ACCREDITATION COMMISSION FOR CONFORMITY ASSESSMENT BODIES

ACCREDITATION SCHEME MANUAL

Document Title: **Accreditation Procedure For Laboratories**

Document Number: **ACCAB-ASM-8.0-L**

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Revision Number	Revision Date	Paragraph Number	Description of Revision	Revision Author

8.1	**Purpose:**
8.1.1	The purpose of this document to explain the process of accreditation followed by ACCAB as per the International Standards and Guides to the Laboratories that demonstrate competence and conformity with the relevant accreditation criteria.
8.1.2	The Laboratories include Testing & Calibration Laboratories, Medical Laboratories, Proficiency Testing Laboratories and Reference Material Producers.
8.2	**Scope:**
8.2.1	Applicable to the accreditation schemes operated by the ACCAB for the Testing & Calibration Laboratories, Medical Laboratories, Proficiency Testing Laboratories and Reference Material Producers.
8.2.2	The applicable international standards and normative documents are as follows: a. ISO/IEC 17025:2005 General requirements for the competence of testing and calibration laboratories. b. ISO 15189:2007 Medical laboratories -- Particular requirements for the quality and the competence. c. ISO/IEC 17043:2010 - Conformity assessment -- General requirements for proficiency testing d. ISO Guide 34:2009 General requirements for the competence of reference material producers. e. OECD GLP(Good Laboratory Practice) f. GCP(Good Clinical Practice) g. Relevant International Standards, ACCAB:- Standards, Advisories and Conformity Assessment Requirements and ILAC (International Laboratory Accreditation Cooperation):- requirements, advisories or guidelines as applicable.
8.2.3	The accreditation process starts with the filing of the duly completed application for accreditation and is followed by an adequacy assessment and onsite assessment. The process is concluded with the decision on accreditation. The post accreditation process commences thereafter.
8.2.4	The accreditation assessment process deployed by ACCAB shall accommodate the Laboratories of all sizes and carrying out wide range of activities.
8.3	**Responsibility & Authority:**
8.3.1	The Chief Executive Office is responsible for overseeing this process with support from the

	respective Divisional Heads (DHs), Technical Advisory Committee (TAC), Assessment Team & Accreditation Approval Committee (AAC) of ACCAB.
8.4	**Operation:**
8.4.1	**General :**
8.4.1.1	Laboratories can request ACCAB in person, by post, by telephone or by e-mail for relevant information on Accreditation, alternatively the ACCAB accreditation process, and relevant documentations is made available to the customers on the ACCAB website www.accab.org .
8.4.1.2	Testing & Calibration Laboratories, Medical Laboratories & Other Laboratories can fill up a Quotation Request Form ASM-8.0-F-01, which is also made available to the customers on the ACCAB website www.accab.org.
8.4.1.3	The applicant should read and understand ACCAB's Accreditation Scheme Manual especially the Requirements for Granting and Maintaining Accreditation and the Current Fee Structure before submitting the application in the prescribed format.
8.4.1.4	It is expected that the applicant Laboratory has a specific & assured plan of action for obtaining the ACCAB accreditation and nominate a senior & accountable person to coordinate all activities related to the accreditation process. The person nominated should be familiar with the Laboratory's documented quality system.
8.4.1.5	An applicant Laboratory shall ensure that a quality manual is prepared in accordance with the requirements specified in the ACCAB Accreditation Scheme Manual and this should be supplemented by a set of other documents such as procedures, work instructions, records etc.
8.4.1.6	The Applicant Laboratory shall ensure that the procedures described in the Quality Manual and other documents are being implemented. Preferably the applicant Laboratory must have conducted at least one Internal Audit and one Management Review before the submission of application.
8.4.1.7	All Laboratories are required to participate in Proficiency Testing, Measurement Audits or Inter Laboratory Comparisons as necessary. Please refer ACCAB Policy Document ASM-PD-1.0.
8.4.1.8	All Laboratories are required to demonstrate Traceability, Measurement Uncertainty and Measurement Capability, as applicable. Please refer ACCAB Policy Document ASM-PD-2.0.
8.4.1.9	The cost of ACCAB Accreditation is outlined in the Schedule of Fees ASM-11.0- A to F which is issued annually and is available on the ACCAB website.
8.4.2	**Application for Accreditation:**
8.4.2.1	The Laboratory shall submit the duly completed application form and the applicable annexure along with a copy of the quality manual and other relevant documents and records to ACCAB. The application form and the documents can be submitted electronically. The application must be accompanied with the prescribed application fee.

