REGULATION FOR ACCREDITATION

RENAR Code: **RE 01**

Date of approval: 30.10.2013

Date of application: 04.11.2013

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CHAPTER 1 - ACCREDITATION – DEFINITION, SOCIAL ROLE, PURPOSE

Accreditation is a third-party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks.


Accreditation:
- Gives trust in the technical competence, impartiality and integrity of the bodies performing the conformity assessment;
- Contributes to increasing the competitiveness of products, services and persons within a globalized market;
- Contributes to promoting the free movement of products, services and persons;
- Promotes the protection of life, health and safety of the persons, of environment and safeguarding consumer interests.

Accreditation activity follows the basic principles:
- Transparency and public availability
- Representation of public interest
- Voluntary character (for the regulated area it has a mandatory character)
- Independence towards the possible predomination of any specific interests
- Collaboration with the regulatory authorities
- Impartial treatment of the complaints/appeals
- Harmonization with the European and International rules of accreditation
- Free access to accreditation without discrimination
- Confidentiality assurance
- Application of harmonization standards according to Table 1.

Accreditation is important for the functioning of a market oriented towards quality and offers the advantages to the economical actors, such as:
- Mitigation of risk for products and services;
- Avoiding multiple evaluations;
- Increasing the trust of clients.
CHAPTER 2 - TERMS, DEFINITIONS AND ABBREVIATIONS

2.1 TERMS AND DEFINITIONS

In this document the definitions from the in force versions of SR EN ISO/CEI 17011 SR EN ISO/CEI 17000 are used.

Specific accreditation scheme – set of rules and requirements applicable to national accreditation body and to conformity assessment bodies established with the purpose to attest CABs competence to carry out specific assessment tasks foreseen in the harmonized legislation at communitary level or in the national legislation, as is the case.

Specific accreditation regulation - document prepared by RENAR, part of the specific accreditation scheme – endorsed – which completes or, if the case, details, the requirements of the regulatory document and/or of the reference accreditation standards and which is endorsed, according to the law, by the regulating authority.

Competent authority: body of central public administration, responsible for regulating a field within its competence.

Empowerment: generic term used in this document to refer to the attribute of a competent authority to approve the specific conformity assessment tasks to be carried out by third-party organizations with view to the application of EU and national legislation (designation/approval/recognition/authorization/registration etc.).

Regulated area – field, coordinated by a competent authority, for application of European / national legislation harmonizing the conditions for the marketing of products/services/processes which require accreditation of conformity assessment bodies, as defined in art. 2 paragraph (10) of Regulation (EC) no. 765/2008 of the European Parliament and of the Council, with view to empowerment.

Assessment team – team appointed by RENAR for the assessment of a conformity assessment body

Lead Assessor – assessor having the full responsibility for the specified assessment activities.

Accreditation scope – description (as accurate as possible) of the activities, fields with view to accreditation.

2.2 ABBREVIATIONS

CAB – Conformity Assessment Body

CHAPTER 3 - RENAR – SHORT DESCRIPTION

3.1 GENERAL INFORMATION ON RENAR, HISTORY, LEGISLATION
Name: Romanian Accreditation Association – RENAR
Fiscal Code: RO 4311980
Address: Bucharest, Calea Vitan no. 232, Sector 3, zip code 031301
IBAN Code: RO41RNCB0077011436420001
Bank: BCR SECTOR 6
Telephone / Fax: 021/402.04.71/ 021/402.04.89
E-mail: renar@renar.ro

Romanian Accreditation Association – RENAR is a nongovernmental, non-profit public utility organization, established on the basis of Law 21/1924 with its further modifications, its legal personality being recognized by Civil Sentence no. 1966 /07.08.1990 (file no. 1975/PJ/1990) of District 1 Low Court Bucharest.

The Association is officially recognized as the sole national accreditation body, based on the GD 23/2009 and on the provisions of Regulation (EC) no. 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing regulation (EEC) no. 339/93 and operates on the basis of RENAR Statute, under the coordination and surveillance of the Ministry of Economy, Trade and Business Environment (METBE).

RENAR carries out the accreditation activity according to SR EN ISO/IEC 17011 – General requirements for accreditation bodies accrediting conformity assessment bodies.

### 3.2 INTERNATIONAL RECOGNITIONS

In order to demonstrate compliance with the criteria set out in the standard SR EN ISO/IEC 17011, RENAR is peer evaluated by European Accreditation which is recognized by the Commission as the European accreditation infrastructure under Article 14 of Regulation (EC) no. 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing regulation (EEC) no. 339/93, after the consultation of the Member States.

RENAR is signatory of the European and international agreements: EA-MLA, IAF-MLA and ILAC-MRA for the following fields:
- testing, including medical analysis;
- calibration;
- management system certification;
- product certification.

### 3.3 EXTERNAL PARTICIPATIONS

RENAR is:
- member of EA, European Co-operation for Accreditation from 1999;
- member of IAF, International Accreditation Forum from 2002;
- founding member of ILAC, International Laboratory Accreditation Co-operation from 1996.
RENAR has representatives in all technical committees of EA, IAF and ILAC.

### 3.4 INTERNAL PARTICIPATION

RENAR is:
- member of Romanian Standardization Association;
- member of Romanian Chamber of Commerce and Industry;
- founding member of Foundation for Quality National Prize - J.M. JURAN.

