

Calibration Laboratories Department

Management Procedure for Assessments of Calibration Laboratories/Reference Material Producers/Biobanks

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APPROVAL

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1. Scope and Field of Application

The present procedure describes the modalities to be applied by the ACCREDIA-DT assessors and personnel for the preparation and performance of scheduled on-site assessments for accreditation, renewal, surveillance and extension, and unscheduled assessments (supplementary and extraordinary). This document applies to on-site assessment activities of Calibration Laboratories/Centres, Reference Medical Laboratories, Reference Material Producers, and Biobanks.

The term “assessment” is used to refer to the following types of assessment:

- On-site assessments: assessments carried out in person at the Laboratory’s sites.
- Remote assessments: assessments carried out remotely using electronic means.
- Blended assessments: assessments conducted partly in person and partly remotely.

2. Reference Documents

2.1. Internal documents

- PG-01 Procedure for document management;
- RG-13 Regulations for the accreditation of calibration laboratories;
- RG-18 Regulations for the accreditation of the Reference Materials Producers;
- RG-22 Regulation for the accreditation of Research and Development Biobanks;
- RG-07 Code of Ethics and Conduct;
- RT-25 Requirements for the accreditation of calibration laboratories;
- RT-26 Requirements for the accreditation of flexible scope;
- RT-34 Requirements for the accreditation of Reference Materials Producers;
- RT-38 Requirements for the accreditation of Research and Development Biobanks;
- RT-39 Requirements for participation in proficiency testing (PT) and/or interlaboratory comparisons (ILC);
- PG-07-DT Qualification, use and monitoring of the assessors and experts;
- CO-03-DT Contractual Agreement for Assessors and Experts - Department of Calibration Laboratories;

Documents are to be considered applicable in their current revision, unless otherwise specified.

2.2. Internal Forms

Form	Name / Description
MD-09-03-DT	Findings raised by ACCREDIA DT and request for treatment;
MD-09-07-DT	Reservations forms LAT/RMP/BBK;
MD-09-05-S-DT	Checklist for Calibration Laboratory assessment (System Assessor) – scheme UNI CEI EN ISO/IEC 17025:2018;
MD-09-05-T-DT	Checklist for Calibration Laboratory assessment (Technical Assessor) – scheme UNI CEI EN ISO/IEC 17025:2018;
MD-014-RMP-S-DT	Checklist RMP for System Assessor – Schema UNI CEI EN ISO 17034:2017;
MD-014-RMP-T-DT	Checklist RMP for Technical Assessor – Schema UNI CEI EN ISO 17034:2017;
MD-09-12-S-DT	System assessor – Checklist for the assessment of a Biobank – UNI EN ISO 20387:2024;
MD-09-12-T-DT	Technical assessor – Checklist for the assessment of a Biobank – UNI EN ISO 20387:2019;
MD-08-01-DT	Documentation Assessment;
MD-09-02-DT_LAT	Notification and Assessment Plan, LAT scheme;
MD-09-02-DT_RMP	Notification and Assessment Plan, RMP scheme;
MD-09-02-DT_BBK	Notification and Assessment Plan, BBK scheme;
MD-08-05-DT	Technical report RT- <i>nnn/aa</i> ;
MD-08-06-DT	Experimental Assessment Report RC- <i>nnn/aa</i> ;
MD-08-07-DT	List of Findings (RT and RC);

3. Acronyms and definition

3.1. Acronyms

CSA DT:	Sectoral Accreditation Committee for the Calibration Laboratories Department;
DDT:	Directorate of Department of Calibration Laboratories;
DT:	ACCREDIA Calibration Laboratories Department,
STD:	Department Technical Secretariat;
ATM DT:	Assessors' Monitoring Officer;
FT:	Technical Officer;
GVI:	Assessment Team;
EVA:	Assessor in charge of monitoring the ACCREDIA Assessors;
OSR:	Observer;
NC:	Non-Conformity;
OSS:	Concern;
Cm:	Comment;
RV:	Assessment Report;
CAB:	(Conformity Assessment Body): for the purposes of this procedure, the term CAB refers to Calibration Laboratories (LAT scheme – ISO/IEC 17025); Medical Reference Laboratories (LAT scheme – ISO/IEC 17025 and ISO 15195); Reference Material Producers (RMP scheme – ISO/IEC 17034); and Research and Development Biobanks (BBK scheme – ISO 20387);
PT:	Proficiency Test;
ILC:	Interlaboratory Comparison;
S_ILC:	Small Interlaboratory Comparison.

3.2. Definitions

For the purposes of this document, the terms and definitions in the ISO/IEC 17011 and ISO/IEC 17000 standards apply.

When the terms and definitions are not included in the aforementioned standards, the terms and definitions of the ISO 9000, ISO/IEC 17025, ISO 17034, ISO 15189, ISO 15195 and in the relevant ACCREDIA Regulations apply.

4. Preliminary actions

4.1. Appointments

The FT, appointed by DDT to follow the application case for at least one accreditation cycle, identifies the Assessors and any Technical Experts, who will have to assess the CAB. The GVI includes, as a rule, a System Assessor, one or more Technical Assessors and possibly one or more Technical Experts, for the BBK scheme, at least during the accreditation phase, a GDPR Expert and an IT Expert are always appointed. In the GVI, in every single on-site assessment, a Lead Assessor (usually the system assessor) must always be present. The assessors of the GVI, unless otherwise decided by the DDT, will also be assigned during subsequent surveillances (or other) to the same CAB during the next four years (duration of the accreditation agreement). An exception is the Technical Assessor in charge of assessing internal calibrations: this activity is assessed once for each accreditation cycle.

The selection of Assessors and Technical Experts by the FT is carried out so that their competencies cover:

- in the case of accreditation, renewal, and extension, the entire scope of accreditation of the CAB and, where applicable, its internal calibrations;
- in the case of surveillance, the sampled scope of accreditation for that specific assessment.

The members of the GVI are indicated in the quotation submitted by STD to the CAB for acceptance. Upon receipt of the accepted quotation and/or the order, STD prepares the appointment letters. Any changes to the GVI may be requested by the CAB or proposed by the FT, in accordance with the provisions set out in Regulations RG-13, RG-18 and RG-22.

Upon renewed acceptance by the CAB following changes to the GVI, the process of preparing the appointment letters by STD is repeated.

