Title	**Regulation for the accreditation of Research and Development Biobanks**
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Preparation	Approval	Authorization	Application Date
The Department Director	The Directive Council	The General Director	31-10-2020

INDICE

0. FOREWORD

ACCREDIA's objective is to contribute to the creation of trust in the conformity assessment system - called to assess and certify compliance with the requirements established by the national and international technical standards applicable to organizations that carry out *biobanking* - and to ensure the effectiveness and uniformity of approach by the Operators of the system, thus favouring the growth of the competitiveness of the national production system and the improvement of citizens' well-being.

To this end, ACCREDIA, through the Calibration Laboratories Department, accredits

organizations that carry out *biobanking* through the management/treatment of biological material and/or biological resources for biotechnological research and development, including all types of data relating to this material, operating in compliance with the requirements of the UNI EN ISO 20387 standard and ACCREDIA, EA (*European cooperation for Accreditation*), ILAC (*International Laboratory Accreditation Cooperation*) documents,

ensuring that these possess and maintain over time the required organizational, procedural, technical and professional requirements, in terms such as to generate, in all the social and economic parties involved - and, in particular, in the users - a high degree of trust in the work of these subjects and in the value of the certificates of conformity issued by them.

This document does not apply to organizations that carry out *biobanking* activities of biological material intended for the production of food/feed, to laboratories that perform analyses for the production of food/feed and/or therapeutic use.

In line with the objectives indicated above and in accordance with the guidelines expressed by its statutory bodies - in order to better ensure the effectiveness of the accreditation process - ACCREDIA Department of Calibration Laboratories has developed specific rules and appropriate criteria for applying the general requirements of the regulatory references applicable, formalized through the issue of this Regulation (as well as through other documentation to be used in conjunction with the Regulation itself).

This document takes into account the evolution of the applicable regulatory references, the experience gained by ACCREDIA and the indications expressed by the Statutory Bodies of ACCREDIA, aimed at improving the accreditation system.

0.1. INTRODUCTION

The application of the requirements of the reference standard UNI EN ISO 20387 and other applicable documents has the aim of promoting the creation and maintenance of user trust in accredited *biobanking* activities and in the impartiality and integrity of technical and commercial operations associated with them.

Accreditation in accordance with UNI EN ISO 20387 certifies the competence of organizations that carry out *biobanking* activities indicated in the scope of accreditation and the implementation of a management system that generally complies with the principles of the UNI EN ISO 9001 standard.

Organizations that carry out *biobanking* activities accredited by ACCREDIA Calibration Laboratories (hereinafter ACCREDIA DT) operate within the framework of national regulations and are deemed competent to distribute materials to support both private and public research and development

activities. This objective can be achieved thanks to the correct and effective application of this Regulation.

0.2. SCOPE AND FIELD OF APPLICATION

This Regulation applies to organizations that carry out *biobanking* activities of biological material obtained from multicellular organisms and microorganisms for research and development with the exclusion of biological material intended for the production of food/feed, to laboratories that perform analyses for production of food/feed and/or therapeutic use.

The purpose of this document is to describe the procedures to which they must comply:

a) organizations that carry out *biobanking* activities, i.e. biobanks, for:

- submit the request for accreditation pursuant to the UNI EN ISO 20387 standard;
- collaborate in the assessment carried out by ACCREDIA DT and in all the acts connected to it;
- implement the corrective actions required following the results of the accreditation procedure and all related acts;
- stipulate the accreditation agreement;
- collaborate in the subsequent surveillance and maintenance of accreditation;
- submit requests for extension, variation and renewal of accreditation;
- implement the ACCREDIA DT requirements in cases of suspension, reduction, renunciation and withdrawal of accreditation.

b) ACCREDIA DT, in carrying out the following operations:

- accreditation;
- surveillance and maintenance of accreditation;
- changes in the scope of accreditation;
- renewal of accreditation;
- extension of accreditation;
- suspension of accreditation;
- reduction of accreditation;
- withdrawal of accreditation;
- renunciation of accreditation.

In the relationship between ACCREDIA DT and the organizations, the circulars/provisions that will be issued by ACCREDIA DT and which will be shared with the interested parties and included in the ACCREDIA LS-16 document must also be considered as a source of contractual obligation.

Based on the principle of specialty, an ACCREDIA DT circular/provision prevails over the general provisions contained in the applicable Regulations.

ACCREDIA DT considers mandatory:

a) Mandatory documents issued by EA/ILAC;

b) any applicable provisions deriving from the resolutions adopted by the General Assemblies of the Bodies referred to in the previous point;

c) any provisions issued by Public Authorities;

d) any applicable provisions issued by the Institutional Bodies of ACCREDIA (e.g. Board of Directors, Steering and Guarantee Committee, Committee for Accreditation Activities, etc.).

Regarding the provisions referred to in points b, c, d, ACCREDIA DT will be responsible for informing the biobanks about the issue of specific circulars.

ACCREDIA DT also considers the FAQs issued by the EA Laboratories Committee and the ILAC Technical Committee to be evaluated in the event of disputes.

This General Regulation and the specific Regulations for accreditation standards are subject to specific approval by the Board of Directors of ACCREDIA (Article 14 of the ACCREDIA Statute), subject to the favourable opinion of the Committee for Accreditation Activities and are issued under the authority of the President. ACCREDIA. The Steering and Guarantee Committee is also involved in the process for consultation.

0.1. NORMATIVE REFERENCES

The regulatory references to be considered for the application of this Regulation are reported in the document ACCREDIA Department of Calibration Laboratories LS-16 "Standards and reference documents for the accreditation of Biobanks", in the revision in force, including all applicable ISO, ILAC and EAs documents.

This Regulation also refers, where and as applicable, to the ACCREDIA documents/prescriptions:

- ACCREDIA Statute (ST-00);
- Regulation for the Application of the Statute (ST-01);
- Regulation for the proceedings of the Accreditation Committee (RG-04);
- Regulation for the proceedings of the Sector Accreditation Committee of Dept. of Calibration Laboratories (RG-04-DT);
- Regulation for the proceedings of the Steering and Guarantee Committee (RG-05);
- Regulation for the proceedings of the Appeals Commission (RG-06);
- Regulation for the use of the ACCREDIA Mark (RG-09);
- ACCREDIA price list (TA-00);
- Accreditation contractual agreement (CO);
- Application for accreditation (DA-00);
- Accreditation Application for Biobanks (DA-12);
- Applicable ACCREDIA Technical Regulations, including RT-38;
- EA, ILAC and other documents applicable to Biobanks.;

For each of the ACCREDIA documents cited, the latest current revision applies and can be freely downloaded from the Institutional and Operating Documents area and/or from the Calibration Laboratories Department area of the ACCREDIA site.

0.3. TERMS AND DEFINITIONS

Accreditation: attestation by a national accreditation body certifying that a particular conformity assessment body meets the requirements set by harmonized standards and, where applicable, any additional requirements including those set out in the relevant sectoral programs, to carry out a specific Conformity assessment activity (EC No 765/2008 Chapter 1, Article 2, paragraph 10).

Note: Accreditation consists of a declaration of adequacy (adequacy audit and therefore not compliance and conformity audit) of the organization and of the procedures adopted by CAB in providing a competent, coherent and impartial service, as it results from full compliance with the reference rules/regulations.

National Accreditation Body: the sole body in a Member State that performs accreditation with authority derived from the State (EC No 765/2008 Chapter 1, Article 2, paragraph 11).

Conformity Assessment Body (CAB): a body that performs conformity assessment activities, including calibration, testing, certification, and inspections (EC No. 765/2008 Chapter 1, Article 2, paragraph 13). For the purposes of this Regulation CAB is a Biobank.

Biobank (BBK): legal entity or part of a legal entity that performs *biobanking* (UNI EN ISO 20387 *§*3.5).

Biobanking: process of acquisitioning and storing, together with some or all of the activities related to collection, preparation, preservation, testing, analysing and distributing defined biological material as well as related information and data (UNI EN ISO 20387 *§*3.6).

Biological material: any substance derived or part obtained from an organic entity such as a human, animal, plant, microorganism(s) or multicellular organism(s) that is(are) neither animal nor plant (e.g. brown seaweed, fungi) (UNI EN ISO 20387 §3.7).

Acquisition: act of obtaining possession and/or custody of biological material and/or associated data (UNI EN ISO 20387 *§*3.2).

Storage: maintenance of biological material under specified conditions for future use (UNI EN ISO 20387 *§*3.47).

Preparation: activities, taking place in a laboratory after acquisitioning, to make biological material ready for further use in the life cycle, storage or distribution (UNI EN ISO 20387 *§*3.37).

Preservation: act to prevent or retard biological or physical deterioration of biological material (UNI EN ISO 20387 *§*3.34).

Distribution: process of providing selected biological material and/or associated data to recipient(s)/user(s) (UNI EN ISO 20387 *§*3.20).

Life cycle: consecutive and interlinked processes applied to biological material and associated data from collection, if applicable, acquisition or reception to distribution, disposal or destruction (UNI EN ISO 20387 *§*3.29).

Destruction: process of eliminating biological material and/or deleting associated data, beyond any possible reconstruction (UNI EN ISO 20387 §3.18).

Disposal: act of removing a biological material and/or associated data usually for scrapping, destruction or returning to provider/donor (UNI EN ISO 20387 §3.19).

Finding: an assessment result of the formal evaluation by ACCREDIA DT and classified as Non-conformity, Concern and Comment.

Non-conformity (NC): finding indicating the presence of a deviation/shortage that:

- endangers the reliability of the results/performance/services produced by the CAB and/or;
- affects the capacity of the CAB management system to retain the established quality level of conformity assessments or indicates a failure in the functioning of the management system and/or;
- threatens the credibility of the accreditation process or the integrity/honesty of ACCREDIA and/or;
- reveals a failure to respect the applicable mandatory requirements of the scope of accreditation and/or;
- derives from the repeated failure to resolve a previously formalized CAB concern.

ACCREDIA DT will also issue an NC if it becomes aware that the CAB established in Italy does not comply with the ACCREDIA Circular issued in connection with the application of Community Regulation 765/2008, with particular reference to Art. 7 (Cross-frontier Accreditation). Please note that it is forbidden for a CAB established in Italy to request accreditation in a scheme/sector to another accreditation body, if the same accreditation can be provided by ACCREDIA and if the CAB is not already covered by ACCREDIA accreditation in that scheme/sector.

> Note 1: The NC is formulated by ACCREDIA DT Assessors through a clear identification of the finding and must indicate the evidence on which the finding is based and the reference to the specific requirement that has been violated.

Note 2: NC may result in the adoption of one of the sanctions described in paragraph 6

Concern: finding caused by a partial implementation of a requirement (normative or referred to Accreditation Regulations) but which does not affect or is likely to affect directly or immediately the quality of CAB performance and results.

Note 1: The Concern is formulated by ACCREDIA DT Assessors through a clear identification of the finding and must indicate the evidence on which the finding itself is based and the reference to the specific requirement that has been violated.

Note 2: An unclosed concern of the subsequent periodic assessment can be reclassified as Non-Conformity.

Comment: ACCREDIA DT finding raised towards the CAB not resulting from the finding of an objective failure to meet a requirement, but to prevent such a situation from occurring (as potentially feasible) and/or to provide guidance for the improvement of documents and/or operational modalities of the CAB

An immediate formal response to the findings made as comments is not required.

