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ENTE ITALIANO DI ACCREDITAMENTO

Calibration Laboratories Department

Regulation for the accreditation of Research and Development Biobanks

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NOTE *The present document represents the English version of the document under reference at the specified revision. In case of conflict, the Italian version will prevail. To identify the revised parts reference must be made to the Italian version only.*

PREPARATION
Management System Head Officer

APPROVAL
Directive Council

AUTHORIZATION
Director General

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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 organisations that carry out biobanking activities, i.e., that manage biological material and associated data for research and development purposes, in compliance with the requirements of the ISO 20387 standard and the relevant documents of ACCREDIA, EA (European cooperation for Accreditation), and ILAC (International Laboratory Accreditation Cooperation).

ACCREDIA ensures that such organisations possess and maintain over time the required organisational, procedural, technical, and professional requirements, in a manner that generates a high level of confidence in their activities and in the value of the conformity attestations they issue, among all relevant social and economic stakeholders – in particular, end users.

This document does not apply to organisations carrying out biobanking activities of biological material intended for the production and/or analysis of food/feed, or for 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 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 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 ISO 9001 standard.

Organisations carrying out biobanking activities accredited by ACCREDIA Calibration Laboratories (hereinafter ACCREDIA DT) operate within the framework of national regulations and are considered competent to distribute biological materials and associated data in support of both private and public research and

development activities. This objective can be achieved through the correct and effective implementation of this Regulation.

0.2. Scope and Field of Application

This Regulation applies to organisations carrying out biobanking activities of biological material obtained from multicellular organisms and microorganisms for research and development purposes, excluding biological material intended for the production and/or analysis of food/feed or for 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 application for accreditation pursuant to the 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 arrangement;
- collaborate in the subsequent activity of 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. Directive Council, 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 Directive Council 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 ACCREDIA President. The Steering and Guarantee Committee is also involved in the process for consultation.

0.3. 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 Sectoral 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 Arrangement (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 valid revision applies, which can be freely downloaded from the ACCREDIA website.

0.4. 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* (ISO 20387:2024 *§*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 (ISO 20387:2024 §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) (ISO 20387:2024 §3.7).

Finding: result of the assessment, formalised 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.

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 Nonconformity.

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.

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, ISO 20387).

Scope of accreditation or accreditation field of application: the specific conformity assessment activities for which accreditation is requested or has been granted.

Note: The scope of accreditation of BBK, namely the concise description of the activities together with the sites at which they are carried out, is set out in the Accreditation Table (a document attached to the Accreditation Certificate) through the following fields:

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

Report: a report is a communication of either internal or external origin that does not in itself constitute a complaint, but indicates an area of attention relating to potential Nonconformities involving accredited CABs and/or their clients and/or certified organisations.

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 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 assessments consistent with a specific accreditation scheme that ACCREDIA DT performs towards a CAB during the accreditation cycle, which ACCREDIA DT has set in **4 (four) years.**

Assessment plan: description of the activities and the organisation of an assessment.

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;
- remote assessment;
- document review;
- assessment without notice;
- interviews.

On-site assessments: assessments carried out in person at the Biobank's premises.

Remote assessments: assessments carried out remotely using electronic means.

Blended assessments: assessments conducted partly on-site and partly remotely.

Note: for the purposes of this regulation, unless otherwise specified, the term "visit" is used to refer to an assessment, whether on-site, remote, or blended**.**

Assessments without notice: assessments carried out by ACCREDIA DT at one or more CAB sites, without prior notification of the assessment plan.

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: Addition of a conformity assessment activity to the scope of accreditation (variation of the table attached to the Accreditation Certificate involving the introduction of at least one new sector).

Modification of the scope of accreditation: modification of the conformity assessment activities within the scope of accreditation (variations of the table attached to the Accreditation Certificate that do not involve the addition of a new sector, e.g. change of material types, modification of storage conditions, change of a method, new site).

