1. PURPOSE

This document describes overall rules applicable to laboratory works carried out in temporary and/or mobile facilities of laboratories other than their permanent facilities that were accredited and/or are planning to be accredited by NBE. This document was prepared for the use of Conformity Assessment Body (CAB) and assessors.

2. SCOPE

This document covers laboratory activities (testing, calibration, sampling) carried out in temporary and/or mobile facilities of the laboratory

3. DEFINITIONS

Mobile Laboratory: Fully-equipped, self-sufficient and mobile laboratory that is capable of carrying out laboratory activity under controlled environmental conditions. A mobile laboratory operates under the centre and is subject to the same accreditation requirements and its scope is confined to that of the central laboratory. A mobile laboratory is usually a fully-equipped and climate-controlled vehicle (a lorry and/or motor vehicle).

Temporary Laboratory: A fully-equipped laboratory capable of carrying out laboratory activity under controlled environmental conditions established for a temporary period of time in a place dedicated to the laboratory in the client's facilities. Operating period of temporary laboratories must not exceed 1 year.

Field Laboratory Activity: Testing, calibration and sampling carried out by laboratory personnel in a place other than the permanent facilities of the laboratory (on-site, in a temporary and mobile facility).

4. GENERAL RULES

4.1 In case of a laboratory provides on site laboratory services, specially developed procedures or instructions shall be used for the related on site activity in which services are to be provided. It shall be ensured that the personnel uses the most recently revised and updated version of the related procedure or instruction.

Laboratories providing services in such a way shall satisfy the following criteria as a minimum requirement:

- Laboratory services that provide or will provide laboratory services shall be defined under the same accreditation framework and within a single quality system. All administrative and technical documents shall be associated with the central quality system (service capabilities, organizational structure, transport of reference instruments in vehicle(s), settlement requirements, certification operations etc.).
- Records evidencing legal relation between the central laboratory and the mobile and temporary laboratory shall be presented by the laboratory.
- Temporary and mobile laboratories shall be defined specifically in the quality system

including information about their scope, location, personnel etc. Such definition shall include at least specific definition of vehicles/units used, license plate number, chassis number, make and model, driver's name and surname. Mileage information of the vehicle shall be recorded every day during the mission.

- Location of temporary and mobile laboratories shall be tracked and the purposes for which the laboratories are used shall be recorded (GPS, vehicle tracking system etc.).
- Testing/calibration/sampling activities carried out in temporary and mobile facilities shall be recorded through a fixed camera placed in the temporary/mobile facilities in a way to indicate information on date and time and conformity of the activity with sufficient quality (appropriate resolution etc.).
- The laboratory shall specify in its documentation the minimum period of time when field laboratory activities can be carried out safely and the maximum number of field laboratory activities that personnel can realize in one day within the related scope and present such documentation to NBE upon request. Duration of laboratory activity shall comply with standards, if any and/or regulatory requirements. Calculation about the maximum period of time that one staff member can work in a working day shall comply also with the Labour Law.
- The laboratory shall determine its monthly programme for activities to be carried out by temporary and mobile facilities and send the programme to NBE e-mail. Any deviation from the programme shall be sent to NBE e-mail 2 days in advance at the latest.
- Laboratories that want to carry out activities in their mobile and temporary laboratories in those scopes that are already in their permanent facilities but not in their mobile and temporary laboratories shall apply for a scope extension.
- Mobile and temporary laboratories are considered as a branch in accreditation processes. The scope of the laboratory shall include which laboratory activities will be carried out on-site, mobile or temporary way, the unit which will carry out the activity, specific identification (vehicle plate number, specific name of the temporary facilities etc.).

Laboratories that want to carry out field laboratory activities shall state in the application form under which scopes they will carry out activities on-site, mobile or temporary way along with the information (CMC value, sampling etc.) that is required within the framework of this guidance. Mobile and temporary facilities shall be indicated as branch in the application form.

In case laboratory activity is carried out on the client's site, or in its temporary or mobile facilities, it should be indicated with " * " in the "Testing Method" column in the scope of test and medical laboratories and in the "Remarks / Calibration Method" column in the scope of calibration laboratories. An example illustration is given below.

Measured Quantity / Calibrated Items	**Measurement Range**	**Measurement Conditions**	**Calibration and Measurement Capability (Extended measurement uncertainty k=2) (±)**	**Remarks/ Calibration Method**

Material Concrete Compressio n Testing Machine Calibration	200 kN ≤ *F* ≤ 3000 kN	Compression with a 1st class load cell	0.32%	**Calibration procedure prepared in accordance with TS EN 12390-4 Standard** *F:* Measured value (*) On the client's site, or its temporary or mobile facilities

4.2. Control of Documents and Records

The laboratory shall determine and **document** quality management and technical responsibilities for all its mobile or temporary facilities other than its permanent facilities. For each facility, a technical personnel with signature authority shall be nominated. This personnel shall have sufficient training in the field of the service and the management system shall evidence and record it.

