual application closing, or reduction or withdrawal of accreditation does not dismiss the Entity to fulfil the financial obligations applicable until the enforcement date, IPAC being able to start the juridical or legal actions necessary to be fully reimbursed.

IPAC shall not refund any payments made by the Entity to IPAC concerning acts occurring before the effective date of termination of an application or withdrawal of accreditation, as applicable.

11.1.6 Juridical Obligations

The Entity shall accept that IPAC and its collaborators can never be claimed responsible by the 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 juridical or legal dispute, the Entity shall accept to submit to the juridical 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 Body Statute, in accordance with the Regulation for the Accreditation Symbols (DRC002), available in IPAC website. If the Entity is authorized to use or to make available to its clients, other symbols licensed or authorized through IPAC (see DRC002), it will have to fulfil the corresponding rules of use, as established or communicated by IPAC.

If the accreditation is withdrawn, the Entity is obliged since the enforcement date to cease all use and to collect all the advertising material with reference to the Accredited Body Statute, or using the Accreditation Symbol(s), with priority to those publicly exposed. The Accreditation Certificates and Technical Annexes are property of IPAC, and IPAC can request to receive them back or be destroyed 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 with this General Regulation, the documents herein referred to, and the applicable legislation.

11.2.2 Cooperation Duty

IPAC has the duty to dialogue and to cooperate with its clients and remaining interested parties, in order to know its expectations and be able to timely respond and continuously improve the accreditation service provided. However, IPAC cooperation cannot go beyond the provision of information and clarifications in generic terms and publicly available, 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 Board to oversee IPAC impartiality.

11.2.4 Confidentiality duty

IPAC protects its clients’ confidential data and information obtained through the accreditation process, including those from the assessments, using confidentiality clauses in agreements with IPAC collaborators and external staff (e.g. assessors, experts, members of commissions, regulatory bodies), and controlling the access to confidential information. In what concerns the handling of personal data, this is detailed in its Privacy Policy (DRC004), publicly available in its website.

Under the framework of peer evaluations carried out by EA, IAF and ILAC, IPAC will have to provide access to the information and data of its clients to enable it to demonstrate the proper performance of the national accreditation system, upon prior signing of confidentiality agreements. IPAC may also share information and assessment data with proprietary and regulatory schemes owners, as required and applicable.

IPAC may provide information about its clients to third parties upon prior knowledge and acceptance by the clients. If IPAC is required by law or contractual obligations to provide information about its clients without obtaining prior acceptance, IPAC will notify the concerned clients if there is no legal impediment or if it is not already known to them.

11.2.5 Advertising duty

IPAC publishes and publicizes all accreditations granted, namely through a Directory of Accredited Entities in its electronic site, which lists the general data and contact details for each accredited Entity, as well as the corresponding accreditation scope. IPAC may also use other media and advertising media, campaigns or events, on equal terms and non-discriminatory for the accredited entities.

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

IPAC also publishes all sanctions using the means judged adequate, taking into consideration the proportionality of the implications and response from the Entity, and communicating to the bodies considered relevant, namely regulatory bodies.

11.2.6 Duty of Information and Communication of changes

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

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

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

Whenever any of the accreditation standards is reviewed, IPAC will adopt the new version of these documents, agreeing with the stakeholders a plan and transition period for compliance with the new versions, that respects any international guidelines that may have been established. If, after the corresponding transition period, an accredited Entity does not demonstrate compliance with the requirements that have become applicable, IPAC will withdraw the Entity’s accreditation (wholly or in part, as applicable).

11.2.7 Representation duty

IPAC represents and defends the interests of the national accreditation system, at the national and international level, namely in the European and international arena. IPAC will communicate the results of its intervention and participation in these federative accreditation organizations to its clients through its website or technical committees, meetings or announcement letters.
12 ANNEX - Flowchart of the Accreditation Process

The flowchart below represents IPAC’s operation in general, and it can be modified and adapted for specific cases, respecting always the principles of impartiality, competence and confidentiality and the applicable normative provisions.