

1. PURPOSE

The purpose of this guide is to define the method and conditions regarding the accreditation of laboratories, medical laboratories, proficiency testing providers and reference material producers that service under the same legal entity in more than one premise or temporary unit. References in this guidance to bodies shall be deemed made, in terms of the aforementioned conformity assessment activity, to those bodies which undertake such activities.

2. DEFINITIONS

2.1 Head office: Usually refers to the management centre of the legal entity and is the structure that carries the responsibility of creating and maintaining a joint management system for the bodies which provide services through branches in different locations.

2.2 Branch: Refers to permanent locations other than the centre where conformity assessment activities are carried out and which can be held legally responsible.

2.3 Site: Refers to the business set in a certain location with the intention to stay there permanently.

2.4 Temporary Unit: Refers to the unit temporarily allocated at a certain location, able to access the required equipment and personnel for conducting conformity assessment activity. These units are usually located in a certain location to provide services for the period of the work for a certain amount of time. A temporary unit can not be accredited on its own.

When conducting assessment relating to the temporary unit, G-2-42 Guidelines for Field Laboratory Activities shall also be taken into account for laboratory activities.

3. IMPLEMENTATION

3.1 Requirements for the Accreditation of Bodies Providing Services Through Branches or Temporary Units

3.1.1. All locations providing services must be under the legal responsibility of the legal entity. This legal entity must meet the commitment of being held legally accountable expected of a legal entity for the relevant accreditation standard. Entities must demonstrate their commitments by records indicating the relationship with the legal entity relating to the legal responsibility of their temporary units.

3.1.2. The NBE-New Business Education Foundation must be notified of the personnel who legally represent the body operated as a branch. Authority of the representative personnel must comprise at least the formation and implementation of a management system to be used collectively, at a minimum, as well as cooperation with NBE within the scope of the accredited activity.

3.2 Requirements for Bodies Accredited with Branches Regarding the Integrity of Management Systems

- 3.2.1.** A management system in conformity with the relevant accreditation standard must exist and be implemented in a manner to involve all branches/temporary units. Every branch/temporary unit which uses the joint management system must be specified in the quality documentation. The quality documentation must include or make reference to the rules to be followed by relevant branches/temporary units, required procedures and instructions. Branches/temporary units must be able to access the joint management system documentation.
- 3.2.2.** Responsibility to ensure the integrity of quality management system used at the branches/temporary units belongs to the top management of the legal entity.
- 3.2.3.** In all branches, a staff must be assigned responsible for quality who can directly contact the quality staff in charge of management system or management representative at the head office. The quality officer must have the authority and responsibility required for implementing the management system at the branch and ensure its continuity. The quality staff is also responsible for cooperating with the centre for planning and implementing all yearly internal audits.

3.3 Requirements for Performing Accreditation Assessment

Following the review of the abovementioned conditions, in order to conduct the assessment, the conditions listed below must also be taken into account:

- 3.3.1.** The body must inform the NBE-New Business Education Foundation via the Application Form before the assessment about which branch/temporary unit is carrying out the conformity assessment activities subject to the accreditation request.
- 3.3.2.** All branches/temporary units of the bodies providing services through branches or temporary units shall be subject to on-site assessment during initial accreditation and re-accreditation assessments according to the risk-based assessment criteria under the relevant accreditation scheme.

3.4 Performing Surveillance Assessments

- 3.4.1** During the 48-month period when the accreditation is valid, every branch/temporary unit shall be subject at least once to a surveillance assessment under the risk-based approach. The method used in assessment shall be evaluated according to the relevant accreditation scheme
- 3.4.2** The centre shall be subject to surveillance assessment periodically.

3.5 Conformity Assessment Documents and Externally Provided Services

When the bodies providing services through branches or temporary units receive services from other branches/temporary units operating under the same legal entity, such branch/temporary unit which provides the service shall not be considered as a subcontractor in conformity assessment documents (testing reports, calibration certificates etc.).

3.6 Suspension, Withdrawal and Cancellation of the Accreditation

Where it is determined during the surveillance assessment that the joint management system is not implemented effectively within the general structure, accreditation can be temporarily suspended or withdrawn. In cases when there are negative conditions which only affect one branch or a few branches, accreditation of the relevant branch or branches or the activities carried out at temporary units can be suspended or withdrawn.