### 3.5 RENAR’S FIELDS OF COMPETENCE

RENAR’s fields of competence are to be found on its website (www.renar.ro), under section Accreditation.

### 3.6 DEVELOPMENT OF NEW FIELDS OF COMPETENCE

For the development of new fields of competence, RENAR applies Policy P-02.

**CHAPTER 4 - CRITERIA FOR OBTAINING ACCREDITATION**

The criteria for accreditation are classified in the following categories:
- Legal-administrative criteria;
- Economical-financial criteria;
- Competence criteria.

#### 4.1 Legal-administrative criteria

CAB should be a juridical, identifiable person, founded based on the in force legislation in Romania or on the in force legislation in the country where the CAB operates, in case of cross frontier accreditations.

In CAB’s documents shall be foreseen the object of activity of the body according to the activity for which accreditation is requested, according to in force edition of NACE codes.

The body applying for accreditation should not be in a process of bankruptcy or legal liquidation.

In order to prove the fulfillment of the criteria, CAB shall make available to RENAR the following information (see 5.3.1 and 5.3.2):
- Identification data: name of the organization and if the case, of the body, name in short, legal status, registration unique code, fiscal code, foundation year;
- Contact data: office address, addresses of the working points or of the critical locations, telephone, fax, e-mail address, web page etc.;
- Data regarding the structure of the shareholder;
- Data regarding affiliation or other types of connections with other bodies, such as professional associations, groups etc.

CAB shall submit the following documents - see (5.3.1 and 5.3.2):
- Copy of the ORC Registration Certificate (including for the working points) or, if the case, Fiscal Registration Certificate;
- Copy of the legal entity founding document (statute, judge decision, articles of association, normative documents, association documents etc.);
- Copy of the documents regarding the main office of the body, including the working points (property act, rental contract, etc.)
- Copy of an actual valid attestation certificate which contains an extended report on the legal person out of which the CAB is part of (respectively: identification data, legal form, identification unique code, J, object of activity, type of capital, social capital, shareholders/associates, administrators, branches, subsidiary/working points).

NOTE: For extension there is no need to submit the above foreseen documents, unless there are modifications to these documents. The copies shall be signed by the legal representative of the cab and stamped for proving the conformity with the original document, and submitted to renar on paper.

4.2 ECONOMICAL-FINANCIAL CRITERIA

The CAB should be stable from financial point of view. The income sources of the CAB should be correctly identified; they should have a viable business plan and a balanced budget. On the date of the application for accreditation, the CAB will make available to RENAR the most recent approved financial balance, the income and expenses budget, business plans etc. and will provide information regarding the business figures and estimations, prognosis, orientations. From CAB’s documents and financial records should result that the CAB activity is not under financial pressures.

CAB shall submit the following documents - see (5.3.1 and 5.3.2):
- Copy of the valid fiscal attestation certificate or self declaration of the legal representative who requests accreditation stating that the body does not have debts to the state budget on the date the documents are submitted;
- Copy of the last balance sheet (recorded at the competent authority) and the copy of the paper which prove that the balance sheet was submitted to the authority;
- Copy of the civil insurance document (policy, deposit etc.). In the regulated area, for the accreditation with view to notification, the civil and professional insurance shall cover European Economic Area.

4.3 COMPETENCE CRITERIA

The CAB shall have a management system which is designed, documented, implemented and maintained to assure the fulfillment of all the specific requirements of the standards and guides which are relevant for the requested accreditation scheme. During the evaluation process CAB should prove the implementation of the documented management system.

The CAB shall have a well defined organizational structure in order to assure the development of all processes described in the relevant standards and guides.

The CAB shall demonstrate that has competent personnel for the tasks it undertakes.
The CAB shall develop the conformity activity against documented procedures in order to assure valid, traceable and irrefutable results.

The CAB shall respect all the in force legislative provisions that have incidence with the developed activities.

The CAB shall have such infrastructure as to allow putting into force the conformity evaluation procedures it uses.

The CAB shall make available to RENAR the management system documents and records – see (5.3.1 and 5.3.2):

- organizational chart, process diagrams, organizational schemes etc. resulting that all functions of the functions of the management systems are covered;
- the documents defining the activities that it develops and for which the accreditation is requested, containing the conformity evaluation procedure and the referential that are used.
- a complete list with all normative documents that are related to the developed conformity evaluation activity. This list will be updated during the validity period of the accreditation.

In order to establish the CAB’s competence for the requested scope, RENAR’s assessment teams will use in the assessment process the accreditation requirements as mentioned below.

### 4.4 ACCREDITATION REQUIREMENTS

The accreditation services applicants and the accredited CABs shall respect the requirements defined in the reference standards, European and national applicable legislation and in EA, IAF and ILAC applicable documents.

Explanation and customization of the accreditation requirements is made by RENAR in the specific regulations for accreditation series of documents. These documents are available on RENAR’s website within each set of documents associated to the accreditation scheme.