CAB findings management: activities that must be carried out by the CAB against the findings formalized by ACCREDIA DT.

All ACCREDIA DT findings formalized as Non-conformities/Concerns, according to the above criteria, must be appropriately reviewed by the CAB, which must transmit to ACCREDIA DT **within 10 (ten) working days** from the receipt of the confirmation letter, an adequate result plan including:

For Non-Conformity: Correction (where applicable), Root Cause Analysis, and Corrective Actions related to the identified causes, indicating the timing of implementation. Closing evidence for this type of findings should be evaluated positively by ACCREDIA DT prior to the approval (granting or extension of accreditation) of the CSA. For maintenance and renewal, the CSA may issue a positive resolution based on sufficient information showing that the response to these findings is satisfactory.

On-site assessment may be required to ensure that Corrective Actions are implemented effectively.

For Concerns: correction, Root Cause Analysis, and , when deemed necessary by the CAB in relation to the causes identified, Corrective Actions, with the timing of implementation If deemed necessary by ACCREDIA DT, evidence of Corrections and/or Corrective Actions is evaluated in ACCREDIA DT documentary form prior to the subsequent on-site assessment. Depending on the nature and number of Concerns, ACCREDIA DT can establish that even for this type of findings, the closure evidence must be positively assessed before the resolution (granting or extension) of the CSA.

For Comments: This type of finding can be managed with the opening of an Improvement Action, or it may not be implemented. In the first case, the degree of implementation of the same is verified by ACCREDIA DT during the first useful assessment while in the second case the reasons for non-implementation must be recorded.

If a CAB does not transmit to ACCREDIA DT the finding management plan or documentary evidence required, within the terms applicable to the various cases, the ACCREDIA DT Department may send the documentation to the relevant CSA, for the adoption of sanctions (see §6).

ACCREDIA DT findings formalized at the end of the audits can be reclassified by ACCREDIA DT's Technical Officer/Director following a review of the results.

Risk: effect on an activity that may derive from certain processes/activities carried out by the CAB, including the work of its internal staff and collaborator.

It is recommended that the CAB identify risk indicators proportional to the expected effect and the probability of occurrence of a given situation.

Impartiality: presence of objectivity.

Types of conflicts of interest are covered in the Technical Regulation RT-38.

Accreditation Scheme: a set of ACCREDIA DT rules, defined procedures and activities for granting, extending and maintaining accreditations in accordance with different standards (es. ISO/IEC 17025, ISO 17034, UNI EN ISO 20387).

Scope of accreditation: specific conformity assessment activities for which accreditation is required or has been granted.

Accreditation Table: describes the scope of accreditation through the description of the following fields:

- area;
- sector;
- biological material;
- associated data;
- storing conditions;
- activities;
- processes/procedures;
- locations.

Sector: identifies within a certain area (biological material of human origin, biological material of plant origin, biological material of animal origin, biological material from microorganisms) a set of biological materials that specify the scope of competence of the biobank.

Biological material report: document issued by the BBK based on the requirements of §7.12 of UNI EN ISO 20387.

Assessment: a process undertaken by ACCREDIA DT to assess the competence of a CAB, based on one or more standards and/or other regulatory documents, for a definite scope of accreditation.

Assessment Programme: a set of evaluations consistent with a specific accreditation scheme that ACCREDIA DT performs towards a CAB during the accreditation cycle, which ACCREDIA DT has set in 4 years.

Assessment techniques: methods used by ACCREDIA DT to perform assessments.

NOTE: the assessment techniques for this Regulation may include, but are not limited to:

- on-site assessment;
- off-site assessment;
- document review;
- assessment without notice;
- interviews.

On-site assessment: visits by ACCREDIA DT (initial, supplementary, programmed or non-programmed surveillance, extension, renewal) instrumental to the process of granting, maintaining, extending and renewing accreditation.

Off-site assessment: remote assessment of a physical or virtual site of a CAB, using electronic means.

Note: A virtual site is an *online* environment that allows people to run processes, for example in a *cloud* environment.

Assessments without notice: audits performed by ACCREDIA DT without notice to the CAB at its main office or, where applicable, at its branch offices.

Interview: assessment technique through which the ACCREDIA DT Assessment Team during on-site/off-site assessments interfaces with the CAB functions involved, in order to assess the degree of knowledge and effectiveness of the same.

Accreditation cycle: validity period of accreditation, which begins after the date of the decision to grant the initial accreditation or renewal of accreditation. ACCREDIA DT has set the duration of the cycle to 4 years.

Accreditation granting decision: decision to grant, maintain, extend, reduce, suspend or withdraw accreditation.

Granting of accreditation: release of accreditation for a specific scope of accreditation**.**

Maintenance of accreditation: confirmation of the continuation of accreditation for a defined scope**.**

Extension of accreditation: add conformity assessment activities to the scope of accreditation**.**

Reassessment: assessment carried out to renew the accreditation cycle. For the purposes of this regulation, the reassessment is indicated as a renewal.

Assessment plan: description of activities and organization of an assessment

Accreditation Reduction: a sanction that provides for the elimination of a part of the scope of accreditation of a CAB within a certain scheme.

Suspension of accreditation: a sanction of partial suspension of the scope of accreditation of a CAB under a given scheme, or total suspension of the accreditation of a CAB for an entire accreditation scheme for a specified period.

Withdrawal of Accreditation: cancelling of a CAB entire Accreditation Scheme.

Renunciation of accreditation: a request for renunciation of accreditation submitted by the CAB for any reason (e.g. non-acceptance of changes in the price list, non-acceptance of changes in the regulations governing the accreditation activity, etc.)

Transfer of accreditation: a procedure for transferring accreditation to a CAB, by means of Verification, by an Accreditation Body signatory to the EA MLA or ILAC MRA agreements, to ACCREDIA DT. With the transfer the CAB loses the original accreditation, to begin accreditation with ACCREDIA DT.

Transfer of ownership of the accreditation: Procedure for transferring the accreditation to a CAB, by means of verifications, to another legal entity through the sale of a company or business unit, merger by incorporation or any other legal operation that involves the modification of tax code and/or VAT number.

Technical Officer: ACCREDIA DT person responsible for managing the assessment phases for accreditation, surveillance, maintenance, renewal, extension, reduction, suspension or withdrawal of accreditation, coordinating the activities of System Assessors and Technical Assessors.

Department Technical Secretariat: appointed by ACCREDIA DT to provide information to BBKs applying for accreditation, to biobanks already accredited and to their users.

System Assessor: a qualified person appointed by ACCREDIA DT, alone or as part of an assessment team, for the assessment of the compliance of a biobank Quality Management System with the applicable reference standard and ACCREDIA DT requirements.

Technical Assessor: a qualified person appointed by ACCREDIA DT for the assessment of the technical competence of a biobank in compliance with applicable standards, ACCREDIA requirements and technical standards applicable to the activities for which the BBK is accredited or has required accreditation.

Technical Expert: Qualified person appointed by ACCREDIA DT, who works under the responsibility of an assessor, to provide specific knowledge or experience regarding the assessment of specific *biobanking* activities.

Assessment Report: a document that outlines the outcomes of a BBK's competence, including the assessment of the management system, operational and technical procedures verification and accreditation table.

EVA: assessor in charge of monitoring the ACCREDIA Assessors.

It should be noted that in cases where in the documents cited above, different definitions are given for specific terms relating to biological materials, preference must be given to the definitions contained in the standard.

0.4. ACRONYMS

- **ACCREDIA DT**: ACCREDIA Department of Calibration Laboratories;
- **CSA DT**: Sector Accreditation Committee for the Calibration Laboratory Department;
- **CdA**: Committee for Accreditation Activities;
- **DDT**: Direction of Department of Calibration Laboratories;
- **RST**: Department Practices Review Technical Office;
- **FT**: Technical Officer;
- **STD**: Department Technical Secretariat;
- **CAB:** Conformity assessment Body
- **BBK**: BiobanK.

1. CRITERIA AND INFORMATION FOR ACCREDITATION

1.1. INFORMATIVE PHASE

Any BBK can send a written, verbal or computerized request to STD to know the details of accreditation.

Upon receipt of the request, STD will provide the address of the website www.accredia.it to the company, from which it can download the list of valid ACCREDIA DT documents, which includes useful documentation for accreditation.

In any case, the feasibility study of the accreditation process cannot begin until ACCREDIA DT has received the application for accreditation, compiled in all applicable parts in accordance with the requirements of the next point and complete of all the attachments required by it in the appropriate form.

Unless otherwise indicated, the references for ordinary correspondence are as follows:

- Legal Office: ACCREDIA, Via Guglielmo Saliceto, 7/9 - 00161 Roma;
- Operating headquarters: ACCREDIA Calibration Laboratories Department, Strada delle Cacce, 91 – 10135 Torino.

If you are using e-mail or fax, you are required to send all communications to the appropriate e-mail boxes or to the numbers listed on the site www.accredia.it.

When necessary, a preliminary meeting at the ACCREDIA DT headquarters can be arranged with a time commitment of no more than half a day to clarify the accreditation process to the Applicant and to the BBK concerned. These meetings, which may be joined by experts in Biobanking activities, do not imply any reciprocal commitment and should not be advisory (even involuntary).

If the applicant wishes for a preliminary on-site assessment, the latter is specified in a special technical and economic estimate and billed in man-days according to the terms of the current ACCREDIA price list. This assessment may result in the identification of deficiencies in the system or in the competence of the Applicant for accreditation, for which no ACCREDIA DT corrections or corrective actions are required. In any case, the outcomes of this evaluation will not affect the outcome and the duration of any subsequent accreditation request. Only one preliminary audit can be conducted against a single BBK.

The BBK that intends to initiate the accreditation process must complete the accreditation application (DA-00 and DA-12 which can be written in Italian or English) with all the required data and send it with the relevant documents to STD of ACCREDIA DT. The application must be signed by a representative of the BBK, duly authorized.

Accreditation may relate to the *biobanking* activity performed only in one place (main headquarters) or organised in more than one (multisite, with main headquarters and secondary units).

Any requests for accreditation for biological material sectors not included in the appendix to the DA-12, or in any case that differ from the existing ones, are reviewed by the Department Management in order to proceed to insertion of the same at the first meeting of CSA DT.

If ACCREDIA DT receives questions about foreign-based activities, the provisions of Regulation (EC) 765/2008, PG-12 *Cross-Frontier* Accreditation Policy, EA and ILAC documents apply.

Upon receipt of the application, DDT appoints the FT that will manage the process.

In addition to managing the accreditation operations and then the ordinary maintenance, the appointed FT will follow any extensions or variations in the accreditation scope. The appointed FT normally manages the BBK at least until the next renewal.

ACCREDIA DT issues accreditation to the legal entity, or a well-defined part of it, responsible for all the accredited activities of the BBK.

Accreditation as a Calibration/Test/Medical Laboratory and/or Reference Material Producer does not certify its compliance with the UNI EN ISO 20387 standard since *biobanking* includes activities that are not considered in the scope of accreditation of the previously mentioned CABs. However, accreditation as a Calibration/Test/Medical Laboratory and/or Reference Material Producer is accepted by ACCREDIA DT as evidence of technical competence of the requirements of the UNI CEI EN ISO/IEC 17025, UNI EN ISO 15189 and UNI EN ISO 17034 standards. applicable to the UNI EN ISO 20387 standard.

