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- 2) Vocabulary and abbreviations:

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- 3) Modality of review
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- 6) Records

Scope:

This procedure is applied to the accreditation process of conformity assessment bodies.

Responsible for the application:

Heads of Department/accreditation officers are responsible for applying this procedure.

Amendement

The accreditation procedure has been completely resumed.

Established on:17/01/2023

By: Heads of Technical

Departments

Visa:

Verified on: 17/01/2023

By: Quality Manager

Visa:

Approved on: 19/01/2023

By: General Director

Visa:



1. Object

The purpose of this procedure is to define the general procedures for implementing the assessment, monitoring and reassessment process according to the requirements of the ISO/IEC 17011 standard and other applicable requirements (MLA).

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2. Vocabulary and abbreviations:

Conformity assessment: demonstration that specified requirements are met. Note 1 to entry: Specified requirements can be formulated in normative documents such as regulations, standards and technical specifications.

Conformity Assessment Body: body that carries out conformity assessment activities, excluding accreditation.

Accreditation criteria: criteria defined in internationally recognized and accepted normative documents and which aim to promote confidence in organizations that meet these criteria.

Assessment: process implemented by an accreditation body to determine the competence of a conformity assessment body, on the basis of standard(s) and/or other normative documents, and for a scope of accreditation defined.

Remote assessment: Assessment of the geographical site or the virtual site of a conformity assessment body by means of electronic means.

Surveillance assessment: Systematic iteration of conformity assessment activities as the basis for maintaining the validity of the claim of conformity

Note: Surveillance is an assessment carried out by ALGERAC after initial assessment or renewal until the expiration of the accreditation to ensure that the CABs continuously meet the accreditation requirements.

Complementary assessment: a complementary assessment may be necessary if unresolved critical reservations have been identified by the assessment team in order to obtain additional information or evidence regarding the measures taken to address them.

Additional assessment (Extraordinary): may take place, following complaints, changes in the organization of the CAB subject to assessment (significant reorganization, transfer of accreditation), significant modification of accreditation requirements (transition).

Renewal (Reassessment): Assessment carried out in order to renew the accreditation cycle.

Preliminary visit: the preliminary visit is an evaluation realized on the proposal of ALGERAC, when the CAB is not able to correctly report the technical information concerning its application for accreditation. , or to describe the fields, scopes or activities covered by its request for accreditation.

Assessor: person who carries out, alone or as a member of an assessment team, the assessment of a Conformity Assessment Body.

Evaluation team: all the members designated to participate in the implementation of an evaluation procedure and whose respective rights and duties are defined in the ALGERAC procedures.

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Accreditation manager: permanent person who monitors the accreditation file of the CAB and who can attend the evaluation as an observer.

Lead assessor (LA): quality assessor appointed to ensure the evaluation and lead an evaluation team, for the coordination of the work, the meetings for the opening and closing of the evaluation work, the follow-up any discrepancies and the preparation of the final evaluation report.

Technical Assessor (TA): evaluates the technical adequacy of the provisions put in place in accordance with the accreditation criteria.

NB: the LA/TA is responsible for assisting the expert in the evaluation of the technical requirements of the accreditation reference system.

Technical Expert (EXP): person designated by an accreditation body, working under the responsibility of an assessor, who brings specific knowledge or expertise within the scope of the accreditation to be assessed but does not carry out an assessment of independently.

Supervisor (SUP): person in charge of evaluating the performance of an evaluator within the framework of the monitoring and evaluation of competences.

Observer (OBS): person who accompanies the evaluation team, but who does not evaluate.

Critical deviation: a critical deviation is a deviation that calls into question the reliability of the results or the ability of the management system to maintain the level of quality of the conformity assessment services (non-satisfaction of a requirement)

Non-critical deviation: a non-critical deviation whose result does not affect or is not likely to affect directly and immediately the quality of the conformity assessment services. An accumulation of non-critical deviations concerning the same requirement may reveal a major shortcoming in the system and will therefore be considered as a critical deviation. A non-critical deviation systematically affecting several departments, activities and personnel will be considered critical.

A non-critical deviation identified during two successive assessments becomes critical because it proves that the system is faulty.