<table>
<thead>
<tr>
<th>No.</th>
<th>CAB type</th>
<th>Accreditation standard</th>
<th>Other applicable documents</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Laboratory</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.1</td>
<td>LE</td>
<td>Calibration laboratories</td>
<td>SR EN ISO/CEI 17025</td>
</tr>
<tr>
<td>1.2</td>
<td>LI</td>
<td>Testing laboratories</td>
<td>SR EN ISO/CEI 17025</td>
</tr>
<tr>
<td>1.3</td>
<td>LM</td>
<td>Medical laboratories</td>
<td>SR EN ISO 15189</td>
</tr>
<tr>
<td>1.4</td>
<td>LR</td>
<td>Medical imaging and radiology laboratories</td>
<td>SR EN ISO 15189</td>
</tr>
<tr>
<td>2</td>
<td>IC Proficiency Testing Providers</td>
<td>SR EN ISO/CEI 17043</td>
<td>Applicable legislation. (note: where there are differences between official version of a Directive)</td>
</tr>
<tr>
<td>No.</td>
<td>CAB type</td>
<td>Accreditation standard</td>
<td>Other applicable documents</td>
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</tr>
<tr>
<td>4</td>
<td>PR Product certification bodies</td>
<td>SR EN 45011 / SR EN ISO/CEI 17065</td>
<td>International and regional applicable guides.</td>
</tr>
<tr>
<td>5</td>
<td>SM Management system certification bodies</td>
<td></td>
<td>RENAR applicable policies and regulations.</td>
</tr>
<tr>
<td></td>
<td>5.1 SA Food safety</td>
<td>SR EN ISO/CEI 17021</td>
<td></td>
</tr>
<tr>
<td></td>
<td>5.2 SM Management systems for:</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>5.2.1 MC Quality</td>
<td>SR EN ISO/CEI 17021</td>
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<tr>
<td></td>
<td>5.2.2 MM Environment</td>
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<td></td>
<td>5.2.3 MD Medical devices</td>
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<td>5.2.4 OH Occupational health and safety</td>
<td>SR EN ISO/CEI 17021</td>
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<td>5.2.5 EN Energy</td>
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<td>5.3 SI Information security</td>
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<td>5.4 FS FSSC</td>
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<td>6</td>
<td>PS Persons certification bodies</td>
<td>SR EN ISO/CEI 17024</td>
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<tr>
<td>7</td>
<td>ON Conformity assessment bodies in regulated area with view to notification</td>
<td>SR EN 45011 / SR EN ISO/CEI 17065 SR EN ISO/CEI 17021 SR EN ISO/CEI 17025</td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>OC Bodies involved in the assessment and verification of constancy of performance for construction product.</td>
<td>SR EN 45011 / SR EN ISO/CEI 17065 SR EN ISO/CEI 17021 SR EN ISO/CEI 17025</td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>OR Conformity assessment bodies in regulated area against European regulations</td>
<td>SR EN 45011 / SR EN ISO/CEI 17065 SR EN ISO/CEI 17021</td>
<td>9.1 OR (Reg. UE 333/2011) 9.2 OR (Reg. UE 1151/2012) 9.3 OR (Reg. UE 834/2007) 9.4 OR (Reg. UE 1221/2009)</td>
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<tr>
<td>10</td>
<td>OV Greenhouse gas emissions verification bodies</td>
<td>SR EN ISO 14065</td>
<td></td>
</tr>
<tr>
<td>11</td>
<td>OT BODIES CARRYING OUT CERTIFICATION AND/OR INSPECTION OF PACKAGING, CONTAINERS AND STRUCTURES FOR CARRIAGE OF DANGEROUS GOODS BY ROAD</td>
<td>SR EN ISO/CEI 17020 SR EN 45011 / SR EN ISO/CEI 17065</td>
<td></td>
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</table>

In the regulated area, the interpretation of the accreditation requirements is made taking into account the provisions/guidances foreseen in the guidelines issued by the European Commission for the respective normative documents, as well as these foreseen in the EA, IAF and ILAC Guides prepared for the harmonized application of the accreditation standards, when such guides exists.

For the accreditation of conformity assessment bodies for designation with view to notification the requirements of EA-2/17:2009 applies.

4.5 MODIFICATION OF ACCREDITATION REQUIREMENTS
In case one of the accreditation standards is revised or the normative documents (Directives, UE Regulations, Romanian normative documents) from the regulated area are revised, RENAR adopts the modifications in its criteria and gives a reasonable transition time period to the interested parties, according to Policies P-07, respectively P-08.

The CAB has the obligation to keep themselves informed on RENAR documents regarding the changes of the accreditation standards and normative documents within the regulated area (Directives, UE Regulations, Romanian normative documents) and of the other applicable documents (regulations and guidelines) by consulting RENAR’s websites.

CHAPTER 5 - ACCREDITATION PROCESS

5.1 CYCLE OF ACCREDITATION

An accreditation cycle lasts four years from the date of issue of accreditation certificate according to the scheme of Figure 1. Maintaining accreditation is conditioned upon surveillance scheduled intervals. Renewal of accreditation involves submitting a new application with nine months before the expiry of accreditation (in order to ensure the continuity) and respecting the similar stages of initial accreditation.

Fig.1 – Cycle of accreditation

5.2 THE FLOW OF THE ACCREDITATION PROCESS

The accreditation process is described in Figure 2 below.
5.3 THE STAGES OF ACCREDITATION PROCESS

5.3.1 Initial information

RENAR provides information about the accreditation process through the documents available on RENAR’s website, www.renar.ro, under section “Accreditation process / Documents for accreditation / Portfolio of informative documents”.

The section "Portfolio of informative documents" contains a set of documents, customized for each accreditation scheme as well as a set of forms which shall be filled in by the CABs when applying for accreditation.

