Requirements for Telefication listed Laboratories

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This document describes in detail the procedures and requirements regarding laboratory quality system requirements, to become a Telefication listed laboratory.

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Revision record sheet

NOTE: The person who initiated the document or modified the document is responsible for maintaining this record sheet (in case of use please remove revision information)

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1 Introduction

1.1 About Telefication

Telefication is a third party test laboratory and third party certification body. The Dutch Council for Accreditation (Raad voor Accreditatie: RvA) has accredited Telefication to ISO/IEC 17025 (laboratory) and NEN-EN-ISO/IEC 17065 (product certification).

More information about Telefication is available in *RD_560, About Telefication*

1.2 About this document

This document is applicable for non-accredited laboratories and intended as a guide to identify the minimum requirements to become a Telefication listed laboratory.
The benefit to be Telefication listed is that Telefication will accept the test results of the assessed laboratory.
Telefication shall review as appropriate the requirements for the suitability and competence of laboratories carrying out inspection and testing in accordance the ISO/IEC 17025.

2 laboratory quality system assessment approach

The general requirements for the competence of calibration and testing laboratories are based on the ISO/IEC 17025:2005.

Telefication performs an examination of the quality system of laboratories to verify the compliance with the selected ISO/IEC 17025:2005 clauses and additional requirements. The examination takes account of existing certificates, e.g. EN-ISO 9001:2008.

A Listed Testing Laboratory Certificate will be issued and acquired the status of a Telefication Listed Testing Laboratory when has found that the management system complies with the relevant provisions of ISO/IEC 17025:2005.

If the laboratory wishes to be recognized as a Telefication listed Testing Laboratory, it should be able to demonstrate that it is impartial and that it and its personnel are free from any undue commercial, financial and other pressures which might influence their technical judgement. The Listed Laboratory should not engage in any activities (e.g. development & production) that may endanger the trust in its independence of judgment and integrity in relation to its testing activities.

Telefication listed laboratories shall be periodically (at least annually) be assessed to verify continuous compliance with the provisions of the selected ISO/IEC 17025:2005 clauses and additional Telefication requirements.
Therefore Telefication schedules an examination of surveillance audit results. If available the results of regularly performed follow-up audits under an existing Laboratory Certificate are used (which the laboratory should make available).

3 Application and ordering for quality system certification

By submitting the form: *Questionnaire for quality system approval* (RF-300) the applicant provides Telefication with some basic information of his quality system. With this information the activities needed for assessment and certification of the quality system are determined and a quotation is prepared. If needs be, Telefication will contact the applicant to request for further information. This inquiry without any obligation: detailed planning and assessments will begin after the applicant has accepted the quotation and returned the signed order for assessment to Telefication.

4 Examination program of laboratory quality systems

4.1 The examination program

After confirmation, an examination program will be made by Telefication, detailing the activities
Necessary to determine whether the quality system of the laboratory meets the requirements.
This program includes the verification of existing certificates (if available), a schedule and planning for additional assessment (if necessary) and the verification of the results by Telefication. Telefication will plan the assessments in consulting with the laboratory.

The assessment is concentrated in 2 areas, one is the assessment of the quality system of the laboratory and second the technical assessment where agreed test performance verifications will be held to check if the laboratory has the knowledge/know how and the competence to perform the tests in accordance with particular technical standards.

4.2 Documentation examination and assessment

Following the examination program Telefication will perform a document examination if possible.
Preceding an audit, the laboratory will be informed of determined non-compliances. After the assessment has taken place Telefication verifies the results and an audit report will be drafted.
If non-conformities still exist, reassessments may be scheduled. The examination is closed when it is determined that the quality system meets all the requirements or when the applicant terminates the process without positive result.

All required data, including third party certificates and audit reports shall be made available by the applicant.
Telefication reserves the right to arrange additional assessment until full compliance with the requirements set in this document.

5 Requirements for Laboratory quality systems to become Telefication listed laboratory

Section 4 and section 5 of the ISO/IEC 17025:2005 is applicable and will be reviewed. Some additional requirements / exceptions are listed below:

5.1 Applicable requirements

Laboratory quality systems have to comply with all the requirements of ISO/IEC 17025:2005 (E) with the exception of the following clauses or sections:
a) clause 5.6.2.1, calibration replaced by paragraph 5.1.6 Calibration;
b) Clause 5.6.2.1.2;
c) Clause 4.5.2 and 4.5.3 replaced by additional requirement see 5.1.3 Subcontracting.

There are some requirements that are not included in the ISO/IEC 17025:2005.
These differences, indicated as supplementary requirements, are described in the following subsections. Where possible, reference is made to the corresponding ISO/IEC 17025:2005 clauses. In Telefication questionnaire with number RX_050 “Checklist Telefication listed ISO 17025-2005” are defined the requirements.

5.1.2 Management system: (ISO/IEC 17025:2005: clause 4.2)

The quality system shall include written procedures with regard to communication with Telefication.
Any changes to the documented quality system, in so far they effect the requirements of this document, must be advised to and agreed by Telefication before being introduced. Telefication will take particular care to respect confidentiality and to give a prompt response to issues of a commercially sensitive nature.

Provision must be made for Telefication to undertake, or have undertaken, surveillance of the operational quality system. Telefication has the right to make unexpected visits if there is serious doubt that the requirements continue to be met.