If there is evidence of fraudulent behaviour, or BBK deliberately provides false information or conceals the information, ACCREDIA will proceed to reject the application and reserves the right not to offer other services to the BBK (in the case of already accredited BBK, the process of withdrawal of accreditation shall be started).

Note: in the case of withdrawal due to fraudulent behaviour/false information, the BBK can no longer apply for accreditation.

1.2. QUOTATION

To get a cost quotation for accreditation costs, the BBK must submit the Accreditation Application Form (Documents DA-00, DA-12, with all attachments), properly completed and sent by e-mail to the appropriate box mail at segreteriadt@accredia.it or at the address of the above-mentioned operating office. General information can also be issued by phone.

The application must be signed by the Legal Representative of the BBK or by a duly authorized delegate. The applicant BBK must be a legal entity, that is, a natural person or legal person who assumes the obligations and rights deriving from the business and in possession of a VAT number. Public institution (e.g. REGIONS, PROVINCES, MUNICIPALITIES, PUBLIC BODIES I.N.P.S., I.N.A.I.L, UNIVERSITIES) are legal subjects too.

For foreign BBKs, legal entity definitions apply in different countries, according to local law.

Individuals may not apply for accreditation, except for individuals holding VAT number (see also CERTIF 2012-04 REV4 and subsequent revisions).

The quotations will be formulated according to the prices applied by ACCREDIA DT, contained in the TA-00 document published on the ACCREDIA website.

RST firstly assesses the completeness and correctness of the application received, and then verifies that ACCREDIA DT has enough competence and resources to carry out the required accreditation.

In case the BBK carries out activities already covered by accreditation (in particular as a Calibration, Test, or Medical Laboratory), ACCREDIA DT, considering that attestation sufficient to demonstrate compliance with the applicable requirements, takes it into account when preparing the estimate and in the organization of assessments.

If the outcome of the evaluations is positive, RST, by written notice, notifies the BBK of its acceptance of the application within **60 calendar days** from the date of the receiving protocol and prepares an estimate for the accreditation activities following the price list.

The lack of one or more of the documents required in DA-12, or the existence of macro deficiencies in the content of the documents transmitted (including the application), does not allow the initiation of the accreditation process; in such a case, RST requests in written form (by letter and/or fax) the missing documents and/or the missing information to the BBK and waits for them **for 12 months from the date of the request for integration**.

If within this period RST has not received the necessary documentation:

- if the process has not started yet, RST informs the BBK that the deadlines for initiating the procedure have expired; if the BBK wants to restart the accreditation process, it will have to submit a new formal request for accreditation;
- if the process is started (document analysis), the provisions of paragraph 3.2.1 "Closure of the Accreditation Process" apply.

In the technical cost estimate it is also notified to the BBK:

a) the name of the FT to which the BBK shall refer in its relations with ACCREDIA DT;

b) the names of Assessors whom ACCREDIA DT intends to appoint for the evaluation of the BBK and of any Experts (where very specific technical and/or statistical aspects should be analysed).

The names of the ACCREDIA DT Assessors, qualified according to the ACCREDIA DT procedures, are approved by the CdA, upon proposal of the Department's Direction.

The names of the Assessors and Technical Experts designated for assessment activities are communicated in advance to the BBK, which may refuse them by sending to ACCREDIA DT **within 5 working days** their reservations in writing, which must be motivated.

ACCREDIA DT does not provide curricula vitae of its Assessors and Technical Experts.

However, it may, upon request, provide information on the ongoing collaborations of its Assessors and Technical Experts with potentially competitive BBKs. The Assessors may be replaced with other ones of equal qualifications, upon DDT's assessment of the validity of the grounds on which the refusal is based. A refused assessor may be proposed again by ACCREDIA DT only after having ascertained that the conditions for refusal have been overcome.

BBKs may reject Assessors (or ask for them to be replaced) for the following reasons:

- deontologically incorrect behaviour (to be demonstrated to ACCREDIA DT with objective evidence of their behaviour in the field and only after the BBK has expressed reservations about the Assessor’s work));
- conflict of interest (to be communicated to ACCREDIA DT which will verify its consistency on the basis of the prior declarations provided by the Assessor); if the reasons given are considered valid, the question will be evaluated in the ACCREDIA/Assessor relationship.

Assessors employed by ACCREDIA DT cannot be rejected to the affected BBK except for serious reasons of incompatibility which must be explicitly disclosed to the Department's Director.

2. ACCREDITATION PROCESS

Once the Order/Acceptance of the estimate from the BBK is received, the process of accreditation is started in the following four phases:

a) Preliminary operations;

b) Examination of documentation;

c) On-site assessments;

d) Decision-making process.

Assessment must include all *biobanking* activities and all operational sites.

In the event that BBK outsources critical processes and suppliers are qualified through second-party audits, ACCREDIA DT will be able to attend this audit in order to assess the methods of qualification.

Accreditation can be done in conjunction with another recognized Accreditation Body in EA and ILAC. In this case, the execution of steps b) and c) can also be carried out using assessors appointed by the other Accreditation Body. A copy of relevant documentation in Italian or English must be provided officially to ACCREDIA DT by the other Accreditation Body (or provided by ACCREDIA DT to the other Accreditation Body).

During the evaluations the BBK may indicate, at its choice, any limitations of the accreditation field and formalized in DA-12.

Limitations may also be imposed by ACCREDIA DT following the outcome of the evaluations. In both cases these restrictions must be formalized. The BBK must send the DA-12 revision to FT. FT vice versa informs the BBK by means of a registered letter of the limitations to be submitted at the CSA DT decision.

2.1. PRELIMINARY OPERATIONS

2.1.1. Identification of Assessors and communication to the BBK

For each accreditation and/or renewal process, an assessment team is appointed.

The assessment team includes a System Assessor (normally responsible for co-ordinating), one or more Technical Assessors depending on the *biobanking* activities and any possible Technical Expert.

The Assessors are chosen among those included in the Assessors List. Several assessors may be assigned to different stages of the assessment process. Assessors are required to provide the Experts with all information about applicable requirements and procedures followed by ACCREDIA DT.

The names of the members of the assessment team are listed in the quotation sent by the STD to the BBK for acceptance.

2.1.2. Appointment/Acceptance of the assignment

Once the acceptance of the assessment team is obtained by the BBK, the formalization of the assignment is carried out.

Unless otherwise decided by the Department Director for technical reasons or for reasons of force majeure, the Assessors appointed will be also in charge of the subsequent BBK surveillance over the next four years (the term of the Accreditation Agreement).

It should be stressed that ACCREDIA DT Assessors and/or Technical Experts being required to sign an Agreement with ACCREDIA DT are obliged to comply with the requirements of impartiality, independence, confidentiality and declaration of no conflict of interest with the BBK in question and its potential subcontractors of critical activities.

2.2. DOCUMENT REVIEW

During the review of the documentation of the BBK, the assessment team must assess the compliance of the system as documented, with the requirements of the regulatory documents and the contractual requirements foreseen by ACCREDIA DT, contained in this Regulation and other technical applicable Regulations/Documents in order to assess whether the documentation presented is satisfactory in form and content, and if the conditions exist for carrying out the assessment visit.

Accreditation covers all Biological Materials that are part of the required accreditation scope, managed after obtaining the accreditation. However, as accreditation may include existing Biological Materials, the evaluation of the documentation also extends to the management of these, when the BBK so requests.

The above-mentioned documentary review is carried out and notified to the BBK within 90 calendar days of receiving the order/acceptance of the quotation.

Following the results of the documentary evaluation, FT proceeds as follows:

- if the outcomes are positive, the next stage of accreditation is carried out (see point 2.3);
- if the results are not positive and documentary changes are required to BKK, FT proceeds with the notification of the outcome and the consequent request for adjustment. The BBK must propose corrective actions/corrections within **10 working days** and implement them within a maximum **of 6 months** from the request for adaptation;
- if the negative outcomes persist for the third evaluation, the accreditation process is interrupted by applying the provisions of point 3.2.1 "Closure of the accreditation process";
- after the expiry of the 6-month period following the request for adjustment without the BBK having so provided, the interruption of the accreditation process shall be started, applying the provisions of section 3.2.1 "Closure of the accreditation process".

If from the review of the documentation presented - as well as of any direct contact with the requesting BBK - is clear that the BBK does not have sufficient competence and impartiality, ACCREDIA DT will interrupt the accreditation process, applying the established provisions at point 3.2.1 "Closure of the accreditation process".

2.3. NOTIFICATION AND ON-SITE ASSESSMENT PLAN

2.3.1 Preparation and notification of the plan

FT agrees with the applying BBK and with the Assessors involved, the date for on-site assessment, prepares and transmits the "Notification and On-site Assessment Plan" document to the BBK, with the purpose of formalizing the composition of the group, the goals, the field, the criteria and the significant elements of on-site assessment.

During the accreditation process, one or more on-site assessments must be carried out in order to ensure compliance with all applicable requirements for all kinds of Biological Material and for all activities.

The On-site Assessment Plan should be structured so that all aspects of the BBK activity affected by the accreditation process are adequately verified.

If the BBK subcontracts activities evaluated by ACCREDIA DT as critical and the qualification takes place through second-party audits, ACCREDIA DT reserves the right to include in the plan an assessor to attend the audit in order to evaluate how the BBK qualifies the subcontractor on site.

If the application for accreditation relates to the activity carried out in multiple locations, each of the locations must be assessed on site.

At least **10 (ten) calendar days before** the date of the on-site assessment, the BBK must send to ACCREDIA DT the MD-19 form "Information on specific risks existing in the work environment and protective measures", filled in with information on the location of the verification and any special risks existing in the workplace where the verification will be carried out.

If the MD-19 form is not received on time, ACCREDIA DT reserves the right to proceed with the on-site assessment. In this case, the Laboratory will have to deliver the appropriately completed document to the Head of the Assessment Team.

ACCREDIA DT assessors shall commit to comply with the safety conditions received.

2.3.2 Acceptance of the plan

On-site assessment can only be carried out after receipt of the BBK acceptance of the document "Notification and On-site Assessment Plan" of the notification and the programme by the BBK. Such acceptance must arrive **within 3 business days** of receiving it.

In the event that FT, after repeated attempts, failed to agree with the BBK on the dates of the On-site Assessment, it will also send the plan of visit at least **10 working days** in advance.

This operation can be repeated at most two more times.

If the BBK does not declare its willingness:

- In the case of **accreditation**, the provisions of paragraph 3.2.1 "Closure of the Accreditation Process" shall apply";
- In the case of **accreditation already in effect**, the provisions of paragraph 6.1.3 "Suspension decided by ACCREDIA DT" shall apply".

2.4. ON-SITE ASSESSMENT

2.4.1 General

On-site Assessment aims at verifying the implementation of the quality management system and examining the technical aspects of *biobanking* activities, such as those relating to staff competence, the suitability of resources and premises, the suitability of critical processes and storage, transportation and distribution of biological material and associated data. The on-site assessment also extends to the effective implementation of biosafety and bio protection requirements.

