Requirements for Kiwa listed Laboratories

RD_050, Issue: 14

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

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)

Revision	**Section number**	**Page number**	**Date**	**Remark(s)**	**issued by**
9	-	2	15-04-2013	Revision record sheet added & footer text changed	AG
9	5.1.3 & 6.5	11	12-04-2013	Surveillance table interval updated and section 5.1.3	AG
10	1.1 + annex A	4 & 13	28-09-2016	Section 1.1 revised, updated reference to standard 17065, annex A updated.	AG
11	Annex A		28-02-2018	Annex A deleted	AG
12	Section 5	8 & 9	09-05-2019	Version updated in accordance ISO 17025:2017 elements	AG
	Section 5.1.2	8		General regulation and directive requirements are added as additional requirements to be reviewed.	
13	Section 5.1	8	28-6-2021	Reference to G.05.01-F-65-NL 17025 Laboratory assessment report	AG
	Section 6.5	10		Section 6.5 updated	
	Annex A	11		Annex A deleted	
	Section 1.1	4		Deleted reference to RD_560	
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Contents

1 Introduction

1.1 About the unit Wireless / EMC & FSS Products

Kiwa Nederland B.V. (unit Wireless / EMC & unit FSS Products), hereinafter to be referred to as Kiwa is a third party test laboratory and third party certification body. The Dutch Council for Accreditation (Raad voor Accreditatie: RvA) has accredited the unit wireless & EMC (legal entity of Kiwa NL B.V.) to ISO/IEC 17025 (laboratory) and NEN-EN-ISO/IEC 17065 (product certification).

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 Kiwa listed laboratory.
The benefit to be Kiwa listed is that Kiwa will accept the test results of the assessed laboratory.
Kiwa shall review as appropriate the requirements for the suitability and competence of laboratories carrying out inspection and testing in accordance the ISO/IEC 17025:2017.

2 laboratory quality system assessment approach

The general requirements for the competence of calibration and testing laboratories are based on the ISO/IEC 17025:2017.

Kiwa performs an examination of the quality system of laboratories to verify the compliance with the selected ISO/IEC 17025:2017 clauses and additional requirements. The examination takes account of existing certificates, e.g. EN-ISO 9001:2015.

A Listed Testing Laboratory Certificate will be issued and acquired the status of a Kiwa Listed Testing Laboratory when has found that the management system complies with the relevant provisions of ISO/IEC 17025:2017.

If the laboratory wishes to be recognized as a Kiwa 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.

Kiwa listed laboratories shall be periodically (at least within 14 months) be assessed to verify continuous compliance with the provisions of the selected ISO/IEC 17025:2017 clauses and additional Kiwa requirements. Checklist G.05.01-F-65-NL 17025 Laboratory assessment report will be used.
Therefore Kiwa 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 Kiwa 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, Kiwa 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 Kiwa.

4 Examination program of laboratory quality systems

4.1 The examination program

After confirmation, an examination program will be made by Kiwa, 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 Kiwa. Kiwa 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 Kiwa 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 Kiwa 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. Kiwa 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 Kiwa listed laboratory

All sections the ISO/IEC 17025:2017 is applicable and will be reviewed. Some additional requirements / exceptions are listed below:

5.1 Applicable requirements

During the audit the requirements as defined in G.05.01-F-65-NL 17025 Laboratory assessment report are applicable and will be reviewed.

5.1.2 Management system: (ISO/IEC 17025:2017: clause 8.1.1)

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

The laboratory must proof that top-level management and test personnel carrying out the tests are not the designer, manufacturer, supplier, purchaser, owner, user of maintainer of the equipment they measure nor the representative of any of those parties.

Absence of conflict of interest in business association or professional federation (membership of business association, working groups and technical commissions) must be demonstrated during the audits.

Payroll allowance shall not depend on the number of assessments carried out or on the results of those assessments.

Availability of liability insurances unless liability is assumed by the member state.

Provision must be made for Kiwa to undertake, or have undertaken, surveillance of the operational quality system. Kiwa 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 Kiwa (for example: Dutch or English).

5.1.3 Subcontracting: (ISO/IEC 17025:2017: clause 6.6)

Subcontracting as documented in the ISO/IEC 17025:2017, clause 6.6 is not applicable, unless it has been verified and agreed by Kiwa.

5.1.4 Inspection and testing (ISO/IEC 17025:2017: clause 7.7)

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

5.1.7 Communication with Kiwa

Kiwa 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 Kiwa and the responsibilities for communication with Kiwa.
Pending on the changes, Kiwa may impose an additional audit.

6 Laboratory certification

6.1 The contract between the laboratory and Kiwa

Upon establishing compliance with the requirements for laboratories, Kiwa 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 Kiwa, unless otherwise agreed.

6.2 The Kiwa Certification listed certificate

After concluding the contract, Kiwa 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 Kiwa may immediately be suspended or withdrawn by Kiwa 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 Kiwa.

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).

Kiwa 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

The interval between 2 assessments is a maximum of 14 months.

7 Conditions and fees

The General conditions of Kiwa - Kiwa are applicable.

Kiwa 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.