In compliance with the methods and criteria indicated in the document PG-07-DT, DDT also assigns any OSR, trainee assessors and EVA.

FT sends the Assessors and/or Technical Experts the documentation relating to the relevant assignment (see Table 1), together with the appointment letters, which are deemed to be accepted by tacit consent, i.e. if no notice of unavailability is received within 3 working days of their transmission.

ATM sends the appointment letters to any OSRs, trainee Assessors and EVAs; in this case as well, tacit consent applies.

4.2. Document Review

Prior to the on-site assessment, the members of the GVI shall gather all available information relating to the CAB through a careful review of the application submitted by the CAB, where applicable, including the self-assessment and all supporting technical and scientific documentation submitted with it (see Table 1).

The FT ensures that the GVI is provided with appropriate documents containing information on previous assessments, as well as documents and records of the CAB useful for the evaluation (see details in Table 1).

For this purpose, the documentation submitted by the CAB may be sent by the FT to the assessment team via email or through a shared OneDrive folder.

Assessors shall take into account any communications already sent by ACCREDIA to the CAB during the preliminary stage of acceptance of the application for accreditation, and verify whether the CAB has provided a satisfactory response. Such communications are sent by the FT to the Assessors together with the remaining CAB documentation.

Where strictly necessary, the assessors may request to FT any additional documents necessary to complete the examination of the documentation, for the subsequent preparation of the assessment (e.g.: further CAB documents, etc.).

In the review phase of the CAB documentation, the assessment team must verify the conformity of the system as documented to the requirements of the normative documents as well as the requirements established by ACCREDIA and reported in the ACCREDIA Technical Regulations (RT-25, RT-34, RT-38, RT-39 e RT-26). The self-assessment shall be evaluated as if it were a documented procedure of the CAB.

Particular attention should be paid to assessing the consistency between what is declared by the CAB and what actually emerges from the review of documentation, with regard to critical activities such as internal calibrations and subcontracting. In the event of discrepancies (e.g. where the Technical Assessor considers that the CAB performs internal calibrations not declared in the accreditation application), the Assessor shall promptly report this to the FT.

In the case of significant deficiencies related to internal calibrations, the Technical Assessor shall inform the FT and the members of the GVI of the impact of such deficiencies on the CMC/accreditation scope requested by the CAB.

For RMPs, accreditation covers all RM batches included in the requested scope of accreditation, produced after accreditation has been granted. However, since accreditation may also include existing batches, the document review shall also extend to the production of these batches, where requested by the RMP.

Table 1 below summarises the documentation to be provided to Assessors depending on the type of application.

Table 1 – Documentation to be provided to the members of the GVI

TYPE OF APPLICATION			
	ACCREDITATION	RENEWAL	EXTENSION
Application (DA-00, DA-05, DA-09) and annexes	X	X	X
RV Assessment Report (accreditation/latest renewal/relevant extensions)		X	X
Any communication between ACCREDIA DT and the CAB	X	X	X
Treatment of findings (MD- 09-03-DT) of the previous assessment compiled with any evidence supporting the treatments proposed by the CAB		X	
Checklists (MD-09-05-S-DT/ MD-014-RMP-S-DT/ MD-09-12-S-DT compiled in "self- assessment" mode from the CAB	X	X	X
MD-08-01-DT relative to the last system/technical assessment		X*	
MD-09-01-DT and MD-19 confidentiality forms compiled by CAB	X	X	X
Notification and assessment plan accepted by the CAB (MD-09-02-DT)			
	X	X	X
Documentation relating to complaints received by ACCREDIA DT	X*	X*	X*

(*) If necessary (when applicable and/or if the assessor should evaluate the evidence and/or effectiveness of activities not closed in previous application cases)

In the case of LATs with a **flexible scope**, the evidence of validation of the revised methods is also provided.

4.2.1. Accreditation, renewal and extension procedures

In the case of accreditation, renewal and extension, the CAB documentation to be assessed consists of the application, together with all associated documentation, including internal calibration procedures where applicable. In the case of renewal, the documentation also includes all records and information relating to previous assessments, both on-site and documentary.

Upon receipt of the documentation, the Assessors will examine it, according to the timetable set out in the Agreement with ACCREDIA DT, depending to their respective competences and keeping in mind the applicable requirements.

Table 2 – Document Review – Forms to be completed by the members of the GVI

Results of the document review to be submitted to the FT					
	Application case			Assessors	
	Accreditation	Renewal	Extension	System Assessor	Technical Assessor/Expert
MD-08-01-DT	X	X	X	X	
MD-08-01-DT	X	X	X		X
MD-08-05-DT (technical report) + MD-08-07-DT	X	X	X		X

It is reminded that:

- the documentation to be assessed by the System Assessor also includes the self-assessment attached to the application;
- the documentation to be assessed by the Assessors also includes DA-05/DA-09/DA-12

4.2.2. Scheduled and unscheduled surveillances procedures

In the case of surveillance application cases, both scheduled and unscheduled, the CAB documentation to be reviewed consists of all records and information relating to previous assessments, both on-site and

documentary, and, where necessary, documents and laboratory records relevant to the evaluation (see Table 3).

It is noted that, in the case of LATs with a flexible scope, both a document review and an assessment will be carried out.

The FT shall transmit this documentation, including MD-09-05-S-DT / MD-014-RMP-S-DT / MD-09-12-S-DT, completed both by the CAB and by the Lead Assessor, so that the GVI can verify the effective closure of previously requested corrective actions and obtain a comprehensive overview of the CAB, in order to identify which clauses of the standard and which aspects require further in-depth evaluation during the assessment.

In particular, for Calibration Laboratories (and for Reference Material Producers that make use of a LAT), the assessment shall include the evaluation of the measurement comparison participation programme.

Table 3 – Documentation to be provided to the members of the GVI

	Surveillance Application case
Application (DA-00, DA-05, DA-09, DA-12) and Annexes	
RV Assessment Report (accreditation/relevant extensions)	X
Treatment of findings (MD-09-03-DT) of the previous assessment compiled with any evidence supporting the treatments proposed by the CAB	X
Checklists (MD-09-05-S-DT/ MD- 014-RMP-S-DT) compiled in "self-assessment" mode from the CAB	X
MD-08-01-DT relative to the last system/technical assessment	X*
MD-09-01-DT and/or I'MD-19 confidentiality forms compiled by CAB	X
Notification and assessment plan accepted by the CAB (MD-09-02-DT)	X
Documentation relating to complaints received by ACCREDIA DT	X*

(*Where necessary (when applicable and/or where the Assessor is required to evaluate evidence and/or the effectiveness of activities not closed from previous procedure cases and/or the handling of comments).