The financial-accounting information about RENAR is to be found under section „Accreditation process/ Financial information”. For additional information or clarifications the CAB representative shall address to RENAR Secretariat.

In case of applications of CABs from other countries Policy P-15 shall apply.

5.3.2 Accreditation application

For each accreditation scheme, CAB submits to RENAR office an application for accreditation accompanied by the afferent forms, documents and records.

Application for accreditation shall be submitted to RENAR office by a CAB empowered delegate.

Applications for accreditation are to be found in the portfolio of informative documents available on the RENAR website under section - Accreditation process.

The application for accreditation shall be signed and stamped by the legal representative of the organization of which the CAB is part of.

CAB must pay registration and initiation tariff. The tariffs are available on RENAR’s website, www.renar.ro, under section - Accreditation process – Tariffs.

In the voluntary area, RENAR does not accept the application for accreditation of a CAB that did not carry on conformity assessment activities for the fields it requesting accreditation for.

The application for accreditation is registered at RENAR’s secretariat only in case it is accompanied by the documents and records mentioned in „The List of documents submitted by the CAB”.

The respective documents and records are checked to ascertain whether they are complete, and if a document or record is missing, the application is not registered.
Note: In the regulated area, in case the CAB requests accreditation for several Directives or standards, the documents and/or administrative-legal documents and economical-financial documents shall be submitted in one copy.

In the regulated area, the CAB shall apply for accreditation for each Directive, Regulation etc. and the application shall be treated as initial accreditation.

RENAR takes into consideration all information from previous accreditations, if there are any.

The CAB can apply for several standards within the same normative document, if the CAB has differentially documented the conformity assessment procedures/modules/systems, depending on the applicable standard for the respective conformity assessment procedures/modules/systems.

The accreditation scope of the empowered bodies shall refer to the normative document which contains the requirements, to the reference accreditation standards, as well as to the product/products category/processes/services/personnel/activity group for which the CAB is competent to carry on.

5.3.3 Accreditation application review

The purpose of this stage is to establish if the legal and financial documents are adequate – see 4.1.1, 4.1.2 and if RENAR has the necessary resources to carry on the assessment with view to accreditation.

The CAB is informed on the appointed team and may object to the composition of the team according to RENAR’s Policy P-22.

This stage can be finalized with one of the following decisions:

- acceptance of the application and appointment of the assessment team. The composition of the team is communicated to the CAB and it has the opportunity to object according to Policy P-22; in case the CAB is requesting accreditation in the regulated area, the assessment team can include the representatives of the competent authority who can accompany the assessment team in all the stages of the assessment process, as observer.
- not accepting the application accompanied by the corresponding motivation;
- determining the need of carrying on a preliminary visit with the CAB agreement.

No matter the decision, the CAB will be informed with regard to the completion of this stage and to the taken decision.

In case of a CAB requesting accreditation in the regulated area, the competent authority representatives may participate during the application review.

5.3.4 Preliminary visit

Following the completion of the application review it can be decided a preliminary visit to be carried on, with the agreement of the CAB. The purpose of the visit can be:
• to obtain additional information related to the management system (structure, facilities, personnel);
• to check the way the activities are controlled by the CAB, including the multiple sites, headquarters abroad, subcontracted activities, etc;
• to conclude on the accreditation scope to be assessed.

The preliminary visit may conclude with a list of found deficiencies. If the estimated time period for solving the deficiencies is to big, thus the accreditation process may not be finalized within a reasonable time frame (maximum 1 year since the date of concluding the contract), the file shall be returned to the CAB.

The accreditation contract shall be concluded only in case the deficiencies found during the preliminary visit are solved.

In order to resume the process, the CAB shall submit another application. In this case the accreditation initiation tariff shall not be paid.

In case the accreditation was requested by the CAB for the regulated area, the representative of the competent authority may participate to the preliminary visit.

5.3.5 Contracting

The accreditation contract is available on RENAR’s website www.renar.ro. The accreditation contract is concluded following the application review, after the preliminary visit was performed – if the case.

Usually, the contract is signed at the RENAR premises. If the accreditation contract, issued in 2 copies is sent to the CAB, CAB returns 1 copy signed by the legal representative of the organization of which the CAB belongs to.

The provisions of the accreditation contract are not negotiable; they are the same for all CAB types.

5.3.6 Document and record review

The purpose of this stage is to assess the compliance of the CAB’s documented system against the relevant accreditation requirements by analyzing the relevant documents and records submitted by the CAB. At this stage, the assessment team may require in addition other documents or records, if deemed necessary.

CAB pays the tariff for the document and record review based on the invoice issued by RENAR.

During the document and records review the assessment team may find non-conformities, improvement opportunities or documentation conformity.

If the assessed documents and records demonstrate compliance with the accreditation requirements for the requested scope, the assessment team will proceed to the next stage, respectively the on-site assessment (on-site and witness assessment).
The list of findings (improvement opportunities, non-conformities) shall be sent to the CAB.

For the found improvement opportunities the CAB shall not make the root analysis, but shall send to RENAR the revised documents, if requested.

In case there are found non-conformities RENAR may decide not to continue with the accreditation process.

The accreditation process may resume if the CAB is submitting a new application for accreditation, only after the non-conformities were solved. In this case the initiation tariff shall not be paid again.

5.3.7 Preparation for assessment

The CAB pays the on-site assessment tariff based on the invoice issued by RENAR.