The quality scheme or equivalent documentation shall be available in a language readily understood in the local working environment and in a language acceptable by Telefication (for example: Dutch or English).

5.1.3 Subcontracting: (ISO/IEC 17025:2005: clause 4.5)

Subcontracting as documented in the ISO/IEC 17025:2005, clause 4.5 is not applicable.

5.1.4 Inspection and testing (ISO/IEC 17025:2005: clause 5.9)

Policy that Telefication will be informed in case test results are brought into doubt e.g. test equipment being out of calibration

5.1.4 Control of quality records (ISO/IEC 17025:2005: clause 4.13)

The following records shall be kept for at least 10 years after last product has been tested:
a) The quality manual and quality schemes or equivalent documentation;
b) The quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc;
c) Details of any amendments to the quality system documentation together with the notification of agreement from Telefication where required;
d) Reports from Telefication on all routine visits and unannounced visits.

5.1.5 Internal Quality Audits (ISO/IEC 17025:2005: clause 4.14)

The effective implementation of the quality system, including the requirements of this document, shall be verified at least annually by means of internal audits. The audit results and follow up actions shall be formally documented and made available to Telefication on request.

5.1.6 Calibration

When using external calibration services, traceability of measurement shall be assured by the use of calibration services from laboratories that can demonstrate competence, measurement capability and traceability. The calibration certificates issued by these laboratories shall contain the measurement results, including the measurement uncertainty and/or a statement of compliance with an identified metrological specification see also 5.10.4.2 of the ISO/IEC 17025:2005.

5.1.7 Communication with Telefication

Telefication shall be informed prior to any major amendment to the quality system of which the laboratory may surmise that they will affect the approval of the quality system.
Examples of major amendments are:

a) new laboratory location;
b) organization or management structure;
c) introduction of new standard;
d) change in scope of testing;
e) Negative inter laboratory comparison or proficiency-testing results.

The quality system shall incorporate the duties for establishing needs for informing Telefication and the responsibilities for communication with Telefication.
Pending on the changes, Telefication may impose an additional audit.

6 Laboratory certification

6.1 The contract between the laboratory and Telefication

Upon establishing compliance with the requirements for laboratories, Telefication will send a contract to the laboratory. Contracts are valid without predefined time-limit, until:
a) replaced by another contract between the same contracting partners, or;
b) cancelled by one of the contracting partners.

After cancellation is announced the contract will terminate at the end of the second month following the date that the written announcement has been sent or received by Telefication, unless otherwise agreed.

6.2 The Telefication Certification listed certificate

After concluding the contract, Telefication will issue a certificate to the laboratory.
The certificate is normally valid for a period of three years after date of issue, After this period the certificate is renewed after a re-examination.

6.3 Expiration, suspension and withdrawal of certificates

Any certificate issued by Telefication may immediately be suspended or withdrawn by Telefication when:
- The markings are abused by the certificate holder, or;
- Complaints are received, from e.g. the purchasers, regarding certified and marketed products and these complaints are substantiated by supplementary examinations that reveal non-compliance's, or;
- It was granted on the basis of false or misleading data or documentation provided, or;
- Withdrawal is requested by the certificate holder.

Any certificate expires when:
- The certificate is replaced by another certificate, or;
- The certificate is withdrawn by Telefication.

The certificate holder is informed of intended on actual suspension or withdrawal in writing. In such cases the manufacturer may no longer apply the markings to *any* product involved. In cases of suspension the conditions relating to the reissue of the certification is included in the suspension notification document.

6.4 Application for modification

Modifications (change in scope of testing, introduction of new standard) are handled as an addition to the original application. The laboratory request for approval of such a modification by using the form Questionnaire for quality system approval (RF-300).

Telefication performs an additional examination, and when needed an additional assessment. The need for such assessment will depend on the nature of modification(s) and the existing experience from previously performed audits. Upon successful completion of the examination, the certificate will be updated.

6.5 Surveillance audits

Re-examination will be performed in accordance the following information:

Telefication will define depending on the audit result the surveillance interval per laboratory.
This surveillance interval is related to the result of the audit (see table below). In case of an assessment of a new laboratory the assessment should be performed 2 consecutive years. After the 2 performed audits the audit result of the last audit will be reviewed against the surveillance interval table and timing of next audit confirmed with client. The audit interval will be 2 years in case the previous audit result is in line with the shown table below

(possibility 1). In case the result is in line with possibility 2 and 3 of the table, assessment should be performed yearly.

Surveillance audit interval table			
Possibility	Minor	Major	Audit interval
1	≤4	no	2 years
2	≥5		1 year
3		≥1	1 year

Telefication will plan an audit at the laboratory facilities.
If other certificates were accepted as part of the certification process their validity will be checked and their surveillance audits are taken into account. Results of these audits should be made available to Telefication. Telefication verifies audit results and corrective actions are requested if necessary.

Telefication may schedule extra surveillance audits if deemed to be necessary.

7 Conditions and fees

The General conditions of Telefication are applicable.

Telefication will charge fees for the audits. These fees may be broken down in several categories. Costs are usually retrospective (based on fixed hourly rates), plus travel and accommodation expenses and where applicable the fees charged for technical experts.

An estimation of the fees will be included in the quotation for quality system approval upon request.
Clients may be required to make an advance payment to cover expenses to be incurred.

Annex A Additional information

For more information on quality system certification, please contact us:

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