4.3. Measurement comparisons for calibration laboratories

The types of measurement comparisons and the way their results are managed by ACCREDIA DT for the purposes of assessing the technical competence of LATs are described in Regulation RT-39.

In the case of PT/ILC, the Technical Assessor, during the document review, must evaluate its validity and results: the suitability of the provider must be verified, both in terms of compliance with ISO/IEC 17043 and in terms of CMC/accreditation scope, better requests than those of the LAT; the uncertainties used by the LAT with respect to the CMCs required for the purpose of validating the accreditation table must also be assessed; where applicable, any corrective actions proposed by the LAT following unsatisfactory results should also be verified.

In the case of S_ILC, the Technical Assessor, during the document review, will perform the same checks already described for PT/ILC but, if the participant is also the organizer, will evaluate the evidence provided by the LAT for compliance with the main requirements of the ISO 17043 standard, reported in paragraph 6 of document EA-4/21.

If the measurement comparison is a measurement audit, the Technical Assessor assesses, during the document review stage (MD-08-01-DT), the suitability of the Calibration Certificate proposed by the LAT in terms of supplier inadequacy, the choice of calibration, and uncertainty.

With regard to measurement audits and on-site experimental assessments, these activities are carried out during the Assessment, as described in section 7.2.5 of this document. Accordingly, during the assessment, they must always be planned and included in the notification under the section dedicated to checks, so that the Technical Assessor can evaluate the application of procedures and the competence of personnel through direct observation of the activity.

5. Preparation of the Assessment

5.1. Preparation of the Notification and Assessment Plan

The FT, having consulted the Lead Assessor, prepares the document "Notification and Assessment Plan", with the aim of formalising the composition of the Team, as well as the objectives, scope, criteria and key elements of the on-site assessment.

Technical Assessors are advised to request in-person experimental assessments, such as the calibration of instrumentation/the production of reference materials/the handling of biological material, which have not been sampled during previous on-site assessments.

5.1.1. Composition of the Team

The names, roles and responsibilities of the members of the Assessment Team are defined, as well as the names of any EVAs and/or OSRs.

5.1.2. Objectives

5.1.2.1. LAT Scheme

They define what must be completed during the Assessment and must include the following:

- assessment of the degree of conformity of the management system of the Laboratory under assessment, or parts of such system, with both the applicable requirements of ISO/IEC 17025, the main requirements of ISO 17043 set out in section 6 of document EA-4/21 where the LAT also acts as an organiser of S_ILC, the requirements of ACCREDIA, EA and ILAC, and other applicable reference standards, as well as any applicable mandatory requirements;
- assessment of the technical competence;
- assessment of the effectiveness of the management system in achieving specified objectives;
- identification of areas for potential improvement of the management system;
- identification of any calibrations and/or technical assessments to be performed on site;
- assessment of the traceability of data and of issued certificates;
- assessment of the implementation and effectiveness of corrective actions identified during previous on-site assessments and/or document review;
- assessment of compliance in the use of accreditation references and, in particular, the use of the ACCREDIA and ILAC accreditation marks, compliance with the provisions of General Regulation RG-13 and dedicated Regulation RG-09, also verifying the company website at all times;
- assessment of the planning and compliance with the programme for participation in PT/ILC;
- assessment of the implementation of ACCREDIA requirements regarding internal calibrations, where applicable.

It is recommended that Assessors interview CAB personnel who have not been sampled during previous on-site assessments (this information is provided in the Notification).

It is also recommended that Technical Assessors sample at least one Calibration Certificate issued immediately after the last Assessment and one recently issued Calibration Certificate, so as to ensure sampling covering the entire period between one assessment and the next.

In the case of schemes accredited with a **flexible scope**, the records and planned/performed activities for which changes have occurred since the previous assessment shall also be verified (RT-26).

5.1.2.2. RMP Scheme

They define what must be completed during the Assessment and must include the following:

- assessment of the degree of conformity of the management system of the Laboratory under assessment, or parts of such system, with the applicable requirements of ISO 17034, of ISO/IEC 17025 where this is referenced by ISO 17034, of ISO 15189 where this is referenced by ISO 17034, of ACCREDIA, EA and ILAC, and of other relevant reference standards, as well as any applicable mandatory requirements;
- assessment of technical competence;
- assessment of the effectiveness of the management system in achieving specified objectives;
- identification of areas for potential improvement of the management system;
- identification of any calibrations and/or technical assessments to be performed on site, where applicable;
- assessment of the traceability of data and documents associated with reference materials (certificates and product information sheets) issued;
- assessment of the implementation and effectiveness of corrective actions identified during previous on-site assessments and/or document review;
- assessment of compliance in the use of accreditation references and, in particular, the use of the ACCREDIA and ILAC accreditation marks, compliance with the provisions of General Regulation RG-18 and dedicated Regulation RG-09, also verifying the company website at all times;
- assessment of the planning and compliance with the programme for participation in PT/ILC, where applicable;
- assessment of the implementation of ACCREDIA requirements regarding internal calibrations, where applicable;
- assessment of the adequacy of the production plan;
- assessment of the homogeneity and stability of reference materials;
- assessment of the adequacy of the reference material distribution process;
- assessment of subcontracted activities.

It is recommended that Assessors interview CAB personnel who have not been sampled during previous on-site assessments (this information is provided in the Notification).

It is also recommended that Technical Assessors sample at least one document associated with a reference material issued immediately after the last Assessment and one document associated with a recently issued reference material, so as to ensure sampling covering the entire period between one assessment and the next.

5.1.2.3. BBK Scheme

They define what must be completed during the Assessment and must include the following:

- assessment of the degree of conformity of the management system of the Biobank under assessment, or parts of such system, with the applicable requirements of ISO 20387, of ACCREDIA, EA and GLOBAL ACI, and of other relevant reference standards, as well as any applicable mandatory requirements;
- assessment of technical competence;
- assessment of the effectiveness of the management system in achieving specified objectives;
- identification of areas for potential improvement of the management system;
- identification of biological material management activities;
- assessment of the traceability of data and of issued Biological Material Reports;
- assessment of the implementation and effectiveness of corrective actions identified during previous on-site assessments and/or document review;
- assessment of compliance in the use of accreditation references and, in particular, the use of the ACCREDIA and ILAC accreditation marks, compliance with the provisions of General Regulation RG-22 and dedicated Regulation RG-09, also verifying the company website at all times;
- assessment of the implementation of ACCREDIA requirements regarding internal calibrations, where applicable;
- assessment of subcontracted activities.