The assessment plan is prepared based on the findings resulted in the documents and records review and on the sampling made according to RENAR's documents. The assessment plan is sent to the CAB.

The assessment plan is flexible enough to allow changes of the planned assessment activities.

The number of on-site assessment days depends on the size and complexity of the scope of accreditation.

The assessment plan shall be accepted by the CAB with at least 10 working days before the on-site assessment takes place.

By accepting the plan, the CAB commits to ensure all conditions for the development of the assessment according to the assessment plan (eg. operation of equipments where appropriate, the availability of documents and records, the availability of personnel). CAB will ensure to RENAR assessment team, if the case, the needed work protection training and the proper equipment. The CAB will provide the assessment team with the necessary confidentiality documents required to be signed.

In case the assessment days are modified, the assessment plan shall be updated.

In case of multi-site organization all sites will be assessed during the initial assessment.

5.3.8 On-site assessment

5.3.8.1 Opening meeting

The on-site assessment begins with an opening meeting where are clearly defined the assessment purpose, the accreditation criteria and are confirmed the assessment plan and the assessment scope.

At this meeting shall participate the representatives of the CAB (personnel of the CAB), including the top management of the CAB.

It is not accepted the presence of CAB's consultants during the assessment.
During the opening meeting the CAB is informed which are the situations when the assessment may be interrupted by the Lead Assessor, such as:

- when the CAB personnel puts pressure on / threat the members of the team;
- when are not assured the adequate conditions for the development of the assessment (logistics);
- when the representatives of the CAB does not cooperate with the assessment team;
- when the CAB representatives does not make available to the assessment team the requested records;
- when the CAB representatives delays the assessment development;
- when the CAB representatives have an aggressive attitude towards the members of the assessment team;
- when the CAB representatives are misleading the assessment team;
- any other situations which may impede on the development of the assessment.

Any last minute changes to the assessment plan are clarified during this meeting.

### 5.3.8.2 The on-site assessment

RENAR’s assessment team assesses the competence of the CAB according to the assessment plan.

The CAB shall demonstrate that is competent and complies with the standard and with the accreditation requirements relevant for the requested scope.

Assessment takes place at the premises where the CAB develops one or more key activities (key activities include: policy formulation, process and/or procedure development and, as appropriate, contract review, planning conformity assessments, review, approval and decision on the results of conformity assessments).

### 5.3.8.3 Findings review meeting

Before the closing meeting a meeting of the team takes place in order to review the findings.

To conduct this meeting, the CAB shall provide RENAR’s assessment team with an adequate work space. After this meeting, the closing meeting will take place where the findings of the assessment will be presented.

### 5.3.8.4 Closing meeting

All top management representatives of the CAB shall participate at the closing meeting.

During the closing meeting the Lead Assessor reports to the CAB the findings resulted following the assessment, including comments on competence and conformity, as well as recommendations as improvement opportunities.
If there were found non-conformities, they are documented, classified and presented by the Lead Assessor to the legal representative of the CAB. The CAB shall send to RENAR the plan of actions containing the corrective actions, according to Policy P-16, in maximum 10 days since the conclusion of the assessment.

In case the Lead Assessor founds that the actions plan sent by the CAB does not include the steps foreseen in Policy P-16 and it is not adequate, he/she requests the CAB in writing to revise the respective plan within maximum 5 working days since the receipt of the address by the CAB. If the Lead Assessor considers that the revised plan is not adequate proposes the accreditation process cessation.

Any divergent opinions between the assessment team and the assessee related to the findings and/or assessment conclusions shall be discussed and, if possible, solved during the closing meeting. If CAB’s management representatives do not agree with the non-conformities raised by RENAR’s assessment team they may appeal according to the procedure PR 09.

5.3.9 Witness assessment

During the witness assessment, RENAR’s assessment team observes the way the conformity assessment specific services are carried on by the CAB, for the requested scope.

The CAB has the obligation to make all the necessary arrangements for RENAR to carry on the witnessing of CAB’s services at initial accreditation and at the surveillances.

The sampled scopes to be assessed by witnessing are established according to RENAR’s documents.

The witness assessment activities are usually carried out for laboratories during the on-site assessment at the CAB premises (office).

The witness assessments carried out after the office assessment took place, both for laboratories and inspection bodies, certification, verification etc., shall be agreed between the Lead Assessor and CAB, and shall be carried out within maximum four months from the date the assessment plan was sent and only upon receipt of CAB’s client acceptance on RENAR participation.

The non-conformities found and classified by the Lead Assessor are made known to the CAB, in writing, in the shortest time possible. The legal representative of the CAB signs the forms and presents the official reaction of the CAB against the raised non-conformities using the agreed correspondence channels (e-mail, fax, regular mail etc.).

In the regulated area, the witness assessments at CAB’s client can not take place before the empowerment was obtained from the competent authority, because the law imposes to the CAB to carry on the conformity assessment tasks only after the accreditation, and subsequently the empowerment, were obtained.
RENAR carries on the witness assessments for products/services/processes/activities/profession from the product category, as defined in the respective regulation/directive/normative document.

Note: In the context of this document by term "product category" shall be understood, as the case: category/class/family/group of product/services/processes/personnel/group of activity.

RENAR may establish together with the competent authority, in the accreditation specific regulations (RS-yy), which are the scopes to be assessed by witness containing the groups of product category, depending on the specific technical aspects.

