

Accreditation Process Procedure

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1. Purpose

- This document describes the general methodology for the accreditation process for Conformity Assessment Bodies (CABs).

2. Scope

- All accreditation services provided by the Saudi Accreditation Center (SAAC) to conformity assessment bodies.

3. Normative References

- ILAC/IF Guide 08/2020: G3: Training course guidelines for residents employed by accrediting bodies.
- ISO/IEC 17011:2017- Requirements for accreditation bodies accrediting conformity assessment bodies.
- The Quality Management System of the Saudi Accreditation Center including all its policies and procedures.
- ISO/IEC 19011:2018- Guidelines for auditing management systems.
- Documents of Saudi Building Code National Committee (SBCNC).
- Documents of International Halal Accreditation Forum (IHAF).
- Documents of Standards and Metrology Institute for Islamic Countries (SMIIC).
- Documents of International Laboratory Accreditation Cooperation (ILAC).
- Documents of International Accreditation Forum (IAF).
- Documents of Arab Accreditation Cooperation (ARAC).
- Documents of Asian Pacific Accreditation Cooperation (APAC).
- Documents of ISO/IEC 17025:2017 (General requirements for the competence of testing and calibration laboratories).
- Documents of ISO 15189:2022 (Medical Laboratories – Requirements for quality and competence).
- Documents of ISO/IEC 17020:2012 (Conformity assessment – Requirements for the operation of various types of bodies performing inspection).
- Documents of ISO/IEC 17021-1:2015 (Conformity assessment – Requirements for bodies providing audit and certification of management systems).
- Documents of GSO 2055-2 (General requirements for halal certification bodies).
- Documents of ISO/IEC 17065:2012 (Conformity assessment – Requirements for bodies certifying products, processes and services).
- Documents of ISO/IEC 17043:2023 (Conformity assessment – General requirements for the competence of proficiency test providers).
- Documents of ISO 17034:2016 (General requirements for the competence of reference material producers).
- Documents of ISO/IEC 17024:2012 (Conformity assessment – General requirements for bodies operating certification of persons).
- Documents of ISO 20387:2018 (General requirement of biobanking).

4. Terms \ Definitions

- As defined in the Vocabulary Guide of the Saudi Accreditation Center.

5. Policies

- Fee of the accreditation process is subject to the Saudi Accreditation Center regulations.
- Commitment of SAAC to operate in accordance with the Accreditation of Conformity Assessment Bodies Regulations.
- The commitment of the CABs to comply with the Accreditation of Conformity Assessment Bodies Regulations.
- The commitment of the CABs to comply with the other relevant laws and legislations.

5.1 Assessment Principles:

Assessment is based on a set of principles that contribute to the effectiveness of the assessment process and enable the decision makers, who are independent of the assessment team, to reach the same conclusions in similar circumstances.

The Assessment team, who manages the Assessment Program, shall:

- Perform their work in an ethical, honest, and responsible manner.
- Carry out assessment activities, each team according to their specialization.
- Perform their work with integrity and impartiality, without any influences on their decisions during the assessment process.
- Assessment results and conclusions as well as the on-site visit reports shall reflect the conformity assessment activities effectively and accurately.
- The ability to think logically for issuing non-conformities during the assessment process.
- Maintaining the confidentiality of the information, with which they got acquainted during the assessment process; additionally, the assessment information shall not be used inappropriately for personal gains.
- The ability to write the report and the results of the assessment in a clear, unambiguous, and evidence-based manner to reach correct conclusions.
- The ability to develop an assessment methodology underpinning the risk-based thinking approach.

5.2 Assessment Program:

- The file manager organizes the evaluation program with consecration risk management with each visits an update the program to be include planning of the accreditation process. before each on-site visit, such that it includes proper planning and guidance for conducting the assessment process and properly achieving the specific objectives of each type of assessment, in order to assess the competence of the CAB in performing all activities within its accreditation scope; taking into consideration that the accredited scope is covered by using several types of assessments during the accreditation cycle, to ensure the continuing compliance of the CAB with the accreditation standards. This is applied using Form F-62.

