Page: 1 / 23

# History of amendments:

Amendments	Date approved
00	16 December 2006
01	09 October 2011
02	09 October 2013
03	09 December 2016
04	29 March 2017
05	30 Avril 2020
06	05 February 2023

Approved by: N. BOUDISSA

**GENERAL DIRECTOR** 



Titre	Page
CHAPTER 1: ACCREDITATION BODY	4
I.1 Purpose of the quality manual	4
I.2 Terms and abbreviation	4
I.3 The Algerian Accreditation Body - ALGERAC	5
I.4 Quality policy	6
I.5 Legal status of the Algerian Accreditation Body, ALGERAC	8
I.6 Authority and responsibility	8
I.7 Management's authority and responsibility	8
I.8 Maintenance of knowledge	11
I.9 Committees	11
a. Activities Accreditation committee	11
b. Specialized Accreditation Committee	11
I. 10- Impartiality	12
a. ALGERAC Impartiality, Independence and integrity	12
b. Impartiality and independence of the Accreditation Activities Committee (AAC)	12
c. Impartiality and independence of the Specialized Accreditation Committees (SAC)	12
d. Impartiality and independence of assessors and experts	12
e. No discrimination	13
f. No pressure	13
g. No advice	13
I.11 Confidentiality	13
a. Staff	14
b. Committees	14
c. Assessors and experts	14
d. Board Management	14
e. Information flow	14
I.12 Legal responsibility and financing	14
a. Liability insurance	14
b. Financing	14
I.13 Accreditation activities	15
a. Activities Description	15
b. Accreditation criteria	15
c. Responding to market demand	15
CHAPTER II. OBLIGATIONS OF ALGERAC AND THE CABS	15
II.1 Obligations of the CABs	15
II.2 Obligations of ALGERAC	15
a. Traceability	16
b. Reference to accreditation and use of symbols	16
CHAPTER III: STRUCTURE	16
a. General organizational Chart	16
b. Functional chart	17
	1

Chapter IV - Human Resources	
IV.1 Personnel of the accreditation body	
a. Competence	
b. Selection and qualification	
c. Duties	
d. Undertakings	
IV.2 Personnel involved in the accreditation activity	
IV.3 Monitoring	
IV.4 Personnel records	
CHAPTER V: ACCREDITATION PROCESS	
V.1 Information and accreditation criteria	
V.2 Application for accreditation	
V.3 Resource review	••••••
V.4 subcontracting the assessment	
V.5 Preparation for assessment	
a. Preliminary visit	
b. Assessment team	
c. Assessment plan	
V.6 Documents and records review	
V.7 On site assessment	
V.8 Analysis of findings and assessment report	
V.9 Decision making and granting accreditation	••••••
V.10 Appeals	•••••
V.11 Surveillance and reassessment	•••••
V.12 Extension of accreditation	••••••
V.13 Suspension, reduction or withdrawal of accreditation	
V.14 Records on CABs	
V.15 Proficiency tests and other type of inter-comparison	······································
CHAPTER VI: MANAGEMENT SYSTEM	
VI.1 Documents control	
VI.2 Records	
VI.3 Non-conformities, corrective actions	
VI.4 Internal audits	
VI.5 Management review	
VI.6 Complaints	

# Page: 4 / 23

#### **CHAPTER 1: ACCREDITATION BODY**

# I.1 Purpose of the quality manual

This manual describes the provisions adopted by ALGERAC to perform its accreditation activity in line with its establishment decree and the relevant national and international standards. It aims to:

- Describe its structure and operation,
- Present its management system.

This quality manual, the documented procedures as well as appendices and forms attached to it represent the reference in order to maintain our mutual recognition agreements with other accreditation bodies at regional and international level.

ALGERAC sets and documents policies and objectives for its activities.

The quality policy presented in the Quality Manual has been distributed to the staff and stakeholders.

Accreditation policies are approved general director. They are circulated and explained to all people taking part in the accreditation process.

The General Director sets each year ALGERAC objectives and presents them to the Management Board.

#### I.2 Terms and abbreviation

**ALGERAC:** Algerian Accreditation Body

**CAB**: Conformity Assessment Body

**EA**: European Co-operation for Accreditation

IAF : International Accreditation Forum

**ILAC:** International Laboratory Accreditation Cooperation

MLA: Multilateral agreement

**MRA:** Mutual Recognition Arrangement **ARAC:** Arab Accreditation Cooperation

**SMIIC:** Standard Metrology Institute for Islamic Countries

**MIM**: Ministry of Industry and Mines

**CAA**: Committee for Accreditation Activities

SAC: Specialized Accreditation Committee

**AC**: appeal commission

GD: General Director

**QM**: Quality Manager

**TS**: Technical Secretary

# 1.3 - The Algerian Accreditation Body - ALGERAC

Under the increasing global market pressure, the economic entities are forced to constantly and rapidly evolve.