It is recommended that Assessors interview CAB personnel, where possible, who have not been sampled during previous on-site assessments (this information is provided in the Notification).

It is also recommended that Assessors cooperate with the GDPR Expert and the IT Expert to ensure adequate verification of data associated with biological material.

5.1.3. Field

It defines:

- the coverage and limits of the Assessment, i.e. which physical locations, organisational units, activities and processes are to be covered by the Assessment;
- the time period covered by the Assessment: in particular, the scheduled date or dates and the timing of the meetings.

5.1.4. Criteria

They are the references against which conformity is determined and therefore include the applicable reference standards (ISO/IEC 17025, ISO 17034, UNI ISO 15195, ISO 20387 where applicable), the requirements of ACCREDIA, EA and GLOBAL ACI, as well as any relevant technical standards for the measurement sectors under review.

5.2. Assessment Team: rules of conduct and responsibilities

5.2.1. Rules of Conduct

In accordance with document PG-07-DT, personnel included in the list of ACCREDIA DT Assessors and Technical Experts undertake, by signing acceptance, to comply with the provisions of the Code of Ethics and Conduct document, RG-07.

It is also recalled that, outside the Assessment, Assessors are authorised to communicate with the CAB solely for the purpose of arranging the logistical aspects of on-site assessments. Any other communication relating to the assessment shall be carried out through the FT responsible for managing the process.

In accordance with the Code of Ethics and Conduct, it is recalled that the behaviour of members of the Assessment Team during the Assessment must comply with the following principles:

- act with awareness of representing ACCREDIA at the CAB;
- communicate with personnel involved in the Assessment in a controlled, courteous and professional manner;
- maintain an open-minded approach at every stage of the Assessment, ensuring clarity when asking questions and careful listening to responses;
- present identified findings calmly, tactfully and in a constructive manner, ensuring that they are clearly understood;
- attempt to resolve any concerns regarding findings through calm and courteous discussion during the Assessment, always presenting the objective evidence supporting the finding;
- in the case of differing opinions regarding a finding, explain to the CAB the ACCREDIA mechanism for submitting reservations and any complaints or appeals;
- remember that, while non-prescriptive advice may be given to the client during the assessment within the framework of mutual cooperation, utmost care must be taken to avoid crossing the boundary into consultancy, which must be strictly avoided;
- if clarification is required on how to apply ACCREDIA policy in relation to specific requirements, these shall be requested from the FT or DDT without interfering with the progress of the Assessment;
- ensure adherence to the planned schedule, verify that each topic is allocated adequate time, and prevent the CAB from resorting to delaying tactics;
- remember that the purpose of the Assessment is to evaluate the CAB's competence in a specific field and not to provide an opportunity for the Assessor to demonstrate their own expertise;
- ensure that the Assessment is not disrupted by external factors (e.g. mobile phone calls, etc.);
- ensure that no contact or communication takes place between the CAB and members of the Assessment Team outside the framework of activities controlled by ACCREDIA;
- collect and record evidence relating to the behaviour of CAB personnel and their compliance with requirements, rather than focusing solely on the existence of documents;

- document findings in such a way as to provide a complete report of the evidence observed;
- use the checklist or other equivalent tools, with the aim of understanding the functioning of the CAB and not merely of filling in a table with notes.

5.2.2. Roles and Responsibilities

The roles and responsibilities of Assessors are defined in General Regulations RG-13 and RG-18.

5.2.2.1. Guides and Observers

Where the CAB has appointed guides, these should assist the Assessment Team, acting at the request of the Lead Assessor. Their responsibilities may include, but are not limited to, arranging contacts and interview schedules, ensuring that site safety rules and safety procedures are known and observed by members of the Assessment Team, and acting as interpreters where necessary.

Guides and Observers (e.g. EA/GLOBAL ACI Assessors) may accompany the Assessment Team but are not part of it and must not influence or interfere with the conduct of the activity. OSRs, Trainee Assessors and EVAs have no decision-making functions and shall act in accordance with document PG-07-DT.

5.3. Forms

Based on the tasks assigned to them, Assessors carry out the Assessment in accordance with this procedure, using the ACCREDIA DT forms made available and downloadable from their reserved area of the ACCREDIA website.

It is the responsibility of the members of the Assessment Team to have available the forms required for Assessment activities and, where applicable, the CAB accreditation schedule, also downloadable from the ACCREDIA website.

As a general rule, Assessors shall have available the forms listed in Table 4 below, where, for each form, the access methods to the documents and the references to the relevant operational instructions for correct completion are indicated:

Table 4 – Forms available to Assessors

Form	Access	Instructions for completion
MD-09-03-DT	ACCREDIA website	NA (Self-explanatory)
LAT: MD-09-05-S-DT RMP: MD-014-RMP-S-DT BBK: MD-09-12-S-DT	ACCREDIA website	NA (Self-explanatory)
LAT: MD- 09-05-T-DT RMP: MD-014-RMP-T-DT BBK: MD-09-12-T-DT	Reserved area	NA (Self-explanatory)
MD-09-07-DT	ACCREDIA website	NA (Self-explanatory)
MD-08-05-DT - RT MD-08-06-DT -RC MD-08-07-DT	Reserved area	//
MD-08-01-DT	Reserved area	//

(*)For renewal and surveillance application cases only

5.4. Logistics of the Assessment

It is the responsibility of the Lead Assessor to manage and coordinate the logistical aspects of the Assessment for all members of the Assessment Team and, in this regard, to handle communications with the CAB.

The Lead Assessor shall also, at this stage, request from the CAB the possible availability of a reserved area for the Assessment Team to hold preliminary, interim and final internal meetings. The Lead Assessor shall perform this function also when the Assessment is conducted remotely.