CAB: Conformity Assessment Body

GD: General Director

TQD: Technical/Quality Director

DAR: Director of Administration and Resources

Accreditation Procedure



PRO 12 Rév 12/17-01-2023

FCD: Finance and Commercial Director

HD: Head of Department
AM: Accreditation Manager
LA: Evaluation Team Leader
TA: Technical Evaluator

EXP: Expert **PV**: Minute

3. Modality of review:

The Quality Manager reviews this procedure each time it is necessary for improving the functioning of the ALGERAC system.

4. Reference documents:

- ISO/IEC 17000 "Conformity assessment vocabulary and general principles"
- ISO/IEC 17011 "Conformity assessment General requirements for accreditation bodies accrediting conformity assessment bodies"
- ISO/IEC 17025 "General requirements for the competence of testing and calibration laboratories"
- ISO/IEC 17020 "General criteria for the operation of different types of bodies performing inspection"
- ISO/IEC 17021-1 "Requirements for bodies providing audit and certification of management systems" Part 1: Requirements
- ISO/CEI 17024 "General requirements for certification bodies certifying persons"
- ISO/IEC 17065 "General requirements for bodies operating product certification.
- ISO 15189 Medical laboratories requirements for quality and competence
- ISO 19011 "Guidelines for management system auditing"
- GEN 01: quality manual
- PRO 03: Procedure for backing up computer data and updating the website
- PRO 07: Committee management procedure
- PRO 16: Accreditation decision
- PRO 18: tariffs and accreditation fees
- PRO 22: Recusal processing
- PRO 25: Procedure for surveillance, renewal and extension of the scope of accreditation
- GEN 14: Skills Matrix
- PRO 29: Remote Assessment Procedure
- PRO 26: Accreditation procedure for Multi-Site CABs
- PRO 31: accreditation transfer procedure
- PRO 30: Risk Management Procedure

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5. Description of the procedure

I- Step I- Receipt of a request

Flux	Description	Respon sabilit é	Doc
Accreditation request and payment of fees Administrative admissibility	The candidate formulates his request using the accreditation request completed by the documents listed in the appendix of the accreditation request according to the activity and payment of the file filing fees.	CAB HD/AM	DOC 01 DOC 01-1 DOC 01-2 FOR 04 FOR 05 FOR 05-1 FOR 06 FOR 07 FOR 07-1 FOR 07-5 PRO 18
study	2) Administrative admissibility study:		
Request missing documents	Administrative admissibility study and Inform the CAB in the event of missing documents and review of resources by examining the database of assessors / experts / GPAC, ensuring the availability of assessors / experts enable and competent in the subject scope of the accreditation request.(*)	HD/AM	FOR 29 FOR55 GEN 14
Admissibility file	In the event of inability to process the request (lack of competence), ALGERAC informs the applicant of the possibility of calling on a foreign assessor/expert with the financial impact that this may entail.	HD	FOR 55
Admissioney	The completion of the file cannot exceed a period of six (06) months. Beyond this period, the file is considered closed.		
Yes	The realization of the preliminary visit is optional and takes place when ALGERAC wants to ensure that there are no obstacles to the evaluation. This visit will allow you to		
Proliminary visit (optional)	size the evaluation in relation to the number		
Preliminary visit (optional)	of evaluators / experts and the duration (sites, activities,	HD/AM	FOR 55
-	additional skills required) (see appendix 01)		
1	In the event that ALGERAC finds a blocking element,		
Establishment and transmission of the accreditation agreement and	the evaluation can only take place once the obstacle has been removed.	CAB	DOC01
the quote	Once the file is admissible, Assignment of a file number. the request is validated by the CEO	HD/AM GD	DOC 01-2
Validation of the agreement and the quote	3) Establishment and transmission of the agreement and the estimate of the cost of accreditation to the CAB for validation.	FCD HD	DOC02 FOR44 FOR48
Yes classify the file	The estimate is established according to the composition of the designated evaluation team as well as the duration of the evaluation (H/d) according to appendix 03, Subject to a risk analysis carried out by the HD concerned.	AM HD	PRO 18 PRO30 FOR 77-1
	If necessary in a specific field, the HD can call on an expert to provide it with additional information on the activity		