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

Reduction of Accreditation: cancellation of part of a CAB's scope of accreditation. (variation of the table attached to the Accreditation Certificate involving the complete removal of one or more sectors). It may be requested by the CAB or decided by CSA DT as a sanctioning measure.

Suspension of accreditation: implementation of temporary restrictions for all or part of a Biobank's scope of accreditation. It may be requested by the Biobank (self-suspension) or decided by CSA DT as a sanctioning measure.

Withdrawal of Accreditation: sanctioning measure of cancellation of a CAB's accreditation for an 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 held by 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: a qualified person appointed by ACCREDIA DT, who works under the responsibility of an Assessor within the assessment team, to provide specific knowledge or experience regarding the assessment of particular technical aspects. The expert may interact directly with the CAB.

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.

0.5. Acronyms

- ACCREDIA DT: ACCREDIA Department of Calibration Laboratories;
- CSA DT: Sectoral Accreditation Committee for the Calibration Laboratories Department;
- CdA: Committee for Accreditation Activities;
- DDT: Directorate of Department of Calibration Laboratories;
- RST: Departmental Technical Office for File Review;
- 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.

In the case of using e-mail, it is required that all communications be sent to the designated e-mail addresses indicated on the website 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 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 Applicant 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 Management of *Cross-Frontier* Accreditations, 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 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 ISO/IEC 17025, ISO 15189 and ISO 17034 standards. applicable to the 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 obtain a quotation for accreditation costs, the BBK must submit the Accreditation Application form (Documents DA-00, DA-12 with all attachments), duly completed and sent by e-mail to the dedicated mailbox segreteriadt@accredia.it.

The application must be signed by the BBK's Legal Representative or by an authorised delegate. The requesting BBK must be a legal entity, that is, a legal person, either natural or juridical, that assumes the rights and obligations arising from the exercise of the enterprise and holds a VAT number, or part of a legal entity, such as biobanks belonging to a Research Entity, IRCCS, or University. A public juridical person is also considered a legal entity (for example: REGION, PROVINCE AND MUNICIPALITY, PUBLIC ECONOMIC ENTITIES, PUBLIC INSTITUTIONAL ENTITIES such as INPS, INAIL, UNIVERSITIES, etc.).

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 quotation 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 (sixty) calendar days** from the date of the receiving protocol and prepares a quotation for the accreditation activities following the price list.

The absence of one or more of the documents required in DA-12, or the existence of major deficiencies in the contents of the documents submitted (including the application), does not allow the start of the accreditation procedure; in such a case RST requests by e-mail from the BBK the missing document(s) and/or the missing information and waits for them for **12 (twelve) 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.

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 the Assessors that ACCREDIA DT intends to appoint for the assessment of the BBK and of any Experts (e.g. privacy experts, cybersecurity experts) The names of the ACCREDIA DT Assessors, qualified on the basis of ACCREDIA DT procedures, are approved by the CdA, upon proposal of the Department Management.

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 (five) 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 Directorate.

2. Accreditation Process

Once the order/acceptance of the quotation by BBK has been received, the accreditation process is initiated, which is divided into the following four stages:

a. preliminary operations;
b. document review;
c. on-site/remote/blended assessments (visits);
d. decision-making process.

Assessments 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 scope 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 Directorate 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 **4 (four) years** (the term of the Accreditation Arrangement).

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.

The accreditation covers all Biological Materials falling within the scope of the requested accreditation, handled both before and after the accreditation is granted. In the former case, adequate evidence must be available to demonstrate that the biological material was handled in accordance with the requirements of the Standard.

The above-mentioned document review is carried out and notified to the BBK within **90 (ninety) calendar days** from receipt of 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 outcomes are not positive and documentary amendments by the BBK are required, FT shall notify the outcome and submit the corresponding request for adjustments. The BBK shall submit the corrected and/or supplemented documentation within a maximum period of **6 (six) months** from the request for adjustment;
- If negative results persist following the evaluation of the modifications, the accreditation process shall be terminated in accordance with the provisions set out in point 3.2.1 "Closure of the accreditation process";

- after the expiry of the **6 (six)-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".

