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**EMTAC**

**LABORATORIES PVT LTD**

**Procedure to deal with unusual situations/extraordinary events or circumstances**

Doc. No. : EM/CMP-31010817  
Issue No : 02  
Issue Date : 12.12.2017

	<p><b>1.0</b> The purpose of this document is to define EMTAC’s policy regarding actions to be taken in the event of any emergency situation that prevents access to certified clients/new clients, such that planned activities like surveillance, preliminary visits, drawal of samples cannot take place during the emergency situation.</p> <p><b>1.1 Definition-</b></p> <p><b>Extraordinary Event or Circumstances:</b> A circumstance beyond the control of the certification body or Licensee/applicant commonly referred to as “Force Majeure” or “act of God”. Examples are war, strike, riot, political instability, geopolitical tension, terrorism, crime, pandemic, flooding, earthquake, malicious computer hacking, other natural or man-made disasters.</p> <p><b>Remote Assessment:</b> An assessment of the physical location or virtual site of Licensee/Applicant, using electronic means.</p> <p><b>Virtual Site:</b> A virtual site is an online environment allowing persons to execute processes e.g. in a cloud environment.</p> <p>Examples of remote assessment include: webinars/web meetings, teleconferencing , online video/audio services, remote access to organization’s data processing and management systems, databases, etc.</p> <p><b>2.0 Surveillance Activities</b></p> <p>2.1 If EMTAC is unable to complete surveillance audits because of the emergency condition, EMTAC may give flexibility in audit dates. The</p>	



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surveillance activities will be completed as early as possible once the emergency situation has been lifted.

2.2 EMTAC shall also manage its accreditation assessments by considering alternative methods as mentioned in the IAF MD 4 on conducting remote assessment to continue oversight on accreditations granted.

**3. Preliminary Activities**

3.1 The new application received during the emergency condition shall be processed in the following one of the two ways depending on the Accreditation body's policy and requirements on remote audits.

- a. the manufacturer shall submit the application along with the required documents as defined by EMTAC. In the event of application being acceptable, the remote audit will be conducted with the consent of NABCB.
- b. In case remote audit is not feasible applicant will be allowed to send the product for testing, which will reduce the delay in the certification process in the emergency situation. Preliminary Audit shall be conducted on site as soon as the emergency condition is lifted.

Further processing of the application shall be done as per the general procedures and guidelines for certification EM/CMF 02010117.

**4.0 Eligibility criteria for remote assessment**

The acceptability of and the extent of remote assessment techniques will vary from organization to organization and will depend on circumstances such as level of technology available to the organization, the organization's assessment preference, resources, etc.

The use of remote assessment by EMTAC will be on voluntary basis, by mutual agreement, or may be initiated by the EMTAC as per assessment needs (initial office assessment for new scheme / standard within the same accreditation scheme, surveillance, investigations, verifications, etc.).

EMTAC will carry out the remote assessment after review of the need on case by case basis. Remote assessment methodology will be decided by EMTAC depending on the complexities involved.



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Remote assessment is permitted under one or more of the following conditions:

- Complaint investigation
- Travel to applicant/licensee or specific location is not reasonable (i.e., for safety reasons, travel restrictions, etc.)
- Onsite office assessment is not possible due to a circumstance beyond the control of the organization, commonly referred to as "Force Majeure" or "Act of God"
- The applicant/licensee has a proven track record of conformance at the location of the remote assessment and EMTAC has determined the activity as low risk level.
- When timing of the assessment does not support the travel logistics required to conduct the assessment on site.

**5.0 Remote assessments shall not be permitted in the following conditions**

5.1 When the Licensee has a history of non-conformance at the location being assessed.

5.2 Where the scope and/or the competence of personnel is critical, and requires an on-site assessment

5.3 Licensee has changed location and/or address

**6.0 Qualification Criteria for Remote Assessment**

6.1 The licensee qualifies the eligibility criteria for remote assessment as described above.

6.2 All the information (records, data, documents etc) of the applicant/Licensee are readily available in electronic formats or document reader.