It is of utmost importance for these structures to ensure confidence in products and services conformity to technical specifications, in order to eliminate technical barriers to trade, promote fair competition and regulate market operation.

Accreditation is an attestation issued by a third party concerning a conformity assessment body. It provides the formal proof of this body competence in carrying out specific conformity assessment activities.

Since 2000, Algeria realized the urgent need to establish a national accreditation body, to be able to withstand globalization.

ALGERAC's role is to provide accreditation for conformity assessment bodies, which want to have a credible reference of their technical competence.

Accreditation is not only a factor for promoting exports it can also be an instrument in the service of public authorities whose role is continuously increasing in the framework of the economic development.

Indeed a test, calibration or inspection report, or the conformity certificate of a system, product, process or person are more credible if they are granted by a body whose impartiality and technical competence have been proved according to objective internationally accepted criteria by the markets.

Market surveillance activities aimed to ensure consumers and environmental protection are of public authority resort.

Therefore, accreditation contributes to the elimination of technical barriers to trade.

# Page: 6 / 23

# 1.4 Quality policy

Accreditation is the most reliable tool to testify to the competence of a conformity assessment body (CAB) such as testing, analysis, calibrating laboratories, inspection and certification bodies (system, product, persons).

Accreditation, which is a voluntary and not-for-profit activity, not only removes trade barriers; as goods and services circulate freely on the national, regional, and international markets, but also stimulates national economic competitiveness.

In order for ALGERAC to carry out the duties entrusted to it, those consisting of ensuring confidence, independence, and competence of conformity assessment bodies (CABs) and as the General Director, I am personally committed to:

- making available all the means needed for ALGERAC to do its job objectively acting;
- ensuring the confidentiality of all information related to accredited bodies or candidates for accreditation, with the exception of favourable accreditation decisions;
- To guarantee the confidentiality of all information concerning accredited conformity assessment bodies or candidates for accreditation, unless permitted or prohibited by law after notified the customer.
- to implement and regularly improve the effectiveness of our management system, based on policies and procedures, in accordance with the requirements of the ISO/IEC 17011 standard and the applicable documents according to the requirements of the EA (the European Cooperation for Accreditation), ILAC (International Laboratory Accreditation Cooperation), IAF (International Accreditation Forum), ARAC (Arab accreditation cooperation), AFRAC (African Accreditation cooperation), and the Institute for Standardization and Metrology for Islamic Countries (SMIIC)) in order to maintain our recognition at the national, regional EA and International ILAC levels for the activities (inspection, testing and calibration laboratories);
- regularly improving effectiveness, as to be recognised domestically, regionally, and internationally;

- to file with the EA authorities, three requests for recognition of the ISO/IEC 17021-1, ISO/IEC 17065 and ISO 15189 accreditation standards respectively for management system certifiers, product, process and service certifiers and the Medical Biology Laboratories.
- jointly with my team, better meeting the needs of interested parties: accredited conformity assessment bodies and their clients (manufacturers, service providers, entrepreneurs, installers, etc.), public authorities, consumers, as well as institutes of standardisation, metrology, research and development, and innovation institutions;
- promoting the process of accreditation in favour of CABs;
- informing accredited laboratories or those applying for accreditation, about taking part in proficiency testing and inter-comparison events organised by peers;
- that each member of my team members has the qualification and required expertise to better carry out the duties entrusted to them, and shall continually improve their competence through standard watch, and continuing training actions;
- Encouraging the establishment of a multidisciplinary network of accredited CABs (laboratory, inspection, certification) in order to spread good practices and harmonise competences.
- encouraging the development of national metrological competences in order to support and give confidence about conformity assessment;
- Encouraging our organization to be more active in the work of the EA / IAF / ILAC / ARAC
   / SMIIC technical committees.

I shall do my best to organise, maintain, and improve any useful relationship with our foreign partners, directly and through international and regional organisations in order to exchange our experiences, and win their trust so as to get recognised.

I bear the responsibility for all decisions of accreditation.

Quality manager is responsible for ensuring the implementation and maintenance of the management system, and is accountable to the general director for the pertinence and performance of the system, and any possible needed improvement.