- The file manager monitors the implementation of the assessment program and its review, to assess the extent to which its objectives have been fulfilled and identify opportunities for improvement.
- The G.M / Director of the Department or his delegate monitors the status of the accreditation files and updates their status continuously (active, expired, renew, withdrawn, or suspended).

5.3 Assessment Techniques:

- Collecting and verifying information: The assessors collect the information necessary for the evaluation process and evidence.
- Personal interviews: through which the relevant persons are interviewed during the evaluation process to ensure their competence and verify their roles.
- Witnessing the activities: See how the activities conduct and ensure that they match documented.

For assessment of testing and calibration and medical laboratories, Proficiency Test Provider, Reference Materials Producer, and Biobanking witnessing should cover but not limited to:

- Accreditation scheme requirements to be followed.
- Products tested and range of tests.
- Used methods and selection and their control.
- Equipment available, calibration and its management.
- Witnessing of testing procedures (As planned program).
- Performance in proficiency testing programs.
- Sampling and testing processes, assessment of uncertainty, checking of calculations and data transfers and record keeping.
- Reporting of test results.

For assessment of inspection bodies, conducted through insure the requirement:

- The efficiency of the staff and the efficiency of the inspectors who were observed.
- Contract formation, scoping and planning of inspection activities.
- Inspection procedures.
- Where possible, field witnessing of inspection activities, including sampling.
- When assessing an inspection body, the inspectors to be witnessed shall be selected by the SAAC.
- Verify how the inspector makes the decision during the inspection process.
- How to appropriately select the inspection team.
- When using measuring equipment, its efficiency, calibration, and how to manage it must be seen.
- Analyze inspection results.
- Keeping records and creating reports and content.

For assessment of management system certification bodies and certification of persons bodies:

- The scheme to be evaluated and the scope of accreditation are determined based on the application submitted by the Conformity Assessment Body, and the Accreditation Manager reviews the application to ensure it contains sufficient information for that purpose.
- If the scheme is not issued by an international, organizational, or local legislative body, then the compliance of the scheme and its owner must be verified according to the specific inspection checklist and in accordance with IAF MD25 and model number F-06 as follows:
 - The scheme owner submits a request to the center for reviewing the scheme, obtaining approval, and determining the optimal assessment method.
 - The scheme owner is requested to fill out model number F-06 and submit supporting documents.
 - SAAC determining the optimal assessment method according to this scheme and includes this determination in form F-06.
 - This scheme is included among the schemes on which the center conducts assessments and grants accreditation.
 - Requests for evaluation based on it are accepted from interested Conformity Assessment Bodies.
- Verification and viewing of audits by the certification body based on the field to be relied upon. This may take several days, and may also extend to several different geographical locations as well as the branch offices of the certification body.
- In initial applications, the assessment team shall assure covering stages 1 and stages 2 of the audit of the applicant for accreditation to cover at least one critical sector of the critical sectors to be accredited for, using form F-02.
- Reviewing and verifying records and documents: through which previous records are reviewed and verified.
- Certification body required to fill form F-03 to collect the mandatory data as per IAF MD12 & IAF MD 15.
- If CAB fails to comply with the requirements of IAF MD 12 / IAF MD within 10 working days, SAAC has the right to issue a non-conformity status directly. Additionally, SAAC may extend the period for an equivalent duration, provided that the CAB provides justified reasons for the delay*.

For assessment of certification bodies and halal certification bodies:

- The scheme to be evaluated and the scope of accreditation are determined based on the application submitted by the Conformity Assessment Body, and the Accreditation Manager reviews the application to ensure it contains sufficient information for that purpose.
- If the scheme is not issued by an international, organizational, or local legislative body, then the compliance of the scheme and its owner must be verified according to the specific inspection checklist and in accordance with IAF MD25 and model number F-06 as follows:

* G.M / Director of the Department has the right to extend the period for 10 working days based on the justification reasons provided by CAB.