6. Execution of the Assessment

6.1. Notification and Assessment Plan

The FT, in accordance with the applicable Regulations (RG-13, RG-18, RG-22), having agreed the date of the Assessment and the related schedule with the relevant parties (CAB and members of the Assessment Team), submits to the CAB, for acceptance, the Notification and Assessment Plan form, reminding the CAB, where not already done, to also complete form MD-19 or form MD-09-01-DT in the case of a remote Assessment. Once these document(s) have been duly completed and signed for acceptance by the CAB, the FT forwards them to the members of the Assessment Team.

It is recalled that, in accordance with the applicable Regulations (RG-13, RG-18, RG-22), the Assessment may only be carried out upon receipt of the CAB's acceptance of the notification and programme.

6.2. Phases of the Assessment

The Assessment comprises the following phases:

- preliminary meeting of the Assessment Team;
- opening meeting with the CAB;
- Assessment of the CAB;
- performance of system and technical assessments;
- where applicable, conduct of measurement audits and on-site experimental assessments;
- where applicable, interim meetings of the Assessment Team;
- possible interruption of the Assessment;
- preliminary Assessment Team meeting prior to closure of the Assessment;
- closing meeting with the CAB.

6.2.1. Preliminary meeting of the Assessment Team (GVI)

This is a meeting of the members of the Assessment Team to discuss the Assessment arrangements and allocate tasks. It is generally informal and is held prior to travelling to the Assessment site.

Where, for logistical reasons, it has not been possible to organise such a meeting before arriving at the CAB, the Lead Assessor may arrange it prior to the opening meeting, in accordance with the times set out in the plan.

In the case of monitoring activities conducted in conjunction with the Assessment, the EVA shall hold the preliminary meeting with the Assessors in accordance with document PG-07-DT.

6.2.2. Opening meeting with the CAB

During the opening meeting between the Assessment Team and the representatives of the CAB, the Lead Assessor shall:

- a. introduce the members of the Assessment Team together with their respective tasks;
- b. clarify the roles and responsibilities of any ACCREDIA Evaluators (EVA), guides (i.e. persons appointed by the Laboratory to accompany the Assessors), Trainee Assessors and OSRs;
- c. present the objectives of the Assessment, which shall be carried out in compliance with safety conditions;
- d. present the Assessment plan, clarify any points not understood and agree any changes thereto;
- e. define the details of any calibrations to be performed in the presence of the Technical Assessor, where applicable;
- f. define any process, or part of it, for the production of reference materials to be carried out in the presence of the Technical Assessor;
- g. define biobanking activities to be carried out in the presence of the Technical Assessor;
- h. present any division of the team into sub-teams and identify the verification phases to be assigned to each sub-team, in order to optimise the Assessment timeline;
- i. agree on the timing and methods for the assessment of any off-site calibrations, where applicable;
- j. agree on any changes to the Assessment plan;
- k. present the assessment procedure and the CAB's right to submit reservations;
- l. recall the commitment of each member of the Assessment Team:
 - to maintain confidentiality of information relating to the CAB;
 - to immediately communicate to the CAB at least any nonconformities involving serious risks (safety, environment and quality);
- m. inform the CAB that, during the Assessment, confidential meetings of the Assessment Team may be required;

- n. request confirmation of the presence of the Management or a representative of the CAB at least at the closing meeting, and complete the list of persons taking part in the Assessment (MD-09-03-DT, MD-09-05-S-DT, MD-014-RMP-S-DT);
- o. provide the CAB with the opportunity to request any further clarifications;
- p. formalise the safety arrangements as required in the Notification and Assessment Plan, verifying compliance with the safety conditions previously communicated through document MD-19.

6.2.3. Assessment of the LAT/RMP/BBK

Generally, following the opening meeting, a brief visit by all members of the Assessment Team shall be arranged to the technical facilities of the Laboratory/Reference Material Producer/Biobank.

6.2.4. Conduct of system and technical assessments

6.2.4.1. General

Assessment activities always include the evaluation of both technical and system aspects.

6.2.4.2. Methodology

Assessment activities shall be of two types:

- “horizontal” assessment, primarily focused on one or more clauses of the standard and their implementation;
- “vertical” assessment, consisting of the verification of the implementation of the standard requirements within a specific activity area.

Information is collected through interviews with personnel, observation of activities, and analysis of records. Only verifiable information may constitute Assessment evidence and shall be recorded. Assessment evidence is based on samples of the available information. Interviews are one of the key means of collecting information and shall be conducted in a way appropriate to the situation and the person being interviewed; they constitute evidence and shall therefore be recorded as such.

The Assessor shall take into account the following:

- a. interviews should be conducted using language appropriate to the persons and functions addressed;
- b. interviews should, wherever possible, be conducted during normal working hours and at the interviewee’s usual workplace;
- c. every effort should be made to put the interviewee at ease before and during the interview;
- d. the purpose of the interview and of any notes taken shall be explained;

- e. interviews may begin by asking individuals to describe their work;
- f. questions should be phrased so as to avoid influencing the responses;
- g. the results of interviews shall be summarised and reviewed with the interviewee;
- h. interviewees shall be thanked for their participation and cooperation.

Assessment activities shall be carried out with the aid of the checklist.

The checklist consists of a list of standard clauses aimed at verifying compliance with the applicable requirements of both the standard and ACCREDIA.

Assessors are required to use the prepared checklists and to complete them in electronic format.

It is recommended that evidence of the assessment of the effectiveness of corrections resulting from document reviews and of corrective actions arising from the previous Assessment be recorded in the checklist, and that details be reported on the documents received (MD-08-01-DT and MD-09-03-DT) from the FT assigned to the task.

At the end of each significant phase of the Assessment, the Assessor shall briefly present the outcome of the assessment to the relevant person, verbally communicating any identified deficiencies giving rise to findings. The Assessor shall specify that the findings will subsequently be reviewed by the Assessment Team, and then classified as Nonconformities, Concerns or Comments in accordance with RG-13/RG-18/RG-22.

6.2.4.3. Flexible Scope – LAT Scheme

The Technical Assessor shall verify that, following updates to technical procedures, the LAT has complied with the limits of the CMC (in terms of uncertainty and measuring interval) recognised for the Laboratory.

A sample of recently issued Calibration Certificates, produced following updates to such methods, shall be requested in order to verify the above.

6.2.5. Possible conduct of measurement audits and/or on-site experimental assessments

Where the Assessment includes a measurement audit and/or an on-site experimental assessment, with reference to document RT-39, the activity shall be recorded, but the results shall be presented in a specific Experimental Assessment Report (MD-08-06-DT RC), prepared by the assigned Technical Assessor after the Assessment, and shall be transmitted by the FT to the Laboratory as soon as it becomes available. In the case of NC or Cm, the Technical Assessor shall also complete form MD-08-07-DT.