During an accreditation cycle, RENAR shall carry on at least one witness assessment for each product category/field.

Depending on the requirements of the normative document (e.g. if the applicable conformity assessment modules/procedures/systems does not foresee activities to be carried on by CAB’s client, such as audits, inspections, in the event of a challenge or similar), the witness assessments are replaced by at least one assessment of records (e.g. assessment of files).

In case the witness assessment can not take place, RENAR can assess the CAB’s competence through the following assessment techniques:
- interview with CAB’s personnel who is involved in the application/order review, in carrying on the conformity assessment tasks, in the reporting documents review, in the decision making process etc.
- assessment of records (e.g. personnel files) and in case of surveillance there shall be assessed the way the personnel maintains and updates its competence;
- checking of case studies prepared by the CAB;
- assessment of tasks simulated by the CAB;
- assessment of how CAB checks calculations, projects etc.

In case, in the previous accreditation cycle, there were not carried on witness assessments for the accredited scopes due to the lack of clients or due to reasons imputable to the CAB, RENAR shall not accept CAB’s accreditation renewal application for the respective scopes.

5.3.10 Follow up assessment

The purpose of the follow up assessment is to check the effectiveness of the implementation of the corrective actions.

The Lead Assessor may decide the place for the follow up assessment development depending on the nature of the non-conformities and on the presented evidences, as follows:
- at RENAR premises
- at CAB’s premises
- at CAB’s client premises

The Lead Assessor decides the way the follow up assessment shall develop, according to Policy P-16.
5.3.11 Assessment reporting

After the on-site, witness and follow up assessments were concluded, RENAR sends to the CAB the assessment report.

In case it is foreseen in the normative documents/RENAR documents, the assessment report is sent to the competent authority with view empowerment.

The assessment report is a document which is intended only for the CAB.

RENAR prepares and issues the assessment report respecting its own documents regarding the confidentiality, the CAB being responsible by the subsequent use of this report.

5.3.12 Decision-making

The accreditation decision is taken by the Accreditation Council based on the assessment report and on other information in order to prove the fulfillment of the accreditation requirements, after the CAB pays the tariff for decision-making based on the invoice issued by RENAR.

The decisions may be:

- granting / not granting or partial granting of accreditation, in the stage of initial, renewal, extension of accreditation, transfer of accredited activity to another organization or in case of modifications of conditions within which the initial accreditation was granted (modification of the name, of the main office or working points of the CAB, of the technical conditions within which the accreditation was granted);
- total/ partial suspension of accreditation and lifting the suspension;
- withdrawal / restriction of accreditation;

In case of a decision for not granting, withdrawal, suspension or restriction of accreditation the applicant/accredited body shall be informed in writing on the reasons leading to the respective decision.

In case of surveillance assessments, when the conditions within which the accreditation was granted are not modified, RENAR may confirm the continuation of accreditation based on the assessment report.

RENAR communicates to the CAB the decision of the Accreditation Council. Based on this communication the CAB can pick up the accreditation certificate at RENAR’s premises or, if requested, will receive the accreditation certificate by courier.

The accreditation certificate will be picked up/received by CAB and will be published on RENAR's website only after all the invoices issued by RENAR related to the accreditation process tariffs where paid by the CAB.
After the accreditation decision-making, the CAB receives the accreditation certificate together with:

- the national accreditation symbol (which contains the national accreditation mark),
- the surveillance program,
- RENAR questionnaire on the evaluation of its services.

The accreditation certificate identifies the scope for which the accreditation was granted, for each location, according to the accreditation requirements. The accreditation certificate is valid 4 years since the date of decision for initial accreditation or renewal of accreditation.

On request and against a specific tariff, RENAR may issue accreditation certificates in English language.

In the regulated area, in case of a CAB which requests accreditation before the obtaining of empowerment, according to the applicable normative document, accreditation is granted under the following conditions:

- all stages of the accreditation process were concluded and assessed with positive results, all non-conformities raised by RENAR being closed;
- witness assessments are going to be carried on at the first client of CAB for each product category/field (see Note of 5.3.9). In this case, CAB shall inform RENAR, in writing on the following:
  - relevant data on the client;
  - relevant data on the product/ service/ process/ activity/ profession and product category (see Note of 5.3.9);
  - evaluation procedure/ module/ system used by the CAB;
  - European standards, associated technical regulations etc.;
  - data proposed for carrying out activities at CAB's client.

The date of the witness assessment will be agreed between RENAR and the CAB, after the CAB's client agreement.

These conditions does not apply in case of a CAB which has been previously empowered, without being accredited, and had the possibility to carry on the conformity assessment services in the respective regulated areas.

RENAR will carry on a witness assessment for the respective product/ service/ process/ activity/ profession and will inform the competent authority in the field with view to analyse the opportunity to participate as observer, by its representative, to this witness assessment.

In case RENAR granted accreditation, before the CAB obtained the empowerment, it shall communicate the decision to the CAB and will specify the limits within which this is granted:

- the CAB shall not issue any certificate under accreditation for a product/ service/ process/ activity/ profession from a product category (see Note of 5.3.9), until RENAR carries on a witness assessment at the first CAB's client for the product category/ field for witness assessment within which this category is included;
- the CAB has the entire responsibility for the assurance of a competent review of the request/application of its client.
- in case is proved that CAB has issued a certificate and RENAR did not carried a witness assessment as mentioned above, RENAR withdraws the accreditation according to the provisions of the accreditation contract.