In the event that numerous and serious findings are identified by the Assessors during the review of the documentation, the BBK may request a meeting with ACCREDIA DT involving the System and/or Technical Assessor, in the presence of a Technical Officer. Such a meeting, to be held at ACCREDIA's premises or remotely and with a duration not exceeding half a day, is intended for the analysis and clarification of the identified deficiencies and must not take on the nature of consultancy (even unintentionally). The activity shall be quoted and invoiced in accordance with the conditions set out in ACCREDIA's current pricelist.

2.3. Notification and On-site Assessment Plan

2.3.1. Preparation and Notification of the Plan

FT agrees with the applicant 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.

Where the BBK outsources critical processes and the suppliers are qualified through second-party audits, ACCREDIA DT reserves the right to include an Assessor in the plan in order to attend such audits, for the purpose of assessing the manner in which the BBK performs the qualification.

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 BBK 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 (three) business days** from receipt thereof.

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 the assessment at least **10 (ten) working days** in advance.

This operation can be repeated at most two more times.

If the BBK still does not declare its availability:

- 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 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.

ACCREDIA DT may carry out assessments on site, remotely, or in a blended format, making use, where appropriate, of the Biobank’s Information Technology (IT) systems. In all cases, ACCREDIA DT shall perform an appropriate preliminary feasibility analysis in order to determine whether an assessment may be conducted fully remotely or in a blended mode.

In particular cases (e.g. in cases of accreditation, renewal and unscheduled 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 (five) 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. Should this occur, it shall be the responsibility of the Lead Assessor to request and/or ensure the immediate removal of the observer.

ACCREDIA DT can perform remote assessments, 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 ISO/IEC 17011 standard and applicable ACCREDIA DT documents;
- provide assessors and/or BBKs with any clarification regarding the requirements of ISO 20387, and, where applicable, ISO/IEC 17025, ISO 15189, ISO 17034, ACCREDIA DT documents.

The On-site Assessment, carried out by appointed Assessors following the methods of 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 assessment;
- initial meeting with the presence of the Directorate, Technical Directorate, 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 shall make a dedicated room available to the assessment team, preferably equipped with an internet connection, for the assessors' preliminary, intermediate and final internal meetings.

The BBK shall also allow the Assessors access to its premises and records for the purposes of carrying out the on-site assessment. Where the presence of Assessors at a second-party audit of an external supplier of critical activities is envisaged, the BBK shall arrange the logistics in advance, agreeing the dates and obtaining authorisation for the presence of the Assessors.

2.4.2. Preliminary meeting prior to the opening of the 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 must:

a. introduce the assessment team with its tasks;
b. clarify 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. explain the purposes of On-site Assessment, which shall be carried out in compliance with the safety conditions;
d. outline 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. agree on the timing and modalities for the assessment of any off-site tasks;
g. agree on possible variations in the On-site Assessment Plan;
h. illustrate the assessment process and the possibility of the BBK to make reservations;
i. remind the commitment of each member of the group to the confidentiality of the information;
j. make known that confidential meetings of assessors may be needed during the assessment;
k. request confirmation of the presence of the Directorate 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. offer 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.

Such a meeting shall be envisaged both in the case of an on-site assessment and in the case of a remote assessment.

2.4.4. Carrying out the on-site assessment

2.4.4.1. General

The assessment activities are carried out using the ACCREDIA DT checklists, on which the assessment team records, for each requirement, the details of the checks performed with respect to the BBK's conformity with the provisions of the applicable standards and with ACCREDIA DT requirements.