- The scheme owner submits a request to the center for reviewing the scheme, obtaining approval, and determining the optimal assessment method.
 - The scheme owner is requested to fill out model number F-06 and submit supporting documents.
 - SAAC determining the optimal assessment method according to this scheme and includes this determination in form F-06.
 - This scheme is included among the schemes on which the center conducts assessments and grants accreditation.
 - Requests for evaluation based on it are accepted from interested Conformity Assessment Bodies.
- The review will focus on the experience of the professional staff in the product sectors that will be covered based on the field to be relied upon, and the selection of the laboratories that conduct the tests on the basis of which the certificate is obtained. As well as monitoring of manufacturers and their production including any market monitoring activities (depending on the type of certification scheme). In particular, to obtain accreditation for halal certification bodies, it is necessary to verify that Islamic rules are met and that employees adhere to Islamic law and values.
 - Reviewing and verifying records and documents: through which previous records are reviewed and verified.
 - Reviewing reports and results.: through which the powers and validity and accuracy of the results are verified.
 - Applications and review: through which applications are verified as in item (8-1)
 - Visit plan, objectives and reasons: through which the visit plan is prepared as in item (8.3.1)
 - Steps of the visit: through which the work is carried out as in item (8-3-2)
 - Visit reports: which the work is carried out as in item (8-3-3-14)
 - Review of Non-conformities: through which the is carried out as in item (8-3-3-11)

5.4 Classification of Non-Conformities:

5.4.1 Nonconformity: If the finding does not meet the requirements of the relevant standards or the requirements of the Saudi Accreditation Center and directly or indirectly affects the validity and accuracy of the results within the reports or certificates issued by the CAB, so the CAB provides the root cause analysis, and submits the Corrective action with evidence within an agreed time. It may require a follow-up visit to assess corrective actions based on potential risks.

5.4.2 Observation*: It is a note on a document or practice that does not affect the validity and accuracy of the results within the reports or certificates issued by the conformity assessment body, despite its fulfillment of the requirements of the relevant standard and the requirements of the Saudi Accreditation Center. So that the CAB submits the corrective action to the observation and can assure that it is closed in the next assessment and does not prevent the accreditation of the CAB.

* The repetition of the observation leads to raising its classification to a state of non-conformity.

5.5 Technical Committee:

After the assessment process is completed. Moved to the next step which is decision-making. The File Manager nominates the members of the technical committees from the approved assessors list (experts from the approved list may be used if there is no assessor in the same field, provided that at least one of the committee members is an approved assessors) and submits them to G.M / Director by transferring the file to the technical committee to study the application so that the committee is not less than two compensation with makes sure that the specializations of the appointed members of the committee cover all scopes of the conformity assessment body; it is possible that the committee member can cover more than one scope; provided that he/ she did not participant in the assessment process, thereafter the request is transmitted electronically to the committee members through SAAC information system. In the account of each member there is a folder containing the following:

- Accreditation application form.
- The final assessment report that includes the assessment summary.
- Team recommendations.
- Reports of follow up visits verifying the correction of the non-conformities if reported.
- Non-conformities, if any, their closure and related corrective actions.
- The scope under accreditation.
- All documents and other relevant information as well as any other official document related to the application.

5.6 Recommendation of Decision-Making (Granting / Renewing / Continuing* / Extending / Reducing / Suspending / Renewing the Accreditation / Withdrawing / Rejecting) the Accreditation of the Conformity Assessment Body:

The technical committee reviews the assessment results and the CAB's closure of all cases of non-conformities with their submission of corrective actions along with the approval of the assessment team of the submitted evidences and their feedback; accordingly, the technical committee provides its recommendations based on what is deemed appropriate.

***Note:** Decisions for the continuation of accreditation after the periodic assessment visit or follow-up (or suspension or cancellation of accreditation at the request of the conformity assessment body voluntarily); the decision is made by the G.M / Director of the concerned department.

5.7 The decision is raised to the Technical Committee for decision making concerning the results of the periodic assessment visit / follow-up visit / re-accreditation, in the following cases:

- The inability of the conformity assessment body to fulfill the technical requirements of the relevant standards or SAAC requirements.
- The inability of the conformity assessment body to fulfill the regulatory requirements approved by SAAC.
- The occurrence of non-conformities during the follow-up visits and failure to complete the relevant corrective actions.
- Request to extend the scope during the periodic assessment visit.