8.4.2.2	The Laboratory shall provide up to date information on its staff and facilities, and specifying as precisely as possible types of activities for which accreditation is sought to ensure clarity and to prevent any delays in processing the application. It is ACCAB policy to define the scope of accreditation in terms as precise as possible. This is so that the Laboratory's clients and stakeholders will know accurately and unambiguously the range of activities covered by a Laboratory's accreditation. Please refer ACCAB Guidance Documents ASM-GD Series for further details.
8.4.2.3	The ACCAB provides no guarantees to the applicant Laboratories that their application for accreditation shall be successful. In such cases the ACCAB reserves the right to forfeit the application fee.
8.4.2.4	The ACCAB shall issue an acknowledgement to the applicant on receipt of the application, the quality manual, other relevant documents and the requisite fees. On receipt, the application shall be examined by ACCAB for its completeness in all respects. ACCAB may request for additional information/clarification(s), if necessary from the applicant Laboratory. If the application is found complete in all respect, a unique ACCAB Registration Number shall be allocated to the applicant, which shall be used for correspondence with the ACCAB thereafter.
8.4.2.5	The applicant Laboratory shall be informed in writing if ACCAB is of the opinion that an assessment cannot result in accreditation on the basis of either the documents and / or information provided by the Laboratory or ACCAB's own policy, its competence and the availability of suitable resources, experts and its ability to carry out the initial assessment in a timely manner.
8.4.2.6	The ACCAB Chief Executive Officer/Divisional Head shall deal with the application and the case file being maintained thereafter. All information of the Laboratory shall be kept strictly confidential, subject to freedom of information required.
8.4.2.7	An Application for Accreditation will be open for the period of 180 days from the date of Application and will be considered closed if the Laboratory does not respond in terms of payment of fees or to any formal communication from ACCAB. In such cases, ACCAB will give 30 days' notice of closure of application and once closed reapplication and payment of fees is necessary.
8.4.3	**Additional Accreditation:**
8.4.3	If an ACCAB accredited Laboratory wishes a second or further accreditation against another internationally accepted standard or for that matter any recognized and accepted standard or the Classification or Location, the procedure is the same as for a new accreditation. However, in such case, the assessment effort by the ACCAB may be limited to cover the areas not covered by the existing accredited system and certain specific areas as decided by ACCAB.
8.4.4	**Already Accredited Laboratories:**
8.4.4.1	In case an Applicant Laboratory is already accredited for the applied scope by another Accreditation Body, the ACCAB may grant accreditation after a reduced assessment; however