On-site assessment activities can be 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 recalled that the purpose of on-site assessments for accreditation is to verify the conformity of the BBK with the requirements of the applicable standards and of the EA, ILAC and ACCREDIA DT application documents, for the purpose of attesting the technical competence of the BBK to perform the activities included in the scope of accreditation.
Mandatory regulations, for example those relating to safety, administrative liability, etc., do not fall within the accreditation requirements and are not subject to assessment, unless such requirements are expressly referred to by the applicable standard.
The conduct to be adopted by ACCREDIA DT assessors in the event of potentially violated mandatory requirements is described in § 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 assessments, 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-conformity or any BBK reservations. In this case, the copies must be enclosed to the checklist and sent to the relevant 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. System Assessor Tasks

The System Assessor must verify the compliance of the BBK management system with the requirements of reference standard ISO 20387, of EA, 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, equipment management and staff;
- evaluates the compliance of the use of references to accreditation and, in particular, 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 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 labelling;
- 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, extraction / isolation of biological materials / derived macromolecules, aliquoting of biological materials;
- 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 the 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 that give rise to findings. 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 identified by the Assessors of mandatory requirements falling within the scope of the audit shall be reported as NCs.

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 Directorate 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 assessment was interrupted with the relevant motivations.

If, on the other hand, the Directorate 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 Directorate 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 acknowledgement 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 (three) working days**; the acceptance of the reservations made by the BBK is subject to the Department Director.
- request the BBK to sign the report containing the findings and the overall conclusion of the on-site assessment; this report is also signed by the members of the assessment team, each for the findings within their area of responsibility.
- 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 process and granting of accreditation

3.1. Actions following on-site assessment

3.1.1. Request for findings management plan and related documentation

Following the on-site assessment, FT and/or DDT, after reviewing the findings identified by the Assessors and reserving the right to modify and/or reclassify them, officially send the final version of the findings to the BBK, together with the request for the findings management plan, including:

- For Non-Conformities: the correction (where applicable), an analysis of the extent and root cause, and corrective actions addressing the identified causes, with an indication of the implementation timeframe; closure evidence for this type of findings must be positively assessed by ACCREDIA DT prior to submission of the case to the CSA DT.
- For Concerns: the correction, an analysis of the extent and root cause, and, when determined by the BBK in relation to the identified causes, the corrective actions, with an indication of the implementation timeframe. Evidence of corrections and/or corrective actions is reviewed in documentary form prior to the next on-site assessment. Depending on the nature and number of Concerns, ACCREDIA DT may require that, even for this type of findings, closure evidence be positively assessed before submission of the case (for accreditation granting or scope extension) to the CSA DT.

- For Comments: the reasons for any decision not to implement them. If, on the other hand, the BBK intends to address the comment, for example by undertaking an improvement action, the resulting actions will be verified by ACCREDIA DT at the next available assessment.

The BBK must notify FT **within 15 (fifteen) 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 (three) 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 (six) 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 (fifteen) 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 corrections/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 Sectoral 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 (five) working days** of the resolution, submits the results to the BBK, including the 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 arrangement with ACCREDIA (CO-00).

The BBK is required to return the signed Accreditation Arrangement within **30 (thirty) calendar 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.

Acceptance of the Arrangement and inclusion in the list of accredited BBKs commit the BBK to maintain its organisational structure and operations in compliance with the requirements set out in this Regulation, in all other applicable ACCREDIA documents, and in the applicable general and sector-specific standards and regulatory 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 **4 (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 **5 (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 (fifteen) days** from the date of the CSA DT resolution, DDT shall notify the BBK of the closure of the accreditation procedure by registered letter with acknowledgment of receipt or by certified email (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 BBKs, 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 scheduled assessments and by means of unscheduled assessments, 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 assessments, 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.

During the validity period of the accreditation, the BBK is required to inform ACCREDIA of the initiation of new projects/collections of biological material within the scope of its accreditation.

4.1.1. Scheduled surveillance on-site assessment

Normally, the surveillance activity is carried out during the period between the accreditation and its renewal, or between two successive renewals, and includes:

- surveillance on-site assessments;
- maintenance activity.