In particular cases (e.g. in cases of accreditation, renewal and non-programmed surveillance as well as those BBKs that have a large number of categories of biological material) FT, in agreement with DDT, evaluates, on the results of the previous assessments, whether participation in the on-site assessment of the FT in charge is required.

The costs associated with the presence of FT on site are borne by ACCREDIA DT under a specially designed annual spending budget.

During the assessment, the presence of observers is also allowed, at the request of the BBK. The BBK must give prior notice of this request to ACCREDIA DT upon acceptance of the plan (§ 2.3.2).

If DDT needs observers to join the assessment (e.g. Trainee Assessors, EA peer assessor ...), it will give prior notice to the BBK providing, if necessary, confidentiality commitment of the Observer However, if the BBK wishes to have reservations on the names of the Observers, it must give reasons in writing to ACCREDIA DT within **5 working days**, after which the names will be deemed accepted. The costs for these observers are borne by ACCREDIA DT.

In no case should the observers interfere with on-site assessment. If this is to happen, the Assessors will be responsible for coordinating the request for immediate removal of the observer.

ACCREDIA DT can perform remote checks, possibly using the Information Technology (IT) systems of the BBK.

When present, the tasks assigned to the FT are as follows:

- collaborate with Assessors to ensure that the assessment is carried out in accordance with UNI CEI EN ISO/IEC 17011 standard and applicable ACCREDIA DT documents;
- provide assessors and/or BBKs with any clarification regarding the requirements of UNI EN ISO 20387, and, where applicable, UNI EN CEI ISO/IEC 17025, UNI EN ISO 15189, UNI CEI EN ISO 17034, ACCREDIA DT documents.

The On-site Assessment, carried out by appointed Assessors following the methods of UNI EN ISO 19011 standard, implies the following phases:

- preliminary meeting of the assessors in order to define and agree on the latest operational details for the on-site assessment;
- initial meeting with the presence of the Director, Technical Director, Personnel responsible for the Management System, and their collaborators;
- carrying out of on-site assessment, with support from the BBK staff;
- intermediate meetings of the assessors, if deemed necessary by the Lead Assessor;

- meeting preliminary to the final meeting, in which the assessors define on-site assessment results;
- final meeting, with the staff of the BBK and taking note of any reservations.

The BBK must make available a reserved room to the assessment team, preferably with computer and internet connection, for the preliminary, intermediate and final internal meetings of the Assessors.

The BBK should also allow assessors to access their premises and archives and, if necessary, their subcontractors', for the purpose of on-site assessment. If the critical activities sub-contractor's auditory presence is expected, the BBK will have to arrange the logistics in advance, agreeing the dates and obtaining authorization for the presence of the Assessors.

2.4.2 Preliminary meeting to open on-site assessment

Prior to the initial meeting with the BBK, a meeting of the assessment team is held to discuss how to evaluate and distribute the tasks.

2.4.3 Initial meeting with the BBK

During the initial meeting between the assessment team and the representatives of the BBK agreed in the Notification and On-site Assessment Plan, the Lead Assessor:

a) introduces the assessment team with its tasks;

b) clarifies the roles and responsibilities of possible assessors ACCREDIA DT (EVA), FT, guides (i.e. those responsible for the BBK to accompany the Assessors), training assessors and observers;

c) explains the purposes of On-site Assessment, which shall be carried out in compliance with the safety conditions;

d) outlines the on-site assessment plan, clarify any points not included, and agree on any changes to it;

e) expose any subdivisions of the group into subgroups and identify the verification phases to be assigned to the subgroups, in order to optimize the timing of the on-site assessment;

f) agrees on the timing and modalities for the assessment of any off-site tasks;

g) agrees on possible variations in the On-site Assessment Plan;

h) illustrates the assessment process and the possibility of the BBK to make reservations;

i) reminds the commitment of each member of the group to the confidentiality of the information;

j) makes known that confidential meetings of assessors may be needed during the assessment i;

k) requests confirmation of the presence of the Director of the BBK or of a Representative at least at the final meeting and to complete and sign the list of persons taking part in on-site assessment;

l) offers the BBK the opportunity to ask for further clarification;

m) formalize the security requirements as required in the Notification Document and On-site Assessment Plan, verifying the existence of the safety conditions previously communicated through the MD-19 document.

This meeting is to be foreseen both in the case of an on-site assessment and in the case of a remote check.

2.4.4 Carrying out On-site assessment

2.4.4.1 General

Assessment activities are carried out using the ACCREDIA DT checklist, which includes a list of questions aimed at verifying the compliance of the BBK with the provisions of the standards and ACCREDIA DT requirements.

The BBK can view, on the website www.accredia.it the checklists used by the Assessors as a guide to the on-site assessment.

On-site assessment tasks are of two types:

- "horizontal" assessment, mainly focused on one or more points of the standard and their implementation;
- "vertical" assessment, consisting in assessing the implementation of standard requirements in an area of activity.

It is reminded that the purpose of on-site assessments for accreditation is to verify the compliance of the BBK Materials Producer with the requirements of the reference standards, EA, ILAC, ACCREDIA DT application documents, for the attestation of technical competence of the BBK for the execution of the activities indicated in the scope of accreditation. Binding rules, such as security, privacy, administrative responsibility, etc. do not fall within the requirements for accreditation and are not subject to verification, unless expressly stated in the reference standard. The behaviour that ACCREDIA DT Assessors have to keep against potentially violating binding requirements is reported in paragraph 2.4.4.4.

Assessment of the management system will be extended to all applicable requirements, in accreditation and renewal on-site assessment. In surveillance and renewal, the implementation and effectiveness of corrective actions opened following the previous assessment is always checked.

The extension of the assessment to the BBK must also cover the second part audit to the subcontractor of critical activities in the applicable cases.

In carrying out audits, ACCREDIA DT Assessors will have to abstain from requesting BBK copies of the documentation examined, unless it is necessary to demonstrate the objective evidence of non-compliance or any BBK reservations. In this case, the copies must be enclosed to the checklist and sent to the reference FT. No BBK's document may be retained by the Assessors in any way, except copies of Biological Material Report and associated data sampled in archive and/or other documents relating to the assessments taken during the audit that are to be attached to the checklist.

2.4.4.2 Tasks of the System Assessor

The System Assessor must verify the compliance of the BBK management system with the requirements of Reference standard UNI EN ISO 20387, of ILAC and/or Other reference standards ACCREDIA DT prescriptions.

In addition, the System Assessor performs the following tasks:

- organizes and coordinates tasks during on-site assessment, if she/he is the Lead Assessor;
- assesses the managing competence of the BBK key staff discussing aspects related to the management procedures;
- verifies the management aspects related to the collection/obtaining and/or acquisition and reception, labelling, acceptance/registration, cataloguing/classification, preservation, conservation, data management, destruction, packaging, distribution and transport of biological material and the data associated with it , with particular attention to the BBK's compliance with biosafety and bio protection requirements.
- replaces and/or cooperates with the Technical Assessor in the assessment of those general technical requirements such as those relating to environmental conditions, production process, equipment management and staff;
- evaluates the compliance of the use of references to accreditation and the use of the ACCREDIA accreditation mark, with respect to the provisions of these Regulations and the Regulations for the use of the ACCREDIA RG-09 mark.

2.4.4.3 Tasks of the Technical Assessor

The Technical Assessor must verify the technical competence of the BBK in compliance to the requirements of the UNI EN ISO 20387 standard, and the other standards recalled by it, of EA, ILAC and/or other reference standards, ACCREDIA DT specific requirements and technical provisions related to biological material and relevant associated data.

The key tasks that the Technical Assessor must evaluate are the following:

- technical aspects related to the collection/obtaining and/or acquisition: taxonomic classifications of biological materials, any sampling techniques, acceptance of biological materials at the time of obtaining/acquisition and subsequent authentication;
- verification of the validity and appropriateness of pre-analytical and analytical techniques and methods;
- verification of labeling;
- transport and distribution of materials during all phases of the life cycle: this includes transfers both within the premises of the BBK and between locations where different phases are carried out.
- preparation of biological materials: e.g. extraction, duplication, generation;
- preservation and conservation of biological materials;
- laboratory methods when carried out by BBK itself, or qualifications of external suppliers of critical activities;

- any second party audits performed on external suppliers of critical activities;
- management of equipment, procedures and premises;
- issue of reports on biological materials and associated data issued by the biobank including the assessment of the suitability for the intended purpose of the materials themselves.

The Technical Assessor also:

- if Lead Assessor, organizes and coordinates tasks during On-site Assessment;
- verifies the state and adequacy of the structural requirements (structures, dedicated areas, environmental conditions, equipment and facilities) in which the *biobanking* activities are carried out.
- assesses the technical competence of the staff of the BBK by evaluating how they implement the technical procedures by observing experimental activity;
- collaborates with the System Assessor.

2.4.4.4 Formulation of findings

At the end of each significant phase of the On-site Assessment, the Assessor will briefly present the outcome of the assessment to the interviewee, by verbally communicating the deficiencies found. The findings will then be reviewed by the assessment team and then classified as Non-Conformities, Concerns or Comments as per section 0.4 "Terms and Definitions" of this Regulation.

The following is the behaviour that the Assessors must keep against potentially violated binding requirements:

- any violations found by the Assessors on binding requirements not covered by the audit are not to be included in the assessment report;
- any violations encountered by the Assessors on binding requirements linked to the purpose of the audit should be reported as comments to prompt the affected BBK to monitor these aspects during subsequent audits;
- any violations encountered by the Assessors on binding requirements for audit purposes must be reported as NC.

2.4.4.5 Interruption of the On-Site assessment

If during the on-site assessment, serious BBK deficiencies from the requirements of the ACCREDIA DT standard or documents arise, the Lead Assessor, after speaking to FT and/or DDT, may propose the interruption of the assessment to the Director of the BBK.

In case of acceptance by the BBK, the Assessors will carry out the scheduled meetings formalizing the findings so far emerged and registering in the ACCREDIA DT checklist that the evaluation was interrupted with the relevant motivations.

If, on the other hand, the Direction or the BBK appointed staff express their willingness to continue the assessment, the assessors will record that declaration on the ACCREDIA DT checklist and continue the activities planned.

The Lead Assessor is responsible for describing in detail both situations in the on-site assessment report.

If the assessment is interrupted, by agreeing with the Direction or the BBK appointed staff that the conditions for coordinated work are not met, the activity will be invoiced according to the terms of the current price list (p. 7 "Specific cases" of the TA-00 document in force).

2.4.4.6 Final meeting and taking note of reservations

At the final meeting between the assessment team and the BBK's representatives agreed in the document of Notification and On-site assessment Plan, the Lead Assessor must:

- present a summary of the activities carried out;
- submit the opinion on the BBK formulated by the assessment team;
- remind that on-site assessment outcomes are the result of sampling, and therefore other criticalities, in addition to those found, may be present and be identified in subsequent on-site assessments of both ACCREDIA DT and internal audits;
- present any findings, illustrating their content and motivation by seeking the understanding and sharing of the findings by the BBK, specifying that the corrective action part proposed by the BBK must be completed only after the request for Corrective actions by ACCREDIA DT.
- collect any reservations submitted by the BBK; alternatively, the BBK may make reservations by completing its form (MD-09-07-DT) within **3 working days**; the acceptance of the reservations made by the BBK is subject to the Director of the Department.
- request the BBK to sign for acceptance the Report containing the findings and the Feedback Section of on-site assessment; this report is also signed by the members of the assessment team, each for their own expertise/finding.
- issue a copy of the Report to the BBK, containing both the list of findings and the Feedback Section, specifying that ACCREDIA DT reserves the right to confirm or not the contents.