	any such decision shall be taken at the sole discretion of ACCAB.
8.4.5	**Special Cases:**
8.4.5.1	In case a Laboratory requests accreditation for a Conformity Assessment Activity where an established Standard/ Guide is not available or not listed in this document,ACCAB,in consultation with the Technical Advisory Committee shall decide on the suitable accreditation criteria to be followed by the Laboratory .
8.4.5.2	The applicant Laboratory must submit essential documents as evidence to substantiate their claim when they seek accreditation under Special Cases.
8.4.6	**Assessment Process:**
8.4.6.1	**Preparation for Assessment:**
8.4.6.1.1	The ACCAB Accreditation Assessment is normally carried out in three steps namely Documentation Review, Pre-Assessment and Assessment. These three steps can be carried out as three separate events or can be clubbed together depending on the situation. ACCAB shall formally appoint an assessment team consisting of a Lead Assessor to carry out the assessments on the System adopted by the applicant Laboratory. When selecting the assessment team for each assessment, ACCAB shall ensure that their skills are appropriate to the assessment and their availability and they are free from any direct or indirect involvement with the Applicant Laboratory which may compromise their impartiality and independence.
8.4.6.1.2	The ACCAB shall inform the Laboratory of the names of the members of the assessment team and the organization they belong to, sufficiently in advance to allow the applicant Laboratory to object to the appointment of any particular assessor or expert. Such an objection shall be moved by clear reasons and evidence. In such cases the suitable assessment team replacement shall be found.
8.4.6.1.3	The ACCAB shall issue an Assessment Kit consisting of relevant documents and standard forms to the assessment team. The documents and forms are self explanatory and reflect the sequence of activities for planning, conducting and reporting the assessment.
8.4.6.1.4	The respective Divisional Head in consultation with the Lead Assessor shall finalize the arrangements for the assessment visit and the concerned Laboratory shall be advised to ensure that: 1. The important/responsible members of the Laboratory staff are available on the dates(s) of the visit; 2. The Management Representative/Quality Manager (however designated) makes sure that the important/responsible members are aware of the ACCAB assessment procedures which will be followed during the assessment process; 3. A suitable isolated facility/room is made available to the assessment team to hold meetings during the assessment, in order to review the progress of the assessment, to assess the observations and to conclude the paperwork.

8.4.6.2	**Document Review:**
8.4.6.2.1	Document Review is the mandatory step in the accreditation process. It can be conducted prior to the pre-assessment (offsite activity at ACCAB H.O.) or may be clubbed with the pre-assessment (onsite activity at the Laboratory).
8.4.6.2.2	The assessment team shall review all the relevant documents and the records supplied by the Laboratory to evaluate adequacy of its system, as documented, for conformity with the relevant standard(s) and other requirements for the accreditation. The following guidelines are followed while assessing the documentation to achieve uniformity of approach of ACCAB: a) If the intent is taken care of then the alternatives may be accepted. Normally it is the choice of the Laboratory to decide on how they designate or how they intend to have the configuration of their documents. b) Description of the document, for ex. Quality Manual, Corporate QA Manual, Procedures etc., must be clear. c) Current status of the document should be clear. i.e. the issue status of the document and the amendment record revision status should be the same. An amendment record is to be a part of the manual unless for any reason separately maintained. d) The documents should have been reviewed and approved by a specified authority. e) It is left to the Laboratory as to how they present the various sections or chapters in addressing the requirements of the applicable standard. It is recommended that each element/clause is addressed of course with a remark with what is not applicable. The mandatory documented requirements of the management system may be covered in the apex manual or in the lower level documents such as procedures, work instructions, SOPs etc. The assessor may express his opinion or explain the need for having proper language to convey appropriate meaning pertaining to the organization's applicability. f) In respect of approvals: the Laboratory may have approach of reviews and approvals. As an ACCAB Assessor one needs to see whether the reviews and the approvals of the contents have taken place. As long as this control exists, ACCAB need not have any objection to the manner of approvals.
8.4.6.2.3	The time allowance for review and report preparation is normally one assessor day.In case assessor team finds documentation difficult to follow, the CAB may be asked to provide cross reference matrix providing correlation between the assessment standard and their quality system documentation.
8.4.6.2.4	The Document Review Report shall include relevant accreditation standard checklist.The reviewer shall include the quality system documentation references in checklist.
8.4.6.2.5	The report shall provide summary of opportunity for improvement and questions that may be identified as non conformances during the initial assessment. Preferably, the Laboratory and the Lead Assessor will resolve all opportunity for improvements from the document review.
8.4.6.2.6	The Lead Assessor, in consultation with the respective Divisional Head can decide whether to proceed if any of the issues are not resolved before the accreditation pre-assessment / assessment.