The first scheduled surveillance visit is carried out **6 (six) 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 (twelve) 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 NCs 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/reports, 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 (fifteen) working days** of the plan's assessment.

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

4.1.2. Unscheduled surveillance on-site assessment

4.1.2.1. Supplementary surveillance on-site assessment

BBK is required to notify the competent FT of any changes compared with the information previously submitted in the Accreditation Application (for example, changes to key personnel identified by the organisation, changes in the company name, or changes in the registered office).

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 scheduled 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 (ten) working days**; within this timeframe, the BBK may, where appropriate, promptly exercise its right to object to the members of the assessment team, in accordance with the provisions set out in § 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 maintenance of 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 Nonconformities 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 Assesment

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 (ten) 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 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 technical and financial quotation. The assessments are carried out in accordance with the provisions of point 2.2 “Document Review”.

Particularly in relation to points:

a. 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 scheduled on-site assessment.
b. In the case of first accreditation the BBK shall send to the relevant FT the first 10 Reports of Biological Material issued and the related technical records that will be examined during the first surveillance on-site assessment.

4.1.4. Decision-making process and confirmation of maintenance

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

- in the absence of Non-Conformity: FT confirms the accreditation maintenance, through simple records confirming the outcomes, together with any related requests for treatment 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 effective 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. Change of Accreditation Scope

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 scope will be updated in the applicable cases.

4.2. Renewal of Accreditation

If the BBK intends to renew the accreditation, at least **6 (six) 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 relevant FT, in order to arrange the assessments at least **4 (four) 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 calendar year, has obtained extensions, not to assess the extended biological material types/activities; however, such assessments are to be carried out at the first scheduled surveillance.

Upon receipt of the application, RST, **within 30 (thirty) 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 FT 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 cycle.

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 (five) 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, including any relevant records, the Assessors shall examine it and notify BBK of the outcome within **60 (sixty) calendar days** from receipt of the order/acceptance of the quotation. If the outcome is not positive, BBK shall propose and submit the necessary additions and/or corrections to the documentation within **30 (thirty) working days** and, in any case, always prior to the on-site assessment. The amended documentation shall be sent to FT, and the corrections shall be assessed by the Assessors during the 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 **2 (two) years**.

ACCREDIA DT may conduct on-site, remote, or blended assessments, potentially making use of the Biobank's Information Technology (IT) systems. In any case, ACCREDIA DT shall carry out an appropriate preliminary feasibility analysis in order to determine whether it is possible to conduct the assessment entirely remotely or as a blended assessment.

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 on-site 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 Related Assessment

In the case of renewal, in the presence of Nonconformities, submission of the case to CSA DT is permitted provided that the Assessors have positively assessed the findings management plan submitted by BBK, the

evidence of treatments, and that the full implementation of Corrective Actions occurs, possibly at a later date, but in any case, within a maximum of **3 (three) months** after the request for adjustment.

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

4.2.4. Assessment of Visit Results

In the presence of findings classified as Nonconformities 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 Nonconformities that affect the competence of BBK, it can resolve the withdrawal of the accreditation, as established in point 6.3 "Withdrawal 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 § 2.4.1) 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 scheduled 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 may be repeated, provided that the maximum limit of 5 (five years) from the accreditation or the most recent renewal is not exceeded.

5. Extension of Accreditation

5.1. Procedure for the Extension of Accreditation

During the period of validity of the accreditation, BBK may request ACCREDIA DT to modify the scope of accreditation in order to add an Area and/or a Sector.

Where BBK intends to align the on-site assessment for the extension with the first available surveillance assessment, it shall submit the application for extension at least **8 (eight) months** prior to the surveillance expiry date. In any case, the joint on-site assessment shall only be possible provided that the document review has been successfully completed before the surveillance expiry date.

Any requests for extension relating to sectors and/or areas of biological material not covered by ACCREDIA DT (i.e. not included in the Annex to DA-12), or in any case differing from those currently in place, shall be submitted by FT to the Management in order to carry out a review of resources and subsequently proceed with their inclusion at the first available CSA DT meeting.

