R902 - Conditions for Accreditation For Clinical Testing Laboratories Meeting the ISO 15189 Requirements state that an accredited laboratory must “Inform A2LA headquarters within 30 days and in writing of changes or pending changes in any aspect of the laboratory's status or operation that affects the laboratory's legal, commercial or organizational status; organization or management (e.g., managerial staff); plans, policies or procedures, where appropriate; premises; personnel, equipment, facilities, working environment or other resources, where significant; authorized signatories; or such other matters that may affect the laboratory’s capability, or scope of accredited activities, or compliance with the criteria, requirements and conditions for accreditation”.

As such, if your laboratory is to be relocated to a facility that differs from the location that was part of your most recent assessment (the address listed on your scope of accreditation), the progression of events enabling A2LA to reaccredit your laboratory at the new location is as follows:

1) Inform A2LA in writing of the anticipated changes affiliated with the move, including when your laboratory will no longer meet the ISO 15189 requirements at your current location;

2) Clinical Accreditation Services staff will request additional information about the move, such as: extent of the move (new address or within same facility); new equipment acquisition; personnel changes; evidence that equipment has been properly recalibrated, readjusted and verified to give accurate results; and evidence of proper environmental controls within the laboratory to ensure that test method requirements can be met;

3) The clinical laboratory’s accreditation is made ‘inactive’ once the move has physically occurred and until the aforementioned information is received and a determination of ongoing competence is made (either through a document review or through an on-site visit to the new facility).

4) Once the required information is received and reviewed, a decision is made as to whether an assessment is required to verify continued technical competence as detailed on the laboratory's scope. The assessors who most recently visited the laboratory will be consulted on this decision;

5) If the decision is made that the information received is satisfactory to ensure continued technical competency, no further information is requested, the ‘inactive’ status is lifted and the scope and certificate (when appropriate) of accreditation are revised and reissued to reflect the laboratory’s new location.

6) If the decision includes the need for further assessment, the laboratory is informed and the assessment process is initiated. The assessment and accreditation of the new facility should be completed within (ninety) 90 days. Special or extenuating circumstances which affect this time frame will be considered;

Once the assessment and corrective action is complete, the ‘inactive’ status is lifted and the scope(s) and certificate (when appropriate) of accreditation are revised and reissued to reflect the laboratory’s new location.
## Document Revision History

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