General Director

**N.BOUDISSA** 

# I.5- Legal status (Legal status of the Algerian Accreditation Body, ALGERAC)

Creation Decree No. 05-466 of December 5, 2005, specifies in particular that ALGERAC is a public establishment of an industrial and commercial nature (EPIC), endowed with legal personality and financial autonomy:

Page: 8 / 23

- ALGERAC is a public body of an industrial and commercial nature, endowed with legal personality and financial autonomy.
- ALGERAC is governed by the prevailing laws and regulations applicable to the administration in its relations with the State and is deemed as a trader in its relations with third parties
- ALGERAC is under the supervision of the Minister in charge of Standardization (MIM).
- ALGERAC has full decision-making authority on accreditation, including granting, maintaining, extending, reducing, suspending or withdrawing it.

# I.6- Authority and responsibility

ALGERAC is administered by a Management Board, and run by a General Director. Articles 10,11,12,14 and 15 of its creation Decree specify the duties, responsibilities and authority as for the Management Board and for the General Director.

Functions involved in the accreditation processes are documented in "the description the job (FOR 24).

# 1.7- Management's authority and responsibility

Decree No 05-466 in articles 7, 13, 14 and 15, defines the different structures having full authority and responsibility for the operation of the accreditation body.

# 1) Management Board

The Management Board has the responsibility to deliberate on:

- The short, medium- and long-term development projects and programs;
- ALGERAC's proposed annual program of activities and the proposed budget thereto pertaining;
- The business report, balance sheets and financial income statements;
- ALGERAC internal regulations;
- The collective agreement;
- The acceptance and allocation of donations and bequests;
- The draft mutual recognition agreements;
- Relations and pooling of experience with similar foreign bodies;

- The general terms and conditions of conclusion of conventions, agreements, contracts and other instruments binding ALGERAC;
- Measures leading to the development of the accreditation system;
- All proposals by the Managing Director regarding the organization and operation of ALGERAC.

In addition, ALGERAC's Board of Directors deliberates on:

- the general policies of ALGERAC related to the operation and management of the organization
- the analysis of the risks relating to the independence, the impartiality and the objectivity
  of the operation of the accreditation and this at all levels of management and decisionmaking
- the pricing according to annual and multi-annual budgets and programs

# 2) General Director is responsible for:

- To Assure the everyday operation of ALGERAC;
- to ensure the implementation of the deliberations of the Board of Directors and report to it on the measures taken for their execution;
- To Signs decision on granting, maintaining, extending, reducing, suspending or withdrawing accreditation;
- To develop the quality policy for the operation of the accreditation body;
- To Ensure the implementation of policies and procedures;
- To Represent ALGERAC in justice and any civil life aspect;
- to exercise hierarchical authority over all ALGERAC personnel;
- to Recruit and license ALGERAC staff.

The General Director has furthermore missions:

- to sign the notification for maintaining, granting, refusal, renewing, extension, suspension and reduction of any accreditation;
- to Ensure the updating and monitoring the implementation of accreditation politics and procedures according the evolution of the criteria;
- to Ensure the implementation of internal regulations for all committees.

#### 3) Appeal commission

The Board of Appeal is responsible for deciding on appeals from conformity assessment bodies to reconsider any decisions taken by ALGERAC.

# 4) Technical/Quality Director:

Is responsible for coordinating all accreditation activities while ensuring the implementation and proper functioning of the management system.

Page: 10 / 23

# 5) technical Head of department is responsible to:

- Coordinate technical activities in his/hers department;
- Ensure the application of policies and procedures on accreditation;
- Ensure the appropriate processing of accreditation files candidate and accredited CABs;
- Ensure competence of assessors and experts;
- Participate, advise, in the selection of candidate assessors;
- Ensure nonconformities have been appropriately handled;
- Assure the external documents control in the specific field;
- Ensure communication and information to CABs.
- ensure that technical documents are updated and sent to assessors
- to propose improvements and developments of ALGERAC's activity.
- 6) Accreditation manager Has the responsibility of processing the accreditation files.

# 8) Administration and Resource Director

Organize, supervise, control and assure the operation of administration and human resources departments.

# 8) Head of Training department

Is responsible for developing annual training and information programs on accreditation for institutions and conformity assessment bodies.

# 9) Finance and accounting director

To develop the management and safeguarding of accounting and financial documents.

#### 10) Responsible for Human resources

Has the responsibility of staff, assessors and experts files.

#### 11) SI department

- Assure system/ network administration.
- Assist users in handling IT equipment.
- Ensure updates of the system.
- Updates the information on the website in agreement with the head of technical departments
  - 12) **Communication Department:** Develop and implement the internal and external communication strategies adopted by the Executive Board to improve the organisation's brand image.