3. DECISION MAKING AND GRANTING OF ACCREDITATION

3.1. ACTIONS FOLLOWING THE ON-SITE ASSESSMENT

3.1.1 Request of findings management plan and its evaluation

Following the on-site assessment, FT and/or DDT, after reviewing the findings formulated by the Assessors and reserving to modify them and/or classify them differently, officially transmits the final version of the findings to the BBK with its request for corrective actions, to be completed according to applicable operating instructions.

The BBK must notify FT **within 10 working days** of the submission of the request for its findings management plan and implementation times. The times for **corrections and corrective actions** may not exceed **3 months** from the date of submission of the findings by FT, unless justified and approved by DDT, which may authorize dispensations, however not exceeding **6 months**. All evidence must be transmitted at the same time by the established date.

If FT, evaluated the opinion of the Assessors, does not consider the plan notified by the BBK (as content and/or implementation/closing timing) to be acceptable, may ask for **a new proposal within 15 working days** of the plan assessment.

If the second proposal of the findings management plan and/or documentary evidence is not suitable or the timing was not respected, ACCREDIA DT **may perform the closure of the accreditation process as described in point 3.2.1.**

If the BBK, for internal reasons, intends to modify the ACCREDIA DT approved findings management plan, it must promptly notify ACCREDIA DT for approval of the new revised plan.

In the case of Non-Conformity or a significant number of Concerns, a supplementary on-site assessment may be carried out to verify the effective closure of the relative correction/corrective actions. In this case, the provisions of paragraph 4.1.2.1 "Supplementary surveillance on-site assessment" apply.

The findings management plan must be approved by ACCREDIA DT prior to the meeting of the Sectorial Accreditation Committee (CSA DT).

In the case of accreditation, the corrective actions and evidence required for Non-conformity will have to be evaluated positively before the CSA DT meeting.

3.1.2 Assessment of results

Upon completion of the above assessments and with the result, the FT collects all documentation relating to the process; in particular the results of the document review, the results of the on-site assessment, and provides:

- the accreditation table;
- the feedback summary of the process and list of findings by ACCREDIA DT including details of their management;
- the assessment report.

DDT carries out conformity checks on the implemented process with applicable requirements and decides if additional integrations and/or revisions are required (see point 4.1.2.1) before being submitted to the CSA DT.

3.2. CSA DT DECISION ON ACCREDITATION

The CSA DT evaluates the competence of the BBK and decides on accreditation. In the case of granting of accreditation, CSA DT also decides on the timing of the scheduled surveillance. If the BBK has registered a significant number of non-conformities, the CSA DT may decide to increase the surveillances, motivating this need.

SDT, within 5 working days of the resolution, submits the results to the BBK, including Assessment Report and the attachment to the Biological Material Report (Accreditation Table).

The name of the accredited BBK is published on the ACCREDIA website. The granting of accreditation is formalized through a special agreement signed between ACCREDIA and the BBK. Accreditation begins on the date of CSA resolution, but performs its legal effects by the BBK signing the agreement with ACCREDIA (CO-00).

The BBK is required to return the signed Accreditation Agreement within **30 days of transmission**. Otherwise the CSA may apply one of the sanctions provided for in paragraph 6 below.

The accreditation certificate cannot be transferred to third parties.

The signing of the agreement and the registration in the list of accredited BBKs commit the BBK to maintain its organizational structure and operation in accordance with the requirements set out in this Regulation, in all other applicable ACCREDIA documents, applicable standards and general and sectorial normative references.

As regards the use of references to accreditation and, in particular, the use of the ACCREDIA accreditation mark and/or the reference to accreditation, the BBK is required to comply with the provisions of this Regulation and the Regulations for the use of the ACCREDIA RG-09 mark.

The accreditation and the relevant agreement are valid for four years.

If the CSA DT decides not to release the accreditation and considers necessary to have further assessments, DDT shall notify the applicant BBK, within five days of the date of the resolution, the reasons for it and any conditions for continuing the process. In case the BBK decides to continue, ACCREDIA DT prepares a new assessment activity programme and issues the relevant quotation (see point 4.1.2.1).

If the CSA DT decides not to grant accreditation, the provisions of paragraph 3.2.1 "Closure of the Accreditation Process" apply.

3.2.1 Closure of the accreditation process

If one of the conditions set forth in this Regulation to close the accreditation process appears, ACCREDIA-DT submits the file to CSA DT for the adoption of the sanction giving reasons for the closure proposal. Within **15 days** of the date of the CSA DT's decision, DDT will notify the BBK of the closure of the accreditation process by registered letter with return receipt or certified electronic mail (PEC).

ACCREDIA's administration prepares the issue of the related invoice for the services already given.

In case the BBK wishes to initiate a new accreditation process, it will have to submit a new application (DA-00 and DA-12). ACCREDIA DT will operate in full compliance with p. 2 "Accreditation Process".

4. SURVEILLANCE AND RENEWAL OF ACCREDITATION

4.1. SURVEILLANCE

During the period of validity of the accreditation, ACCREDIA DT is required to implement a verification programme to assess, during the accreditation cycle, the scope and the premises of the accredited laboratories, in compliance with the requirements imposed by the regulations (ISO/IEC standards and EA/ILAC documents).

Therefore, all accredited BBKs must be subjected to surveillance activities both by means of programmed checks and by means of non-programmed checks, in order to ascertain the continuous compliance with the provisions of these Regulations, international standards and guidelines and any other applicable regulatory reference.

For the purposes of these checks, all the BBK sites must be accessible to the ACCREDIA DT assessment teams.

As far as on-site surveillance activities are concerned, they are described in a quotation prepared by FT, approved by DDT and transmitted by STD to the BBK at least one month before the period set by the CSA DT.

4.1.1 Programmed surveillance on-site assessment

The surveillance activity is usually carried out in the period between accreditation and renewal of accreditation or between two successive renewals and includes:

- surveillance on-site assessment ;
- maintenance activity.

The first scheduled surveillance visit is carried out **6 months** from the date of granting the first accreditation (date of the resolution of the CSA DT) and the subsequent surveillance visits are carried out **every 12 months**, unless otherwise decided by the CSA DT due to the results of the assessment of accreditation, surveillance or renewal.

In order to determine the man-days of surveillance assessment, ACCREDIA DT conducts periodic risk analysis, based on general indications defined in collaboration with the ACCREDIA Steering and Guarantee Committee which approved them and which include factors such as: the outcomes of previous assessments, outcomes of the internal corrective actions taken by the BBK against internal NC of a technical nature, possible sanctions, the results of the audits of external suppliers of critical activities carried out by BBK, the management of complaints/observations, the management of critical accreditations, the number of biological material reports and associated data issued, etc.

The parameters indicated in general by the CIG are made public in the reserved area of the CABs on the ACCREDIA website.

Any lightening of the surveillance programme can be applied by ACCREDIA DT depending on the experience and capacity of the BBK.

In general, within the period of validity of the accreditation, the management of each biological material and associated activities must be assessed at least once, as well as any aspect of the management system. Furthermore, during each surveillance, the set of verifications on activities related to the type of biological material and sampled locations must nevertheless allow the assessment of a representative set of the scope of accreditation.

Specifically, during a surveillance assessment, the implementation and effectiveness of corrective actions opened as a result of the previous assessment are always verified.

Surveillance on-site assessment planning and carrying out is performed in the same way as those for accreditation assessment. In the event of an interruption of the assessment (see 2.4.4.5 "Interruption of On-site Assessment") ACCREDIA DT will present the file to CSA DT for the adoption of any sanctions referred to in paragraph 6 "Suspension, reduction, withdrawal and renunciation of accreditation".

If FT, evaluating the opinion expressed by the Assessors, does not consider the plan communicated by the BBK acceptable (as contents and/or timing of implementation/closure), may ask for a **new proposal within 15 working days** of the plan's assessment.

If the second proposal of the findings management plan and/or document review are not suitable, ACCREDIA DT may directly submit the case to the CSA DT to take sanctions such as suspension, reduction or withdrawal of the accreditation, applying the provisions of section 6 "Suspension, reduction, withdrawal, renunciation of accreditation".

4.1.2. NON PROGRAMMED SURVEILLANCE ON-SITE ASSESSMENT

4.1.2.1. Supplementary surveillance on-site assessment

The BBK is required to inform the concerned FT on any changes that have occurred since it has previously been communicated by the Accreditation Application (e.g. change of key figures in the organization, change of name, change of location).

In case of significant changes, the provisions of section 6.1 "Suspension" of this Regulation apply.

Based on these communications and/or following the identification of inadequacies by ACCREDIA DT, during programmed assessments or by DDT and/or CSA DT indications, the surveillance activity referred to above may be intensified, after granting accreditation/extension/renewal. In the latter case, the purpose of the assessment is to verify the closure of the findings that rose in the previous assessment, i.e. to verify on site the correct implementation of Corrections and/or Corrective Actions communicated by the BBK.

The BBK is informed promptly and must accept the technical quotation **within 10 working days**; within this timeframe, the BBK may, where appropriate, exercise the right to refuse the members of the assessment team based on the provisions of paragraph 1.2 "Quotation".

If this quotation is not accepted:

- in the case of accreditation, the provisions of section 3.2.1 "Closure of the Accreditation Process" shall apply;
- in the case of maintaining accreditation, the provisions of section 6.1.3 "Suspension decided by ACCREDIA DT" shall apply.

In the event of a negative outcome of the supplementary on-site assessment, the CSA may apply the following measures:

- if the assessment was determined by numerous and serious Non-conformities affecting the competence of the BBK it may decide to withdraw the accreditation as set out in Section 6.3 "Withdrawal of Accreditation";
- if the assessment has been deliberated for specific biological materials or *biobanking* activities, it may decide to grant maintenance/renewal of the accreditation, excluding such categories, as set out in section 6.2 "Reduction of Accreditation".

If the BBK wishes to initiate a new accreditation process, it will have to submit a new Accreditation Application and make all payments as per the ACCREDIA price list (TA-00).

4.1.2.2. Extraordinary surveillance on-site assessment

An extraordinary on-site assessment is imposed on BBK by ACCREDIA DT in the event of customer and/or user complaints or objectively motivated reports received by ACCREDIA DT questioning the compliance of the BBK competence.

The BBK is informed promptly and must accept the technical quotation within **10 working days**; within this timeframe, the BBK may, where appropriate, exercise the right to refuse the members of the assessment team on the basis of the provisions of paragraph 1.2 "Quotation". If this quotation is not accepted, the provisions of paragraph 6.1.3 "Suspension decided by ACCREDIA DT" shall apply".

The costs of such assessments are charged to the BBK only if non-conformities are detected or a large number of concerns are found. Otherwise, ACCREDIA DT will bear the costs.