5.8 Reducing, suspending, withdrawing, or canceling the accreditation of the conformity assessment body in the following cases:

- The general regulation for the accreditation of conformity assessment bodies specifies the conditions in which the accreditation is suspended, withdrawn, or reduced, when an accredited conformity assessment body fails to fulfill the accreditation requirements or when suspension, cancellation or scope reduction of accreditation is made by the conformity assessment body.
- When there is evidence of fraudulent behavior, or the conformity assessment body intentionally provides false information or conceals information, SAAC will initiate the process of withdrawing the accreditation.
- In the event of suspension, the entity must correct its situation within three months from the date of suspension, otherwise the accreditation will be withdrawn, and the entity has the right to request an extension of the deadline for one time only, with an explanation of the reasons for the extension.
- SAAC informs the relevant affected parties of any update on the accreditation status of the conformity assessment body to take the necessary actions.

5.9 Accreditation cycle:

- Accreditation cycle as follows:
 - Three years.
 - Four years.
 - Five years.
- In accreditation of management system certification bodies, the required information must be requested based on IAF MD 12 and IAF MD 15 on an annual basis using the form F-03.
- The accreditation cycle starts at the date on which the decision of granting accreditation was made for the initial assessment or the re-assessment.
- The periodic visits are within a period not exceeding 18 months, except for IAF MDMS and FSMS (cluster-2) where it is only 12 months, from the date of the accreditation decision.*
- CAB is required to renew the accreditation certificate based on a request (platform of accreditation) at least six months before the expiration of the accreditation certificate.
- SAAC conducts an assessment visit to the Conformity Assessment Body to ensure its continued compliance with accreditation requirements. The center may request any additional information before renewal.
- The renewal date starts from the expiration date of the accreditation certificate, and if the renewal decision is issued after the expiration date, the renewal is effective from the decision date.
- If the accreditation certificate expires and the Conformity Assessment Body does not apply for renewal, it must submit a new application for accreditation.

* G.M / Director of the Department has the right to extend the periodic visit period not to exceed 24 months based on the risk-based assessment.

- If the assessment process has already begun before the accreditation expiration but has not been completed before the certificate's expiry, the center has the right to assess the situation:
 - If the delay is justified, Conformity Assessment Body enters the (under renewal) phase. In this case, the Conformity Assessment Body remains in a suspended status until the assessment process is completed.

6. Related documents

There is no comment.

7. Exceptions

There is no exception.

8. Procedures

*All forms that referred to in this procedure are uploaded to the Electronic Information System.

#	Activity	Responsibility	Relevant Documents/Link
8-1	Application review (initial / extending scope/Renew)		
8-1-1	Submitting the application for accreditation via the Electronic Information System for Accreditation.	Conformity Assessment Body (CAB)	Form F-24. Electronic Information System
8-1-2	<ul style="list-style-type: none"> - Receiving application, reviewing the adequacy of accreditation application, and verifying that it is within the scope of SAAC's activities, and reviewing the resources. - If the scheme is not issued by an international, organizational, or local legislative body, it is necessary to verify compliance with the scheme's requirements and its owner according to the specific inspection checklist and in accordance with the document IAF MD25 and model F-06. - If an unacceptable risk to impartiality is identified and cannot be mitigated to an acceptable level, SAAC will not provide accreditation. 	G.M / Director	Form F-64 Form F-06
8-1-2-1	If the application is accepted, file manager will be appointed, and the CAB will be informed.	G.M / Director	Electronic Information System

#	Activity	Responsibility	Relevant Documents/Link
8-1-2-2	If the application is rejected, the application will be closed, and the CAB will be notified and reasons are listed.	G.M / Director	Electronic Information System
8-1-3	Issuing an invoice for the fees of reviewing the application*	File Manager	Electronic Information System
8-1-4	Review the application and check its completeness: <ul style="list-style-type: none"> - If there is missing information in the application, it will be sent back to the CAB to complete it - If there is missing information and specified period of time which designated by file manager has ended, the application will be closed. - If the application is complete, the assessment team will be nominated. 	File Manager	Electronic Information System
8-1-5	Appointment of the assessment team.	G.M / Director	Electronic Information System
8-1-6	Conformity assessment body feedback: <ul style="list-style-type: none"> - Rejection of the assessment team, mentioning the justification for rejection, by the conformity assessment body. Re-appointment of the assessment team, if the justification for rejection is approved, go to step (8-1-5). - Approval of the assessment team by the conformity assessment body, and transfer of the application to conduct the document review (8-2). 	File Manager	Electronic Information System
8-2	Document Review Procedure		
8-2-1	Issuing an invoice of the fees for reviewing the documents (initial assessment visit/ extending scope)*	File Manager	Electronic Information System
8-2-2	Reviewing the CAB documents and providing the file manager with the results of the review.	Assessment Team	Form F-55 Electronic Information System
8-2-3	Document review results: <ul style="list-style-type: none"> - If there are observations on the results, go to step (8-2-2). 	File Manager	Electronic Information System