CHAPTER 6 – NATIONAL ACCREDITATION MARK

National Accreditation Mark attests that a conformity assessment body is competent to carry on specific tasks for the scope for which is accredited.

According to the law, the owner of the national accreditation mark is the Ministry coordinating the activity of the national accreditation body – RENAR that transfers the right on the national accreditation mark.

6.1 THE WAY NATIONAL ACCREDITATION MARK SHALL BE USED

The way the national accreditation mark is used is regulated by rules established by RENAR and the rules are posted on RENAR’s website.

In case a CAB is not using the national accreditation mark for the field for which it is accredited, the documents issued by the CAB in the respective field are not covered by accreditation.

The CAB may refer to its accredited status according to the rules defined by RENAR.

6.2 ROYALTIES

The accredited CAB shall pay royalties according to RENAR tariffs – available on RENAR’s website www.renar.ro.

Each trimester the CAB shall send to RENAR, to the Economic Direction, a self declaration containing the number of documents (certificates, reports etc.) they issued under accreditation, together with their identification elements (serial numbers, numbers, codes, organizations to which they were issued, etc.).

This information will be verified by the Lead Assessor during the next surveillance.

CHAPTER 7 - APPEALS

The CAB can appeal any unfavorable decision according to procedure PR 09, available on RENAR’s website, www.renar.ro.

During the appeal, the status of the CAB is in accordance with the taken decision (suspended, withdrawn).

In case the CAB submits an appeal to a decision of RENAR this not implies that the decision already taken shall not be applied during the appeal treatment period.
CHAPTER 8 – EXTRAORDINARY ASSESSMENTS

Extraordinary assessments shall be carried on in the following situations:

a) complaints to the CAB,
   In this case applies Treatment of Complaints, code PR 08.

b) findings of RENAR regarding the breaching of the accreditation requirements by the CAB (communications of authorities, information collected from the market etc.);
   In this case is appointed an assessment team, is prepared and communicated to the CAB the assessment plan focused on the respective problem and the assessment is carried on in the shortest time possible.

c) relevant significant changes, declared by the CAB, appeared against the conditions under which the accreditation was granted/maintained (including the transfer of accreditation), such as:
   - legal, commercial, property and organizational status;
   - organization/ CAB, top management and key personnel;
   - resources and locations (modifications of the main office or of the working points of the CAB).

In case of accreditation transfer, the Lead Assessor analysis if:
   - the body fulfils RENAR accreditation requirements;
   - the policies and the management system remain unchanged;
   - the management and the key personnel remain unchanged;
   - the personnel remains unchanged;
   - the body from which the conformity assessment activities were transferred does not provide such activities;
   - the specific procedures remain unchanged;
   - the infrastructure (equipments, facilities, site, etc.) remain unchanged.

d) modifications of the conditions within which the accreditation was granted:
   - modifications of the reference standards for CAB’s activity;
   - modifications of the normative documents;
   - modifications of RENAR’s documents, etc.

CAB shall inform RENAR regarding these modifications as mentioned in the contract.

In case of the modifications of the conditions within which the accreditation was granted, following the review of the information received, the Lead Assessor proposes:
   - evaluation of appeared changes within the next surveillance assessment or
   - carrying on an extraordinary assessment.

CAB is informed on the taken decision.

e) Other elements that may affect CAB’s capacity to fulfill the accreditation requirements.
CAB pays the tariff for the assessment on the basis of the invoice issued by RENAR, excepting for paragraph a), when the tariff is paid only in case the complaint was not grounded.

In the regulated area, in case there are suspicions that CAB breached the accreditation criteria, at the request of the competent authority, RENAR shall carry on in the shortest time possible an extraordinary assessment (not planned) of the respective body. The appointed representative of the competent authority may participate at this extraordinary assessment.

In case RENAR has been informed by the competent authority on non-conformities identified to a certification/evaluation document issued under accreditation/empowerment, it will carry on an extraordinary assessment when it will assess all certification/evaluation documents issued in the respective field.

CHAPTER 9 – SURVEILLANCE

9.1 SURVEILLANCE BY ON-SITE ASSESSMENT

RENAR uses the surveillance in order to check the continuous fulfillment of the accreditation requirements by the CAB, according to Policy P-17.

When preparing the surveillance assessment, the Lead Assessor agrees with the CAB the date of the surveillance assessment. At this stage are requested the documents and records which are relevant. The CAB shall send at least the following:

- List of clients/ products to which certification process was finalized or in process of completion (in case certification bodies);
- List of accredited certification activities programmed to be carried on in the following 3 months after the office assessment took place;
- List of PT/ILC participations and the obtained results (in case of laboratories);
- Last internal audit report, respectively management review (if the case);
- Last financial documents prepared by the CAB.

9.2 SURVEILLANCE USING OTHER METHODS

RENAR carries on also other surveillance activities according to its policy P-17.

CHAPTER 10 – EXTENDING ACCREDITATION

Extension application may be submitted only after accreditation is obtained.

The accreditation extension may be requested for the accredited scope as well as for the location(s). The extension of scope shall be made within the same accreditation standard against which the CAB was accredited and within the same accreditation scheme.
In case of accreditation extension or in case of modifications of the conditions within which the accreditation was granted, CAB's request shall be accompanied by those documents and records which are relevant for the respective extension or modification.