# I.8- Maintenance of knowledge

To maintain an appropriate level of technical and managerial competence related to accreditation, ALGERAC has established at all levels a system designed to identify news in standards and other relevant documents.

Page: 11 / 23

Continuous monitoring and the annual evaluation of assessors and experts allow the identification of training and updating needs.

As a full member of ILAC and an associate member of EA, ALGERAC checks systematically information on their web sites and participates in ILAC, aEA technical committees work. As an associate member of ILAC and EA, ARAC and AFRAC, ALGERAC uses the available databases on the websites and the participating work data of technical committees of EA through an internal committee in charge of the normative and regulatory watch.

Periodically, ALGERAC organizes meetings for assessors and experts to harmonies their evaluation practice.

#### 1.9- Committees

#### a) Activities Accreditation committee:

The Accreditation Activities Committee (CAA) is made up of twelve (12) permanent members, appointed by the GD on the proposal of the DCs for a renewable period of three (03) years. The committee encompasses the necessary competencies required for the evaluation of SAC's work, and all other accreditation activities.

#### b) Specialized Accreditation Committee.

Accreditation committees are created, when need be, in order to ensure that ALGERAC's decisions are made competently and impartially. For each SAC member a service agreement is established for a three (03) year renewable term.

To ensure impartiality in its accreditation activities, the top management has delegated its decision-making authority to nine (09) specialized accreditation committees

The testing laboratory committee shall consist of a minimum of five (05) competent members approved by the AAC encompassing the technical areas of accreditation listed to date by ALGERAC.

SAC's list is not exhaustive, and may widen as long as new scopes of accreditation come to be identified. The list includes:

Page: 12 / 23

- Committee of Biology and agrifood,
- Committee of Building- civil Engineering,
- Committee of Mechanics- chemistry- environment,
- Committee of thermal and electrical

The Inspection Committee, the Calibration Committee, the MS Certification Committee, the Product Certification Committee and the Medical Biology SAC, each SAC is composed of a minimum of five (05) members, approved by the AAC.

The conditions of the establishment and functioning of accreditation committees are registered in the committee management procedure (PRO 07).

# I.10- Impartiality

# a) ALGERAC Impartiality, Independence and integrity

Articles 8 and 10 of the Decree 05-466, defining the composition and operation of ALGERAC Management Board insures that balance between different represented parties.

The internal regulation ensures ALGERAC impartiality, independence and integrity.

However, ALGERAC made provisions to avoid any conflict of interests and/or undue pressure on its personnel and decisions made in the assessment process.

The organization chart proves that ALGERAC operates in complete independence, established a management system based on the requirements of standard ISO/CEI 17011, has its own personnel, logo and budget.

# b) Impartiality and Independence of the Accreditation Activities Committee (AAC)

Each member of the committee agrees to abide by his or her obligations of impartiality, independence, and objectivity in his or her work, in accordance with the AAC Rules of Procedure and the Committee Member Confidentiality and Impartiality Commitment (FOR 01).

# c) Impartiality and independence of the Specialized Accreditation Committees (SAC)

Impartiality and independence of the decision making process are guaranteed for the within the SAC by the involvement of all parties concerned by accreditation without predominance of one of the parties.

Participation of interested parties in each specialized committee is documented in (PRO 07).

The details of the decision-making process are presented in (PRO 16) "Decision on accreditation".

# d) Impartiality and independence of assessors and experts

ALGERAC assessors and experts sign an undertaking stipulating their duties in terms of impartiality, independence and confidentiality.

Page: 13 / 23

ALGERAC assessors and experts who have taken part in a CAB assessment or surveillance are not allowed to take part in the decision, either personally or as a member of a specialized accreditation committee.

# e) No discrimination

ALGERAC policies and procedures are applied in a non-discriminatory manner.

ALGERAC services are available to all potential clients without any discrimination, in the limits of ALGERAC field of activity.

# f) No pressure

Permanent or external staff acts in an objective manner, free from any commercial, financial or other pressure likely to compromise their impartiality. They commit themselves to act impartially and to declare in a general way or for a specific mission any past, present or planned link with the CAB under assessment.

The impartiality of the Management Board, members of accreditation activities, members of the specialized committees and the appeal committee. Results from the variety of professional organizations they belong to, and the impossibility for a member or a group to have a predominant influence.

#### g) No advice

Apart from general information on the accreditation system, accreditation criteria and procedures ALGERAC provides neither counselling, nor conformity assessment services.