#	Activity	Responsibility	Relevant Documents/Link
	<ul style="list-style-type: none"> - If the results are approved and no observation found: <ul style="list-style-type: none"> ▪ Inform the conformity assessment body about the results. ▪ Defining the on-site assessment:- - In the event of remarks in the document review which require refuse to complete the accreditation process (go to step 8-2-3-1). 		
8-2-3-1	Informing CAB of refusal with the justifications.	G.M / Director	Electronic Information System
8-2-3-2	Close raised observations from the document review.	Conformity Assessment Body (CAB)	Electronic Information System
8-2-3-3	Review the closure of the observations raised from the document review.	Assessment Team	Electronic Information System
8-2-3-4	Reviewing the results of closing document review observations: <ul style="list-style-type: none"> - If there are observations on the results, go to step (8-2-3-1) - If the results of closure are approved: <ul style="list-style-type: none"> ▪ Inform the conformity assessment body about the results of the review, if there are any observations (go to step 8-2-3-1) ▪ Defining the on-site visit in case the results of closure are approved 	File Manager	Electronic Information System
8-3	On-Site Assessment Procedures		
8-3-1	Pre-Assessment		
8-3-1-1	Preparing the Assessment Plan in coordination with the CAB and uploading it to the Accreditation Electronic Information System.	File Manager	Form F-41 Electronic Information System
8-3-1-2	Coordinating with the CAB to provide them with the assessment plan and obtaining their acceptance of all its contents.	File Manager	Electronic Information System
8-3-1-3	Create assessment program	File Manager	Form F-62
8-3-2	On-Site Assessment		
8-3-2-1	The Opening Meeting	Assessment Team Leader	Form F-41
8-3-2-2	Conducting the Assessment Process	Assessment Team	

#	Activity	Responsibility	Relevant Documents/Link
8-3-2-3	Preparing for the Closing Meeting	Assessment Team	
8-3-2-4	The Closing Meeting	Assessment Team	Form F-41
8-3-3	Post On-Site Assessment		
8-3-3-1	Issuance of the invoice for the on-site assessment fees.	File Manager	
8-3-3-2	Raising nonconformities (NC) with identification of potential risks.	Assessment Team	Form-45 Electronic Information System
8-3-3-3	Reviewing and sending the nonconformities.	File Manager	Form-45 Electronic Information System
8-3-3-4	The CAB's feedback: <ul style="list-style-type: none"> - If the NCs are rejected go to step (8-3-3-5) - If the NCs are accepted go to step (8-3-3-7) 	Conformity Assessment Body (CAB)	Form-45 Electronic Information System
8-3-3-5	G.M / Director conduct study of NC, moreover may request assistances whomever deems appropriate.	G.M / Director	Electronic Mail (E-Mail)
8-3-3-6	Investigating the reasons of rejection and taking the decision: <ul style="list-style-type: none"> - If the decision taken was to keep the NCs, go to next step. - If the reasons for rejection are accepted, the NCs case is deleted or turned into a observation to be identified in the corrective action. - If the reasons of rejection were accepted and the NCs are not found, go to step (8-3-3-14) 	G.M / Director	-
8-3-3-7	Defining the Proposed Corrective Actions (PCA) and root causes (RC) and impact.	Conformity Assessment Body (CAB)	Electronic Information System
8-3-3-8	Reviewing the PCAs and RCs for feedback.	Assessment Team	Electronic Information System
8-3-3-9	Sending the teams' feedback on the PCA to the CAB: <ul style="list-style-type: none"> - If the PCAs were rejected or RCs and impact were not defined, go to step (8-3-3-7) - If the PCAs were accepted and RCs were defined, go to step (8-3-3-10) 	File Manager	Electronic Information System
8-3-3-10	Implementing the corrective actions and providing CAs evidences towards the closure of NCs.	Conformity Assessment Body (CAB)	Electronic Information System