5.1.1. Carrying out the Accreditation Extension Process

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

Within **30 (thirty) 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 and financial quotation;
- if this evaluation is negative, RST announces the need to receive the necessary documentary integrations. These integrations must arrive within **2 (two) 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 and financial 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.

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 arrangement, 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 withdrawal of accreditation, in the event that particularly serious situations emerge, both on a technical and ethical level following the surveillance, supplementary, extraordinary, renewal assessments or from other checks and verifications (e.g., arising from reports).

In accordance with the provisions of the statutory and regulatory rules, the aforementioned sanctioning measures and their duration are adopted by resolution of the CSA DT.

The CSA DT resolutions relating to suspension, withdrawal or reduction shall be communicated to the relevant BBK by means of certified electronic mail (PEC) and subsequently published on the website.

BBK shall inform the affected clients and, where appropriate, the relevant interested parties of the sanction imposed upon it.

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 ACCREDIA accreditation.

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 assessments. 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 surveillance on-site assessments planned for the accreditation cycle shall be carried out.

Should the suspension extend beyond **6 (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 of accreditation does not affect the contractual obligations towards ACCREDIA DT.

6.1.1. Grounds for Suspension

The suspension procedure may be initiated for the following reasons:

a. violation of the accreditation standard requirements / the requirements of this General Regulation, of the Specific Regulations for the accreditation standard (RT), and of the Accreditation Arrangement;
b. failure to return the signed Accreditation Arrangement for acceptance;
c. unavailability of the BBK to undergo a scheduled surveillance assessment within the terms indicated by ACCREDIA DT;
d. negative outcome of the on-site assessments;
e. unavailability of the BBK to undergo unscheduled assessment;
f. contractual insolvency;
g. failure to send the findings management plan or its modification, if requested by ACCREDIA DT, within the deadlines indicated;
h. failure to solve the findings in accordance to ACCREDIA DT procedures;
i. failure to implement corrections and/or corrective actions in cases of biological material reports that have been improperly issued;
j. failure to manage complaints;
k. variations of the legal entity (e.g. change of company name, transfer of ownership of the accreditation);
l. failure to promptly inform ACCREDIA DT of the loss of key personnel identified by BBK;
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 the event of failure to monitor environmental conditions);
o. transfer of BBK;
p. use by an external supplier of BBK assessments critical activities as evidence of its own accreditation or certification.

6.1.2. Suspension Requested by the 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 Nonconformities/ deficiencies that could call into question the validity of their results 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 relevant 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 (twelve) months** within the period of validity of the certificate, upon expiry of which the CSA DT will decide the consequent actions.

The list of accredited BBKs on the ACCREDIA DT website is updated to publish 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 of the self-suspension.

The self-suspension of accreditation does not affect the contractual obligations towards ACCREDIA DT.

6.1.3. Suspension Decided by ACCREDIA DT

If the relevant FT considers, following assessments, that BBK has persistently failed to meet the accreditation requirements or to comply with the accreditation rules, it submits the case to DDT.

DDT informs the BBK of the possible suspension it may face if the above-described Nonconformity persists.

The BBK, once informed of the possible suspension and the reasons justifying it, shall submit any written counter-arguments within **10 (ten) working days** from the notification. FT forwards its report and the observations received from BBK to DDT, which submits the case to CSA DT. CSA DT discusses the suspension, evaluates the respective justifications and the correctness of the procedures followed, and resolves on the measure and its duration.

The suspension measures last for a maximum of **6 (six) months**, but the duration of the measure may be longer than **6 (six) 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 made itself available to undergo the assessments within the prescribed timeframes and/or if the assessments carried out by ACCREDIA DT have not verified the effective resolution of the causes underlying the measure, the case is submitted to CSA DT for the adoption of further sanctioning measures. In particular:

- partial suspension may be converted, by resolution of CSA DT, into total suspension or into withdrawal of the accreditation scope;
- total suspension shall be converted into withdrawal, also by resolution of CSA DT. DDT shall ensure the immediate implementation of the measure.