Procedures related to distribution and update of procedures and documents to the personnel involved in on-site, mobile and temporary laboratory activity shall be established within the existing quality system. Related follow up shall be made through checklists.

4.3. Review of requests, tenders and contracts

The laboratory shall explain in procedures and instructions the practices related to requests, tenders and contracts regarding its operations in mobile or temporary facilities within its existing quality system (receiving requests, submission of tenders, keeping-controlling records, communication with the central system etc.). Information shall be included about whether requests, tenders and activity fall into the scope of accreditation in addition to information about the method regarding the activity subject to the contract.

4.4. Purchasing of Reference Materials and Services

The laboratory shall describe practices and necessary arrangements related to purchasing of reference materials/instruments or services for its operations in mobile or temporary facilities within its existing quality system by supporting these with additional procedures and instructions if necessary.

In cases where purchase is made through central/permanent facilities, measures against any negative event that may occur during the storage, packaging, transportation of the references to mobile or temporary facilities and which may affect the quality of the measurement shall be defined in the related procedures.

4.5. Service to Clients

Considering the cases where a client may see the facilities or visit the laboratory while the laboratory

conducts its mobile or temporary laboratory activity under its existing quality system, the laboratory shall define in the procedure necessary measures for confidentiality and security of other clients' instruments in the laboratory. Positive and/or negative feedback from clients during their visit to the temporary or mobile laboratory shall be evaluated as client feedback-survey results.

4.6. Control of Nonconforming Work

The laboratory shall define in related procedures and implement the policies it will follow in case of any deviation from the contract agreed with the client for its on-site, mobile or temporary laboratory activities within its existing quality system. The laboratory shall clearly define and implement the authorities and responsibilities of personnel employed in the temporary and mobile laboratory upon occurrence of non-conforming work.

4.7. Control of Records

The laboratory shall develop procedures for control of records in the temporary and mobile laboratory. These procedures shall include identification, collection, indexing, access, filing, storage, maintenance, disposal, security and transport of all technical records, particularly the original observations produced on-site or in temporary or mobile facilities. If the records obtained are kept in an electronic environment, the laboratory shall have procedures to protect and back up these records and prevent unauthorized access to or modification on these records until they are stored in the permanent /central laboratory.

A distinctive numbering/record system shall be established for records obtained in the temporary and mobile laboratory. The records shall include information on personnel carrying out the activity and the time when the activity is carried out. If possible, the records shall include sufficient information to facilitate to define the factors affecting uncertainty and to enable to repeat the activity under the conditions that are as close to the original as possible. Environmental conditions such as temperature, humidity and other environmental factors shall be properly recorded along with time information.

There shall be procedures to ensure that all results obtained in temporary and mobile facilities are recorded and reported at the moment they are obtained. All observations or laboratory activity results obtained in temporary and mobile facilities shall be kept. Records shall be made in a permanent way and kept free from rain, humidity, spillage, leakage or other environmental factors that may affect legibility of the records immediately or in the future. Camera records shall be kept for at least 2 years, and electronic records, photocopies or handwritten fax messages etc. shall be kept for at least 5 years (for example, backing up of electronic files in tapes or flash memory / external disk).

4.8. Internal Audit

The laboratory shall include each department of its quality system and its laboratory activities on-site, and in temporary and mobile facilities into its internal audit plans. All elements of laboratory management system shall be addressed and laboratory shall plan the internal audit as being at

maximum 12 monthly periods and carry out the audit. Internal auditor shall visit to audit temporary and mobile laboratories as part of internal audit process.

4.9. Management Review

Management reviews shall be planned and realized at 12 monthly intervals. The laboratory shall review activities of on-site, temporary and mobile facilities and clients' feedback.

5. TECHNICAL RULES

This section includes rules about some technical matters particularly applicable to on-site, temporary and mobile laboratory activities.

5.1. Personnel

The laboratory shall make sure that all personnel carrying out on-site, temporary and mobile laboratory activity is competent to do the necessary job. Records evidencing competency of personnel involved in on-site testing/calibration/sampling shall include training records, analysis of Proficiency Test (PT) samples, Interlaboratory Comparisons (ILC) realized by that person, inter-personnel comparisons between personnel or other proficiency tests and similar laboratory activities carried out in a laboratory environment.

Personnel to be assigned to facilities other than permanent facilities shall be selected from among personnel that is competent to carry out laboratory activity, is able to analyse and interpret the results including statement of conformity or opinions and interpretations, able to report, review and approve the results and in case of any deviation able to decide on the operation to do and its potential impact, and possesses sufficient level of knowledge and experience about both the TS EN ISO/IEC 17025 and the laboratory's quality system.