4.1.3. Maintenance

The maintenance activity includes:

a) assistance for the operation of the BBK
b) the reporting and/or forwarding of ACCREDIA, EA, ILAC or other relevant documentation for the BBK activity;
c) reviewing the updated management system documentation;
d) checking of the first Biological Material Report issued in the case of first accreditation.

The costs of these activities are normally included in the annual maintenance fee that the BBK is required to pay.

Any updates to the technical documentation that also need to be assessed by the Technical Assessors and/or Technical Experts are not covered by the maintenance activities and are subject to a specific quotation. The assessments are carried out in accordance with the provisions of point 2.2 "Document Review".

Particularly in relation to points:

c) The documentation that the BBK may consider convenient or necessary to update, for various reasons, such as the quality manual and/or technical procedures must be sent to ACCREDIA DT within the first programmed on-site assessment.

d) In the case of first accreditation the BBK shall send to the reference FT the first 10 Reports of Biological Material and the related technical records that will be examined during the first surveillance on-site assessment.

4.1.4. Decision-making and maintenance granting

Following the results of surveillance and maintenance assessments (reports by ACCREDIA DT Assessors), as well as subsequent assessments conducted by FT, ACCREDIA proceeds as follows:

- In the absence of Non-Conformity: FT confirms the accreditation maintenance, by simple records of confirmation of results, with related processing requests and corrective actions for any concerns;
- In the case of one or more Non-Conformities, DDT determines whether to confirm the accreditation maintenance or whether to submit the case to the CSA DT with supplementary on-site assessment proposal in order to verify the closure of the emerged findings;
- In the case that a situation of non-conformity is particularly critical, in terms of the number and severity of the violation, of missing, obscure, improper or dubious corrective actions, the procedure is directly submitted to CSA DT for sanctions such as suspension, reduction or withdrawal of accreditation, applying the provisions of paragraph 6 "Suspension, reduction, withdrawal, renunciation of accreditation".

4.1.5. Variation of accreditation field

During the validity of the accreditation, the BBK may request a variation, of the procedures linked to activities already present in the table.

If the BBK intends to make a variation of the accreditation, it will give written notice to ACCREDIA DT by submitting the completed DA-12 with the relevant attachments.

Upon receipt of the documentation, ACCREDIA DT shall apply as per section 2.1 "Preliminary operations" and p. 2.2 "Document Review".

Following the successful outcome of the assessments, the BBK accreditation field will be updated in the applicable cases.

4.2. RENEWAL OF ACCREDITATION

If the BBK intends to renew the accreditation, at least **6 months** before the expiration of the accreditation, it must send the Application for Renewal (DA-00 and DA-12, accompanied by documentation therein) to the reference FT, in order to arrange the assessments at least **4 months** before the expiration of the Certificate.

If the application is not received within scheduled time, ACCREDIA DT will not be able to guarantee the continuity of the accreditation itself.

It is allowed, in the case where the BBK, in the past solar year, has obtained extensions, not to assess the extended biological material types/activities; however, such assessments are to be carried out at the first programmed surveillance.

Upon receipt of the application, RST, **within 30 calendar days,** evaluates whether the documentation submitted by the BBK is complete and compliant with the requests:

- if this assessment is positive, RST formalizes its acceptance and prepares the economic technical quotation for renewal activities;
- if this assessment is negative, RST accepts with reservation the renewal application and requires in writing the documentation integration. Integrations must arrive **within 1 month**; otherwise, the withdrawal procedure shall be applied, as specified in Section 6.3 "Withdrawal of Accreditation ". If the integrations are adequate, then the application is accepted, and the economic technical quotation is set by the FT.

The renewal process is initiated by the same methods as for accreditation, referred to in paragraph 2 "Accreditation Process", with the exception of the following. For the assessment of BBKs, ACCREDIA DT normally appoints Assessors other than those responsible for the previous accreditation.

If the application for renewal, complete with all the annexes provided, does not arrive at the due time and/or the BBK is not made available for on-site assessment of renewal before the accreditation expires, ACCREDIA DT will initiate the Accreditation renewal process, however, the existing accreditation will cease its validity on expiration. Following the renewal resolution issued by CSA DT, a new accreditation number will be assigned to the BBK.

If the application for renewal, complete with all the annexes provided, reaches in time to allow on-site assessment before the expiry of the accreditation, the validity of the accreditation may be

extended by the CSA DT. This prolongation process may be repeated, provided that the 5-year validity limit for the accreditation certificate is not exceeded.

4.2.1. Document review

During the review of the documentation of the BBK, the assessment team shall assess the conformity of the system as documented, with the requirements of the regulatory documents and the contractual requirements of ACCREDIA DT in this Regulation and other applicable Technical Regulations/Documents.

Upon receipt of the documentation, complete with any records, the Assessors shall examine this, whose outcome shall be notified to the BBK within **60 calendar days** of receipt of the order/acceptance of the quotation. If the outcomes are not positive, the BBK will have to propose corrections/corrective actions within **10 working days and implement them within 30 working days**. The modified documentation must be sent to the FT and the corrections will be evaluated by the Assessors during on-site assessment.

4.2.2. Preparation and notification of the plan

In the case of multisite BBKs, it is possible, during the renewal process, not to carry out on-site assessments in all the locations where it operates, provided they have been evaluated in the previous two years.

On-site assessments of renewal, like those of surveillance, are also intended to verify the implementation and effectiveness of corrective actions/corrections related to the findings of previous assessments (e.g., documentary reviews, previous assessments).

Particular attention must then be paid to examining internal audits, reviews, complaints, biological material reports, maintenance and improvement of the management system, conformity of technical activity and the correct use of the ACCREDIA mark and/or the reference to accreditation.

4.2.3. Request of findings management plan and corresponding assessment

In case of renewal, in the presence of Non-Conformity, it is allowed to present the file to the CSA DT provided that the BBK's findings management plan submitted is evaluated positively, the evidence of treatment (Corrections) has been positively evaluated and that the Corrective Actions, if any, are fully implemented, but not later than **3 months** after the request for adjustment.

If the second proposal of the management plan and/or documentary evidence is not suitable, ACCREDIA DT **may take sanctions as described in point 6.**

4.2.4. Assessment of visit results

In the presence of findings classified as Non-Conformity and/or numerous Concerns, the CSA DT may decide on the need to carry out a supplementary on-site assessment **as per point 4.1.2.1** and/or the adoption of a sanction **referred to in section 6.**

If the BBK is not available to carry out the supplementary on-site assessment within one month from the last date of completion of the corrective actions indicated in the plan sent to ACCREDIA DT, or in the event of a negative outcome, the CSA may apply the following measures:

- if the supplementary on-site assessment has been determined by numerous and serious Non-Conformities that affect the competence of BBK, it can resolve the revocation of the accreditation, as established in point 6.3 "Revocation of accreditation";
- if the supplementary on-site assessment has been approved for specific types of biological material/*biobanking* activities, it may approve the granting of the renewal of accreditation, excluding these sectors, as established in point 6.2 "Reduction of accreditation".

If BBK wants to start a new accreditation procedure, it will have to submit a new Accreditation Application and make all payments as per ACCREDIA tariff (TA-00).

4.2.5. Interruption of on-site assessment

In case of interruption of on-site assessment (see point 2.5.4.5) ACCREDIA DT may proceed with the adoption of the sanctions referred to in section 6 "Suspension, reduction, withdrawal and renunciation of accreditation".

4.2.6. Resolution of the CSA DT on renewal

Operations take place in the same way as for the accreditation process, referred to in paragraph 3.2 "CSA DT Resolution on Accreditation ", with the exception of the following.

The CSA DT also decides on the timing of the programmed surveillance, considering the risks related to the CAB and the performance of the previous cycle, to plan the new cycle.

In the event of a negative decision by the CSA DT, either the reduction or withdrawal of the accreditation is carried out, applying the provisions of section 6.2 "Reduction of accreditation" or p. 6.3 "Withdrawal of accreditation".

In special circumstances and for justified reasons, the validity of the accreditation may be extended by the CSA DT beyond the expiration date. This process can be repeated, provided that the 5-year limit for accreditation or renewal is not exceeded.

5. EXTENSION OF ACCREDITATION

5.1. PROCEDURE FOR THE EXTENSION OF ACCREDITATION

The BBK may, during the validity of the accreditation, ask ACCREDIA DT to modify the scope of accreditation in order to extend on or more of the following fields:

- Area;
- Sector;
- Biological material;
- Activity;
- Procedures/processes.

In case the BBK intends to match the extension on-site assessment with the one of the first useful surveillance, it must submit the extension application at least **8 months** before the expiry of the

surveillance. In any case, joint on-site assessment will only be possible if the documentary examination is positively concluded before the expiry of the surveillance.

Any requests for extension to Category/Reference material sector not covered by ACCREDIA DT (not included in the Annex to DA-12), or in any case that differ from the existing ones, are submitted by FT to the Management in order to carry out the resources review and then proceed with the insertion of the same at the first meeting of CSA DT.

5.1.1. Carrying out the accreditation extension process

For the purpose of request for extension of accreditation, the BBK shall send to the reference FT the Extension Application (DA-12), accompanied by documentation required therein.

Within **30 calendar days** of receipt of the application, RST assesses whether the submitted documentation is complete and compliant with the requirements:

- If such an evaluation is positive, RST announces its acceptance and FT prepares the relevant technical cost estimate;
- If this evaluation is negative, RST announces the need to receive the necessary documentary integrations. These integrations must arrive within **2 months**, under penalty of closing the case as set out in 3.2.1 "Closure of the Accreditation Process". If the integrations are adequate, then the application is accepted and the economic technical quotation is prepared by FT.

In the acceptance phase of the extension application, ACCREDIA DT, for the planning of the activities, must take into account the risks related to the BBK and the performances of the BBK during the accreditation cycle.

The extension process is started with the same methods as for accreditation, referred to in section 2 "Accreditation Process", with the exception of the following.

If it is considered that the activities for which the extension is requested are similar to those already accredited, FT proposes to DDT, the appointment of the Technical Assessor only. In these cases, it is also possible to carry out documentary evaluations only, postponing on-site assessment at the time of the first surveillance.

5.1.2. Decision-making and granting of accreditation extension

The operations are carried out in the same way as for the accreditation process, referred to in 3.2 "CSA DT Resolution on Accreditation". As a result of granting the extension of accreditation, ACCREDIA DT will accordingly update the attachment to the accreditation certificate. The extension of accreditation does not extend the validity of accreditation.

This is part of the existing accreditation agreement, which does not have to be renewed.

6. SUSPENSION, REDUCTION, WITHDRAWAL AND RENUNCIATION OF ACCREDITATION

ACCREDIA DT may order sanctioning measures for suspension (partial or total), reduction, or revocation of accreditation, in the event that particularly serious situations emerge, both on a

technical and ethical level following the surveillance, supplementary, extraordinary, renewal visits or from other checks and assessments (e.g. from reports).

In accordance with the provisions of the statutory and regulatory norms, the aforementioned sanctions and the relative duration are adopted by resolution of the CSA DT.

CSA DT resolutions on suspension/revocation/reduction are communicated to the BBK concerned by registered letter A.R., or by PEC and subsequently published on the website DT.

The BBK shall inform the customers involved and, where appropriate, the parties concerned of the sanction against them.