#	Activity	Responsibility	Relevant Documents/Link
8-3-3-11	Study and review the close condition of non-conformance cases	Assessment Team	Electronic Information System
8-3-3-12	Verifying that NCs are closed: <ul style="list-style-type: none"> - If all NCs were closed, go to step (8-3-3-14) - If all NCs were closed but a follow-up visit was required, go to step (8-3-3-13) - If NCs were not closed, go to step (8-3-3-10) - If the NCs were not closed within the agreed timeline, go to step (8-3-3-10). - In cases of NCs are not closed, the deadline may be extended when the entity requests an extension if the justifications are appropriate and for a specific period of time, go to step (8-3-3-10). 	File Manager	Electronic Information System
8-3-3-13	Coordinating with the CAB and providing them with a follow-up visit plan.	File Manager	Electronic Information System
8-3-3-14	Preparing the final assessment report in coordination with the assessment Team	Team Leader	Form F-41 Electronic Information System
8-3-3-15	Reviewing the final assessment report: <ul style="list-style-type: none"> - In case of missing information, go to step (8-3-3-14) - If the report was complete, go to step (8-3-3-16) 	File Manager	Electronic Information System
8-3-3-16	Reviewing the final assessment report: <ul style="list-style-type: none"> - In case of missing information, go to step (8-3-3-14) - If the report was complete, proceed to the Decision-Making Procedure, go to step (8-4) 	G.M / Director	Electronic Information System
8-4	Decision-Making Procedure		
8-4-1	(Granting / Extending / Renewing / Withdrawing / Suspending / Reducing)		
8-4-1-1	Nominating members of the technical committee from the database of assessors (see clause 5.5) consider appropriate specialties and nominated member not participated in the evaluation process for the CAB.	File Manager	Electronic Information System