Usually, the extension assessment is carried on together with the following programmed surveillance assessment, but in case the CAB requests it and after the application review is carried on, an extraordinary assessment may be carried on at another agreed date, under the condition of respecting the procedures and tariffs in force at that date.

The accreditation extension assessment is carried on at the CAB site(s) and is similar to the assessment process, according to the provisions of chapter 5 above.

Accreditation extension is granted within the same validity with that of the current accreditation.

In the regulated area, an extension is:
- an application for other categories/classes/families of products/processes/services/persons regulated by the same normative document and the same accreditation standard;
- an application for other products/processes/services/persons within the same category/class/family;
- an application for another conformity assessment system/module/procedure for the same normative document (Directive/Regulation).

CHAPTER 11 – ACCREDITATION RENEWAL

Renewal of accreditation (reassessment) is required by at least 9 months before expiry of accreditation following the steps outlined in this document, at chapter 5.

Reassessment is similar to an initial assessment, taking into account the experience gained in the previous assessments. Usually, the assessment team is changed after an accreditation cycle.

If the renewal of accreditation application is not submitted with at least 9 months before the expiry of accreditation certificate, is possible that RENAR will not be able to ensure the accreditation continuity thus the last surveillance to be transformed into an assessment for the renewal of accreditation.

In this case on the accreditation certificate issued on “date of initial accreditation” shall be mentioned the date of current accreditation (the date when the Accreditation Council took the decision).

In case the CAB submits the renewal of accreditation application with at least 9 months before the expiry of accreditation certificate, but due to reasons imputable to the CAB the accreditation process can not be concluded until the expiry date of the certificate, RENAR shall issue an initial accreditation certificate which at “date of initial accreditation” shall be
mentioned the date of current accreditation (the date on which the Accreditation Council took the decision).

If the CAB submits the renewal accreditation application within less than seven months, it is possible that the last surveillance can not be transformed in a reevaluation for accreditation renewal.

If the CAB submits the renewal accreditation application within less than seven months to the accreditation expiration date, the tariffs foreseen by RENAR will be those for the initial accreditation, including the tariff for application registration.

If there is a situation of interrupting the accreditation (e.g. accreditation withdrawal, expiration of accreditation certificate) the certificate issued to the CAB it will have the date of current accreditation (the date on which the Accreditation Council took the decision) at “Date of initial accreditation”.

*In the regulated area, the renewal of accreditation application will not be accepted for the scopes for which were not carried on witness assessments in the previous accreditation cycle, as mentioned at 5.3.9.*

**CHAPTER 12 – SUSPENDING ACCREDITATION**

A CAB accreditation is suspended according to the provisions of policy P–21.

*In the regulated area, the decision on suspending accreditation is communicated to the competent authorities.*

For the medical laboratories, the decision on suspending accreditation is communicated to the interested organizations (health insurance houses).

**CHAPTER 13 – REDUCING ACCREDITATION**

A CAB accreditation is reduced according to the provisions of policy P–21.

Accreditation reducing may take place in the following cases:
- the CAB requests it – in this case the application shall be written, mentioning clearly the part of the accredited scope and/or location;
- in case following the assessment the CAB prove that is no longer competent for a part of the accredited scope or for one or more of its locations.

Reducing of accreditation does not affect the validity period of the accreditation certificate.

*In the regulated area, the decision on reducing accreditation is communicated to the competent authorities.*

For the medical laboratories, the decision on reducing accreditation is communicated to the interested organizations (health insurance houses).
CHAPTER 14 – WITHDRAWING ACCREDITATION

A CAB accreditation is withdrawn according to the provisions of policy P–21.

*In the regulated area, the decision on withdrawing accreditation is communicated to the competent authorities.*

For the medical laboratories, the decision on withdrawing accreditation is communicated to the interested organizations (health insurance houses).

CHAPTER 15 - COMPLAINTS

The complaints are treated according to procedure PR 08.

CHAPTER 16 – RULES CONCERNING THE ACCREDITATION OF A MULTI-SITE CAB

RENAR carries on the accreditation of a multi-site CAB according to Annex 1.

CHAPTER 17 – CROSS FRONTIER ACCREDITATION

In case RENAR receives an application from a CAB within Europe or outside Europe the provisions of the Policy P-15 applies.

These applications shall be sent to RENAR secretariat ([renar@renar.ro](mailto:renar@renar.ro)).

CHAPTER 18 – USE OF PT IN LABORATORY ACCREDITATION

RENAR uses the proficiency testings for the laboratory accreditation according to Annex 2.

CHAPTER 19 - WAYS OF COMMUNICATION BETWEEN RENAR AND CAB

The ways of communication between RENAR and CAB are usually the following:

- through RENAR's secretariat,
- through the Lead Assessor appointed for the respective file,

using the official means of communication: fax, e-mails, made available on RENAR's website or courier.

RENAR uses its website [www.renar.ro](http://www.renar.ro) to communicate all necessary information the CAB shall be aware of during the accreditation process.

During the validity period of the accreditation the CAB shall check RENAR's website regularly in order to keep itself informed with the applicable documents (guides, regulations etc.).
### CHAPTER 20 – MODIFICATIONS SINCE THE LAST VERSION

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1. it shall treat it as an application for initial accreditation.
2. an initial accreditation certificate which shall not include the history of accreditation.