The withdrawal 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 accredited BBKs on the ACCREDIA DT website is updated to publish the suspension of the activity.

The suspension of accreditation does not affect the contractual obligations towards ACCREDIA DT.

Suspension for Contractual Insolvency

The full suspension of accreditation may be made by the ACCREDIA General Directorate in the event that payment of the charges due to ACCREDIA DT is delayed by more than **60 (sixty) 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 Directorate The revocation of such suspension measure may be ordered ex officio once the contractual conditions have been restored.

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 relevant 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 restoration of compliance has been verified, FT prepares a report on the assessment activities carried out, which is forwarded to DDT, and submits the case to the CSA DT, which decides whether or not the suspended BBK may resume its activities.

In the case of self-suspension, resumption of activities is authorized by DDT, after receiving from the relevant 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

During the period of validity of the accreditation, BBK may request the relevant FT to modify the scope of accreditation in order to reduce the number of Areas/Sectors.

6.2.1. Reduction Requested by the BBK

For the purpose of requesting a reduction of accreditation, BBK shall submit to STD the Reduction Application (DA-12) accompanied by the required documentation, in particular the assessment of the effects on other accredited sectors. For matters within the competence of RST, the provisions established in the § "5. Extension of Accreditation**"** procedure shall apply.

Upon acceptance of the application, FT examines the reduction request and, with the possible support of Technical Assessors and/or Technical Experts, verifies the presence of any potential effects on other accredited fields. If necessary, additional assessments shall be prepared at the expense of BBK.

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

6.2.2. Reduction Requested by ACCREDIA DT

The reduction of accreditation may be imposed by ACCREDIA DT in the event of:

a. a negative outcome of the assessments (failure to resolve serious Nonconformities that compromise BBK's reliability in performing activities under accreditation);
b. failure to address findings in accordance with ACCREDIA DT procedures;
c. unavailability of key personnel identified by BBK;
d. unavailability of significant equipment for biobanking activities;
e. unavailability of BBK premises.

If FT identifies the occurrence of any of the conditions listed above, and after, if necessary, consulting Technical Assessors/Experts, it shall inform DDT, which in turn shall notify BBK in writing of the potential reduction measure.

BBK, once informed of the potential reduction measure and the related reasons, shall submit any written counterarguments to ACCREDIA DT within **10 (ten) working days** from the notification. FT shall prepare its report on the matter, including the observations received from BBK, for the purpose of presenting the case to CSA DT by DDT.

CSA DT shall discuss the proposed reduction, assess the respective justifications and the correctness of the procedures followed, and make a resolution regarding the measure.

The scope of accreditation shall be modified, where applicable, to reflect the reduction.

6.3. Withdrawal of Accreditation

6.3.1. Grounds for withdrawal

The grounds on which ACCREDIA DT may decide to revoke the BBK's accreditation are related to the persistent and serious failure to fulfil accreditation requirements or accreditation rules.

The following are among the reasons that may lead to the withdrawal of accreditation:

a. failure to resolve the causes that led to a suspension measure;
b. a suspension or voluntary total self-suspension of accreditation lasting more than **6 (six) months**;
c. non-compliance with the Accreditation Arrangement;
d. objective situations which would have prevented the drafting of the Accreditation Arrangement;
e. the failure to pay the sums due; if the BBK persists in its failure for the **6 (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. evidence demonstrating the failure to comply with BBK's competence, impartiality, and integrity requirements;
i. unlawful conduct, whether intentional or negligent, and improper conduct in terms of professional ethics on the part of the BBK, in breach of the principles set out in ethical criteria adopted at national and international level, as well as in the BBK's own code of ethics;
j. evidence of fraudulent behaviour, or instances where BBK deliberately provides false information or withholds information;
k. use of accreditation by BBK in a manner that causes serious harm or disrepute to ACCREDIA and/or to the accreditation and certification system;
l. BBK's bankruptcy;
m. cessation of operations of the entity in which BBK operates, for any reason;
n. BBK's voluntary withdrawal (see §6.4);
o. confirmed fraudulent situations reported by competent authorities within the scope of accreditation.