8.4.6.2.7	If during the documentation review it was found that significant changes are required to the documented system of Laboratory, and additional review after due correction may be required. The additional documentation review would be charged extra to the Laboratory.
8.4.6.2.8	After completion of documentation review, the Lead Assessor provides his recommendation for the pre-assessment. In exceptional circumstances an application may be progressed directly to an assessment.
8.4.6.3	**Pre Assessment:**
8.4.6.3.1	ACCAB recommends a pre-assessment visit by the lead assessor in order to provide the assessor and the Laboratory with a better understanding of what the assessment visit would involve. Pre-assessment can be clubbed with Documentation Review or may not be necessary for Transfer of Accreditation from another Accreditation Body to ACCAB.
8.4.6.3.2	The purpose of the pre-assessment visit is to: 1. Review the Laboratory's quality systems and procedures in the light of document review findings; 2. Review the sites, facilities and equipments; 3. Determine the structures of the applicant Laboratory depending on key activities conducted from the multiple locations, if applicable and to assess the extent of management control from a central office; 4. Assess the degree of preparedness of the Laboratory for the assessment; 5. Define the technical scope of the assessment in precise terms; 6. Determine the time frame, number of the Assessors/Technical Experts required in various disciplines and visits to the sites, logistics, as applicable.
8.4.6.3.3	The pre-assessment visit is normally carried out by the Lead Assessor and generally takes one day.
8.4.6.3.4	The Lead Assessor completes the assessment report and submits to the ACCAB with advice if the assessment can be progressed.
8.4.6.3.5	The ACCAB shall forward the pre-assessment report to the Laboratory along with the suitable dates for the assessment visit.
8.4.6.3.6	If more than 6 months have passed since the pre assessment visit the Laboratory will be informed that another pre-assessment may be necessary.
8.4.6.4	**Accreditation Assessment:**
8.4.6.4.1	The purpose of the accreditation assessment is to appraise the Laboratory's quality and technical management system and determine through use of observation, interviews and reviews the various elements of the system including procedure, records and data whether the Laboratory's system is effectively implemented & meets applicable requirement and is ready to be accredited.

8.4.6.4.2	The ACCAB officer will send a completed assessment visit plan to the Laboratory well in advance. The purpose of this visit plan is to communicate the details of what location/areas/ and specific activities will be assessed by each member of the assessment team with the general time table.
8.4.6.4.3	The accreditation assessment begins with an opening meeting followed by the actual assessment and ends with closing meeting between the ACCAB assessment team and the representatives of the Laboratory.
8.4.6.4.4	At the end of each assessment the Lead Assessor shall submit an Assessment Report as appropriate to bring out the objective of the assessment.
8.4.6.4.5	The ACCAB assessment team shall conduct the assessment of the Laboratory's premises(s) from where one or more key activities are performed.
8.4.6.4.6	The on-site assessment shall commence with an opening meeting at which the purpose of the assessment and the criteria are clearly defined and the assessment schedule and the scope for the assessment are confirmed.
8.4.6.4.7	The ACCAB assessment team shall assess the documentation and implementation of the management system as well as the competence of the Laboratory in accordance with the requirements of the applicable standards and the normative documents during the assessment.
8.4.6.4.8	The ACCAB assessment team can take a representative sample in the areas within the scope of the accreditation.
8.4.6.4.9	The ACCAB requires that the Laboratory demonstrates that it is competent in all the activities at all sites for which accreditation has been applied for.
8.4.6.4.10	The ACCAB's assessment team shall assess at least one complete cycle of the Internal Audit and the Management Review.
8.4.6.4.11	In ordinary situations the onsite assessment shall be concluded with the closing meeting. In the closing meeting the assessment team shall discuss the results of the assessment with the Laboratory. The nonconformity reports are handed over to the Management of the Laboratory, so it can immediately proceed with the implementation of the corrective action plan. The assessment shall not proceed further into next stage unless all Non-Conformities are satisfactorily addressed and closed.
8.4.6.4.12	The assessment team shall witness the process of determining the competence of the Laboratory's Technical Personnel and the degree and effectiveness of the applicant Laboratory's process of determining the competence of the Laboratory's Technical Personnel. The witness assessment shall focus on the issues pertaining to the Laboratory's Technical Personnel competency requirements & training processes rather than against individual personnel.
8.4.6.4.13	For the purpose of the witness assessment, the Laboratory may be requested to provide a list of suitable sites/activities. However the selection of the sites/activities shall be done at the

discretion of ACCAB.