The performance of such activities shall always be recorded both in the checklists and in MD-09-03-DT.

6.2.6. Possible interim meetings of the Assessment Team members

Assessors may, where they deem it necessary, hold interim meetings in order to:

- update the status of the Assessment Plan;
- exchange information useful for the continuation of the Assessment;
- define any changes to the timetable based on emerging needs, particularly in the case of difficulties in carrying out calibrations;
- compare answers to the same question obtained from different interviewees.

These meetings may be held in private (by requesting a suitable room or the clearance of the room being used) or not, at the sole discretion of the Assessors.

Where interim meetings are held, the Lead Assessor shall temporarily suspend the Assessment and, at the end of the meeting, communicate to the CAB Technical Management any changes made to the Assessment Plan.

6.2.6.1. Possible interruption of the Assessment

Where, during the conduct of the Assessment, serious shortcomings of the CAB emerge with respect to the requirements of the standard or ACCREDIA documents, the Lead Assessor, after consultation with the FT and the DDT, may propose to the CAB Technical Management the interruption of the Assessment, as provided for in General Regulations RG-13/RG-18/RG-22.

In the event of acceptance by the Technical Management, the Assessors shall carry out the meetings referred to in sections 7.2.8 and 7.2.9, formalising the findings identified up to that point and indicating in MD-09-03-DT that the Assessment has been interrupted, specifying which findings (major nonconformities) do not allow its continuation.

If, on the other hand, the CAB expresses the intention to continue the Assessment, the Assessors shall record such statement in MD-09-03-DT and proceed with the planned activities.

The Lead Assessor is responsible for providing a detailed description of both situations in the relevant section of MD-09-03-DT.

6.2.6.2. Preliminary meeting of the Assessment Team prior to closure of the Assessment

Prior to the closing meeting with the CAB, the Assessors shall meet in a confidential session to complete form MD-09-03-DT.

During this meeting, the Assessment Team shall review the outcomes of the on-site Assessment, as well as any other information collected, and agree on the conclusions of the on-site Assessment, taking into account the inevitable uncertainty inherent in the assessment process itself. The Assessment Team shall

agree on the approach to be adopted during the closing meeting, as well as the nature of any recommendations/comments, where appropriate, to be provided to the CAB.

In the event of differing opinions by one or more Assessors regarding the decision on the findings to be raised, and following any requests for clarification to the CAB, the Lead Assessor shall decide, after consultation with the FT where necessary, whether to include in form MD-09-03-DT the findings not agreed upon.

6.2.6.3. Closing meeting

During the closing meeting, between the Assessment Team and the CAB representatives agreed in the Assessment Plan, the Lead Assessor, assisted where necessary by the other Assessors, shall:

- present a summary of the activities carried out;
- recall that the outcomes of the Assessment are based on sampling and that, therefore, other issues, in addition to those identified, may be present and may be detected during subsequent on-site assessments by ACCREDIA and during internal audits;
- present the findings (NC, OSS, Cm), explaining their content and rationale, seeking to ensure the CAB's understanding and agreement with the findings;
- present the Assessment Team's summary feedback on the audit results;
- each finding reported in the printable reports of form MD-09-03-DT shall be signed by the Assessor who identified it and by the Laboratory Technical Management; where a finding is identified by both the System Assessor and the Technical Assessor, it shall be signed by both;
- the summary feedback shall be signed by both the Lead Assessor and the CAB Technical Management;
- collect any reservations submitted by the CAB and deliver form MD-09-07-DT (reservation form), recalling that these may be submitted to ACCREDIA within 3 working days from the completion of the Assessment;
- provide the CAB with a signed copy of the printable report of form MD-09-03-DT containing the list of findings identified and the summary feedback, specifying that ACCREDIA reserves the right to confirm or amend its contents within an indicative period of 10 working days. Alternatively, instead of printing the report, it may be sent by email, requesting the CAB to accept its contents.

During the closing meeting, the Lead Assessor shall remind the CAB of the actions resulting from the Assessment, as provided for in General Regulations RG-13, RG-18 and RG-22.

7. **Unscheduled surveillance Assessment**

Unscheduled on-site assessments are carried out in the cases provided for in Regulations RG-13, RG-22 and RG-18.

The unscheduled Assessment shall be conducted in accordance with the same procedures set out in section 6 above, using the same forms. The checklists shall be used as applicable; in any case, at a minimum, the following sections of the system checklist shall be completed:

- the first page and subsequent pages relating to the identification of the Assessment and of the CAB;
- the sections relating to the opening and closing meetings;
- the sections relating to the performance of calibrations/production of reference materials, where carried out.

In order to provide evidence of the implementation and effectiveness of corrective actions, it is recommended that the section dedicated to findings management in file MD-09-03-DT be completed.

8. **Post-Assessment actions**

8.1. **Assessment outcomes**

The members of the Assessment Team are responsible for completing form MD-09-03-DT, each for the sections within their respective competence. They are also responsible for completing the “effectiveness assessment” section of MD-09-03-DT relating to the previous Assessment and the “document assessment” section, although the details shall be recorded on the original documents.

The Lead Assessor shall transmit to the FT, within 5 working days from the date of completion of the Assessment, both the documentation previously provided and the following records:

- MD-09-03-DT, “printable report” section and the “summary feedback” sheet duly signed, or the CAB’s email confirming acknowledgement of the document;
- MD-09-03-DT;
- MD-014-RMP-S-DT / MD-09-05-S-DT / MD-09-12-S-DT, with any attachments;
- MD-09-03-DT from the previous Assessment, completed in the effectiveness verification section;
- MD-08-01-DT of the document assessment, where applicable;
- MD-09-07-DT, if reservations have been raised.

The members of the Assessment Team shall transmit to the FT, within 5 working days from the date of completion of the Assessment, both the documentation previously provided and the following records:

- MD-014-RMP-T-DT/MD-09-05-T-DT/ MD-09-12-T-DT, with any attachments;
- MD-09-03-DT from the previous Assessment, completed in the effectiveness verification section;

- MD-08-01-DT of the document review, where applicable;
- RC, where applicable.