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covered by the request on which the HD can rely to determine the duration of the assessment. The CAB must return the quote and the agreement within a period not exceeding ten (10 days) from the transmission. Beyond that, a reminder is sent to it with an Transmission of confidentiality additional period of five (05) days. In the event of nonand impartiality commitments validation by the OEC, the file is closed. Email 4) Transmission and signature of confidentiality and CAB FOR 01-1 impartiality commitments by the designated team. HD/AM 5) Transmission of the team composition sheet for FOR26 Transmission of the composition validation. sheet 6) The CAB has the possibility of making justified objections to the appointment of an assessor/expert within HD/AM a period not exceeding three (03) days after receipt of the **PRO 22** form. FOR 26 Process the 7) ALGERAC examines the objections in order to determine **PRO 22** CAB recusal their grounds and take the necessary measures. FOR 26 8) In the event of a change in the team, inform the CAB HD/AM and signature of the commitment of confidentiality and FOR01-1 impartiality by the new assessors. Yes Recusal of HD/AM 9) Transmission of the CAB documents to the evaluation a member LA/TA team to carry out the documentary review (quality and FOR 56 **EXP** technique), once the team composition sheet has been FOR 56-1 validated. Email No 10) The evaluation team has a maximum of fifteen (15) days to submit the documentary review report. HD/AM **FOR 56** Documentary review (quality Receipt of the quality and technical documentary review FOR 56-1 and technical) and the CAB is informed of the results Email LA/TA 11) The CAB must respond to the shortcomings and decide EXP to continue and carry out the assessment or take charge of the shortcomings detected within a period not exceeding three (03) months from the date of the notification. CAB Yes FOR 56 Following the response of the CAB or exceeding the Deviations noted deadlines, the HD decides to continue or stop the HD/AM FOR 56-1 accreditation process. LA,TA, **Email EXP** Take charge of No detected **Deviations**

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NB:

(*) The evaluation team is composed of an evaluation team leader (LA) and at least one technical evaluator (TA) and/or technical experts (EXP) and/or supervisors (SUP) and/or Observers (OBS) and/or Trainee assessor (TRA).

Call an expert in the following cases:

- 1. Absence of an authorized technical evaluator in the subject area of the evaluation;
- 2. Scope of accreditation for a rare filed.



Step II: Preparation and on-site evaluation.

Flux	Description	Responsa bilité	Doc
Transmission of tasks and missions of the evaluation team members	12) Transmission by e-mail of the tasks and missions of the members of the evaluation team. If necessary, the CD/RA meets with the team to prepare for the evaluation. The meeting is held in the premises of ALGERAC or in any other appropriate place.	HD/AM	Mail FOR 47
Establishment and transmission of mission orders	13) Establishment and transmission of mission orders to the team.	DAR/ HD/AM	FOR 18
Establishment of the evaluation plan	14) Establishment of the evaluation plan after consultation with the team on the basis of a risk analysis established before	LA	PRO 30 FOR 77-1 FOR 32
Validation of the evaluation plan	15) Validation of the evaluation plan by ALGERAC.	HD/AM	FOR 32
Transmission of the evaluation plan to the CAB	16) Transmission of the evaluation plan to the CAB within a minimum period of five (05) days before onsite evaluation.	LA	FOR 32
	17) Conducting the on-site assessment: After the opening meeting, the assessment team conducts the on-site assessment according to the assessment plan	Aassess ment team	FOR 32 Annexe 02
Presentation of findings Recusal of the none conformities Send the file to the CAS for decision	18) Before the closing meeting, the LA consults with the members of the team in order to reach a consensus on the nonconformities. If the team cannot reach a consensus, the REE calls on the department concerned for an opinion. During the closing meeting, presentation of the findings of the assessment with delivery of the discrepancy sheets. In the case of a not accepted none conformities by the CAB, the LA informs the HD for support. The HD and/or assessor and/or expert not involved in the file handles the case. If the CAB persists in its position, the file is sent to the CAS for decision.	Aassess ment team HD/AM CAB SAC	FOR 02 Annexe 02 PRO 07 PRO 16