8.4.6.5 Opportunities For Possible Improvements (OPIs) & Non Conformances (NCs):

8.4.6.5.1 Opportunities For Possible Improvements (OPIs):

8.4.6.5.1.1 As name suggest, this is a comment recorded by a member of the assessment team when an assessment finding /observation may lead to an Opportunity for Possible Improvement. A representative of the facility must acknowledge (by signature) that the finding/observation has been accurately recorded.

8.4.6.5.2 Non Conformances (NCs):

8.4.6.5.2.1 This is a comment recorded by a member of the assessment team when noting a situation or action which may prejudice the Laboratory's ability to meet ACCAB accreditation requirements. A representative of the facility must acknowledge (by signature) that the Non Conformance finding has been accurately recorded.

8.4.6.5.3 Categorization of Non-conformities:

8.4.6.5.3.1 Non-conformity is considered to be Major:

1. When an applicable requirement of the relevant standard is violated or deficient to such an extent that it can be reasonably concluded as absence of, or failure to implement and maintain the requirement concerned.
2. When there is a failure to implement the management policy.

8.4.6.5.3.2 Non-conformity will be categorized as Minor:

1. When there is a failure to meet a requirement of the relevant system, which may raise significant doubt as to the quality /safety or the capability of the System to achieve the policy and objectives of the Laboratory. However, on basis of further objective evidence it can be reasonably concluded that the finding is an isolated lapse and such a significant doubt can be ruled out, but the situation does require identification and implementation of an appropriate action by the Laboratory, to ensure that there is no continued or further non-conformance in respect of the requirement concerned.
2. Non-conformities related to the same requirement and/or similar activities in different locations may be noted by different assessment teams each of whom may rightly categorize such NCs as minor based on the above guidelines. However, when collectively considered, the NCs may indicate an overall system deficiency leading to major category. The team leader shall take such a possibility into account whilst finalizing the NC reports and advise the auditee accordingly. Grouping similar NCs in one report may also be considered.

8.4.6.6 Reporting the finding of Assessment:

8.4.6.6.1	Pre-assessment: For reporting the findings of this assessment refer Para 8.4.6.3 above.
8.4.6.6.2	At the end of the accreditation/surveillance assessment basically following types of situations may arise.
8.4.6.6.2.1	Type 1: Unconditional Approval

1. Explanation: Requirement of System is/continues to be implemented effectively – A few minor NCs found and all resolved within agreed time period.
2. Decision: Issue/continuance of the certificate of accreditation is recommended.

8.4.6.6.2.2	Type 2 : Unconditional Non-approval

1. Explanation: Requirement of System has not been developed/maintained satisfactorily or implementation has been found ineffective in most of the areas or Management System has broken down.
2. Decision: Depending upon the degree of noncompliance the Team Leader in consultation with other members of the assessment team is to give following recommendations: Limited or full assessment within the stipulated time (max. of 3 months).

8.4.6.6.2.3	In case the auditee does not agree to this, the issue/continuance of certificate of accreditation cannot be recommended.
8.4.6.7	**Corrective Actions & Follow-up of Assessment:**
8.4.6.7.1	The ACCAB requires that the Laboratory takes necessary corrective actions on the Non-Conformance(s)/ other concerns and shall submit a report on the action taken to ACCAB within a maximum period of three months.
8.4.6.7.2	The ACCAB assessment team shall take decision with regard to closure of Non-Conformities.
8.4.6.7.3	The ACCAB may arrange for a verification visit for the closure of the significant Non-Conformities identified during the on-site assessment, the progress is monitored closely and in this regard.
8.4.6.7.4	The ACCAB requires that whatever may be the case all the Non-Conformities raised during the assessment shall be closed before consideration for the Grant of Accreditation.
8.4.6.8	**Accreditation Decision:**
8.4.6.8.1	The Accreditation Approval Committee (AAC) of ACCAB shall prior to making a decision for granting/extending of accreditation ensures that it is completely satisfied that the relevant information provided by the assessment team is adequate to decide that the requirements for the