It is also possible to proceed with the withdrawal of an accreditation at the sole discretion of ACCREDIA for geopolitical reasons, in accordance with regulations concerning international resolutions (e.g., sanctions).

6.3.2. Exceeding the Suspension Time Limit

If the suspension of the accreditation is total and its duration exceeds **6 (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 (twelve) 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 counterarguments within **10 (ten) 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:

- removal of BBK from the list published on the ACCREDIA DT website;
- prohibition from issuing biological material reports bearing the ACCREDIA mark;
- loss of the right to use the ACCREDIA mark.

The withdrawal of accreditation does not entail the termination of contractual obligations towards ACCREDIA DT, which reserves the right to initiate enforcement and cost-recovery procedures, including interest, in the manner provided by law.

6.3.3. Withdrawal Measure

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 assessments 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 remaining open findings, 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 entail the termination of contractual obligations towards ACCREDIA DT, which reserves the right to initiate enforcement and cost-recovery procedures, including interest, in the manner provided by law.

7. Complaints/reports, Reservations and Appeals

7.1. Complaints and Reports

ACCREDIA DT may receive complaints/reports 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.

Complaints and reports must be submitted through the dedicated form available on the website.

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

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

Regarding the behaviour of ACCREDIA DT Assessors (both internal and external), any complaint/report may be filed within **10 (ten) 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 (three) 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

Should the accredited BBK, or one undergoing accreditation, wish to request that ACCREDIA DT reconsider measures taken against it, it may submit an appeal in accordance with the procedures described in document ACCREDIA RG-06.

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. During the pendency of an appeal, decisions relating to the BBK's accreditation matters (e.g., renewals or extensions) shall be taken by the Appeals Committee, which acts in place of the CSA DT.

8. Additional Provisions

For all matters not expressly provided for in this Regulation, the provisions of Article 4 of the Arrangement (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 an unscheduled 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 change includes, for example, changes to the registered office and/or operational site address, whether due to renaming of streets or relocation, as well as changes to contact details (e.g., telephone, fax, e-mail).

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 (unscheduled 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 accredited activity, 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 Management / Personnel authorised to sign Biological Material Reports, or the person responsible for maintaining contacts with ACCREDIA DT.

8.2. Transfer of Accreditation ownership

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

The transfer of accreditation may occur due to the sale of a company or business unit, merger by incorporation, or any other legal transaction resulting in a change of tax identification number and/or VAT number, subject to ACCREDIA DT's assessment of the continued fulfilment of accreditation conditions, verifiable 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 measure is activated until the CSA DT decides on the transfer of accreditation ownership.

In the event of a positive evaluation by CSA DT, ACCREDIA DT will send the new accreditation arrangement 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 in cases where the accreditation may be maintained by the previously accredited entity.

8.3. 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.

8.4. Cyberattacks Experienced by the BBK

The BBK shall promptly notify ACCREDIA of any hacker attacks and/or cyberattacks, detailing their impact on system records/documents and the remedial actions that the CAB intends to implement to ensure information is provided to all potentially affected users, without causing disrepute or undermining the reputation of the accreditation. ACCREDIA reserves the right to carry out extraordinary assessments.

9. Obligations of ACCREDIA

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

9.1. Changes to Accreditation Conditions

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

It is up to the BBK to decide, within **3 (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 Accreditation Arrangement.

9.2. Modifications to the Pricelist

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 a quotation 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 **6 (six) months** of receipt of the communication.

During the notice period, the BBK exercising its right of withdrawal shall be charged at the rates applicable prior to the change, for activities carried out up to the moment of withdrawal only.

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