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	19) Treatment of discrepancies:		
	proposal of an action plan		
Proposal of an action plan	Within a period not exceeding ten (10) days, the CAB sends the filled discrepancy sheets with a proposal for a relevant action plan to the LA.	САВ	FOR 02 Email
1	When the response time is exceeded, a reminder will be notified to it, by the LA, and the CAB must react within five (05) days.		
Evaluation of the relevance	Assessment of the relevance of action plans		
of the action plans	The evaluation of the relevance of the action plans is carried out within 05 days.	LA/TA	FOR02
	Monitoring the implementation of action plans		
Relevant	The monitoring of discrepancies is ensured by the evaluation team until the expiry of the deadline for processing discrepancies.	LA/TA	FOR02
action plans	An additional evaluation (***) may be triggered by the HD at the request of the evaluation team, in order to verify the removal of critical deviations.		
Implementation of the Action Plan	The removal of critical and non-critical deviations for the initial evaluation must not exceed a period of six (06) months after the date of the closing meeting, beyond which the file is presented to the CAS for decision.	LA/HD	FOR 08 FOR 09 FOR 09-1 FOR 10
	All critical none conformities must be settled, as for non-critical none conformities, a relevant action plan is accepted for the passage to the committee to rule on the file.	CAB	EOD 03
Relevant action plans	Verification of the effectiveness of the proposed actions will be done during the next evaluation.	LA/TA	FOR 02
		EXP	
Yes Compleme Assessm			
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(***) Additional assessment:

The process of the complementary / supplementary assessment follows the following steps:

- 1- Transmission of the quote;
- 2- Transmission of the team composition sheet;
- 3- Establishment of an evaluation plan;
- 4- Validation and transmission of the evaluation plan to the CAB;
- 5- Establishment and transmission of mission orders to the complementary evaluation team:
- 6- Transmission of the evaluation report within a maximum period of 15 days.



Flux	Description	Respons	Doc
Ttux	Description	abilité	Doc
Transmission of the report	20) The LA sends the evaluation report to ALGERAC for verification, within thirty (30) days after the closing meeting.	LA	FOR 08 FOR 09 FOR 09-1 FOR 10
Report validation Support from	assessor and the HD/QTD. The HD completes the report's assessment sheet. Transmission of the report to the commercial	HD/TQD	FOR 23
Rapport Validé Yes Convocation of the CAS	22) Summons of the SAC: After the critical deviations have been resolved and/or the deadlines have expired, convocation of the SAC with the agenda and information on the commitment to confidentiality and impartiality. Inform the CAB of the SAC component before the meeting.	HD/AM	PRO 07 FOR 58 FOR 01 Email
Examination of the file by the CAS	23) Examination of the file by the SAC Issue of an opinion by the members of the SAC. The summary of the opinions is drawn up by the president of the committee. On collegial opinion, the committee decides according to PRO 16.	SAC SAC presiden t	FOR 14 FOR 15 FOR 42 PRO 16 PRO 07
Decision by CAS CAB notification	24) Immediately notify the CAB of the CAS decision	HD/AM	FOR 63-8 FOR 63-12 FOR 16 FOR16-1 FOR16-2 FOR16-3
Į.	25) Following the favorable decision to grant accreditation, establishment of the certificate and the technical appendix.	HD/AM	Annexe technique
Establishment of the accreditation certificate and technical annex	26) Establishment and transmission of the monitoring plan to the CAB based on a risk	HD/AM	FOR 66 PRO 30
1	analysis.		
Establishment and transmission of the monitoring plan	27) Transmission of the customer satisfaction sheet.	HD/AM QM	FOR 22
•			
Transmission of the customer satisfaction sheet			

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Step IV - Surveillance assessment

Flux	Description	Responsabilité	Doc
Implementation of the monitoring plan	The surveillance assessment is carried out in accordance with the surveillance plan for the entire accreditation cycle, already transmitted to the CAB at the end of the accreditation.	HD/AM	FOR 66
Translation (FOD (C	01) Transmission of the list of documents to be provided one month before the scheduled evaluation date.	HD/AM	FOR 68
Transmission of FOR 68	The preparation of the surveillance assessment and the choice of the scope of the assessment must be carried out on the basis of a risk analysis.		
Receipt of CAB documentation	02) Receipt of CAB documentation In such case where the CAB does not send the documents on time, the provisions of PRO 23 is applied.	CAB HD/AM	PRO 23 FOR 68
Transmission of the quote	03) Establishment and transmission of the accreditation quote to the CAB for validation	FCD/ HD/AM	FOR 44 Mail
Transmission of confidentiality and impartiality commitments	04) Transmission and signature of confidentiality and impartiality commitments by the team	HD/AM Assessment team	FOR01-1
Transmission of the team composition sheet	05) Transmission of the composition sheet of the evaluation team to the CAB for validation	HD/AM CAB	FOR 32 FOR 18 FOR 08 FOR 09
Completion of step II	06) Completion of Step II is described above with the timelines mentioned in PRO 25	HD/AM	FOR 09- 1 ou FOR 10 FOR 02
CAB notification	07) The CAB is notified for each decision taken by ALGERAC.	HD/AM	Notifica tion latter

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NB:

- 1- In the case of a change of one of the members of the evaluation team, the documentary review step is applicable.
- 2-If the HD is mandated as evaluation lead assessor, the QTD validates the evaluation plans, the evaluation reports.