	accreditation have been fulfilled.
8.4.6.8.2	Where the ACCAB uses the results of an assessment already performed by another accreditation body, it shall have assurance that the other accreditation body was operating in accordance with the requirements of ISO/IEC17011:2004.
8.4.6.8.3	The ACCAB shall inform the Laboratory in writing of the decision taken without undue delay.
8.4.6.8.4	If the Laboratory is not satisfied with any of the decisions taken by ACCAB regarding grant of The accreditation it can file an appeal as per the Complaints & Appeals Procedure of ACCAB-ASM-12.0
8.4.6.9	**Issue of Accreditation Certificate:**
8.4.6.9.1	The ACCAB shall issue an Accreditation Certificate on receiving the accreditation decision by the Accreditation Approval Committee.
8.4.6.9.2	The ACCAB accreditation certificate shall be valid for a period of 3 years. During this period, the Laboratory shall be notified if there is any change in the accreditation procedures and requirements. The Laboratory is notified well in advance before the expiry of this period. The applicant Laboratory shall also have an obligation to inform to ACCAB if any changes at its end.
8.4.6.9.3	The applicant Laboratory must sign the Accreditation Agreement including fulfilling of all the financial obligations due to ACCAB, before receiving the accreditation certificate(s).
8.4.6.10	**Post Accreditation Assessments:**
8.4.6.10.1	During the validity of accreditation, the Laboratory must continuously comply with the requirements of applicable standards and the other requirements specified in the ACCAB's Accreditation Scheme Manual.In this regard ACCAB shall periodically review the validity of Accreditation by conducting surveillance assessment annually and a reassessment within three years. During the accreditation period, the scope of the accreditation may be altered.
8.4.6.11	**Surveillance:**
8.4.6.11.1	The procedures of ACCAB require that all accredited Laboratories are assessed at least twice with an interval of approximately one year from the last date of original accreditation to ensure that an assessment is carried out during the period of validity and re-assessed totally once in three years. The 1st surveillance assessment shall be carried out within 12 months from the last date of accreditation granted.
8.4.6.11.2	The purpose of surveillance assessment is to verify a) that the accredited management system of Laboratory continues to be implemented onsite b) the implication of changes in the Laboratory's operation and to reconfirm continued compliance to the applicable standard, other normative documents and ACCAB procedures.

8.4.6.11.3	The ACCAB shall inform the accredited Laboratory at least two months before the due date of accreditation for conducting the surveillance visit and the Laboratory shall confirm its readiness within 30 days. Any delay in this matter may result in the suspension of accreditation. The Laboratory may request for the extension of the scope of the accreditation at the time of surveillance assessment, which should be clearly mentioned in the application form.
8.4.6.11.4	The methodology for conducting surveillance assessment is similar to the initial assessment although it shall cover only selected areas. The Non-Conformities, if any, shall be closed within three months of conduct of surveillance. Based on the surveillance report along with the other relevant information a recommendation shall be submitted to the Chief Executive Officer of ACCAB for a decision on the continuation of the accreditation or otherwise. ACCAB shall inform the Laboratory, in writing, about the decision.
8.4.6.11.5	The ACCAB shall issue a new certificate of the accreditation after every surveillance assessment while the registration number remains the same.
8.4.6.12	**Reassessment and Renewal of Accreditation:**
8.4.6.12.1	The ACCAB shall inform the Laboratory in writing on the expiry of Accreditation approximately three months in advance and the Laboratory has to respond at least one month before the expiry. If Laboratory does not respond in the prescribed time limit it shall be considered as a fresh applicant Laboratory and another registration number is issued signifying a break in accreditation.
8.4.6.12.2	The procedure for processing of renewal of application is similar to that of the initial application. The Laboratory may request for the extension of the scope of the accreditation, which should be clearly mentioned in the application form.
8.4.6.12.3	The ACCAB shall extend the validity of the certificate by a further period of three years without any discontinuity provided the results of the reassessment visit are positive and all the non-conformances are closed before the expiry of the certificate.
8.4.6.12.4	The ACCAB shall issue a new certificate of the accreditation while the registration number remains the same.
8.4.6.13	**Supplementary/ Extraordinary Assessments:**
8.4.6.13.1	The ACCAB may organize Supplementary/ Extraordinary Assessments as a result of complaints supported by facts and evidence from the interested parties regarding the Laboratory's activities or any adverse publication in the media or misuse of ACCAB logo.
8.4.6.13.2	The ACCAB reserves the right to conduct the Extraordinary Assessments without any prior notice or with very little time between the notification and the execution.
8.4.6.13.3	An Extraordinary Assessment may also become necessary when significant changes occur relevant to the accreditation or any aspect of the status or operation of the Laboratory or in the