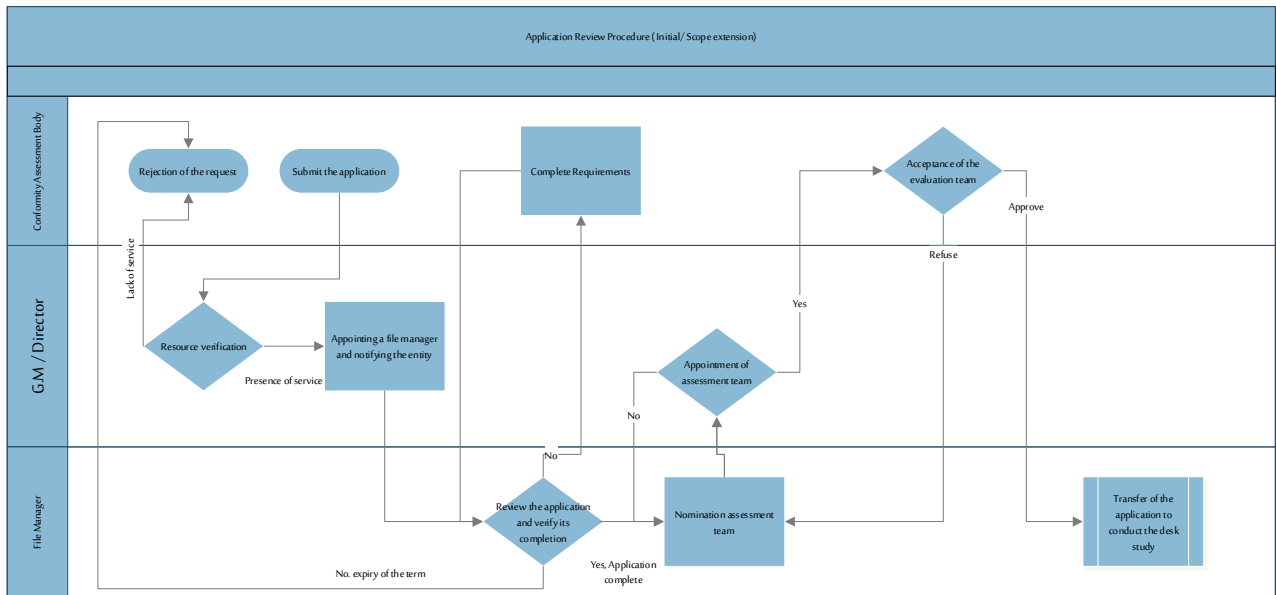
#	Activity	Responsibility	Relevant Documents/Link
8-4-1-2	<ul style="list-style-type: none"> Upon approval of the committee members, move to step 8-4-1-3 If there is no approval, move to step 8-4-1-1 	G.M / Director	Electronic Information System
8-4-1-3	Reviewing the final assessment report along with the relevant documents and making the recommendation.	Technical Committee	Electronic Information System
8-4-1-4	Submitting the Committee's recommendation for decision-making: <ul style="list-style-type: none"> If the recommendation was to accept or reject the application (go to step 8-4-1-4) If a re-application was recommended (go to step 8-3-3-15) 	G.M / Director	Electronic Information System
8-4-2	Decision Making: <ul style="list-style-type: none"> Approval of the committee's recommendation to (grant / extend / renew / withdraw / suspend / reduce) go to step (8-4-4) Approval of the committee's recommendation not to (grant / extend / renew / withdraw / suspend / reduce) go to step (8-4-3) If the committee's recommendation was rejected, the application will be re-examined, go to step (8-4-1-1) 	Executive Director	-
8-4-3	The CAB is notified of the decision and the possibility to submit an appeal.	G.M / Director	Electronic Information System
8-4-4	Issuance of an invoice (for the certificate and scope of accreditation fees)	File Manager	Electronic Information System
8-4-5	Issuance of the certificate and details (list) of the scope of accreditation.	G.M / Director	Electronic Information System
8-5	Assessment Visit (Periodic/ Additional)		
8-5-1	A decision to continue the accreditation is made, if the CAB was complying with the requirements of the relevant accreditation standard.	G.M / Director	-
8-5-2	The application is transferred to the Technical Committee (go to step 8-4) in any of the following cases:	G.M / Director	Electronic Information System

#	Activity	Responsibility	Relevant Documents/Link
	<ul style="list-style-type: none"> - Reducing the scope of accreditation - Suspending the scope of accreditation - Re-accreditation - The inability of the CAB to close out any raised NCs. - If the timeline defined for closure of NCs was exceeded. 		
8-5-3	Updating the directory of the accredited CABs on SAAC Website.	G.M / Director	Electronic Information System