6.1. SUSPENSION

The suspension of accreditation may concern all accredited *biobanking* activities (total suspension) or only part of this (partial suspension) and, in the case of multi-site BBK, may concern one or more of the accredited locations.

The suspension can be ordered by ACCREDIA DT or requested by BBK.

The partial suspension entails, for BBK, the prohibition to issue Reports of biological material under ACCREDIA accreditation, for the activities subject to suspension. The total suspension involves, for the BBK, the prohibition to declare accredited and to issue reports of biological material under accreditation ACCREDIA.

In addition, during the period of suspension, the BBK must comply with the requirements of the Regulation concerning the use of the ACCREDIA mark (RG-09).

The suspension measure is published on the ACCREDIA website.

The suspension does not change the frequency of surveillance visits. However, if the suspension of accreditation is total, on-site assessments shall not be carried out during the period of validity of the suspension, except for those aimed at verifying the overcoming of the causes of the suspension. In any case, all on-site assessments planned for the accreditation cycle shall be carried out.

If the suspension is extended **beyond the six months**, ACCREDIA DT will proceed with the reduction of the accreditation for the part of the activity concerned, or, if the accreditation has been suspended for the whole purpose, ACCREDIA DT will initiate the procedure for the withdrawal of accreditation.

The suspension does not entail the forfeiture of contractual obligations towards ACCREDIA.

6.1.1. Grounds for suspension

The reasons for the suspension proceedings are due to:

a) violation of the requirements of accreditation standards/requirements of these General Regulations, of the specific Regulations for accreditation standard (RT) and of the Accreditation Agreement;

b) failure to return the signed Accreditation Agreement for acceptance;

c) unavailability of the BBK to undergo a programmed surveillance assessment within the terms indicated by ACCREDIA DT;

d) negative outcome of on-site assessment;

e) unavailability of the BBK to undergo non-programmed assessment;

f) contractual insolvency;

g) failure to send the findings management plan or its modification, if requested by ACCREDIA DT, within the terms indicated;

h) failure to solve the findings in accordance to ACCREDIA DT procedures;

i) failure to implement corrections/corrective actions in the case of Biological material reports unduly issued (corrective action could, for example, lead to the decision of the BBK to withdraw the unduly released documentation, because outside the Accreditation of ACCREDIA, or because it does not comply with accreditation rules);

j) failure to handle complaints;

k) variations of the legal entity (e.g. change of name, transfer of ownership of the accreditation);

l) failure to communicate timely the loss of the key personnel of the BBK to ACCREDIA DT;

m) exceptional temporary lack of significant equipment for carrying out accredited *biobanking* activities;

n) temporarily unavailability of the BBK premises where applicable (e.g. in case of non-monitoring of environmental conditions);

o) transfer of BBK;

p) lack of control by BBK over suppliers of critical activities regarding the use by the latter of the accreditation or certification reference;

q) use by a supplier of critical activities of the BBK assessments as certification of their own accreditation or certification.

6.1.2. Suspension required by BBK (Self-suspension)

The BBK has the right to ask ACCREDIA DT for the partial or total suspension of the accreditation at any time. In particular, it must suspend the accredited *biobanking* activities (all or only some of them), in the case of non-compliance/ deficiencies that could call into question the validity of the results of the same or in the case of temporary unavailability or deterioration of resources (e.g. personnel, premises, equipment, etc.).

The BBK transmits the written request for self-suspension to the reference FT, specifying the reasons, indicating its alleged duration and attaching DA-00 and DA-12 if necessary.

FT submits to DDT the self-suspension request. The motivations and the duration associated with the self-suspension request are evaluated by DDT, which can modify and/or integrate the conditions and times for restoring compliance, and in any case have the necessary assessment of full conformity, at the end of the self-suspension period.

The applicant BBK shall be informed by written notice of the assessment activities for the restoration of compliance and of the maximum period allowed, which shall not exceed **12 months** within the period of validity of the certificate, upon expiry of which the CSA DT will decide the consequent actions.

The list of BBKs published on the ACCREDIA DT website is updated to signal the self-suspension of the activity.

The CSA DT is informed of the self-suspension of accreditation.

The BBK is obliged to inform the interested parties involved.

The suspension of accreditation does not result in the forfeiture of contractual obligations with regard to ACCREDIA DT.

6.1.3. Suspension decided by ACCREDIA DT

If the FT considers, as a result of assessments, that the BBK has persistently failed to meet the requirements for accreditation or to comply with the accreditation rules, it shall present the case to DDT.

DDT informs the BBK of the possible suspension to which it is heading while remaining in the non-conformity situation described above.

The BBK, informed of the possible request for suspension and the reasons justifying it, makes its possible counter-deductions in writing **within 10 working days** of the communication. The FT submits its report and observations received by the BBK to DDT, which presents the case to the CSA DT. The CSA DT discusses the suspension, evaluates the respective reasons and the correctness of the procedures followed and decides the sanction and the duration of the procedure.

The suspension measures last for a maximum of 6 months, but the duration of the measure may be longer than 6 months to allow the case to be discussed at the first meeting of the CSA DT that had adopted the sanction.

At the end of the term of the sanction established by CSA DT, the resumption of the activities is carried out as described in paragraph 6.1.4 "Cancellation of suspension".

If the BBK has not been made available to carry out the assessments within the time limits and/or if the assessments made by ACCREDIA DT have not ascertained the effective overcoming of the causes at the origin of the measure, the case will be examined by CSA DT for the adoption of further sanctions. In particular:

- the partial suspension may be transformed, with the decision of the CSA DT, in total suspension or withdrawal of the accreditation field;
- the total suspension is turned into withdrawal, always with the decision of the CSA DT.

The revocation of the partial or total suspension measures, with the consequent reinstatement of the accreditation, must be submitted to the CSA DT.

ACCREDIA DT notifies the BBK of the suspension, giving its reasons and specifying the suspension period deliberated by the CSA DT. In particular, the CSA DT decisions are communicated to the affected BBK by registered letter with return receipt, or by PEC, signed by the President of ACCREDIA.

The list of BBKs published on the ACCREDIA DT website is updated to signal the suspension of the activity.

The suspension of accreditation does not result in the renunciation of contractual obligations with respect to ACCREDIA DT.

Suspension for contractual insolvency.

The full suspension of accreditation may be made by the ACCREDIA General Director in the event that payment of the charges due to ACCREDIA DT is delayed by more than **60 days** from the date stipulated in the contractual terms (payment date indicated in invoice), despite the reminder sent by ACCREDIA DT at the expiry of the **45th day** of delay. This excludes any payment deferral agreements, which must be authorized by the ACCREDIA General Director. The revocation of this suspension order may be made ex officio upon the restoration of the contractual conditions.

6.1.4. Cancellation of suspension

When the BBK considers that the reasons for suspension or self-suspension are exceeded, it shall formally inform the reference FT of the availability of the resumption of activities and attach the necessary documentation.

Depending on the reason for suspension or self-suspension, FT performs the check of compliance resumption by one or more of the following actions:

- document review;
- on-site assessment.

Once the compliance resumption is verified, FT prepares a report on the assessment activities carried out, transmits it to DDT, and presents the case to the CSA DT, which decides whether the BBK activities maybe resumed.

In the case of self-suspension, resumption of activities is authorized by DDT, after receiving from the reference FT an assessment report on the verification activities carried out for the resumption of the BBK activities. The CSA DT is informed of the restart after a self-suspension.

The list of BBK published on the ACCREDIA DT website is updated to report the resumption of the activity.

6.2. REDUCTION OF ACCREDITATION

The BBK may, in the period of validity of the accreditation, request the reference FT to modify the scope of accreditation in order to reduce:

- Area;
- Sector;
- Biological Material;
- Activity;
- Procedures/processes.

6.2.1. Reduction requested by the BBK

For the purposes of the request for reduction of accreditation, the BBK must send the Reduction Application (DA-12) to the Reference FT with the documentation required therein.

FT examines the request and, with the possible support of Technical Assessors and/or Experts, verifies the presence of possible effects on the other *biobanking* activities. If such effects are identified, the BBK is asked to take appropriate corrective action in advance. If necessary, BBKs will be asked for extra-assessments.

FT proposes the required reduction to the CSA DT. CSA DT deliberates on this. The purpose of the accreditation is changed to take account of the reduction.

6.2.2. Reduction requested by ACCREDIA DT

If FT believes that the BBK can no longer guarantee compliance with the applicable requirements, once heard the opinion of Technical Assessors/Technical Experts, it proposes, following the authorization of DDT, a change in the scope of accreditation.

The BBK informed of the request for reduction and the reasons justifying it, will communicate in writing its possible counter-deductions within **10 working days** of the communication. FT presents the case to the CSA DT, which evaluates the respective motivations and the correctness of the procedures followed, discusses and deliberates.

The scope of accreditation is changed to take account of the reduction.

6.3. WITHDRAWAL OF ACCREDITATION

6.3.1. Grounds for withdrawal

The reasons why ACCREDIA DT may decide to withdraw the accreditation of the BBK are related to the persistence and seriousness of the failure in compliance with accreditation requirements or accreditation rules.

Some reasons that can lead to the withdrawal of the accreditation are listed:

a) the failure to resolve the causes which led to a suspension order;

b) a total self-suspension of accreditation lasting more than one year or exceeding 6 months of total suspension of accreditation;

c) non-compliance with the Accreditation Agreement;

d) objective situations which would have prevented the drafting of the Accreditation Agreement;

e) the failure to pay the sums due; if the BBK persists in its failure for the six months following the notification of the suspension measure referred to in paragraph 6.1.2;

f) the negative outcome of the supplementary on-site assessment;

g) non-positive resolution of the renewal of accreditation by the CSA DT;

h) the expiry date of the accreditation, if the BBK has not initiated the renewal of accreditation in good time;

i) evidence demonstrating that the requirements of competence, impartiality and correctness of the BBK have not been met;

j) unlawful, malicious or negligent behaviour, and misconduct in terms of professional ethics by BBK that violate the principles laid down by ethical criteria adopted at national, international level and by the code of ethics of the same;

k) evidence of fraudulent behaviour, or the BBK deliberately provides false information or conceals information;

l) use of accreditation by the BBK such as to cause serious harm and discredit to ACCREDIA and/or the accreditation and certification system;

m) the failure of BBK;

n) the termination of operations of the Body where the BBK operates, whatever the reason;

o) renunciation by BBK (see §6.4).

In the event of withdrawal due to fraudulent behaviour/false information, the CAB will no longer be able to apply for accreditation.

6.3.2. Exceeding the Suspension Time Limit

If the suspension of the accreditation is total and its duration exceeds six months, the accreditation is normally withdrawn, upon deliberation of the CSA DT. The CSA DT may decide to increase this period within the validity limits of the accreditation certificate if the BBK provides evidence of its commitment to overcome the reasons that led to the suspension and in any case not more than 12 months, except for the suspension ex officio.

If FT believes that the BBK has failed, persistently and seriously, to meet the requirements for accreditation or to comply with accreditation rules, it presents the case to DDT.

DDT will inform the BBK in writing of the possible withdrawal should it remain in the non-compliance situation described above.

The BBK will communicate its possible counter-deductions within **10 working days** of the communication, which FT will include among the documentation to be submitted to the CSA DT.