#### I.11 Confidentiality

ALGERAC shall ensure that its clients' information remains confidential. This information may include:

- Any document marked "confidential",
- Any information related to an accreditation application,
- Any material collected during an assessment performed by a permanent structure, an assessing team, or ALGERAC's committees. This may also include the corrective actions implemented by the applicant.
- Any information related to the discussion regarding an accreditation application,
- Any information obtained at the end of an intervention in favor of ALGERAC.

Some information may be regarded as confidential, It included:

- Accreditation decisions (granting, renewal, extension of accredited areas, suspension and withdrawal).

Page: 14 / 23

- efforts aiming at developing or evolving accreditation rules (mainly documents or draft documents that can be used against third parties such as ALGERAC's reference documents and technical guides, as well as translated international guides).

In order to ensure the confidentiality of information; be it oral, or in paper or electronic format, the following measures shall be undertaken:

- a. **ALGERAC** staff: All staff is bound by a confidentiality clause at the signature of their employment contract.
- b. **Committees**: Upon installation of the Accreditation and Specialized Accreditation Activities (CAA), (CAS) and the Appeal Commission (CR) committees and at each meeting the CAA, CAS, CR members sign respectively the risk analysis form and the confidentiality and impartiality (FOR 01), (FOR 01-4) respectively.

#### c. Assessors and experts:

External assessors and experts sign a confidentiality undertaking before being empanelled and appointed in an assessment team (FOR 01-1: confidentiality and impartiality experts or assessors).

For the foreign expert, he signs Commitment to confidentiality and impartiality and Impartiality Foreign Experts (FOR 01-2).

- d. **Board Management:** Upon the installation of the Management Board, each member sign a confidentiality undertaking before sitting on the board (FOR 03: Commitment of the members of the Board of Directory).
- e. **Information flow** Provisions made to ensure confidentiality while using Internet are documented in the procedure "Procedure for the management of computer data and website update" (PRO 03).

# I.12 Legal responsibility and financing

#### a) Liability insurance

ALGERAC activities are covered by an insurance policy.

#### b) Financing

ALGERAC provides itself the financial resources to needed to appropriately perform the accreditation activities.

They are mainly coming from the accreditation fees and training and information activities according to market demand.

#### 1.13 Accreditation activities

#### a) Activities Description

In accordance with articles 4 and 5 of Decree No05-466, ALGERAC' role consists in accrediting all type of conformity assessment bodies.

Page: 15 / 23

# b) Accreditation criteria

Accreditation of CABs is carried out based on national, European and international accreditation standards or other normative documents.

All documents used in the accreditation of a specific type of CAB are identified in the list (LIS 02) - "Applicable standards, guides and résolutions" available on ALGERAC website. They are classified according to their application (M - Mandatory document; G - Guidance document; T/A - Technical/ advisory document; INF. - informative document), This is made accessible to the assessors/experts as well as the CABs..

# c) Responding to market demand

ALGERAC general approach is to be always able to respond to the demands of the Algerian economy and of the CABs active in Algeria, according to international accreditation requirements.

The approach to "Extend to new accreditation activities" is documented in (PRO 17).

# CHAPTER II. OBLIGATIONS OF ALGERAC AND THE CABS

#### II. 1- Obligations of the CABs

ALGERAC asks the CABs to fulfil with the accreditation conditions as stipulated in the accreditation agreement (DOC 02), to observe provisions for the use of the accreditation symbol ILAC MRA combined mark and reference to mutual recognition agreement status (EA MLA) as documented in (PRO 19) and to inform of any major change that might affect accreditation.

# II.2- Obligations of ALGERAC

ALGERAC publishes and keeps up to date at all times, on its website, information on:

- Information on the accreditation criteria (LIS 02: List of applicable standards, guides and resolutions)
- Documents related to the Accreditation Process
- Rules of the Appeals Commission and complaints procedure
- Accreditation demand and other forms
- The list of accredited CABs (LIS 04). The information on the accredited CABs include, in particular: the name and address of the CAB, the scopes accredited and the dates of granting and expiring of accreditations.

- The list of suspended and withdrawal accreditations (LIS 04-1), the information includes:
   CAB's name and address and accreditation number, scopes of accreditation, status, date of withdrawal / suspension and date of end of suspension.
- The list and coordinates of EPTIS and main PT provider

# a) Traceability

ALGERAC Policy on traceability of measurement results is documented in (GEN 03).

