

AC 4.0 Document Review

4.1 Purpose

The purpose of this procedure is to explain that nature and content of document reviews. Documentation reviews are a comprehensive examination of the management system documentation of the conformity assessment body (CAB) for compliance with the relevant accreditation standard and other applicable requirements.

4.2 Scope

This procedure applies when there is a need of documentation review in relation to those applicable assessment techniques as described in AC 11.0 procedure.

4.3 Responsibilities

Assessment team appointed is responsible for conducting the document review, usually team leader or assessor takes the lead to ensure the task is completed appropriately.

4.4 Procedure

The review of quality documentation is the first part of the formal examination of the facility, the purpose of the document review is to ensure that the CAB satisfies the requirements of the accreditation standard and to assist the team leader to prepare briefing material for the assessment team as and if required.

The first task therefore is to confirm the accreditation standard and supplementary accreditation requirements that matches the requested scope of accreditation of the Applicant thru initial inquiry and the filled application form submitted by the CAB.

The document review may not be required for some types of assessment techniques (e.g. reinstatement visit, follow-up visit, as have been described in the procedure AC 11.0.

If the CAB management is unwilling to take its quality system documentation away from its premises or doesn't wish to provide the documents for whatsoever reason, the document review can then be conducted onsite or remotely with the CAB, but an additional charge shall be levied for travel and expenses in addition to any day charges applicable.

If CAB management refuses permission for assessment team to examine some or all of the contents of the management system documentation, the matter shall be referred to the File Manager for resolution.

On receipt of the CAB management system documentation the assigned assessment team shall:

- (a) Review the relevant checklist (e.g. AC 4.7 or as given thru AC 4.2) and verify the referred documentation is in line with requirements of the standard,
- (b) examine the policies and procedures for inconsistencies, lack of clarity or other inadequacies;
- (c) where the documents are found to be not in compliance the applicable matter can be raised either as finding(s) or otherwise as concerning point(s) to be clarified during the assessment, also record appropriate comments to support explanation or a requirement which may need further investigation or clarification by the CAB during the assessment.

If an outcome of the document review states serious issues such as absence of the key policies, procedures or documents in the management system of a CAB, or when there's recommendation to not to proceed for an assessment then the document review report shall be shared with CAB (up to 2 months timeline is advisable for addressing the findings by the CAB or if more time needed it can be agreed with GAC FM), it may not be necessary to provide the document review report to the CAB in case of no findings were raised or when matter not clear are identified to be followed-up during the assessment, care needs to be taken especially where additional review or evidence during the assessment may influence the outcome, to ensure pre-empted

AC 4.0 Document Review

unjustified requirements are not imposed.

The assessment team to ideally provide the document review to GAC 10 days before the date of assessment, in case of non-conformities raised in the document review the dates of assessment to be decided after the corrective actions have been taken by the CAB.

A record of the document review report is retained on the CAB file and is part of the assessment deliverables.

Disposal of Documents: All documents and any other information such as procedures and any copied versions of documents obtained during the assessment to be returned to the CAB by the assessment team or destroyed by an appropriately secure process (shredding, trashing, deleting, formatting – as applicable).

4.5 Associated forms and documents

- AC 2.1 Application form, annex-2 list of documents required.
- AC 11.0 Assessment techniques
- AC 4.7 Checklist ISO 17025
- AC 4.8 Checklist ISO 17020
- AC 4.9 Checklist ISO 17065
- AC 4.10 Checklist GSO 2055-2
- AC 4.12 Checklist ISO 15189 Medical labs
- AC 4.13 Checklist ISO IEC 17021
- AC 4.2 Nonconformity Sheet & Assessment report (Accreditation scheme checklists are also covered within it).