



ADVISORY TO LABORATORY ON REMOTE ASSESSMENT

SUBJECT: FDAS ADVISORY TO APPLICANT LABORATORY ON REMOTE ASSESSMENT

1.0 INTRODUCTION: As a policy ,FDAS has decided to conducts remote/virtual assessment till the prevailing pandemic conditions persist and may also opt for remote assessment when such conditions crop-up and make it difficult to reach the actual site for assessment of Applicant laboratories.

2.0 REFERENCE: This advisory is based on APAC TECO-001 “Guidance on Remote Assessments by Accreditation Bodies” which defines the expected role of the Applicant Laboratories, Assessment team and accreditation bodies. With this advisory laboratory are being informed about the expected role from them.

3.0 REMOTE ASSESSMENT:

3.1 The baseline of the remote assessment is the use of Information and Communication Technology (ICT), to undertake accreditation assessment activities. More advanced and sophisticated form of ICT improves the effectiveness and efficiency of accreditation assessment activities.

3.1 The use of specific information technology of facilitates assessors witness the demonstrated activity, assess the capabilities, locations to determine the competence of the applicant laboratory.

3.2 Virtual opening meeting, closing meeting are organized to brief about the proposed approach of assessment, to convey about the findings of assessment and to seek the feedback, acceptance of the applicant laboratory.

3.3 Adequacy audit of the documents, assessments of the records against the related procedure is performed remotely by accessing the documents and the related records though electronic mails from applicant laboratory.

3.4 Audit and assessment findings are shared to get the feedback from applicant laboratory using electronic mails, when required clarification are exchanged by telephone also.

3.5 When required laboratory provides the evidence through pictures, video, and audio recordings.

4.0 APPLICABILITY: The application of method from ICT are flexible and may cover all mode of communication including telephonic link, including virtual meetings through video conferencing.

5.0 DURATION AND TIMEFRAME FOR CONDUCTING ASSESSMENT: The use of information technology for gathering the information from the applicant involves accessing documents and records, storing,

retrieving, analyzing, recording and transmitting the findings/ observations to the laboratory for clarifications, feedback and acceptance which is time consuming process and more than the on-site assessment.

The assessment of a laboratory involves the stages of assessment and for the scope applied, to be able to make a judgement on grant of accreditation for applied scope.

- Document review
- Records review
- Review of performance in PT/ILC.
- Review of means applied on validity of results and internal audits findings.
- Interviewing.
- Remote witnessing (Virtual).
- Remote Opening meeting (Virtual)
- Remote Closing meeting. (Virtual)

POST ASSESSMENT ACTIVITY: After laboratory submits the details with documentary evidence on corrective action required) to LA and/or Technical assessor, who may seek clarification, if required from laboratory.

The conclusion is that remote assessment requires more man days than the onsite assessment and expected daily use of Information Communication Technology could be 4 hr./day.

6.0 ROLE OF LABORATORY BEFORE ASSESSMENT:

6.1 Designate an individual to facilitate manage and coordinate the arrangements of the remote assessment on behalf of the laboratory.

6.2 Provides laboratory manual, procedures, records, applicable file, as may requested by the LA/ TA or by dealing officer.

6.3 Before sending requested documented information, laboratory is advised to test the electronic means to secure the identity of receiver to maintain security of the information, protecting the confidentiality and eliminating the risk involved in transmission of information.

6.4 Where video conferencing or the advance information technology is required laboratories are advised to test compatibility between assessors and laboratory, by a trail run of the technology to be familiar with before virtual assessment is planned and conducted. It minimizes the risk of failure or loss of time because of the nonfamiliarity.

6.5 Where possible use webcams, cameras etc. when physical evaluation of an event is necessary, recording of remote activities when required should be agreed.

6.6 Assessment is conducted as per the “Procedure for remote assessment of test and calibration laboratories” which incorporates required features from the “Guidelines for remote assessment, APAC TECO-001”.

6.7 In normal circumstances FDAS would limit itself to apply remote assessment for pre-assessment, surveillance, investigation, and verification etc. Other than this, remote assessments require mutual agreement.

6.8 Assessment can be halted if the ICT tools are found to be not suitable during assessment, in the situation like telephone are to be used when internet connectivity is poor.

6.9 Where electronic signature of authorized person of applicant are available FDAS accepts the photocopy of the signature on the document in question and as may be required.

6.10 On request from assessment team members applicant are advised to provide requested documents or records.

6.11 Assessment team members are required to confirm the deletion of confidential information, images, recordings etc., received from applicant laboratory, after the decision on accreditation has been taken. The concerned laboratory and FDAS are to be informed by concerned assessor.

7.0 Laboratories are welcome to seek clarifications if any.