ALGERAC policy accepts traceability from:

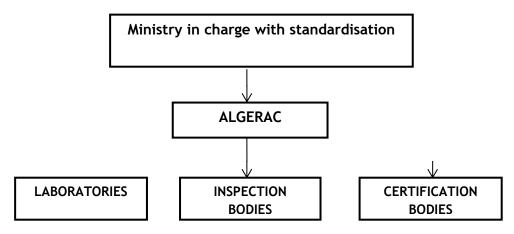
- National Metrology Institutes members of CIPM MRA for quantities/ calibration and measurement ranges with CMS published on BIPM website;
- Calibration laboratories accredited by an AB signatory of ILAC/EA MLA for calibration;
- Certified reference materials provided by a competent supplier
- Using specified methods and/or Consensus standards that are clearly described and agreed by all concerned parties.

# b) Reference to accreditation and use of symbols

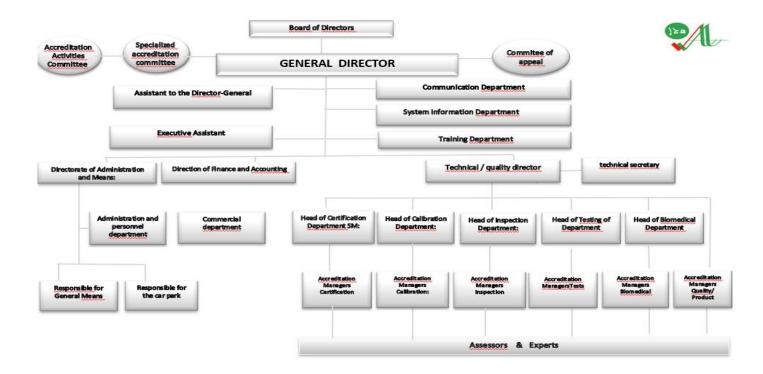
ALGERAC as owner of the accreditation symbol has documented a procedure (PRO 19) for its use and for reference to the accreditation status.

# Chapter III: Structure

#### a) General organizational Chart



#### b) Functional chart



# Chapter IV - Human Resources

# IV.1 Personnel of the accreditation body

# a. Competence

The competence criteria for each person involved in ALGERAC's activities are documented in the procedure for selecting, qualifying and monitoring the competence of evaluators/experts (PRO 06) and the job description (FOR 24).

# b. Selection and qualification

The General Director ensures that ALGERAC has sufficient number of staff with the competence required to perform the overall accreditation activities.

#### c. Duties

For each category of personnel, the scope, responsibilities, duties and requirements of the position are described in the job description (FOR 24).

# d. Undertakings

The conditions of employment, and in particular the rules regarding confidentiality and impartiality, are defined in the employment contract.

# IV.2 Personnel involved in the accreditation activity

ALGERAC can employ external assessors and experts. In this situation, relevant system policies and procedures apply to this category of personnel. Conditions for selection, qualification and monitoring of assessors and experts are documented in the procedure (PRO 06).

# IV.3 Monitoring

Provisions and methods for monitoring of assessors and maintain of empanelment are documented in (PRO 06) "Selection, qualification and follow up of assessors and experts".

Page: 18 / 23

#### **IV.4 Personnel records**

The personal file contains information about the qualifications, training, experience and skills of each person involved in the accreditation process.

ALGERAC maintains a database with updated information on assessors and experts.

#### CHAPTER V: ACCREDITATION PROCESS

The performance of the accreditation process is documented in (PRO 12).

#### V.1 Information and accreditation criteria

ALGERAC accredits CABs according to international standards and documents published by IAF/ILAC/EA/ARAC based on the accreditation criteria, documents and guides relevant to each accreditation system which are listed on the List of Standards, Applicable Guides and Resolutions (LIS 02) available on the website (www.algerac.dz).

# V.2 Application for accreditation

Each CAB applying for accreditation must submit to ALGERAC an application for accreditation of an (inspection body, laboratories) available on the ALGERAC website (DOC 01), Application for accreditation of medical biology laboratories (DOC 01-1), Application for accreditation of product, process and service certification bodies (DOC 01-2), Application for Transfer of Accreditation (DOC 01-3) and the associated forms, including the relevant general information, as well as the scope of the accreditation requested.

ALGERAC performs a thorough review of the information presented by the CAB prior acceptance of the application. This review is recorded in (FOR 55) "Report on administrative review and resource revue.

ALGERAC sends to the CAB a form (FOR 26) in order to approve the persons mandated to review the documentation, FOR 56 Report on quality and technical review documentation and FOR 56-1 report on receivability of methods and/or analytical process in the fields of medical biology.

#### V.3 Resource review

The head of department subject the application is performing a review on available competence and the feasibility to perform the assessment in the period asked for by the applicant CAB. If ALGERAC does not have the capacity to process the application (lack of required competence) it informs the applicant CAB.