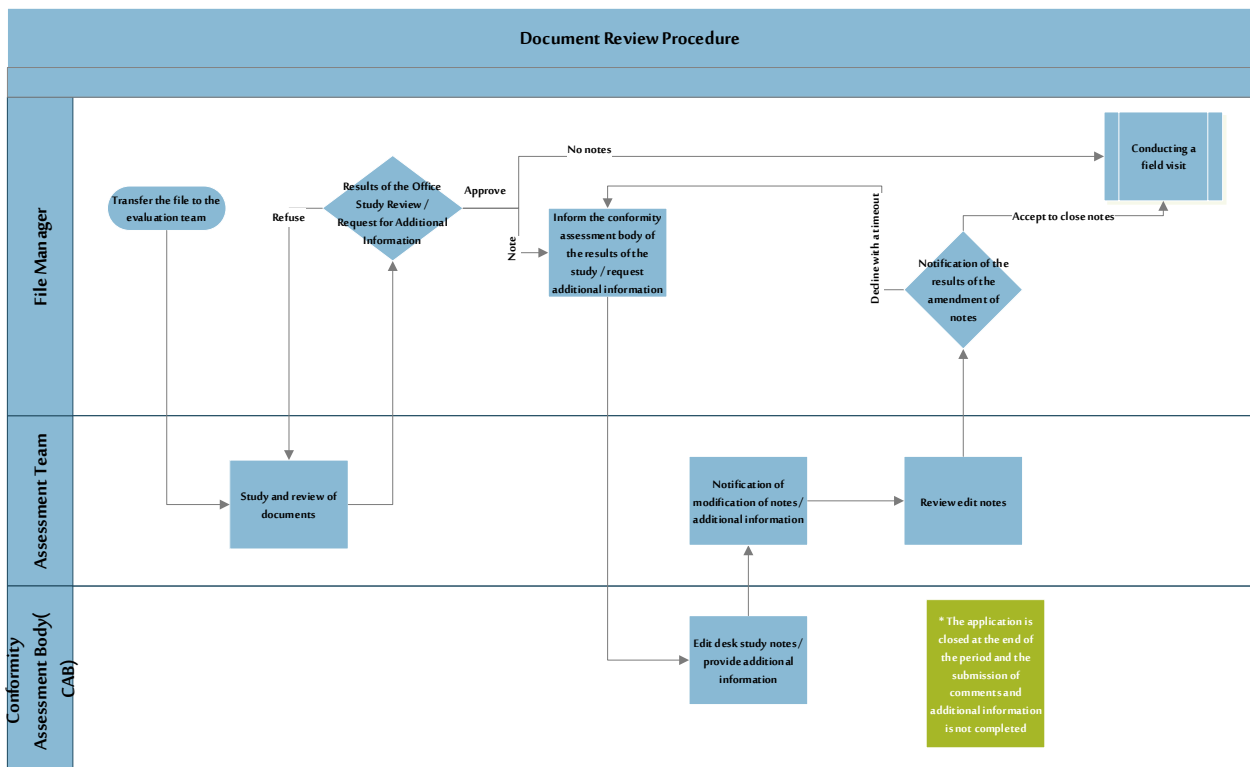
*** G.M / Director of Administration, or a designee, may merge operations billing as he deems appropriate.**

9. Procedures flowchart

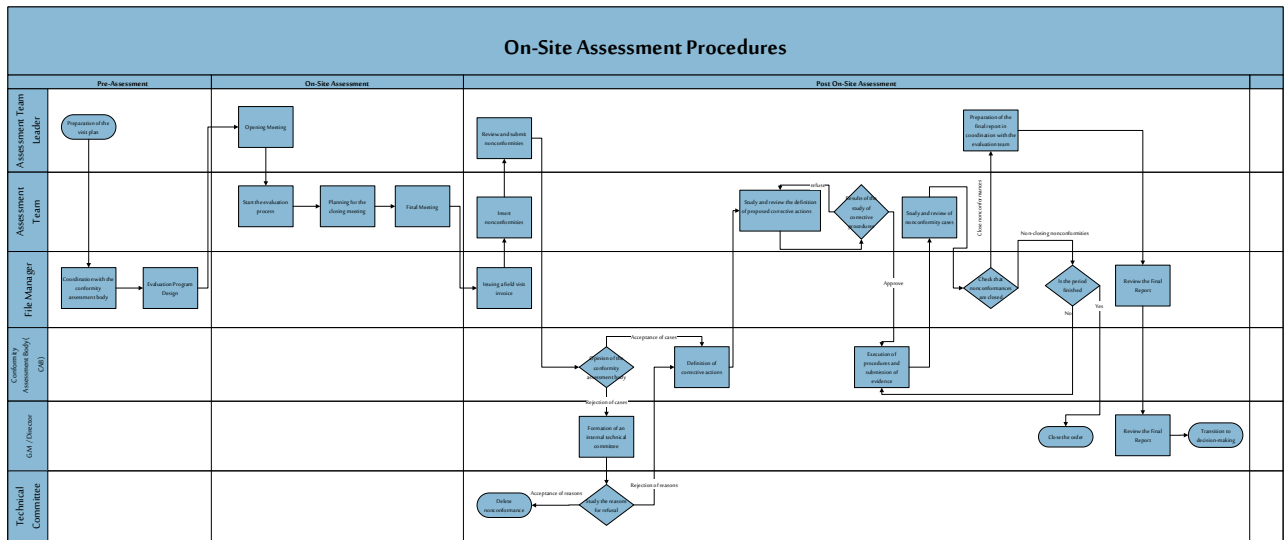
9.1 Application Review Procedure (Initial / Scope Extension)



9.2 Document Review Procedure



9.3 On-site Assessment Procedure



4.9 Decision-Making Procedure