If, following the Assessment and within 5 working days thereof, on the basis of the evidence recorded and/or attached to the checklist, the Assessors identify any findings not notified during the Assessment, they shall be entitled to include such findings in a new MD-09-03-DT, to be transmitted to the FT. The CAB shall in any case have the possibility to submit reservations regarding these findings using the appropriate form.

The FT shall review the received documentation, consider any reservations submitted by the CAB and by the Assessors, assess the conformity of the findings with the applicable requirements, and, where necessary, amend their wording and/or significance and, where applicable, include additional findings.

Subsequently, the FT shall send the Assessment outcomes to the CAB through a formal registered communication.

8.2. Notification of corrective actions

Upon receipt of form MD-09-03-DT duly completed by the CAB in the required sections, the FT shall forward it to the members of the Assessment Team for evaluation. The Assessors shall enter their evaluations in the relevant section of MD-09-03-DT.

Having consulted the Assessors, the FT shall assess the validity of the corrective actions proposed by the CAB, as well as their timing. Where necessary, the FT may request updated documentation or modifications to the corrective actions (in terms of both approach and/or timing), requesting the issuance of a revision of form MD-09-03-DT. Only one modification to MD-09-03-DT is permitted. In such case, the process shall be repeated and the relevant records shall be entered in the appropriate sections of MD-09-03-DT.

Where corrective actions require the update of existing documents, the CAB is obliged to submit the revised documentation to the FT, and the Assessors are responsible for evaluating it in relation to the identified findings.

9. Guidance for the formalisation of findings and classification examples

Assessors are reminded that findings raised during document review and/or on-site assessments shall, as far as possible, be clear and self-explanatory, as they contain the information on the basis of which the competent ACCREDIA bodies decide on the granting, extension, maintenance, suspension, reduction or withdrawal of accreditation.

In practice, the above translates into ensuring that findings are correctly formulated and drafted in accordance with the following:

- clearly indicate the reference to the subject of the finding: document code and revision, instrument identification number, etc.;
- indicate the reference to the requirement contained in the reference document that is considered not to be met by the CAB;
- express the finding in a negative form, highlighting the deficiencies;
- avoid generic findings and describe the reason why the document, equipment, etc. is considered inadequate;
- for findings of a general nature arising from the repetition of the same deficiency, record a single finding including references to the individual occurrences of the identified deficiency;
- where multiple deficiencies relate to the same requirement of the standard, group the findings into a single Nonconformity/Concern referring to that specific requirement;
- in the case of a multisite laboratory, generalised findings identified across multiple sites may be consolidated into a single overall finding; conversely, where a finding is specific to a single site, the relevant site shall be clearly identified.

9.1.1.1. Examples of findings classifiable as NONCONFORMITIES:

- The working standard calibrator “Manufacturer model” exhibited a malfunction during the execution of the calibration in the presence of the Technical Assessor: for functions xxx and yyy the set values are not correctly generated; consequently, it is considered that the relevant CMCs cannot be guaranteed [LAT scheme].
- The outcome of the ILC in which the laboratory participated in 201x, reported in interlaboratory comparison report no. nn-xxxx-yy dated dd-mm-yyyy, was negative (compatibility index greater than one in absolute value) for measurement functions/points xx and yyy, but to date this result has not been analysed [LAT scheme].
- The Calibration Certificate issued on yyyy-mm-dd following the on-site experimental assessment refers to the calibration of xxxx, but reports on page 3 of 3 information relating to stability [“here the information subject to the finding is reproduced”]. Such information is not assessed by Accredia as for these calibrations accreditation is only as a LAT Calibration Laboratory (ISO/IEC 17025) and not as a Reference Material Producer (ISO 17034) [LAT scheme].
- With regard to the declaration of conformity, the criteria under which the laboratory defines its decision rule and associated statistical risk level, where such rule is proposed by the laboratory, have not yet been implemented in the system [LAT scheme].
- The stability of the conductivity solution at the value of nnn uS/cm has not been assessed [RMP scheme].

9.1.1.2. Examples of findings classifiable as CONCERNS:

- The Quality Manual rev. xx dated dd-mm-yyyy and procedure PG nn “title” rev. nn dated dd-mm-yyyy, documents issued and in use at the LAT, have not yet been submitted to the ACCREDIA DT Technical Officer for assessment [LAT/RMP scheme].
- For the first quarter of yyyy, the list of certificates issued under accreditation has not yet been submitted to ACCREDIA DT [LAT scheme].
- The internal audit is not carried out by personnel meeting the specific requirements related to ISO/IEC 17025 as defined in the Laboratory procedure PG nn rev. nn para. nn (ref. internal audit dated dd-mm-yyyy) [LAT scheme].
- The format of the RM label has not been implemented in the system [RMP scheme].
- The methods for risk and opportunity assessment are not defined according to objective criteria [RMP scheme].
- During the present on-site assessment, it was observed that the RMP uses containers of different capacities for material packaging. However, in the production planning phase and consequently in the stability assessment phase, the influence of the primary packaging material and container volumes on the stability of the produced material is not considered [RMP scheme].
- With regard to the use of the ACCREDIA mark, the following is noted:
 - a. the use of the mark has not yet been implemented with reference to MLA/MRA coverage also for the RMP scheme;
 - b. on the RMP website, the ACCREDIA mark is displayed on the homepage without the identification code of the relevant scheme; furthermore, the mark is not compliant with the graphic representation shown in RG-09 para. 12 (ACCREDIA mark within a white frame);
 - c. offer no. nn/XXXX dated dd-mm-yyyy, which includes only services not covered by the accreditation scope, does not clearly identify the non-coverage of accreditation for the products/services offered (ref. RG-09 rev. 09 para. 5.6.5).

A Concern that has not been closed during a surveillance/renewal assessment **shall be reclassified as a NONCONFORMITY in either of the following cases:**

- when the CAB has not implemented any of the proposed treatments/corrective actions;
- when the CAB has implemented the proposed corrective actions, but these have proven ineffective in eliminating the root cause.

In other cases, where the proposed corrective actions have been only partially implemented by the CAB, the Concern shall be closed for the actions already completed and a new CONCERN shall be raised, limited to the actions still in progress.

Where a Concern remains open or has been partially closed, an additional finding (OSS) shall be raised with respect to the lack/ineffective implementation of the planned corrective action.

Concerns that remain open due to the exceptions described above shall in any case be closed during the next scheduled surveillance assessment at the CAB site.