# V.4 subcontracting the assessment

It is ALGERAC's policy to perform assessment for accreditation by its own means. However, if necessary, ALGERAC may engage the services of accreditation bodies' signatories to the EA-MLA/MRA, ILAC/IAF recognition agreements. In such cases, external assessors will comply with ALGERAC procedures. Accreditation decisions will never be subcontracted.

Page: 19 / 23

# V.5 Preparation for assessment

# a. Preliminary visit

ALGERAC policy is not to perform systematically preliminary visits (only one preliminary visit for one CAB).

However, the file manager, upon approval of the head of department can program a preliminary visit to clarify aspects for a better preparation and planning of the assessment.

#### b. Assessment team

For each evaluation, the department head appoints an evaluation team with the necessary skills, consisting of an evaluation manager and an appropriate number of evaluators and/or experts. Evaluators in training, observers, and supervisors may be added to the team.

Each member of the team (assessors and experts) must declare to ALGERAC all past and present links with the applicant for accreditation (FOR 01-1). The department head concerned with the application will send a team composition form (FOR 26) to the CAB for validation.

The CAB has the right to object to the appointment of a team member; such objections will be handled in accordance with the recusal procedure (PRO 22).

#### c. Assessment team

The team leader prepares the assessment plan (FOR 32) in collaboration with the team, using a risk analysis (FOR 77) in accordance with the risk management procedure (PRO 30), and submits the plan to the CAB after validation by the department head.

For initial assessments, all sites and activities within the scope of accreditation will be assessed.

For surveillance and renewals, assessments will be conducted in accordance with the surveillance plan (FOR 66).

#### V.6 Documents and records review

provided by the Prior to the on site assessment the assessment team performs a review of the relevant documents and records CAB

# V.7 On site assessment

The on-site assessment is performed as the procedure (PRO 12).

Where the assessment is not feasible on site, due to unforeseen circumstances, subject to a risk, the HD technique concerned organize a remote assessment without compromising the integrity of the accreditation, the procedure for a remote assessment PRO 29 shall apply..

Page: 20 / 23

# V.8 Analysis of findings and assessment report

Prior to the closing meeting the assessment team comes together, in order to prepare the synthesis of the assessment results to review findings, identify critical aspects and grade them according to the gravity. Findings will be presented and explained to the CAB in the closing meeting.

The management and the follow-up of the findings are ensured according to (PRO 12) for the initial assessment and (PRO 25) for the surveillance assessment, the renewal and extension. Following the assessment, feedback on the progress of the assessment is collected from the assessed CAB through FOR 22.

# V.9 Decision making and granting accreditation

The decision making process is documented in procedure (PRO 16). In case of a positive decision, ALGERAC will issue an accreditation certificate (FOR 16) and technical annexes. Initial accreditation cycle is of three (03) years, renewable for four (04) years.

# V.10 Appeals

Appeals are handled according to the regulation of the appeal commission (GEN 04). The appeal committee, whose members are proposed by ALGERAC and appointed by the Management Board, decides on the appeals filled in by CABs against decision made in the accreditation process. ALGERAC notifies the CAB on the outcome of the appeal and implements the decision of the appeal commission.

#### V.11 Surveillance and reassessment

During the period of validity of an accreditation, ALGERAC performs surveillance assessments, which are more limited in content than an initial assessment.

The first surveillance assessment is performed within twelve (12) months of the effective date of accreditation, and then annually until the end of the cycle according to the surveillance plan already established (FOR 66).

The organization may then indicate its desire to maintain its accreditation by submitting a renewal application to ALGERAC no later than six (06) months prior to the expiration of the current accreditation.

Page: 21 / 23

ALGERAC will conduct a renewal assessment in accordance with the accreditation process procedure (PRO 25).

Renewal of accreditation is granted for a period of four (04) years, with three (03) surveillance assessments.

#### V.12 Extension of accreditation

All application for extension of the accredited scope is processed by ALGERAC as an initial accreditation for the new scope. Extension shall not extend the validity of the accreditation cycle.

# V.13 Suspension, reduction or withdrawal of accreditation

Provisions for the suspension, reduction, or withdrawal of accreditation are documented in the procedure (PRO 23).

In case of repeated failure to fulfil the accreditation conditions as stipulated in the accreditation agreement signed concluded with ALGERAC, the CAB can by subject to sanctions like total or partial suspension, reduction of the scope or withdrawal of accreditation.

Accredited CAB can apply for a total or partial suspension of accreditation, reduction of the scope or withdrawal of accreditation.

Decisions on suspension, reduction or withdrawal of accreditation are made according to the procedure (PRO 16) documenting the decision making process.