The CSA DT decides whether to proceed with the withdrawal of the accreditation and, in that case, the withdrawal measure will be carried out as described in Section 6.3.3 "Provisions of Withdrawal".

The procedure for withdrawal of accreditation involves, with immediate effect:

- eliminating the BBK from the list published on the ACCREDIA DT website;
- prohibition of issuing Reports of biological material with ACCREDIA Mark;
- the loss of the right to use the ACCREDIA Mark.

The withdrawal of accreditation does not result in the abolition of contractual obligations with ACCREDIA DT, which reserves the right to be able to initiate the procedures for the coercive collection and recovery of expenses, plus interest, in the forms provided by law.

6.3.3. Provision of withdrawal

DDT prepares the withdrawal notice, which must be signed by the President of ACCREDIA and sent to the BBK by registered letter with return receipt or certified electronic mail (PEC), and must include at least the following points:

- the declaration of withdrawal of the accreditation;
- the statement that the BBK no longer belongs to the ACCREDIA List of Biobanks;
- the prohibition to continue issuing Reports of biological material associated with ACCREDIA;
- the prohibition of any further use of the ACCREDIA Mark and the accreditation reference;
- the reasons for the sanction;
- the date of entry into force of the sanction.

The accreditation purpose, related to the BBK, published on the ACCREDIA DT website is removed.

6.4. RENUNCIATION OF ACCREDITATION

An accredited BBK may renounce to accreditation at any time and for any reason (e.g. non-acceptance of changes in the price list, non-acceptance of changes in the regulations governing the accreditation activity, etc.).

In the case where the BBK renounces indicating a future moment as the date of termination of accreditation, the following conditions apply:

- up to the moment of withdrawal, the BBK may operate as if it were normally accredited;
- ACCREDIA DT may decide whether, in addition to the normal checks already expected at that time, others should be made;
- ACCREDIA DT may ask for any further warranties to be sure that the activities, until the effective withdrawal of the accreditation, are carried out correctly (e.g., the closure of any findings left open, etc…).

The withdrawal resulting from the renunciation of accreditation is decided by the CSA DT, unless renunciation is submitted by the BBK at the expiry of the certificate, in which case DDT acknowledges the CAB decision and informs CSA DT.

The withdrawal is reported on the ACCREDIA website and on the Register of Accredited Organizations.

The renunciation of accreditation does not result in the forfeiture of contractual obligations with ACCREDIA DT, which reserves the right to apply coercive collection and recovery procedures, plus interest, in the forms provided for by applicable laws.

7. COMPLAINTS/OBSERVATIONS, RESERVATIONS AND APPEALS

7.1. COMPLAINTS AND OBSERVATIONS

ACCREDIA DT may receive complaints/observations in the manner indicated on the ACCREDIA website:

- regarding ACCREDIA DT performance;
- regarding the work of other accredited BBKs;
- regarding third party activities that are related to the activities of accredited or being accredited BBKs.

Within **30 calendar days** of the receipt of the complaint/observation, DDT, after having examined, and assessed the validity of the causes of the complaint/observation, proceeds to take charge of the complaint/observation according to the procedures in force. These procedures guarantee that the examination of the complaint/observation and its management is carried out by a person independent from the subject of the complaint.

Complaints/observations submitted anonymously will not be accepted, in order to avoid making observations for speculative purposes or to disrupt competition.

Regarding the behaviour of ACCREDIA DT Assessors (both internal and external), any claim may be filed **within 10 working days** of the on-site assessment activities.

The BBKs have the possibility to make a confidential report to the Supervisory Body of any behaviour against the Code of Ethics and Conduct by the ACCREDIA DT employees, through the Reporting section on the ACCREDIA WEB site

With the same criteria and modalities of complaints, ACCREDIA DT reports irregular or misleading third-party activities/behaviours that are not attributable to ACCREDIA DT and/or ACCREDIA DT accredited CABs but in any case, regarding accreditation.

7.2. RESERVATIONS

With reference to the findings issued by ACCREDIA DT Assessors, any reservations may be filed within **3 working days** from the on-site assessment.

DDT provides the BBK who has submitted a reservation, the outcome of the assessment made, whether or not the reservation has been accepted, with its reasons.

7.3. APPEALS

If the BBK, accredited or with ongoing accreditation, intends to request ACCREDIA DT to reconsider the measures taken towards it, it may appeal in the manner described in the ACCREDIA RG-06 document.

The management of appeals is the responsibility of the Appeals Commission and does not require any involvement by CSA DT, which is nevertheless informed of the submission and outcome of the appeals. In the existing appeal, decisions on the accreditation process of the BBK (e.g. renewals or extensions) are adopted by the Appeals Commission, which operates in place of the CSA DT.

8. OBBLIGATIONS OF CAB

For all matters not expressly provided for in this Regulation, the provisions of Article 4 of the Agreement (CO-00) shall apply.

8.1. REGISTRY CHANGES

The BBK must communicate to ACCREDIA-DT, through the appropriate form (DA-00, DA-12 and applicable attachments), any registry variation that concerns the aspects described below.

The CAB is also required to promptly inform ACCREDIA DT of all pending legal proceedings concerning the activities covered by the accreditation. The CAB is also required to promptly inform ACCREDIA DT about the administrative and judicial provisions relating to the internal and external staff of the CAB, always in relation to the activities covered by the accreditation. The CAB must not transmit judicial data to ACCREDIA DT, as required by the provisions in force regarding privacy.

Upon receipt of the documentation sent by the BBK, FT verifies that the changes made do not lead to non-compliance with the applicable requirements of impartiality and independence, as well as the impact of the variation on the management system and the technical competence of the BBK.

In the case of significant variations affecting the management system and/or technical competence of the BBK, DDT may establish the measures referred to in paragraph 6.1 and/or arrange for a non-programmed on-site assessment.

8.1.1 CHANGE OF COMPANY NAME

8.1.1.1 Without change of legal entity (without change of VAT number)

This category includes modifications that do not involve a change in the legal entity, i.e. without changing the VAT number/Tax Code (e.g. change of the name of the BBK, closure, bankruptcy, etc.).

In the case of variations of the accredited subject that do not involve changes to the tax code and/or VAT number, following the positive evaluation of the documentation presented by the BBK, ACCREDIA-DT updates the accreditation certificate, except in cases of bankruptcy, for which it is activated the provision of withdrawal of accreditation. The modifications introduced do not change the expiry date of the accreditation certificate.

8.1.1.2 With change of legal entity (with change of VAT number)

The change of the BBK's company name with a change in the VAT number leads to a change in the legal entity that holds the accreditation, therefore there is the need to transfer the accreditation to a new legal entity.

For the transfer of ownership of accreditation to a different legal entity, see the contents of § 8.2

8.1.2 CHANGES OF LOCATIONS AND/OR CONTACT NUMBERS

This type of variation includes, for example, changes in the address of the legal headquarters and/or the operating office, either for change of place, or for transfer and changes in the contact details (e.g. telephone, fax, email).

Following the positive evaluation of the documentation presented by the BBK, ACCREDIA DT, updates the BBK data in its database and on the ACCREDIA website and revises, if necessary, the accreditation certificate.

The change in the address of the operating site due to a transfer of location (moving), involves the self-suspension as described in paragraph 6.1.2 of this document. The assessment can be either

documental or on site (not programmed or coinciding with a surveillance/renewal visit) and is established by DDT considering factors such as: results of previous assessments, criticality, timing and modality of the move, type of calibration accredited, surveillance deadline. The activity will be budgeted and invoiced according to the conditions established by the current ACCREDIA tariff plan (TA-00).

8.1.3 CHANGE OF THE ORGANIZATIONAL STRUCTURE OF THE BBK

The BBK is required to communicate any substantial variation of the organization with respect to what is communicated with the application for accreditation, for example: Technical Direction/ Substitute/Personnel authorized to sign the Biological Material Reports or person who ensures contacts with ACCREDIA- DT

0.2. TRANSFER OF ACCREDITATION OWNERSHIP

The ownership of the accreditation can be transferred to a different legal entity.

Transfer of accreditation may take place through the assignment of a company or business, merger by incorporation or any other legal transaction involving the modification of a tax code and/or VAT number, after ACCREDIA DT's assessment of the maintenance of the conditions for accreditation, which can be checked through the following documentation:

- Chamber of Commerce company registration or equivalent document attesting the legal identity of the BBK;
- a copy of the notary deed from which it is possible to deduce the transfer of the resources relevant to the activities subject to accreditation to the different legal entity (e.g. premises, personnel, equipment)
- organizational structures;
- human resources (in quantitative and competence terms);
- any other applicable condition.

The evaluation will be based on the examination of the documentation sent by the BBK, unless the complexity of the case does not involve on-site assessment.

Following the communication sent by the BBK, a suspension order is activated, until the decision of the CSA DT on the transfer of accreditation.

In the event of a positive evaluation by CSA DT, ACCREDIA DT will send the new accreditation agreement and then update the accreditation certificate and the website. However, the changes introduced do not change the date of expiry of the accreditation.

In the event of a negative evaluation, ACCREDIA DT will report failure to transfer the accreditation of the BBK and will initiate the withdrawal of the accreditation itself, except where the accreditation can be confirmed by the previously titled subject.

8.2. TRANSFER OF ACCREDITATION BETWEEN ACCREDITATION BODIES

The BBK, which intends to apply to ACCREDIA DT for the transfer of accreditation from another accreditation body, signatory to the EA MLA – ILAC MRA agreements, is required to apply for

accreditation in accordance with the provisions of section 1.2., with all the documentation required therein, in addition to the latest assessment report of the ceding accreditation body and the valid Accreditation certificate. The process of transferring accreditation takes place in the same way as the accreditation process.

If the BBK intends to request ACCREDIA DT to transfer the accreditation from another accreditation body that is not a signatory to the EA MLA agreements, the accreditation requirements will apply.

With the transfer the CAB ceases to use the original accreditation and begins accreditation with ACCREDIA.

9. OBBLIGATIONS OF ACCREDIA

For all matters not expressly provided for in this Regulation, the provisions of Article 3 of the Agreement (CO-00) shall apply.

9.1. VARIATIONS OF ACCREDITATION CONDITIONS

When reviewing ACCREDIA DT documents, and unless otherwise indicated in the change statement, the BBK has a three-month (**3-month**) transition period to adapt its operating modalities to the new prescriptions, as applicable.

It is up to the BBK to decide, within **three months** or in any case within the time allowed by ACCREDIA DT, not to comply and to withdraw from accreditation. In that case, it must give written notice to ACCREDIA-DT according to the modalities set out in Convention Agreement.

9.2. MODIFICATIONS TO THE PRICE LIST

Charges for accreditation are determined by the ACCREDIA Directive Council and are listed in the ACCREDIA Price list.

In the event of a variation in rates, even if there is an estimate accepted by the BBK, the services will be invoiced at the rates in force at the time of performance. Therefore, in the event that the prices change, immediately after approval by the CSI (Interministerial Surveillance Commission), the CAB will be promptly informed (by mail or PEC) of the variations, bearing in mind that the updated price list will be published on the ACCREDIA website.

The BBK has the right to renounce to the accreditation within six months of receipt of the communication.

During the period of notice, the BBK exercising the right of renunciation shall be subject to the prices prior to the change, for the activities carried out until the moment of renunciation only.