6. Records:

- Accreditation request (DOC01)
- Technical information for inspection bodies (FOR 04)
- Technical information for test and analysis laboratories (FOR 05)
- Technical information for medical biology laboratories (FOR 05-1)
- Technical information for calibration laboratories (FOR 06)
- Technical information for certification bodies (FOR 07)
- Technical Information Product Certification Body (FOR 07-5)
- Accreditation agreement (DOC 02)
- Estimated quote (FOR 44)
- Evaluation plan (FOR 32)
- Report on the administrative documentary review (FOR 55)
- Report on the quality and technical documentary review (FOR 56)
- Report on the Acceptability of method and/or analytical process (FOR 56-1)
- Evaluation team composition sheet (FOR 26)
- Letter of commitment to impartiality and confidentiality of assessors/experts (FOR 01-1)

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- Mission order (FOR 18)
- Evaluation report for inspection bodies (FOR 08)
- Evaluation report for laboratories (FOR 09)
- Assessment report for medical biology laboratories (FOR 09-1)
- Assessment report for certification bodies (FOR 10)
- Customer satisfaction sheet on the operation of accreditation (FOR 22)
- Evaluation report assessment sheet (FOR 23)
- Discrepancy sheet (FOR 02)
- Invitation (FOR 58)
- Minutes of the meeting of the specialized accreditation committee (FOR 42)
- Opinion of the members of the specialized accreditation committee (FOR 14)
- Decision of the specialized accreditation committee (FOR 15)
- Accreditation certificate (FOR 16, FOR 16-1,16-2,16-3)
- Monitoring plan (FOR 66)
- Letter of notification (FOR 63,FOR 63-1,...,FOR 63-12)
- Annex 03
- Risk analysis and commitment to confidentiality and impartiality of a SAC member (FOR 01)
- List of documents within the framework of a monitoring assessment (FOR 68)
- Analysis of risks related to the programming of evaluations (FOR 77-1)



Annex 1: Preliminary visit

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Where ?	The preliminary visit* can be scheduled on the proposal of ALGERAC and with the agreement of the CAB.
Objectives	 Ensure the admissibility of the file Determine the duration of the evaluation
Nature of the service	Paid by the OEC.
Team composition by CD	HD or AM with an assessor or technical expert, if necessary.
Duration	Minimum 01 day / site
Report of the preliminary visit	Report of the visit
Transmission Deadlines	After ten (10) days, the CD validates the report and sends it to the client.
Terms and Rules Consulting service	No advice during or after the visit.

^(*) The number of preliminary visits is limited to one visit per accreditation request.

Appendix 02: Opening Meeting and Closing Meeting

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The following are the points to be mentioned at the opening meeting:

- Introduction of the participants, and brief description of their roles
- Reminder on the purpose of the assessment
- Confirmation of the assessment plan and other provisions with the conformity assessment body (CAB)
- Presentation of the assessment progress
- Reminder on the assessment standards
- Confirmation of the provisions related to the confidentiality and accuracy of information
- Confirmation of the working language during an assessment
- Information related to findings and their classification
- Confirmation of documentation validity
- Methods for evaluating the sampling strategy Ensuring the availability of resources and logistic means
- Confirmation of the procedures related to health, security, emergencies and safety which are applicable to the assessing team if need be.
- Information regarding the way with which possible findings identified during an assessment are handled
- Right of appeal

The following are the points to be mentioned at the closing meeting:

- General presentation of the assessment results while referring to the previous assessments if need be
- Body"s strong points
- Points of improvement
- Possible additional information on non-conformities or remarks
- Overall assessment with regard to the confidence in the body"s organizational and technical competence to provide the services mentioned within the accreditation perimeter
- Presentation of findings and their impact on accreditation, and the delivering of finding sheets.
- Terms and time limits for findings follow-up, and forwarding of assessment report
- Information on the decision making (SAC)
- Right of appeal