	accreditation criteria. However in these cases the ACCAB shall give sufficient notice to the concerned Laboratory.
8.4.6.14	**Suspending, Withdrawing or Reducing Accreditation:**
8.4.6.14.1	The ACCAB shall make decisions to suspend and / or withdraw accreditation when an accredited Laboratory has persistently failed to meet the requirements of accreditation or to abide by the rules of the accreditation.
8.4.6.14.2	It is a mandatory requirement that ACCAB would expect the accredited Laboratory to demonstrate the compliance with the accreditation criteria regarding the entire scope and that it has complied with these criteria from the date on which the accreditation was granted. In order to demonstrate that the Laboratory has complied with and is complying with the criteria for the complete scope of accreditation, the Laboratory shall provide records of the activities carried out. The concerned part of the scope shall be withdrawn if records do not demonstrate this. If this means that the entire scope is withdrawn, then the entire accreditation is withdrawn.
8.4.6.14.3	It is expected that the Laboratory withdraws the relevant part of the scope by itself, if a Laboratory fails to demonstrate the compliance with the accreditation criteria regarding the scope in question. The ACCAB shall review the validity of the remaining part of the accredited scope.
8.4.6.14.4	The Laboratory can file a fresh application for grant of the withdrawn part of the accreditation at a later date.
8.4.6.15	**Extension of Scope:**
8.4.6.15.1	The Laboratory desirous of an extension of the scope shall submit a written application to the ACCAB.
8.4.6.15.2	The Laboratory must understand the difference within and outside the scope. Extensions within the framework of the same accreditation standard shall be considered Extension within the scope and if not it shall be considered outside the scope. Any requests for accreditation involving a different accreditation standard shall be treated as a new application.
8.4.6.15.3	The ACCAB shall determine the extent of the assessment needed for the extension depending on the size and nature of the extension requested.
8.4.6.15.4	The ACCAB shall not proceed with the request of the extension of scope until such time all non-conformities are closed in the management system of the Laboratory.
8.4.6.16	**Transfer of Accreditation:**
8.4.6.16.1	The accreditation may be transferred at the sole discretion of ACCAB if the Laboratory makes such request in writing if the ownership or name of an accredited Laboratory changes provided: a. The basic resources, infrastructure and other facilities remain intact; b. The Laboratory continues to operate within the legal and the regulatory framework of the

	country in which it operates; c. The documented policy and the management system remain unchanged; d. The general composition of the Laboratory's management and key personnel remain the same; e. The material evidence exists that the former owner(s) do not operate under the same trade name, similar name, related name and similar business activities.
8.4.6.16.2	The ACCAB shall require Laboratory to provide the necessary documents showing that the above conditions are adequately met. The costs for reviewing the documents/ conducting onsite review shall be charged to the Laboratory.
8.4.6.16.3	The ACCAB shall allot the same registration/accreditation number and issue the new accreditation documents provided if such review is positive. The surveillance and the reassessment schedule are subject to change depending on the review.
8.4.6.16.4	ACCAB shall not transfer accreditation / compliance status from one accredited/compliant body to another or from an accredited / compliant body to a non-accredited body.