However, a suspension may not be longer than six (06) months. Suspension is withdrawn when the CAB proves through a complementary assessment that accreditation conditions are fulfilled.

According to rules for using accreditation symbol (PRO 19) suspension reduction or withdrawal imply the CAB has no more the right to claim the accreditation status, or to use the accreditation symbol for services provided under the scope affected by the suspension/reduction decision.

ALGERAC will publish on its web site (<u>www.algerac.dz</u>) decisions of suspension, reduction or withdrawal.

#### V.14 Records on CABs

Heads of accreditation departments maintain records relating to the accreditation process of each CAB to be able to prove that accreditation requirements, including the competence requirements, have been actually fulfilled. Client's files are managed according to the Records control procedure (PRO 02). They are maintained in conditions appropriate to ensure their integrity and confidentiality.

# V.15 Proficiency tests and other type of inter-comparison

ALGERAC policy on inter-comparisons is not to organize itself proficiency tests or other inter-comparisons, but informs CABs to take part in national or international PT schemes. ALGERAC insures that accredited laboratories take part in PT schemes or other type of inter-laboratories comparisons when available and economically feasible. According to GEN 05 « ALGERAC policy on inter laboratory comparisons"

Page: 22 / 23

#### CHAPTER VI: MANAGEMENT SYSTEM

ALGERAC established and runs a management system complying with ISO/CEI 17011 of type "A" and other MLA requirements. ALGERAC management system is operated through documents, which enable it to organize and perform CAB's accreditation. This "documentary system" consists of:

- A quality manual (QM) setting out the overall operating terms of ALGERAC, the quality policy and the legal and standards basis;
- Procedures (PRO) which determine the performance and management of accreditation activities;
- Forms (FOR) used to the record of ALGERAC activities;
- Documents (DOC) supporting specific decision-making and management actions;
- General documents (GEN) setting general or technical provisions;
- The record, which represent the functioning of ALGERAC.

The General Director has appointed the Quality Manager who has the overall authority and responsibility to guarantee that the required procedures are established, and to inform him about the performances of management system and about any need for improvement.

This RM's job is described in the job description (FOR 24).

ALGERAC management system, as described in this manual, complies with:

- National legal requirements
- The requirements of the international standard ISO/CEI 17011 "General requirements for accreditation bodies assessing and accrediting conformity assessment bodies;
- Directives and application guides from international organizations such as IAF, ILAC or EA.

#### VI.1 Documents control

ALGERAC established a documentary system in the aim to:

- Provide concerned persons updated documents;
- Withdraw obsolete versions of documents to prevent their unintentional use;
- Ensure confidentiality.

Page: 23 / 23

The Quality Manager assures the management of the documentary system as described in (PRO 01) Documents control.

Furthermore external documents issued by external authorities from ALGERAC such as ISO, ILAC, IAF, EA, ARAC, SMIIC, etc. and any other national or international authorities, they are managed according to external documents management procedure (PRO 28).

The technical committee has to ensure the monitoring of external documents and resolutions from EA, ILAC, IAF, ARAC, SMIIC and the monitoring of regulation linked to the accreditation activities under the responsibility of the Quality Manager/TS.

The derogations are treated according to the procedure (PRO 20)-"management of derogations" and are recorded by the Quality manager in the form (FOR 60), who reminds them on the occasion of the management review

#### VI.2 Records

The recording system is described in procedure (PRO 02) "Records control"

# VI.3 Nonconformities, corrective actions

The system of identifying and dealing with non-conformities, as well as implementing corrective actions wards off the causes and risks of non-conformity recurrence.

Non-conformity management procedure and corrective/preventive actions are described in (PRO 09).

#### VI.4 Internal audits

ALGERAC organizes internal audits to verify the appropriateness and the effectiveness of the management system and its continuous improvement. All ALGERAC activities are audited at least once a year against ISO/IEC 17011 and other MLA requirements, according to the procedure (PRO 08) "Internal Audit". Internal audits are performed by the Quality Manager and the technical personnel trained in ISO 17011 and ISO 19011 and possessing the appropriate audit sills.

The QM makes the updated list of internal auditors (LIS 08).

#### VI.5 Management review

Yearly, ALGERAC's management organizes a management review to ensure the pertinence, appropriateness and effectiveness of the management system.

The way for organizing and performing the management review is defined in procedure (PRO11) "Management review".

#### **VI.6 Complaints**

ALGERAC records and treats any verbal or written complaint in order to improve its services. The manner to handle complaints is documented in the procedure (PRO 21) "Complaints."