9.1.1.3. Examples of findings classifiable as COMMENTS:

- The need has emerged to adopt, for the assessment of the LAT, a new integrated checklist explicitly covering ACCREDIA DT, EA and ILAC requirements, and consequently to plan training/updating of internal auditors (reference: interview with the RdC and internal meeting minutes between the CAB and Management dated dd-mm-yyyy) [LAT scheme].
- In view of recurring issues related to the reference standard for the quantity Blablabla, it is recommended to consider making fully operational as a reference standard the second Bliblablu system already available at the LAT and currently in “observation” status [LAT scheme]].

10. Annex I

10.1. Breached mandatory and contractual requirements

This document provides guidance on the conduct to be adopted by an ACCREDIA DT Assessor when a breach of legal or contractual requirements attributable to an organisation is identified during the Assessment.

It is, in fact, important to correctly classify identified breaches in order to enable prompt and proportionate management by the CAB, and to reconcile the responsibility of the Assessment Team with the assignment received from the Head of Department.

The following clarifications are provided.

Where the breach of legal/contractual requirements **falls within the scope of the assessment**, the Assessor shall issue a NC or, in any case, a finding referring to the specific violated normative requirement (e.g. breach by a Biobank of privacy legislation relating to samples obtained from donors).

Where the breach of legal/contractual requirements is **only an aspect related** to the scope of the assessment, the Assessor shall raise a Comment (Cm) in order to prompt the Laboratory concerned to keep these aspects under control during subsequent on-site assessments under this scheme (e.g. the provision of personal protective equipment for laboratory technicians and possible breaches of laboratory waste disposal regulations).

Where the alleged breach of legal or contractual requirements **falls entirely outside** the scope of the Assessment, it is appropriate that the Assessor does not report it in the assessment report, as it is outside the scope of the evaluation and because it is not possible to ensure competence on every regulatory aspect not included within the scope of the Assessment (e.g. a possible breach of labour or tax law within a laboratory where this has no impact on calibration results).

In any case, the ACCREDIA DT Assessor shall always consult the Head of Department before proceeding with the drafting of the report, which shall be countersigned by the CAB.

With regard, instead, to the procedure to be followed for the management of information potentially relevant under criminal law arising from ACCREDIA audits, the following procedural steps are envisaged:

- a. Where information potentially relevant under criminal law is collected during the audit at the CAB—as is most often the case—the relevant evidence shall be recorded by the ACCREDIA DT Assessor in the audit documentation. If the information is not relevant to the scope of the audit, it would in fact fall outside the obligation to report.

The Assessor who has identified such information in the CAB audit documentation shall immediately notify the Head of Department by email, indicating the seriousness and

exceptional nature of the case, also to allow the timely management of the issue (the email may be preceded or followed by a telephone call for clarification).

If, based on their respective sector-specific expertise, the persons involved do not consider it possible to exclude potential criminal relevance, they shall immediately involve the Director General and jointly decide on the appropriate course of action; prior to any report to the competent authority, the Chair of the Supervisory Body shall be informed.

- b. Where the information is obtained outside the CAB audit activities (e.g. reports or complaints containing unequivocal evidence), the ACCREDIA staff member receiving it shall immediately report it to the Head of Department, who shall, in all cases, carry out an initial review of the information received. If, based on their sector-specific expertise, they do not consider it possible to exclude potential criminal relevance, they shall immediately involve the Director General and jointly decide on the appropriate course of action, informing the ACCREDIA staff member who received the report, for whom the principles of confidentiality and whistleblowing protection shall apply to the highest degree. Prior to any report to the competent authority, the Chair of the Supervisory Body shall be informed.

With regard to the investigative tools that ACCREDIA DT Assessors may use during audits at CABs, it should be noted that the proper fulfilment of the role of the National Accreditation Body requires audits at CABs to be carried out in a diligent and consistent manner, particularly with regard to the tools used for collecting information that may have legal relevance.

It is necessary, indeed, to consider three different risk scenarios, which must be mitigated:

- negligent failure to seek information suitable for identifying possible unlawful conduct by CABs;
- misuse of the investigative powers of ACCREDIA DT Assessors/Technical Experts, resulting in breaches of both the applicable technical standards and the legal and contractual obligations towards CABs;
- lack of consistency in the investigative techniques and tools used by individual ACCREDIA DT Assessors/Technical Experts.

For this purpose, it is considered appropriate that, during ACCREDIA DT audits, where applicable, invoices (and related proof of payment) issued by CABs to client organisations, including expense reimbursements, are verified.

The following behaviours are not permitted for ACCREDIA DT Assessors and Technical Experts:

- 1.raising findings or conducting investigations relating to regulations that do not fall within the scope of the assessment, as assessments and any findings must be carried out exclusively against applicable standard requirements;
- 2.collecting or evaluating administrative data not relevant to the assessment activities (e.g. breaches of tax law);
- 3.collecting or evaluating sensitive or confidential personal data (e.g. health data of employees).

Where an assessment at subcontractors is foreseen, ACCREDIA DT Assessors shall maintain an observer role, without carrying out independent verification activities separate from the CAB Assessment Team.

As regards the identification of situations in which it is appropriate to submit reports to the public authorities (in the forms provided for by applicable legislation), ACCREDIA DT shall, across all schemes and sectors, make such reports where audit evidence collected during the Assessment at the CAB indicates fraudulent conduct by CAB personnel, involving intent and aimed at altering the outcome of the accreditation assessment, including the provision of false information or the presentation of falsified or otherwise untruthful documents.

Such behaviours alone may, in fact, taking into account the public relevance of accreditation as provided for by applicable European and national legislation, assume criminal relevance, in addition to justifying the ordinary sanctioning measures applied by ACCREDIA (withdrawal, reduction or suspension of accreditation). Reference is made to ISO 17011:2017 regarding fraudulent behaviour.

In any case, the decision to transmit reports to the competent Authority shall be assessed on a case-by-case basis, taking into account all concrete circumstances, in compliance with applicable legislation, the principle of cooperation with competent authorities, and in accordance with the procedural steps set out in this protocol.

The case-by-case approach shall also apply to the identification of the Authority to which the report is to be addressed.

Finally, it should be noted that ACCREDIA DT Assessors and Technical Experts cannot in any case be considered as judicial police officers (a status that can only be conferred by an explicit legal provision), which therefore excludes the attribution of the powers and prerogatives associated with such role.

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