The laboratory shall have policies and procedures for documentation of training, retraining and skill and certification of expertise and subsequent competency monitoring for the personnel carrying out on-site, temporary and mobile laboratory activity. The laboratory's management shall establish the acceptance criteria used to confirm that the personnel is competent to carry out on-site, temporary and mobile laboratory activity.

Temporary and mobile laboratory activity shall be carried out by the personnel employed by the laboratory on a full time basis. The laboratory personnel shall have clear records regarding the authority to carry out laboratory activity at a certain place and operate the equipment. All the records shall be kept and include the date the competency was confirmed.

Competencymatrix shall include information on personnel working in temporary and mobile facilities. The laboratory shall consider personnel employed in temporary and mobile facilities as critical personnel and fulfil necessary operations including notifications etc. required for critical personnel during accreditation process for such personnel as well.

5.2. Accommodation and Environmental Conditions

Technical requirements for accommodation and environmental conditions that may affect results of temporary and mobile laboratory activity shall be documented and personnel shall be able to create the necessary conditions. In the cases where environmental conditions in the field and in mobile laboratory may affect laboratory activity results, the laboratory shall keep records of these conditions during implementation of all the activities. The records shall show that the environmental conditions have not affected laboratory activity to make the results invalid. There shall be records showing that requirements of methods for laboratory activities are satisfied. The laboratory shall clearly define the external environmental conditions and the limits thereof under which the infrastructure (tools etc.) to be used for field activities can be operated to the extent that will not jeopardize results of laboratory activity to be realized.

The laboratory shall keep sufficient records to indicate an effective separation between neighbouring areas hosting activities that are incompatible with each other in temporary and mobile laboratory activity. Such records may be floor plans, photos etc.

5.3. Calibration/Testing/Sampling Methods Measurement Uncertainty

Laboratories shall have and implement sufficient procedures to estimate measurement uncertainty with regards to all temporary and mobile laboratory activities. When such procedures are appropriate, environmental conditions in the field shall be taken into account additionally. In case of detecting different CMC values or measurement uncertainty values, such difference shall be indicated in the application form and further evaluated within the system.

5.4. Equipment

Usage status of equipment in the central laboratory and/or field laboratory activities shall be defined clearly. Records about traceability of references and working standards used (certificates, labels, instrument information cards) shall be accessible during the service. Objective evidence showing that intermediate checks of equipment are carried out systematically before and/or after the service shall be recorded.

There shall be procedures for safe transportation, receipt, handling, protection, storage, retention, and disposal or return of measuring instruments used in field laboratory activities. A list of all equipment used during laboratory activities in mobile and temporary facilities shall be kept in the laboratory.

5.5. Sampling

Sampling for testing laboratories shall be carried out under the procedures applied in quality management system with additional procedures where necessary.

5.6. Operations Applied to Testing Samples and Instruments Received for Calibration

The laboratory shall have a system for definition of testing/calibration/sampling materials. This definition information shall be kept during the period when the sample remains in the laboratory. The system shall be designed and operated in a way to prevent testing/calibration/sampling materials, records of those from interference the information about them in other documents.

Following acceptance of testing/calibration/sampling materials to the laboratory, any anomalies or deviations from normal or specific requirements described in testing/calibration/sampling method shall be recorded along with received date and time of the sample.

5.7. Assuring the Quality of Testing and Calibration Results

Objective evidence showing that intermediate checks of equipment are carried out systematically before and/or after the service shall be recorded. Temporary and mobile laboratories shall be taken into consideration when the studies conducted for proficiency tests or interlaboratory comparisons and requirements of the standard shall be satisfied.

5.8. Reporting of Results

The laboratory shall meet the requirements specified in the ISO/IEC 17025 standard for the reports/certificates regarding testing/calibration/sampling activity.

Start and end time of the activity (and waiting period if specified in the related testing/calibration/sampling standard) shall be recorded in raw data forms or equivalent documents of field site laboratory activities. Such document shall also include information about the personnel carrying out the activity and the environmental conditions.

All the records in the process shall clearly indicate where, when and in which facility the activity is carried out. In case there is no clear address information, location information shall be recorded and indicated in the report approximately and in a way to include GPS location information. The report/certificate shall also include information about external environmental conditions.

Information about the scope and subfield shall be included in the report/certificate (For example; Field of scope: Temperature, Subfield: Thermometer with Indicator, Field of scope: Mass, Subfield: Weighing instrument). Reports/certificates shall be numbered by the centre and report/certificate shall be transmitted electronically to the centre on the same day.