Guide & summary procedure for test & calibration or medical laboratory accreditation

GBAR accreditation involves an external audit of the arrangements to provide a laboratory service to a defined standard of practice.

GBAR approach is to ensure that during its accreditation activities it is seen to be open, transparent, fair, and technically and administratively proficient. We aim to be reliable, repeatable and responsive and renowned for our user friendliness.

In order to ensure that the needs and requirements of laboratory stakeholders are met, GBAR will operate to a documented quality management system. The organization encourages the setting of quality objectives and plans in order to implement quality policies. It is keen to ensure that all personnel are familiar with quality policy to ensure customer satisfaction. Health, safety and welfare of staff are important and visitors to all sites shall be treated with respect and due consideration shall be given to their safety while on site.

GBAR encourage the upholding of professional values and is committed to good professional practice and conduct by promoting awareness of the sustainability of the planet's resources by using recyclable/renewable materials and minimizing the production of waste and energy use.

GBAR recognizes the importance of the applicability of standards to all stakeholders within the standards community and to that end is cognizant of ISO/IEC 17011:2017.

The GBAR fee policy is one of reasonable affordability for laboratories. To this end it is GBAR strategy to retrieve the costs of its accreditation activities from a levy based upon the turnover of the laboratory or for non-commercial or government laboratories, number of tests conducted.

Fees are based upon initial accreditation and ongoing accreditation surveillance. Guide 52 defines fees more fully.

1 Make a formal application for accreditation. Test laboratories should use GBAR(F)50 or Medical Laboratories should use GBAR(F)62.

2 If application and intermediate correspondence confirm appropriateness, an invoice for an administration fee as defined in GBAR(G)52.

3 The applicant test & calibration or medical laboratory is required to comply with the requirements of ISO 17025 or ISO 15189 and to maintain a Quality Management System that is cognizant of ISO 9001:2015.

4 GBAR will review the application, may ask further questions and if application and intermediate correspondence confirm appropriateness, an invoice for an administration fee as defined in GBAR(G)52 will be issued.

5 Upon receipt of full payment. GBAR will request manuals, procedures and forms to be sent.

6 GBAR will send key documents to the applicant that the applicant, if successful would need to comply with. These are:

- GBAR(D)10 Contract

- GBAR(D)11 Memorandum of understanding
- GBAR(G)10 Accreditation marks and logos
- GBAR(G)53 Terms and conditions
- GBAR(G)20 Code of Conduct
- GBAR(G)30 International Affiliations
- GBAR(G)32 Authority
- GBAR(I)01 Use of marks

7 The applicant sends to GBAR the documentation for operation of a test & calibration or medical laboratory.

8 GBAR shall review and comment. If necessary, GBAR will require the applicant to amend and respond before the next step.

9 Upon a successful accreditation decision, GBAR will issue a contract & MOU. Sample contracts can be provided prior to application upon request.

10 GBAR shall issue a provisional accreditation certificate when satisfied that the document structure is adequate. The applicant is listed on GBAR website as “PROVISIONAL BODY”

11 The applicant conducts the test or calibration activities. The applicant sends GBAR photocopies or scanned or electronic records of all the documents related to that work. These shall be in accordance with the documents that GBAR had earlier reviewed.

12 GBAR will as soon as is convenient conduct site witness of the applicant’s test and calibration activity. The applicant is required to pay GBAR’s Assessor day-rate fees, plus travel and accommodation expenses.

13 Upon a successful site visit review, the applicant’s accreditation becomes Full. Applicant is listed on GBAR website with caveats if applicable.

14 The applicant continues to conduct test and calibration laboratory activities but does not need to send paperwork.

15 GBAR will monitor the level of the test & calibration or medical laboratory activity and conduct accreditation reviews to suit.

16 GBAR will arrange listing of the test & calibration or medical laboratory in the International register at www.gbar-ab.org.

NOTE

It is most important that the applicant clients are given the opportunity to understand the relationship between GBAR and national governments, etc. The applicant is therefore instructed not to imply or cause to be inferred that GBAR act with the approval of the government. That is why Terms and Conditions are so important. GBAR guide ASB(G)32 is also useful and GBAR has no objection to the applicant issuing one to each of their clients prior to accepting work.

GBAR activity is strategically directed by its relationship with the risk involved. The busier the laboratory is the more risk is involved and the more surveillance activity is required. The laboratory is therefore obliged to advise GBAR of the level of activity, either by revenue or test activity an order

that appropriate levels of accreditation surveillance may be maintained.

Where GBAR has appointed an Assessor for a specific geographic region or country then the term “GBAR” used in this guide is applicable to the Assessor.

END

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