6.3 The licensee has virtual meeting capabilities, including audio (and video when used), aptitude, and resources (on-site IT, personnel, and tools).

6.4 The licensee and the assessment team are competent to navigate an online meeting, and remote personnel are competent to participate

6.5 The licensee is able to provide a representative that is capable of communicating in the same language as the assessor.

6.6 Difference of time zone, if any, must be supportive to licensee and assessors.



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6.7 The licensee is ready for any additional expenses associated with the remote assessment process such as fees for teleconference, webinar, audio/visual, etc.

6.8 Remote assessment techniques are not prohibited by the standards or scheme requirement.

**7.0 Conduct of Remote Assessment**

7.1 Once EMTAC accepts the request of Licensee for remote assessment after review, or decides to carry out remote assessment on its own, the normal process of onsite assessment will apply as mentioned in the general procedures and guideline EM/CMF 02011117 and Scheme for the relevant product.

7.2 The specific dates & time period to perform a remote assessment shall be decided by EMTAC. The duration of a remote assessment may differ from that of your onsite assessment, depending on what aspects are planned to be covered. In addition, it is also likely that the assessment may be fragmented with individual activities happening over the course of a longer period.

7.3 The mode of communication and the IT platform between the EMTAC Assessment team and licensee for conducting remote assessment, sending documents or clarification on issues shall be pre-defined and communicated.

7.4 The key personnel of licensee shall be available during remote assessment. Personnel with specific technical or administrative responsibilities will need to be available for their relevant parts of the assessment.

7.5 Appropriate measures shall be taken both by EMTAC and the licensee to safeguard confidentiality of data in any form or the impartiality during the remote assessment.

7.6 Both remote Assessment team and the licensee should make their best efforts to confirm what was heard, stated and read throughout the remote assessment. In case if the remote assessment team is not able to review, in part or in full, any specific activity, a record shall be made.

7.7 If at any time during the assessment process, the licensee cannot support the remote assessment process or the assessor(s) cannot perform the assessment sufficiently using the remote assessment approach then the licensee must have an onsite assessment for those functions that could not be assessed using remote assessment.



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7.8 The remote assessment team in consultation with EMTAC may terminate the remote assessment prior to completion due to an inability to maintain satisfactory connections or conditions during the scheduled time. This shall be recorded in the assessment report.

**8.0 Post Remote Assessment Activities**

8.1 Assessment findings (Non-conformances, Concerns etc.) shall be documented by the Remote Assessment team and provided to the licensee in writing in a timely manner at the closure of Remote Assessment or just thereafter. The Remote Assessment team shall debrief the licensee on the assessment findings at the end of each day and in the Closing Meeting of the Remote Assessment.

8.2 The assessment report shall be provided by the Remote Assessment team in the prescribed time period as per EMTAC procedure and shall include the details of the standards/requirements, or part thereof, for which compliance is assessed and findings, documents and records reviewed.

8.3 The Remote Assessment team shall confirm to EMTAC, the deletion of any confidential documents, records, recordings etc. of the licensee, as available with it during the Remote Assessment, on completion of the process.

Product certification may give rise to almost an indefinite number of variable and unique situations. It is not possible to foresee all such possible situations and document appropriate procedures for action.

Wherever, any such situation arises that is not amenable to the documented procedures,

Chief of Certification (COC) is authorized to take a decision in consultation with CEO/Director.

In all such cases care should be taken to ensure that the integrity of the certification scheme and the basic principles of the certification scheme are not compromised.

Efforts shall be made to speedily complete all actions and decisions so as to ensure that neither the licensee nor the integrity of the certification process suffers due to undue delays in the process.

The licensee shall be kept informed about the reasons behind the decision.



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The CAB and the top management shall be apprised of all such decisions.